MEMORANDUM

TO: Nevada Cannabis Compliance Board

Dr. Bryan J. Young
Cannabis Compliance Board Member

FROM: RAD Source Technologies, Inc.;
Eric D. Hone and Joel Z. Schwarz, H1 Law Group; and
Kimberly Maxson-Rushton, Cooper Levenson

SUBJECT: Written Materials for January 19, 2021 Public Workshop re: Nevada Cannabis Compliance Regulation 12.065

Dr. Young,

Petitioner RAD Source Technologies, Inc. ("RAD Source") submits the following information and materials for your consideration in connection with the January 19, 2021 public workshop regarding Nevada Cannabis Compliance Regulation ("NCCR") 12.065, adopted by the Cannabis Compliance Board ("CCB") on July 21, 2020.

RAD Source appreciates your consideration of these materials and information and looks forward to a discussion of the regulation at issue at the upcoming workshop.

I. RAD SOURCE AND THE RS 420 LINE USED TO DECONTAMINATE CANNABIS

For over 20 years, RAD Source has been the industry leader in manufacturing renewable, non-isotope, ionizing radiation products worldwide. RAD Source was founded with the purpose of creating safer irradiation methods than those used at the time, which involved radioactive gamma sources.

RAD Source's patented and proprietary QUASTAR® technology produces high output X-rays efficiently and reliably for a wide variety of applications including blood,

cell and tissue, insects, biological research, and viral inactivation. Currently, RAD Source's equipment is used in hundreds of major hospitals, pharmaceutical labs, healthcare institutions, and renowned universities worldwide. RAD Source's client list includes the American Red Cross, the Mayo Clinic, and the U.S. Food and Drug Administration's National Center for Toxicological Research, to name a few.[1]

A. RAD SOURCE'S X-RAY PROCESS

As an initial matter, it is important for the CCB to understand RAD Source's x-ray process and its safety and efficacy in decontamination of products for human consumption.

RAD Source uses x-ray technology as the active means of producing ionizing radiation. Because the effect achieved by the RAD Source equipment on the applications served (for example, blood irradiation, small animal research, phytosanitary applications, antimicrobial and pathogen reduction in food and other materials) is due to *ionizing radiation*, the term "its x-ray process" is interchangeable with the term "ionizing radiation."[2]

B. IONIZING RADIATION

Ionizing radiation is any type of particle (photon) or electromagnetic wave that carries enough energy to ionize or remove electrons from an atom. There are three types of electromagnetic waves that can ionize atoms: higher energy UV, x-rays, and gamma-rays. Because ionizing radiation is a term describing the effect of removing electrons from an atom, how it is produced (via gamma or x-rays) is by and large irrelevant. This is why FDA and USDA regulations allowing the use of ionizing radiation for pathogen

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[1] For more information about RAD Source the RS 420 machines, *see* RAD Source White Paper and RS 420 Operator's Manuals, copies of which are attached hereto as **Exhibits 1 - 4**.

[2] *See* letters from Aaron Jezghani, Ph.D. and Roger Kern, Ph.D., attached hereto as **Exhibits 5 and 6**, respectively,

reduction, antimicrobial decontamination, and phytosanitary treatment do not distinguish between gamma or x-ray produced ionizing radiation.[3] In short, it is widely understood and accepted that gamma and x-ray irradiation are functional equivalents operating at different energy levels.

C. UTILIZATION OF IONIZING RADIATION ON PRODUCTS CONSUMED BY HUMAN BEINGS[4]

First and foremost, there has been a published study on ionizing radiation and its effect on medical marijuana, which concluded that ionizing radiation is safe and effective method for decontaminating of medical marijuana. [5]

Moreover, while it would be impossible to include *all* third-party studies/assessments regarding the use of ionizing radiation on products consumed by humans, the following are studies and work performed using RAD Source equipment:

- "Phytosanitary Irradiation: Technology and Efficacy," Andrea Beam, Supervisory Biological Scientist, USDA – CPHST Miami Lab, Power Point Presentation.
- "PPQ Irradiation Program: Research and Future Directions," Laura Jeffers, USDA – APHIS-PPQ, Center for Plant Health Science and Technology.
- "APHIS PPQ Phytosanitary Irradiation Program," Laura Jeffers, USDA – Field Operations, Plant Protection and Quarantine – APHIS – USDA.

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[3] The unit of measurement for absorbed doses of ionizing radiation, the Gray (Gy), likewise does not distinguish between gamma or x-rays as the source of the ionizing radiation.

[4] Clearly, cannabis is not food. In any event, Title 21, Chapter I, Subchapter B, Part 179 of the Code of Federal Regulations ("C.F.R.") specifically uses the term, and permits, "ionizing radiation" for food treatment. The regulation further sets forth the operational parameters for x-ray equipment that is approved for use on food. RAD Source's RS 420 machines are fully compliant with these parameters. The RS 420 machines conform to federal safety and operational guidelines, and are surveyed for safety on two occasions before being put into use.

[5] *See* Hazekamp et al. study, a copy of which is attached hereto as **Exhibit 7**.

- "Effect of X-Ray Irradiation on Reducing the Risk of Listeriosis in Ready-to-Eat Vacuum-Packaged Smoked Mullet," Journal of Food Protection, Vol. 69, No. 7, 2006, PP 1561-1564. Andrews, et al.
- "Reduction of Vibrio vulnificus in pure culture, half shell and whole shell oysters (crassostrea virginica) by X-ray,"International Journal of Food Microbiology, 130, 2009, pp 135-139. Mahmoud.
- "X-ray Machines Help Kill Bacteria in Food," MS Ag Communications, 05/07/2010.[6]

D. DECONTAMINATING CANNABIS

Given the multiple steps involved in harvesting, drying, processing, and packaging marijuana, it can be difficult to maintain perfectly sterile conditions throughout the entire marijuana production process. Moreover, just like cultivating any other crop, marijuana is subject to a wide range of potential contaminants including yeast, mold, mildew, insects, and other pathogens. The most concerning pathogen in the marijuana industry is *Aspergillus*. There have been documented cases of medicinal marijuana patients who have died from aspergillosis, a condition caused by inhaling *Aspergillus* spores.

In order to ensure the safety of the product ultimately delivered to the consumer, cultivators utilize decontamination processes in the everyday processing of marijuana product and in converting nonconforming product into safe, useable product. RAD Source has numerous test results from multiple states, including Nevada, that show its use of X-ray treatment on marijuana reduces pathogens to "too few to detect" levels, while having little to no impact on THC, terpenes, or moisture. Furthermore, there is no change to the core characteristics of the product after treatment. One such study was

[6] Copies of the foregoing are attached here to as **Exhibits 8-13**.

conducted in Nevada at the request of the Department of Taxation, Marijuana Enforcement Division using a RAD Source machine. The confirming results of that study are in the CCB's files.

II. THE BAN ON RAD SOURCE'S EQUIPMENT IMPOSED BY THE DEPARTMENT OF TAXATION MARIJUANA ENFORCEMENT DIVISION, AND RESULTING LITIGATION BY RAD SOURCE[7]

From March 2017 through March 2019, Nevada marijuana cultivators utilized the RS 420 Line in everyday processing of marijuana to reduce yeast, mold (e.g., *Aspergillus*), and other pathogens and in converting nonconforming product into safe, useable marijuana product. During this time, the Department received numerous communications and documents from RAD Source relative to the use of the RS420 Line. In addition, as part of their duties, inspectors from the Department were in facilities using the RAD Source machines. The Department therefore was well aware that growers were using RAD Source's technology to treat marijuana.

In March 2019, with no advance notice to RAD Source, the Department imposed a self-described, statewide "moratorium" (i.e. ban) on RAD Source's machines. After initial communications in March and April 2019, in which the Department insisted that RAD Source get FDA approval or an exemption for its machines – which was impossible to do - the Department went radio silent and refused to communicate further with RAD Source and refused to meet with RAD Source to address the ban. The Department chose this course of action despite the fact that RAD Source: (1) answered all of the Department's initial questions regarding the RAD Source X-ray irradiators, (2) gave an in-depth analysis about the impossibility of FDA approval or an exemption given

[7] Additional information and documents regarding the Department's ban, RAD Source's attempts to communicate and meet with the Department, and the litigation brought by RAD Source ultimately resulting in a writ of mandamus can be found in RAD Source's *Second Amended Complaint*, RAD Source's *Application for Order to Show Cause Why a Writ of Mandamus Should Not Issue*; and RAD Source's *Reply in Support of Application for Order to Show Cause*, copies of which are attached hereto as **Exhibits 14-16**.

cannabis is a controlled substance and not a food and not under the FDA's authority, (3) explained that RAD Source's X-ray irradiators met FDA requirements for food, and (4) provided a white paper with detailed information and references that RAD Source's X-ray irradiators were safe to use.

The ban negatively impacted RAD Source, straining its relationships with existing Nevada customers and preventing any new machine sales. As a result of the Department's refusal to communicate or meet with RAD Source, even after RAD Source retained legal counsel, RAD Source had no option but to commence a lawsuit against the Department. On November 7, 2019, RAD Source filed an action (the "Action") seeking a writ of mandamus to lift the ban and monetary damages.

On June 24, 2020, the court in the Action entered a Minute Order setting forth its intent to grant the writ of mandamus RAD Source had requested.[8] On July 7, 2020, the Court entered a Writ of Mandamus (the "Writ").[9] In the Writ, the Court ruled in pertinent part:

> 3. The Department violated NRS 453D.200(f) and failed to perform acts which the law compels it to perform by prohibiting the use of the RS 420 Line without any justification, hearing, or notice.
>
> 4. Additionally, the Department violated NRS 453D.200(f) … by creating impossible standards for RAD Source to meet, namely requiring FDA certification or an FDA letter of exemption in order to lift the ban on the RS 420 Line.
>
> 5. …[T]he Department has acted arbitrarily and capriciously by banning RAD Source's RS 420 Line, which is a safe and effective method for treating marijuana.
>
> * * *

[8] *See* Minute Order, a copy of which is attached hereto as **Exhibit 17**.

[9] A copy of the Writ is attached hereto as **Exhibit 18**.

> 10. The Department's self-defined "moratorium" on ionizing radiation technology is in violation of Nevada's Administrative Procedures Act because the moratorium was enacted in violation of NRS Chapter 233B.

The Court specifically ordered the Department to "*immediately lift the prohibition on the RS 420 Line and allow the RS 420 machines to return to operation" and to "cease and desist from requiring the RS 420 Line to meet the impossible FDA Requirement.*" (emphasis added).

III. REGULATION 12.065

On May 29, 2020 – while the Action was pending but before the court had set forth its intention to grant the Writ - the CCB published initial draft regulations relating to the cannabis industry. Included in the notice of the draft regulations was an invitation to interested parties to submit comments to the proposed regulations on or before June 9, 2020. There was nothing in the initial draft regulations pertaining to labeling cannabis or cannabis products decontaminated using any form of radiation.

On June 18, 2020, a regulatory workshop was held wherein the proposed regulations were submitted to the CCB in anticipation of the initiation of the CCB's oversight effective July 1, 2020. Again, there was nothing in the proposed regulations noticed for consideration and adoption pertaining to labeling cannabis or cannabis products that were decontaminated using radiation, nor was there any discussion relative to such during the workshop. However, on July 3, 2020 — after the entry of the June 24, 2020 Minute Order in the Action, and thus, after the CCB was aware that the Writ would be entered — the CCB published final proposed regulations, which for the first time included proposed Regulation 12.065:

> Proposed Regulation 12.065 – Cannabis treated with radiation.
>
> If any cannabis or cannabis product has been treated with radiation at any time, any and all packaging of the irradiated cannabis or cannabis product must include labeling that contains the following statement: "WARNING: This product contains ingredients that have been treated with irradiation"

in bold lettering, along with the Radura symbol as used by the US Food and Drug Administration.

On July 21, 2020, the CCB adopted NCCR 12.065, which was slightly different than the proposed regulation first published just 18 days earlier. In its final form and as adopted, NCCR 12.065 provides:

> **12.065 Cannabis treated with radiation.** If any cannabis or cannabis product has been treated with radiation at any time, any and all packaging of the irradiated cannabis or cannabis product must include labeling that contains the following statement: "NOTICE: This product contains ingredients that have been treated with irradiation" in bold lettering, along with the Radura symbol as used by the U.S. Food and Drug Administration.

IV. RESOLUTION OF THE ACTION AND RAD SOURCE'S PETITION

On November 5, 2020, RAD Source and the Department attended a mediation with Justice (Ret.) Michael Cherry, wherein the parties agreed upon the terms of a settlement to resolve the Action and to potentially avoid further litigation with respect to NCCR 12.065. On December 7, 2020, the Department approve the settlement, and the settlement was approved by the CCB on December 18, 2020.

Pursuant to the terms of the settlement, on December 3, 2020, RAD Source submitted a petition to repeal or amend NCCR 12.065 (the "Petition").[10] In the Petition, RAD Source identified multiple issues with NCCR 12.065, including:

- NCCR 12.065 was promulgated with less than 30 days' notice violating NRS § 678A.460(1)(a), (b).
- The regulation does not define the term "radiation," which can apply to a number of common practices in the cannabis industry, including exposure to sunshine, ambient lights, grow lights, and decontamination using radio

[10] *See* RAD Source's Petition, a copy of which is attached hereto as **Exhibit 19**.

frequency (used by one of RAD Source's competitors) and ionizing radiation (used by RAD Source's RS 420 Line).

- The regulation appears to target only post-harvest decontamination using ionizing radiation. In other words, the regulation appears to target RAD Source, and appears to have been introduced as retaliation against RAD Source for the Writ entered by the Court in the Action.
- The regulatory warning is neither supported by scientific evidence nor was it promulgated by legislation.
- The FDA does not construe over the counter drugs decontaminated using ionizing radiation to be harmful to the public and therefore it does not require any labeling.[11]
- The CCB is in possession of scientific studies, data, and other reports and information, which clearly show the use of ionizing radiation, and specifically the use of x-ray irradiation by a RAD Source machine, is a safe and effective method for decontamination of cannabis flower. The requirement of a label suggesting exactly the opposite is ***counterproductive to public health and safety***.

[11] *See* FDA Notice, a copy of which is attached to RAD Source's Petition.

EXHIBIT 1

Introduction

Cannabis is increasingly becoming legal at the state level in the United States for medical and/or recreational use. Each state has to contend with the question of how to ensure the safety of a new product that is not covered under any existing federal safety guidelines. The purpose of this whitepaper is to address the efficacy and safety of x-ray irradiation, a form of ionizing radiation, in the treatment of cannabis.

RAD Source is proud to offer the RS 420 equipment line for the safe and effective irradiation/decontamination of cannabis: the RS 420 X-Ray Irradiator, the RS 420•M X-Ray Irradiator, and the RS 420•XL X-Ray Irradiator. Within the United States, the RS 420 line has been approved for use in the treatment of cannabis in multiple states. As well, some states do not require approval of this type of unit from an enforcement perspective. RAD Source also works with state agencies other than enforcement to comply to any other regulations the state may have as it pertains to the actual equipment itself.

By way of an overview, the RS 420 X-Ray Irradiator is a cabinet X-ray device that conforms to 21 CFR 1020.40 for optimal safe use. The units in the RS 420 line are equipped with either a single or dual X-ray Emitter. It rotates individual canisters around this X-ray Emitter for a specific period of time so that ionizing radiation (photons) is delivered to the contents of the canisters. RAD Source deems this process as "Photonic Decontamination". The RS 420 line utilizes proprietary, patented technology. *See* Patents 7,346,147 7,515,686, and patents pending. RAD Source's EPA Establishment number is 94602-GA-1

The RS 420•M X-Ray Irradiator and the RS 420•XL X-Ray Irradiator utilize the same technology (ionizing radiation) at smaller and larger capacities.

Please refer to the Specification Sheets, Operator's Manuals, and Standard Operating Procedures for information regarding the safety and function of each device in the attached appendices:

Appendix 1: RS 420 X-Ray Irradiator

1.1 Specification Sheet for RS 420 X-Ray Irradiator

Appendix 2: RS 420•M X-Ray Irradiator

2.1 Specification Sheet for RS 420•M X-Ray Irradiator

Appendix 3: RS 420•XL X-Ray Irradiator

3.1 Specification Sheet for RS 420•XL X-Ray Irradiator

The Public Health and Safety Concerns

Just like cultivating any other crop, cannabis is subject to a wide range of potential contaminants including yeast, mold, insects, and other pathogens.[1] The most concerning pathogen in the cannabis industry is *Aspergillus*. While no state has reported an overdose from medicinal cannabis among those that have legalized its use, there have been documented cases of medicinal cannabis patients who have died from aspergillosis, a condition caused by inhaling *Aspergillus* spores.[2]

Given the multiple steps involved in harvesting, drying, processing, and packaging cannabis, it can be difficult to maintain perfectly sterile conditions throughout the entire cannabis production process.[3] In order to ensure the safety of the product ultimately delivered to the consumer, growers utilize decontamination processes in the everyday processing of cannabis product and in converting quarantined product into safe, useable cannabis product.[4]

How X-Ray Irradiation Works

1. What is Ionizing Radiation?

Irradiation is the process by which an object is exposed to radiation. Simply stated, radiation is energy transmitted in waves or a stream of particles, photons. Think of radiation as energy that travels and spreads out as it goes, *i.e.*, the visible light that comes from a lamp in your house or the radio waves that come from a radio station (RF).

This particle stream has a defined *Wavelength* depending on the emission method used to generate the photons. Wavelengths can vary from the size of a building, to the size of the nucleus of an atom. Wavelength is important for penetration, wavelength of visible light can not penetrate clothing or walls, but the wavelength of X-rays and gamma can, thus giving the latter the ability to apply treatment (photons) to the center of the flower in Cannabis. Although the gamma methodology uses radioactive isotopes such as Cesium-137 and Cobolt-60 to produce photons, the method does not leave the targeted material "Radioactive". In order to become radioactive like the gamma source, decay of the isotope would have to be transferred to the target material, it is not, only photons. This is never an issue with X-rays, they are not from an isotope.

The other types of electromagnetic radiation that make up the electromagnetic spectrum are microwaves, infrared light, ultraviolet light, X-rays and gamma rays. See the figure below depicting the electromagnetic spectrum.[5]

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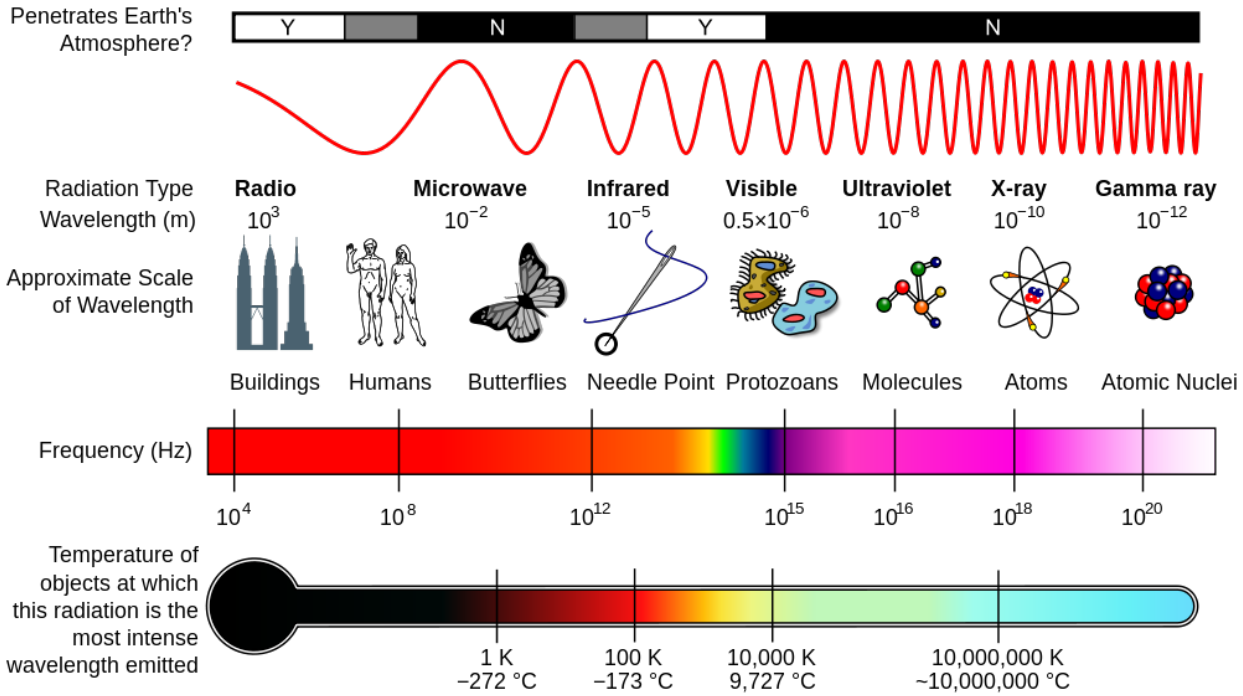
[1] Hazekamp, Arno, Evaluating the Effects of Gamma-Irradiation for Decontamination of Medical Cannabis, Frontiers in Pharmacology, 2016, 7: 108.
[2] Gargani, Yousef et al., Too Many Mouldy Joints – Marijuana and Chronic Pulmonary Aspergillosis, Mediterranean Journal of Hematology and Infectious Diseases, 2011, 3.
[3] *See* Hazekamp, *supra*.
[4] *Id.*
[5] Figure courtesy of http://www.sun.org/encyclopedia/electromagnetic-spectrum.



Ionization is the process by which an atom or a molecule acquires a negative or positive charge by gaining or losing electrons, often in conjunction with other chemical changes. Ionizing radiation can come from either natural radioactive isotopes (sometimes referred to as "gamma") or from a non-radioactive electronic X-ray tube (Emitter). Ionizing radiation produces photons which inactivate DNA in living pathogenic organisms (e.g., mold and bacteria).

Because of the penetrating properties of ionizing radiation and the ability to neutralize microorganisms, ionizing radiation is used to sterilize or reduce the microbial load of many different types of products such as medical devices, packaging, cosmetics, foods, and agricultural products.

2. How Does Ionizing Radiation Treat Cannabis?

Irradiation reduces or eliminates mold, related toxins, and other pathogens in cannabis.[6] Importantly, the therapeutic components of the product remain unaltered. Ionizing radiation has no humanly discernable effect on cannabinoids and terpenes.[7]

In layman's terms, the process can be described as follows: pathogens (such as mold, fungus, *Aspergillus*, etc.) are living organisms. Cells of living organisms normally grow and divide to form new cells. Radiation works by making small breaks in the DNA inside cells. Because DNA is required for an organism to replicate, this damage either destroys the pathogen or

[6] *See* Hazekamp, *supra*.
[7] *Id.*

renders it unable to reproduce.[8] As a result, the pathogen cannot pass on to the human during consumption and/or the pathogen cannot replicate in the human.

Other decontamination methods are not viable options, as they either affect the chemical content or texture of the product (*i.e.*, through the use of heat, steam, chemicals such as ozone, etc.) or do not penetrate the product deep enough to treat beyond the surface of the dense cannabis flowers.[9]

3. Why is X-Ray Irradiation the Preferred Method?

As depicted in the preceding chart, there are several types of ionizing radiation, ranging from radio waves to gamma rays.

The use of X-ray sources for ionizing radiation is the preferred method for the treatment of cannabis because radioactive isotopes (gamma sources) pose an environmental and security risk.[10] Unlike the "clean" process used with X-ray sources, gamma sources result in a harmful byproduct that requires particularized methods for storage and disposal, a burden and risk for the local jurisdiction, and carry stringent licensing requirements. In fact, the Department of Energy at Los Alamos specifically has a program in place designed to remove gamma sources and replace them with X-ray sources (which they deem as equivalent alternatives) as a means to reduce security risks associated with radioactive isotopes and terrorist activity.[11]

4. Is Ionizing Radiation Safe?

Yes. Irradiation is a safe, widely-utilized, and highly-studied process that is used for a variety of applications including sterilization, diagnostic imaging, blood transfusion, immunology and oncology research, and agriculture, among others.[12]

Ionizing radiation has been used for more than a decade in Canada and the Netherlands specifically for the treatment of marijuana. The RS 420 line has been given either permission or written "permission is not required" for use in the treatment of cannabis by marijuana regulators in multiple states.

Relevant to products treated for human consumption, food irradiation is endorsed by the FDA, the World Health Organization (WHO), the Centers for Disease Control and Prevention (CDC),

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[8] Radiation Therapy Basics, American Cancer Society (ACS), available at: https://www.cancer.org/treatment/treatments-and-side-effects/treatment-types/radiation/basics.html.
[9] *See* Hazekamp, *supra*.
[10] For additional information regarding the differences between X-ray and gamma sources, refer to Gamma vs. X-Ray Comparison, available on RAD Source's website at https://www.radsource.com/wp-content/uploads/2016/06/Gamma_vs_X-ray_Comparison_082415.pdf.
[11] See, https://osrp.lanl.gov/ .
[12] Uses of Radiation, United States Nuclear Regulatory Commission (NRC), available at: https://www.nrc.gov/about-nrc/radiation/around-us/uses-radiation.html.

and the U.S. Department of Agriculture (USDA).[13] Specifically, food irradiation is beneficial for prevention of foodborne illness, preservation, control of insects, delay of sprouting and ripening, and sterilization that may be present in untreated food product.[14]

RAD Source and Its Technology

RAD Source is the developer of the RS 420 line of X-ray Irradiators.

1. About RAD Source

RAD Source was founded in 1997 for the purpose of creating non-gamma irradiation alternatives.[15] Even prior to the more recent security issues associated with radioactive gamma sources, RAD Source was dedicated to solving environmental disposal and related practical issues associated with "hot" source equipment (Isotope based). RAD Source introduced its first products in 1999 and has become the leading provider of renewable, non-isotope, ionizing radiation replacements for self-shielded gamma irradiators worldwide.[16]

RAD Source's patented and proprietary QUASTAR® technology produces high output X-Ray radiation efficiently and reliably for a wide variety of irradiation applications including, but not limited to, blood, cell and tissue, insects, biological research, and viral inactivation.[17] RAD Source equipment is utilized for one application or another in close to all 50 states.[18] It is recognized by the U.S. government as a safe alternative to gamma source irradiators, where over the last 3 years, Rad Source has replaced radioactive isotope (gamma) based irradiators throughout the country and now is extending the program to other countries desiring replacement of gamma sources.

Currently, RAD Source equipment resides in more than 300 major pharmaceutical labs, healthcare institutions, and renowned universities around the world.[19] RAD Source boasts an

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[13] Food Irradiation: What You Need to Know, United States Food and Drug Administration (FDA), Food Facts, June 2016, available at: https://www.fda.gov/food/buy-store-serve-safe-food/food-irradiation-what-you-need-know.

[14] *Id; see also* MSU, X-ray Machines Help Kill Bacteria in Food, 2010 ("X-ray does can kill dangerous bacteria that make people sick, such as salmonella, E. coli, vibrio, shigella, and listeria. The process simply removes harmful bacteria and does not alter the food product in any other way."); Journal of Food Protection Vol. 69, No. 7, Effect of X-ray Irradiation on Reducing the Risk of Listeriosis in Ready-to-Eat Vacuum-Packaged Smoked Mullet, 2006, at p.1564 ("In summary, X-ray irradiation proved to be an effective treatment to control L. monocytogenes [listeria] on smoked mullet without adversely affecting sensory quality."); International Journal of Food Microbiology 130, Reduction of Vibrio Vulnificus in Pure Culture, Half Shell and Whole Shell by X-ray, 2009, at p. 135 (concluding x-ray irradiation is an effective treatment to control foodborne pathogenic microorganism vibrio on oysters).

[15] *See* RAD Source website available at: https://www.radsource.com/

[16] *Id.*

[17] 2019 Capabilities Statement, RAD Source.

[18] Figure depicting RAD Source presence throughout the United States.

[19] *See* RAD Source website, *supra.*

impressive and extensive client list including the American Red Cross, the Mayo Clinic, and the FDA – National Center for Toxicological Research, to name a few.[20]

2. The RS 420 Equipment Line Restricts the Radiation Dose That Can Be Delivered

Gray (Gy) is a measure of ionizing radiation dose in the International System of Units (SI).

A Dose is the accumulated amount of Gy to be delivered to the cannabis material by the RS 420.

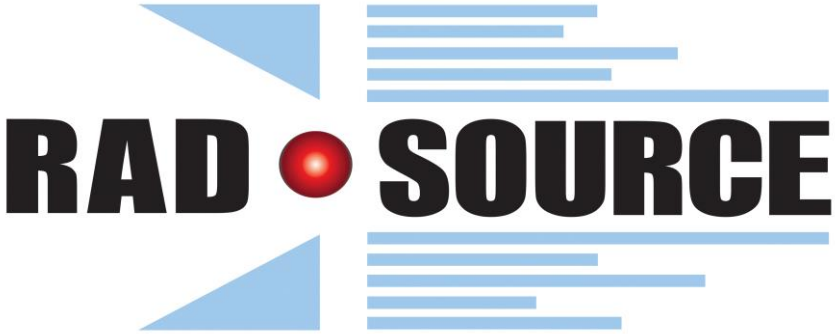
The effective Dose for a typical cannabis operation is 1600 Gy to 2000 Gy, with the dose determined by the bioburden of the facility itself. RAD Source works with the grower to determine the appropriate dose to be effective for decontamination. The occurs initially with the grower and remains intact after that.

Further, all RAD Source equipment complies with safety standards contained in 21 CFR 1020.40 for Cabinet X-ray devices.

The RS 420 commonly utilizes a photon energy of less than or equal to 160 (keV). This is well below the 7.5 (MeV) maximum under the FDA's regulations for food irradiation. Thus, if cannabis was federally permissible and driven by food standards, the RS 420 would comply with the regulations that govern the irradiation of products for human consumption.

[20] *See* RAD Client List, updated 2018, available at: https://www.radsource.com/our-clients/.

EXHIBIT 2



RS 420 Operator's Manual

Rad Source Technologies, Inc.

MKT-019
Revision 1
Effective Date: 06/27/2017

About This Manual

The information in this publication is provided for reference only. All information contained in this publication is believed to be accurate and complete. Rad Source Technologies, Inc. shall not be liable for errors contained herein, nor incidental or consequential damages in connection with the furnishing, performance, or the use of this material.

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User Responsibility

In order to operate properly, this product must be installed, operated, and maintained in accordance with the procedures described herein.

Periodic inspection of the RS 420 will aid in detecting anything that may cause problems with the unit's operating performance. If any part is found to be worn, broken, or damaged in any way, immediately contact Rad Source Technologies, Inc.

Only Rad Source Technologies, Inc. authorized persons should perform repair procedures.

Any alteration to the RS 420, not in accordance with the procedures set forth by Rad Source Technologies, Inc., places sole responsibility on the user for any malfunction resulting from faulty maintenance, improper repair, damage, or alteration by any person other than Rad Source Technologies, Inc. authorized persons.

⚠ WARNING The RS 420 should only be operated by AUTHORIZED PERSONNEL who have thorough knowledge of the proper use of the device. The Key for the unit (See Fig. 3) should be accessible only to Authorized Personnel.

Questions about its use should be addressed to Rad Source Technologies, Inc. at (678) 765-7900 or email service@radsource.com.

System Description and Indications for Use

The RS 420 is a cabinet X-ray device with a single X-ray Source. It rotates individual canisters around this X-ray source for a specific period of time so that irradiation is delivered to the contents of the canisters. The RS 420 utilizes proprietary, patented technology. (Patents 7,346,147 and 7,515,686)

Indications for Use

The RS 420 is intended for the irradiation of mold and fungus remediation.

Safety Information and Symbols Used

Specific notations are used in this manual to call attention to conditions that could potentially result in injury, damage to equipment, or require special attention.

WARNING, CAUTION, and NOTE may be used throughout this manual and on the RS 420 to emphasize important and critical information. You must read these statements to help ensure safety and to prevent product damage.

⚠ WARNING Indicates a potentially hazardous situation which if not avoided could result in death or serious injury.

⚠ CAUTION Indicates a potentially hazardous situation which if not avoided could result in minor or moderate injury. It may also be used to alert against unsafe practices.

NOTE: Used to notify people of installation, operation, or maintenance information that is important, but not hazard-related.

IMPORTANT SAFETY INSTRUCTIONS

Also note the additional SAFETY instructions will be found throughout this manual and ALL must be heeded.

⚠ WARNING This unit is to be installed only by factory-authorized personnel. DO NOT ATTEMPT to install or otherwise apply or attach any electric power to the unit prior to contacting Rad Source Technologies, Inc. at service@radsource.com or call (678) 765-7900.

⚠ WARNING The machine is extremely heavy and movement should only be done AFTER CONSULTING WITH the manufacturer. NEVER attempt to move the machine once it has been installed BEFORE contacting the manufacturer. Sudden movement, or movement over uneven floors, inclines, or declines may result in tipping. A level floor is required for installing this unit.

⚠ WARNING This unit is to be serviced by trained personnel only. Do not remove any covers or adjust any screws, bolts, or related fasteners.

⚠ WARNING This manual instructs how to use the RS 420. If you disregard the instructions or information in the manual, you could be assuming responsibility for damages, costs, or injury incurred by such disregard.

⚠ WARNING This device is equipped with safety interlocks incorporated into the chamber door and X-ray tube access panel to prevent the unit from operating when the chamber is open. Overriding, modifying, adjusting, or in any way defeating these interlocks is hazardous.

⚠ WARNING If any obvious mechanical damage is detected or suspected, cease use immediately, and contact Rad Source Technologies, Inc. at (678) 765-7900.

⚠ CAUTION Please keep unit dry. When cleaning, do not allow cleaners or water to drip into panels or chamber. Only use damp cloth with mild detergents for cleaning.

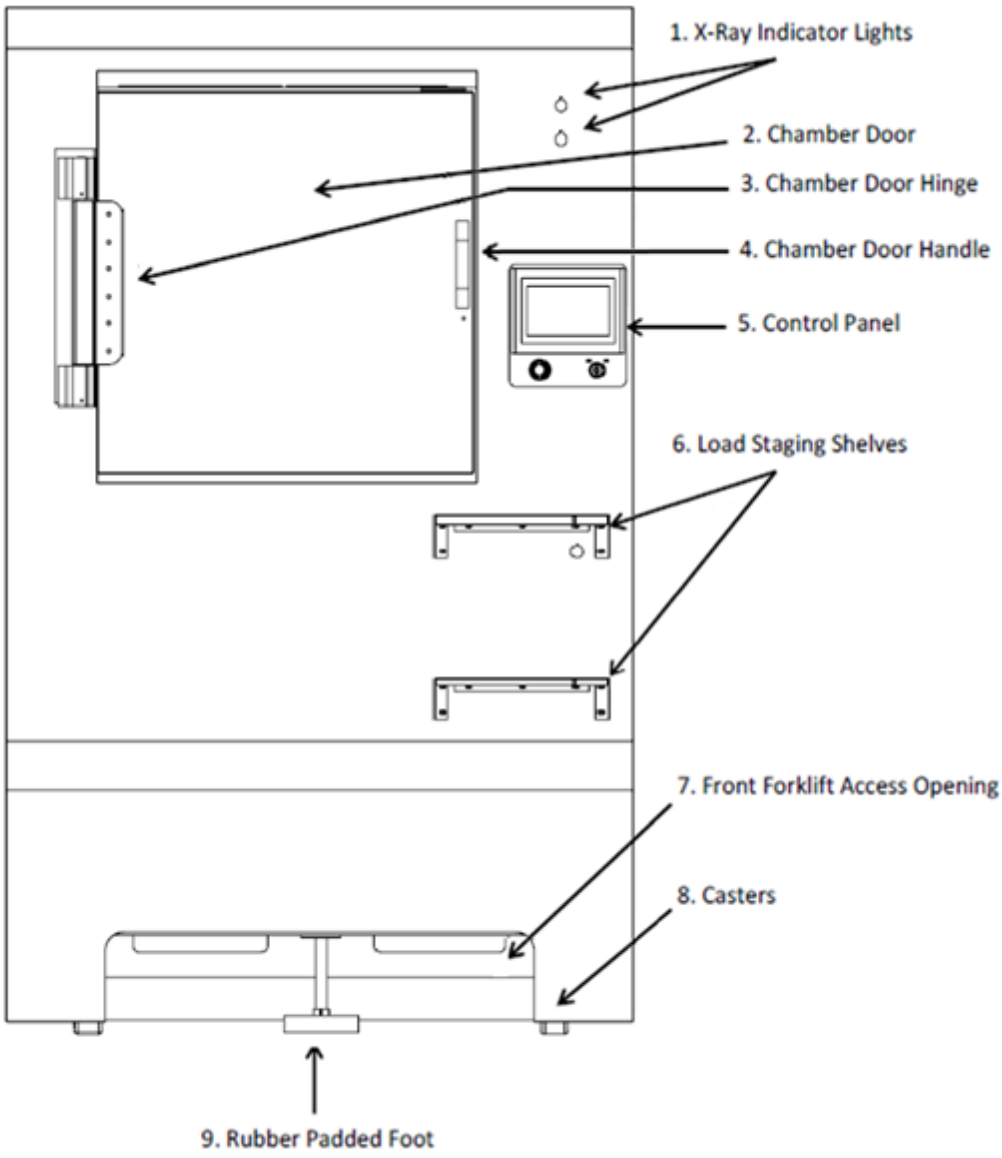
⚠ CAUTION Do not use the top of the unit as a storage area, or place any heavy items or items containing liquids or materials that may harm the unit if leaked or spilled on top or inside.

System Components

Illustrations of the RS 420 components and item descriptions are found in this section and in the following sequence:

Fig. 1 – Front View of RS 420
Fig. 2 – Rear View of the RS 420
Fig. 3 – Front View with Chamber Door Removed
Fig. 4 – Canister
Fig. 5 – Canister Holder with Canister Properly Inserted

Fig.1: Front View of the RS 420



1. **X-ray Indicator Lights** – Two red lights. They will flash in an alternating fashion to indicate when X-rays are being produced. They will both light red when the machine is momentarily evaluating conditions prior to turning on X-rays.

   NOTE: Failure of one of these lights during operation will result in that particular light not operating and the Fault Light will then flash as the failed light normally would. This will not discontinue the Cycle in progress, however, the failed light should be replaced immediately so the X-ray Indicator Lights operate normally. Should both X-ray Indicator Lights fail, the Fault Light will flash at a high rate, indicating the failure and the machine will not operate until the Lights are fixed.

2. **Chamber Door** – This is a heavy door made primarily of shielding material in the form of lead which shields the X-rays in the irradiation Chamber (See Fig. 3). It is held in the closed position by a magnetic latch that is released only by pressing the Door Release Button on the Control Panel.

   ⚠ CAUTION The Chamber Door should be operated gently and NEVER SLAMMED or RAPIDLY OPENED or RAPIDLY CLOSED.

3. **Chamber Door Hinge** – Holds the Chamber Door and allows it to operate freely. It is adjustable only by the manufacturer.

4. **Chamber Door Handle** – Used to open and close the Chamber Door using the non-mechanical magnetic latch. The handle itself does not operate any mechanical latch mechanism, but is used only for ease of operating the Door itself.

5. **Control Panel** – Contains operating and display controls and indicators.

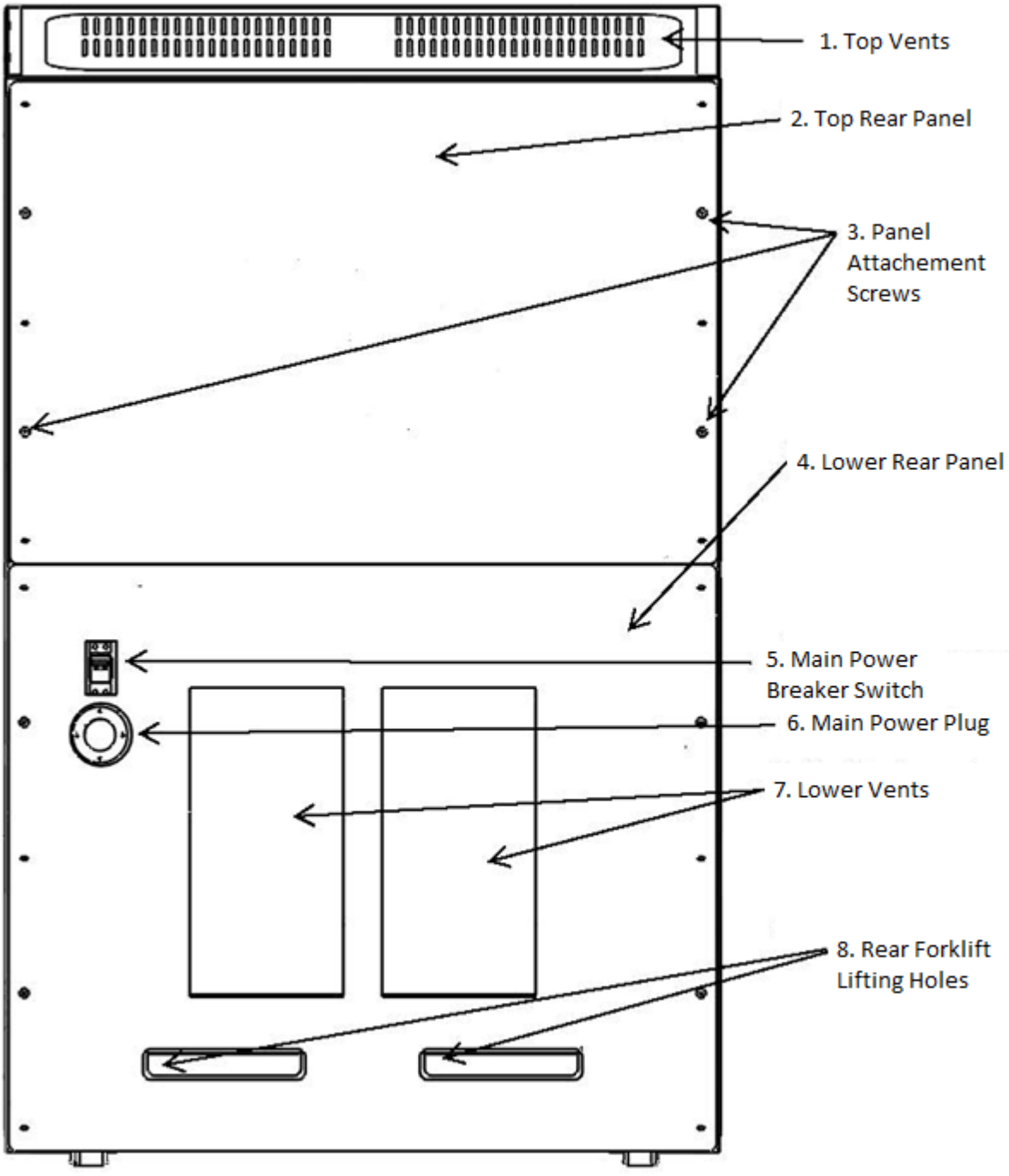
6. **Load Staging Shelves** – Removable shelves may be used to stage Canisters for loading or unloading into the Chamber.

7. **Front Forklift Access Opening** – This allows forklift access for lifting machine only for manufacturer authorized transport.

8. **Casters** – Allow for movement of the machine within a location and ONLY ON LEVEL floors.

9. **Rubber Padded Foot** - Is lowered from its base to mitigate movement.

Fig.2: Rear View of the RS 420



1. **Top Vents** – For allowing heat to escape interior of cabinet. It should never be covered or restricted.

2. **Top Rear Panel** – For maintenance access only.

3. **Panel Attachment Screws** – For retaining all access panels.

4. **Lower Rear Panel** – For maintenance access only.

5. **Main Power Breaker Switch** – Supplies main power to the machine. Should not be shut off unless required for relocating or otherwise removing the machine.

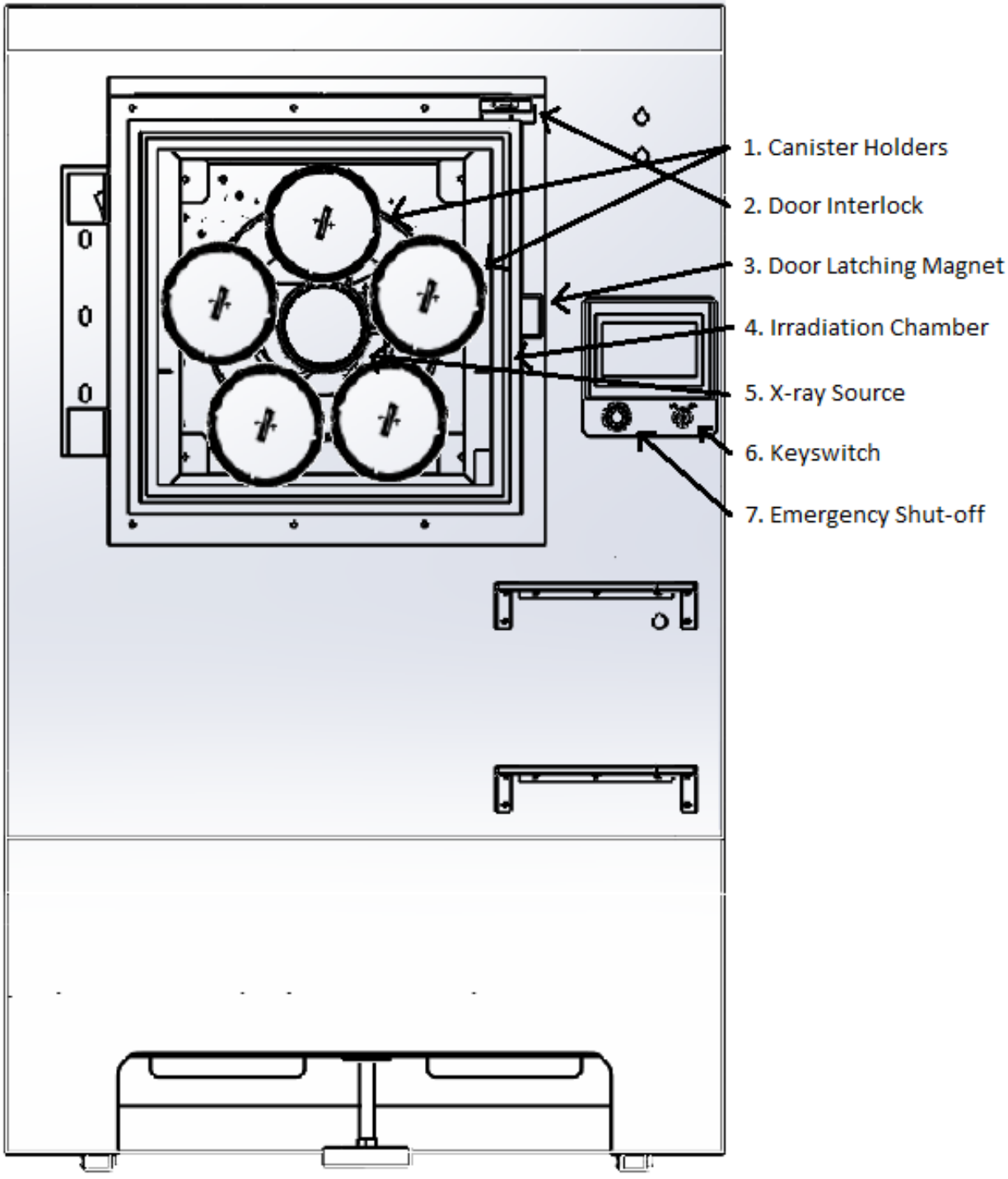
⚠ CAUTION The RS 420 at rest still requires power for its low voltage vacuum power supply which is used for continuous maintenance of the X-ray Source. By shutting off this switch ALL power is removed, including the vacuum power supply and this will cause deterioration or destruction of the X-ray Source over a period of time.

6. **Main Power Plug** – The main power plug, once installed, should never be removed and should periodically be inspected for proper seating. Also, see 5 above.

7. **Lower Vents** – For allowing heat to escape interior of cabinet. It should never be covered or restricted. (Its optional feature for RS 420 version)

8. **Rear Forklift Lifting Holes** – Allows full insertion of forklift lifting tines from front of machine through the rear of the machine.

Fig. 3 Front View with Chamber Door Removed



1. **Canister Holders** – These are affixed to the rotation mechanism and carry the removable Canisters around the X-ray Source. The Canisters are loaded into these Holders.

2. **Door Interlock** – The Door Interlock is a safety mechanism designed to terminate power if the Chamber Door is opened during X-ray operation. The Door has a "tongue" which is aligned to insert into this when the Door is closed, thereby activating the Door Interlock circuit.

⚠ WARNING Never insert anything into the interlock switch or otherwise alter or override the interlock in any way.

3. **Door Latching Magnet** – The Chamber Door utilizes a non-mechanical latching mechanism which is magnetic. The Magnet is de-activated by selecting Door Release on the control panel to allow the Door to be opened. The default state for this mechanism is "on" so that the Door, if closed, will be in a latched mode. Always keep this Magnet clear of small magnetic objects since they can interfere with the normal operation of the Door.

4. **Chamber** – This houses the X-ray Source and is made primarily of shielding material in the form of lead.

5. **X-ray Source** – The X-ray Source is cylindrical and emits radiation outwardly, irradiating the Canisters as they rotate around it. This should not be touched.

⚠ WARNING No objects should EVER be stored inside the Chamber. Nothing should ever inhibit or interfere with the rotation of the Canister Holders.

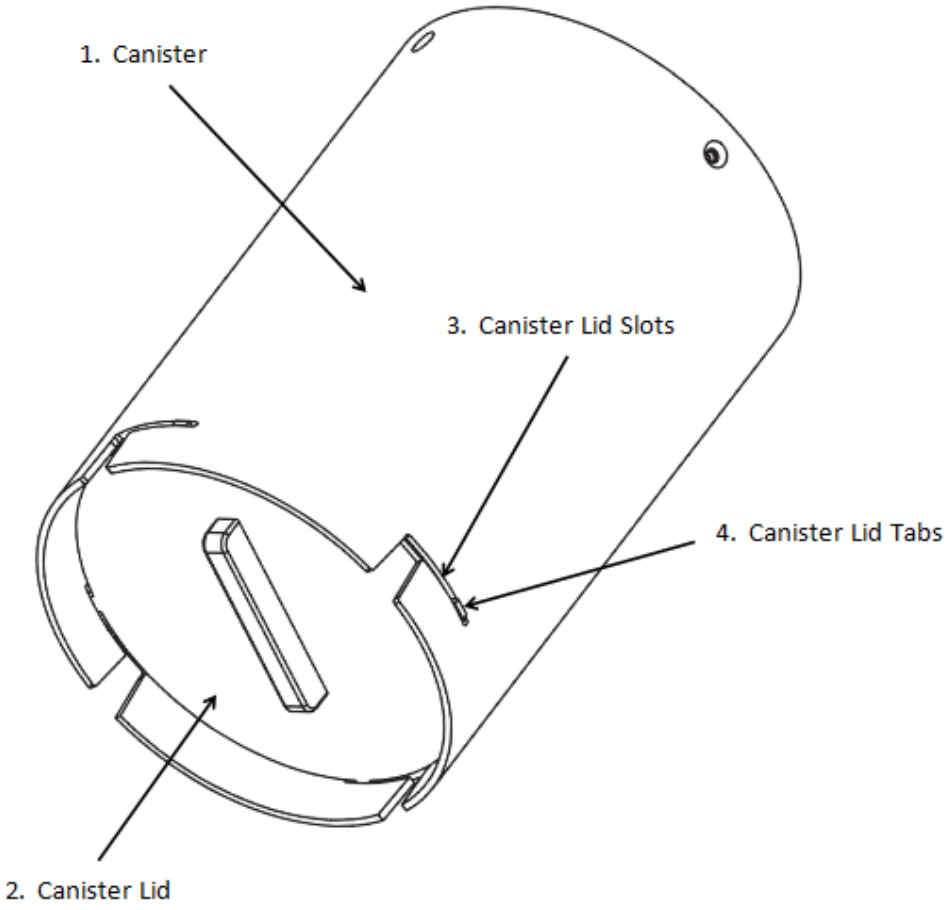
6. **Key Switch** – The Key Switch has 3 positions. On and Off and Momentary Reset. When turned all the way to the left, the unit is in the Off mode and is completely non-operational (aka. "at rest"). This would be its position during long down times (days, e.g.). When turned once to the right (clockwise), the Key Switch is in On, its Standby mode. We turn the Key switch once again to the right (clockwise), The key will go to Momentary position and when we release it, it will back to On position again. This is the time the system is on position and the Green Led turn ON.

7. **Emergency Stop or E-Stop Button** – When pressed, all processes are immediately stopped. The E-Stop Button should remain depressed until the emergency is resolved. Investigate the reason the E-Stop Button was pressed before resuming normal operation. If the E-Stop Button is pressed for any reason during a Cycle, turn the Key to the Off position, turn the E-Stop Button clockwise to release it, and turn the Key to the On position to resume normal operation.

⚠ CAUTION The E-Stop Button does not remove all power to the machine. The X-ray tube vacuum pump power supply, relay K1, and safety relay remain powered.

⚠ CAUTION Whenever the E-Stop Button is pressed, either accidently or due to an emergency, ALWAYS turn the Key to the Off position before resetting the E-Stop Button.

Fig. 4 Canister



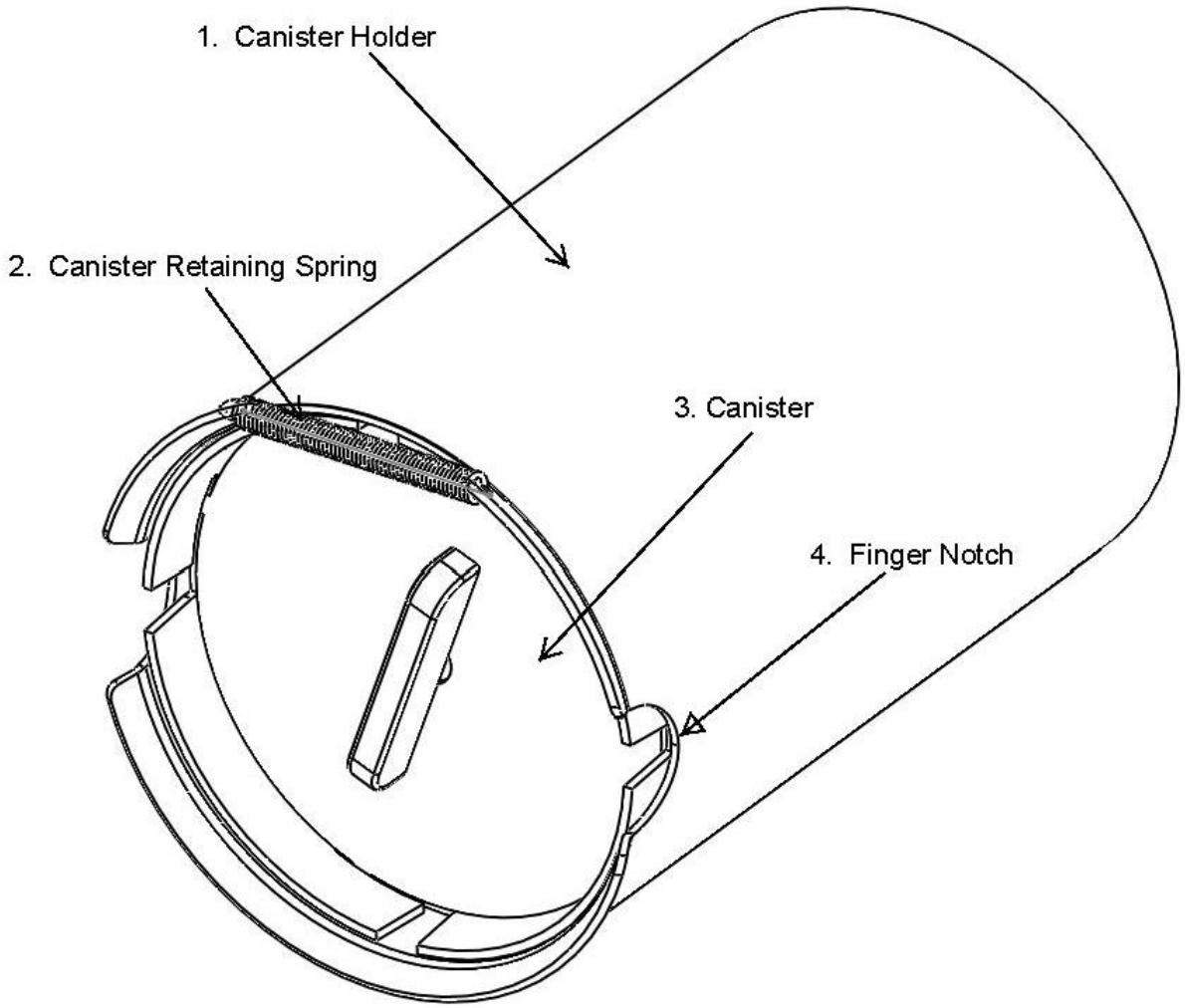
1. **Canister** – This is required for containing the products intended to be irradiated. The standard Canister is approximately 7" in diameter by approximately 6" in overall height. The Canister bottom is fixed in place and the removable lid has a handle.

⚠ WARNING The Canister is required since it contains the product to be irradiated within the field of irradiation. ALWAYS use the Canister when irradiating products in a Cycle. NEVER USE ANY OTHER CONTAINER EXCEPT THE CANISTERS PROVIDED WITH THE RS 420.

2. **Canister Lid** – The Canister Lids secure the product within the Canister and must always be properly seated before inserting into the machine. The removable lid operates by simply aligning the Canister Lid Tabs to the Canister openings, seating the Tabs down, and then twisting the Canister Lid all the way to the end of the Canister Lid Slots.

3. **Canister Lid Slots** – These Slots secure the Canister Lid in place. The Canister Lid Tabs must be against the end of these Slots to properly seat the Canister Lid.

Fig. 5 Canister Holder with Canister Properly Inserted



1. **Canister Holder** – This is attached to the rotation assembly within the Chamber and is used to hold the Canisters during irradiation. It is aluminum with a slight flare at its opening to allow the Canisters to be easily inserted.

   The Canister Holders should rotate orbitally around the X-ray Source and on their own axes, which allows more uniform irradiation to the products.

2. **Canister Retaining Spring** – This is part of the Canister Holder and serves to indicate to the operator that the Canister has been fully inserted into the Canister Holder and will remain there for the Cycle. In the event the Canister Retaining Spring catches on any part of the Canister during removal, gently slip the Spring up over the Canister to complete removal without damaging the Spring.

3. **Finger Notch** – Allows the operator to remove the Canisters from the Canister Holder after the Cycle has been complete.

Installation and Site Requirements

Physical Requirements

The RS 420 requires an area approximately 5 feet wide by 4 feet deep. It requires a height clearance of 7 feet. The rear of the machine should never be up against a wall and should allow free movement of air. Do not place the machine closer than 8 inches to the rear wall.

Each side of the machine also requires the free movement of air and therefore, should be no closer than 6 inches to any wall or device. Because the cooling system relies on cool, ambient air, any restriction in air flow will result in restricted operation or no operation due to an inability to cool the machine.

The unit is mounted on casters and when it is in place, the Rubber Padded Foot is lowered from its base to mitigate movement.

Floors on which the unit will be located must be capable of bearing its load. The unit weighs approximately 2,160 pounds and is caster mounted.

⚠ WARNING A level floor is required for installing this unit. The unit is heavy and tipping or movement may result in a dangerous situation.

Electrical

Since a power cord will be connected to the RS 420, it is recommended that a fuse disconnect switch be available within 6 feet of the RS 420's location. The RS 420
6 kW Unit requires 220 VAC/Phase ± 10%, 3 Phase, 50/60Hz, 40Amp.

⚠ WARNING Risk of electric shock. Exterior panels should only be removed by Rad Source authorized maintenance personnel.

⚠ WARNING Unit must be connected only to supply voltage rating marked on the unit and receptacle must be of GROUNDED TYPE (true earth ground is required).

⚠ CAUTION The plug on the rear of the RS 420 should never be forced or otherwise pressed up against a wall. Sufficient clearance should be allowed so that the plug is never at risk for being compromised because of physical stress.

⚠ CAUTION If your facility performs generator tests, then the user must turn the Key to the Off position before the generator test is performed. After the test is over, the user may turn the Key to the On position and resume normal operation.

Environmental Conditions

Indoor Use in an air-conditioned environment:

- Max Temp (F): 82
- Min Temp (F): 62
- Humidity Range: 0 - 90%

Humidity above 50% may result in reduced cooling efficiency.

Cooling

The end user will provide a turn-key Water Cooling Chiller that will be safe, have rugged construction, and is easy to transport, install and maintain in accordance with all pertaining Standards and Codes specific to this kind of equipment. The water cooling system will be used for the removal of heat generated by the X-ray Tube in the irradiator.

Cooling System requirements

Flow Rate : 3.5 to 4.5 Gal/Min
Max Pressure : 40 PSI
Max Temp(F) : 85
Min Temp(F) : 65

Note: It's important to use only stainless steel, aluminum or Plastic component on cooling system connection since the use of Brass, copper or any yellow metal will corrode the
X-Ray tube.

The water chiller must be filled with CLEAN, DEMINERALIZED / PURIFIED WATER ONLY. (NOTE: Unit CANNOT be filled with DI water.)

⚠ CAUTION The cooling vents on the back of the unit should be clear of any obstruction to allow free airflow when the irradiator is operating. Do not place the machine closer than 8 inches to the rear wall. Each side of the machine also requires the free movement of air and therefore, should be no closer than 6 inches to any wall or device.

If the "Cooling Required" warning on the Display Screen is frequently active, it may be due to an overly warm operating environment. Make sure environmental conditions are good and that there are no restrictions on the water chiller.

Operating the RS 420

⚠ WARNING The RS 420 should only be operated by AUTHORIZED PERSONNEL who have thorough knowledge of the proper use of the device. The Key for the unit (See Fig. 3) should be accessible only to Authorized Personnel.

Questions about its use should be addressed to Rad Source Technologies, Inc. at (678) 765-7900 or email service@radsource.com.

Indications for Use

The RS 420 is intended for the irradiation of mold and fungus remediation.

Operating the RS 420

Turning the system on

It should be performed by AUTHORIZED PERSONNEL only. Turn the key right to the RESET position until the Emergency Stop go away then turn the key to the left to the ON position. The machine is ready to operate when the following screen is displayed.

Fig. 6: Initial Screen on RS 420

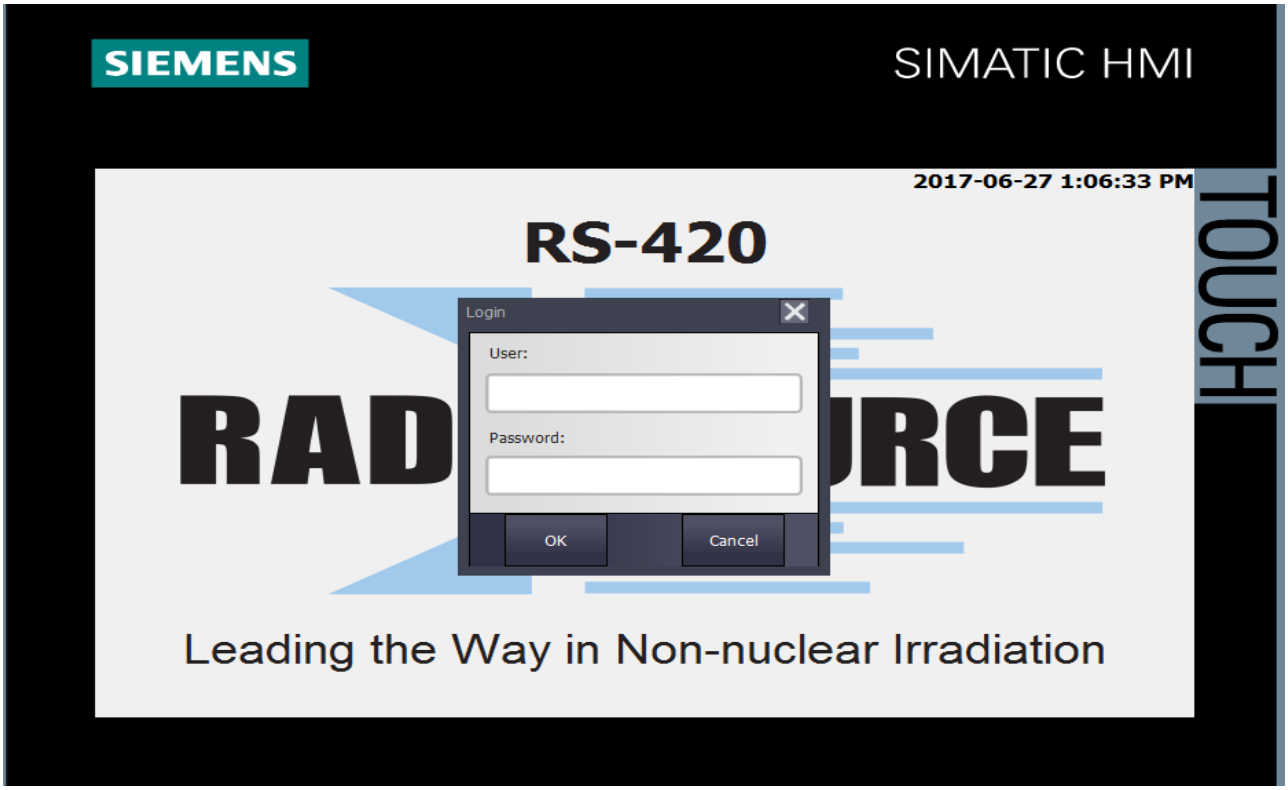
ADMINISTRATION INFORMATION

Adding a user

1. Touch the screen to bring up the login. If this is the first use of the system, login using:

User Name: admin
Password: Contact Rad Source for First Password
Press OK, then touch anywhere on the screen again to complete the login process. Admin should change password once logged in (see **USER INFORMATION PAGE 23**).

Fig. 7: Login Screen

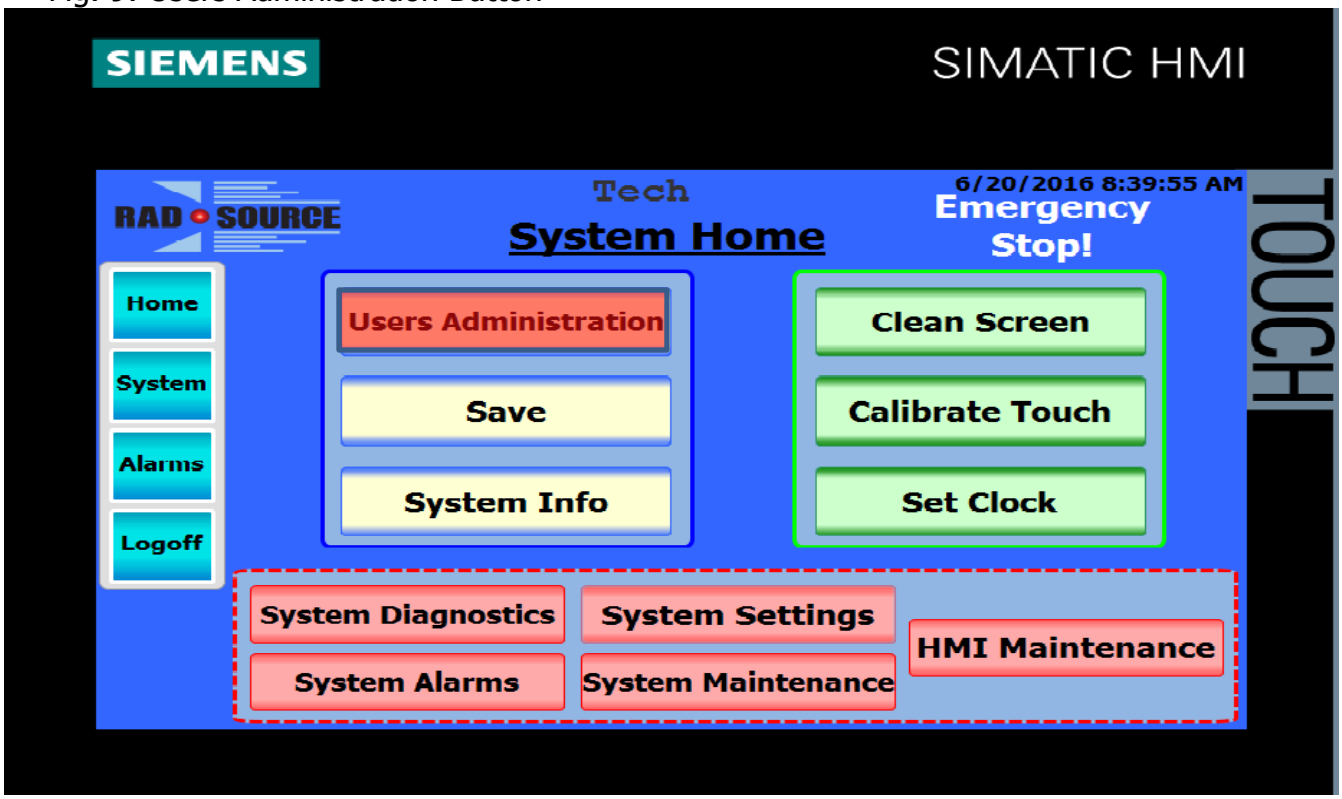


2. Select System

Fig. 8: System Button

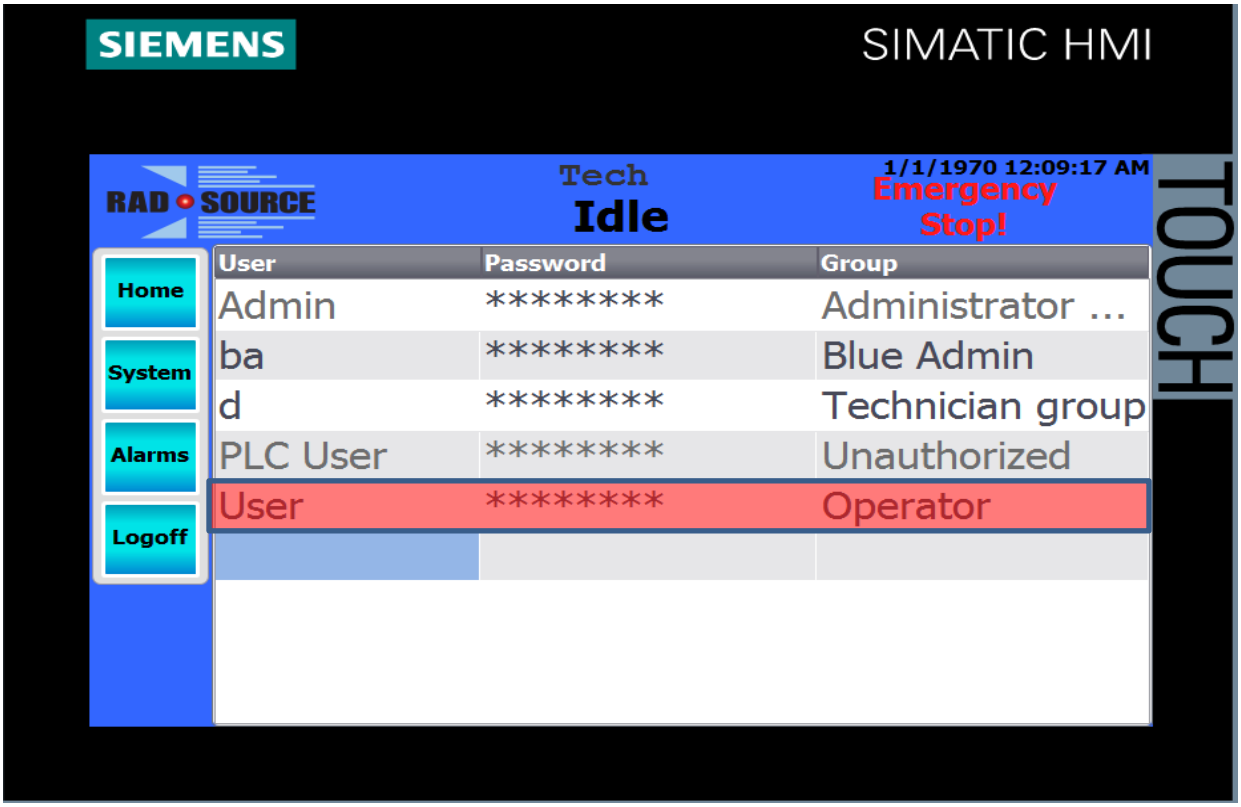
3. Select Users Administration

Fig. 9: Users Administration Button



4. In the User column, double tap directly below the last user field to bring up a key pad.

Fig. 10: New User Field

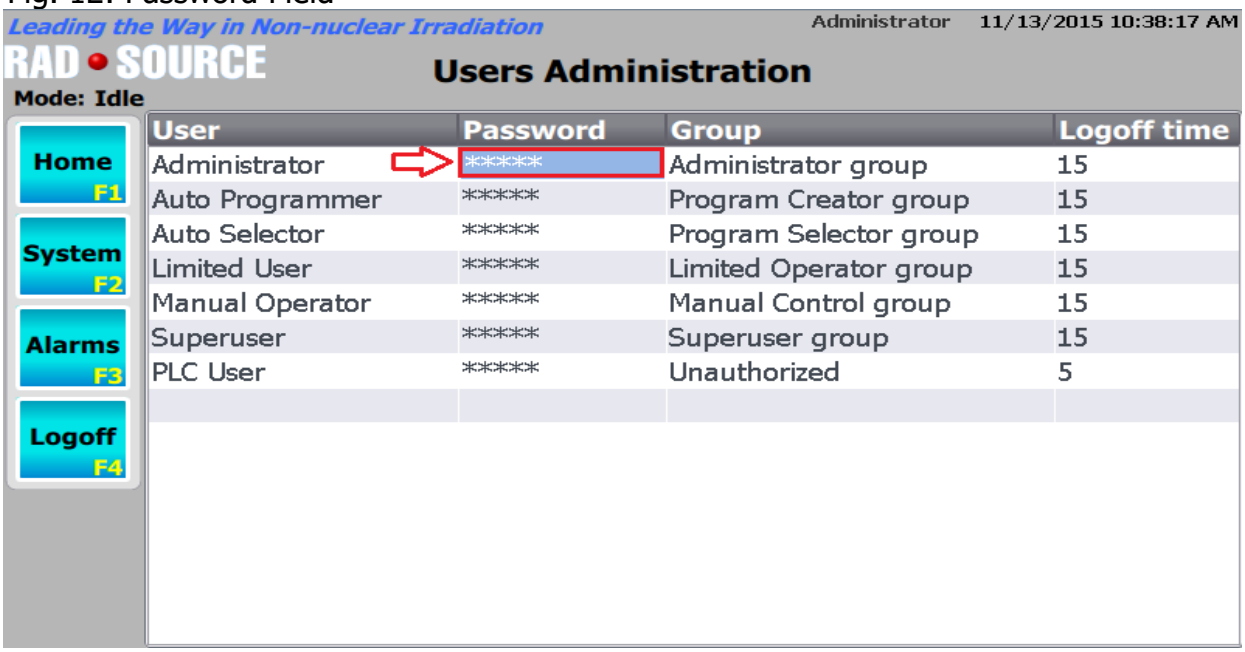


5. Enter desired user name (40 character limit) then press the enter key.

Fig. 11: Enter Key

6. Double tap the field to the right of your new user under the Password column.

Fig. 12: Password Field



7. Enter and record a generic password (4-24 character limit, no special characters e.g. /, *, %, (,) etc.) and repeat the password in the confirmation box below.

NOTE: New Users should be notified to change the passwords upon login (see **USER INFORMATION PAGE 23**). For security reasons 8 * will always be displayed in the password field.

8. After the password is created the Users will sort alphabetically.

Fig. 13: Authorization Table

Using the table below, assign the user to their appropriate group based on their authorized privileges. Administrators should only assign personnel for their appropriate groups/sections.

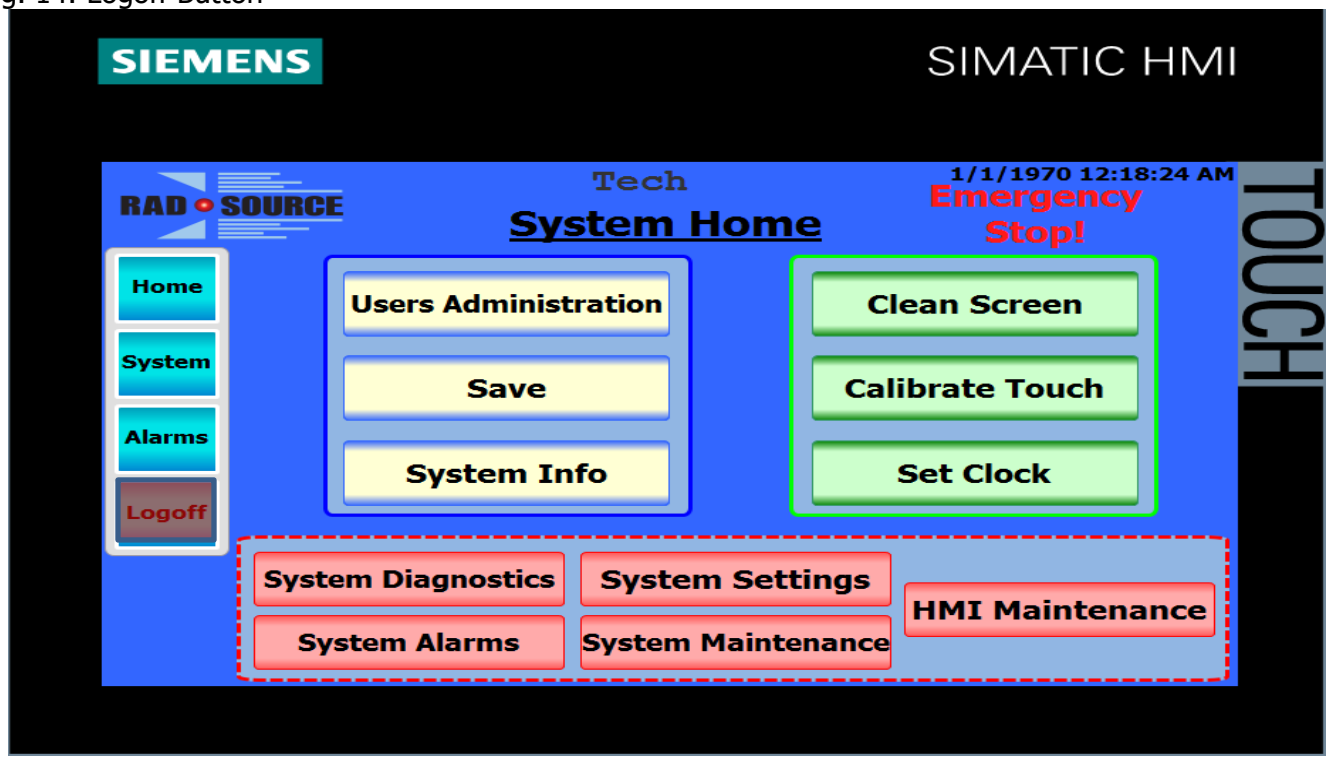
NOTE: Some functions are only available to field technicians.

	Admin	Programmer	Selector
Create/assign Users	X		
Monitor machine status	X		
Change experimental parameters	X		
Create experiments manually	X	X	
Select and run programs	X	X	X
Edit programs	X	X	
System menu access	Full	Limited	Limited

9. Assign the inactivity Logoff Time appropriate for the user (no data is lost if system inactivity logoff occurs).

10. When finished, press Logoff (all changes will be saved). Then select Logoff, again.

Fig. 14: Logoff Button



USER INFORMATION

Removing a user

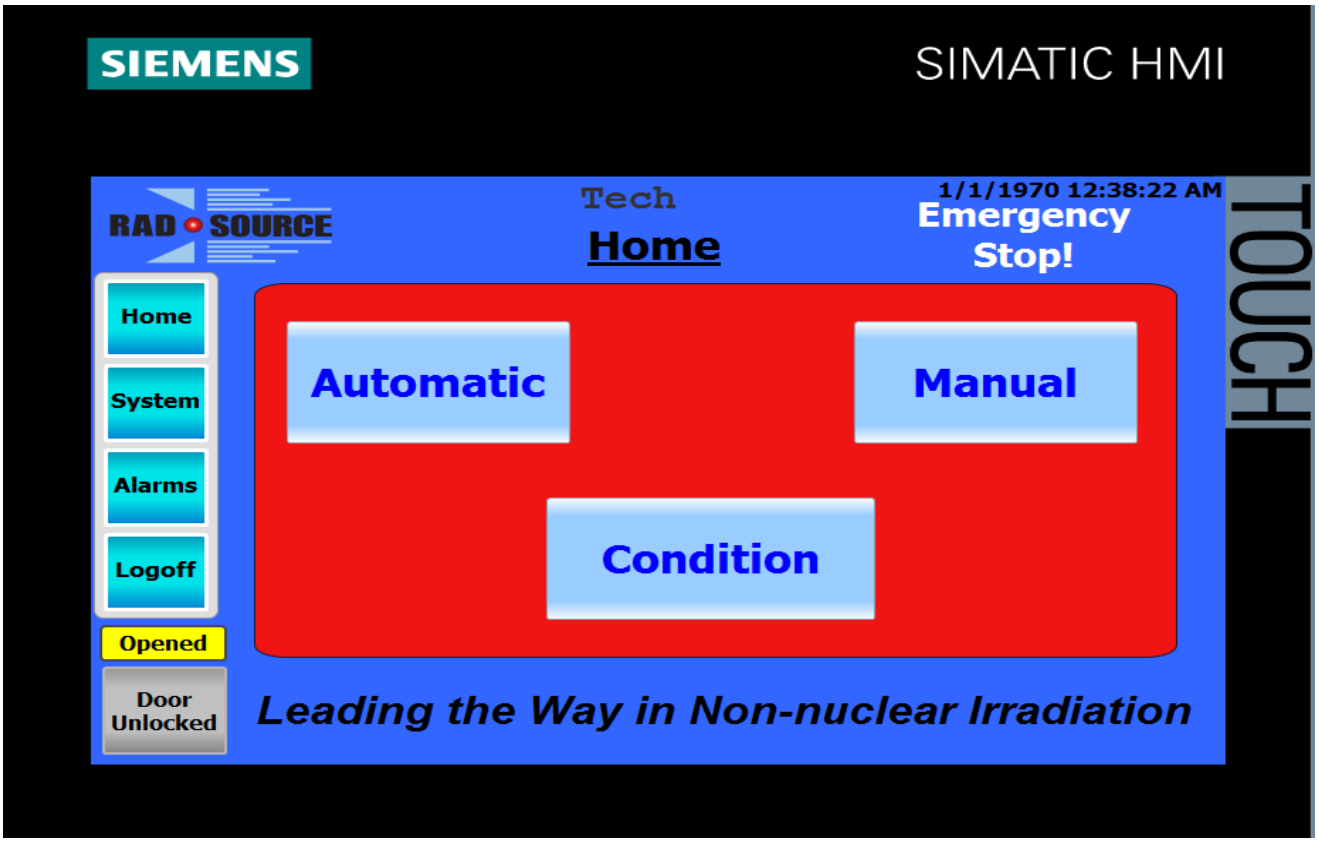
1. Select System (See Fig. 8)
2. Select Users Administration (See Fig. 9)
3. In the User column, double tap the User field you wish to remove to bring up a key pad. (See Fig. 10)
4. Delete the User name then press enter (See Fig. 11). All fields should be removed.

Changing a password

1. Touch the screen to bring up the login (See Fig. 7). New Users should sign in using the information given to them by the Admin.
2. Press OK, then touch anywhere on the screen again to complete the login process.
3. Select System (See Fig. 8)
4. Select Users Administration (See Fig. 9)
5. Double tap the Password field to the right of your user name and create a new password (4-24 character limit, **no special characters** e.g. /, *, %, (,). (See Fig. 12 and 13)

   NOTE: For security reasons 8 (*) will be displayed in the password field.
6. Hit the home button to return to the main screen.

Fig. 15: Home Button



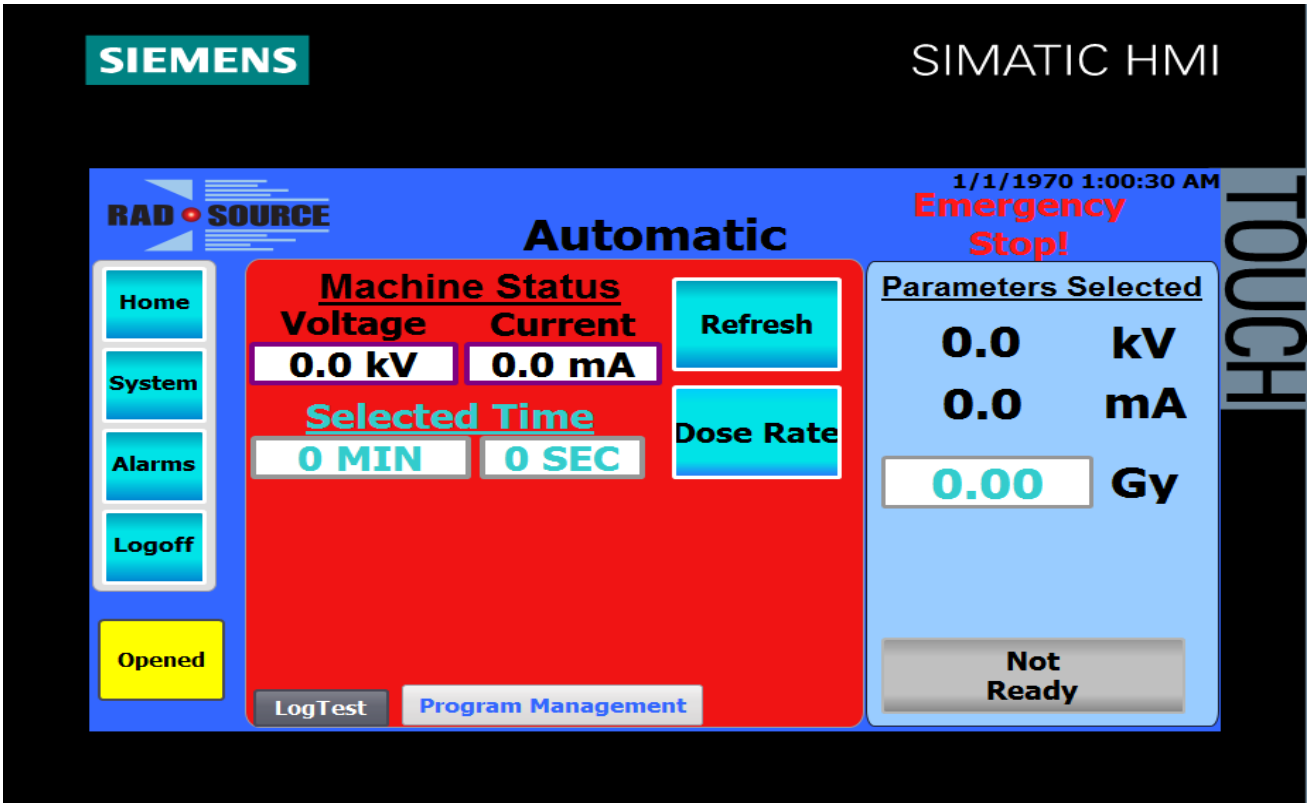
MACHINE OPERATION

Writing a new Automated Program (Admin, Programmer)

1. Touch the screen to bring up the login. Login using your username and password.
2. Then select the Automatic bottom on screen.
3. On Automatic screen the used can adjust and changing the Dose gray.
4. The PLC will determine the time of expose base on the gray amount typing by user in the Gy box.

NOTE: The Voltage and Current status are set on Program for MAX Value.

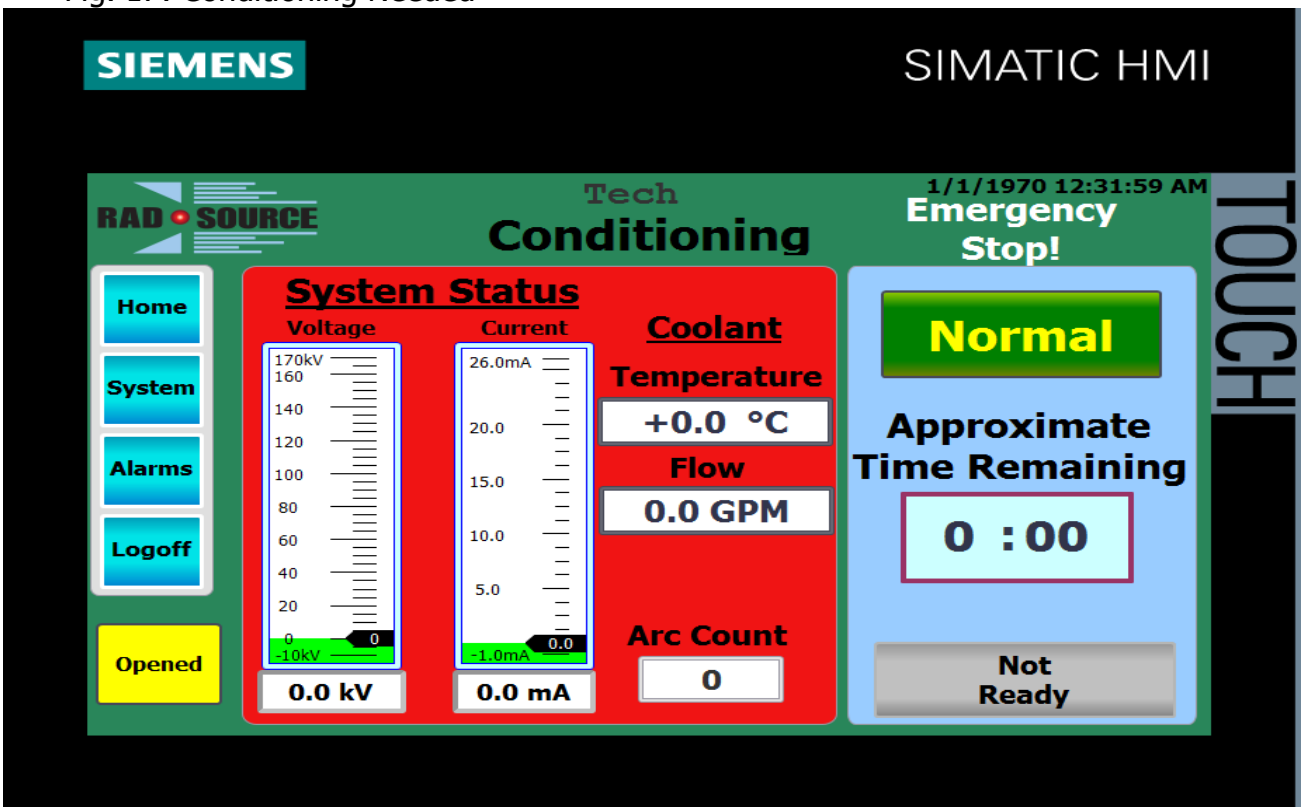
Fig. 16: Automatic Screen



Performing an X-Ray tube Conditioning

1. A prompt will appear if Conditioning is needed.

Fig. 17: Conditioning Needed



NOTE: The condition mode is set to 15 min, running down time before Automatic mode starting. (At least once every 24 hours) and 30 min on extended running down time if not running for 7 days.

ALARMS: If alarm sounds, press Alarms on the left and read the prompt. Press Reset Alarms in the bottom right.

Fig. 18: Alarms Button

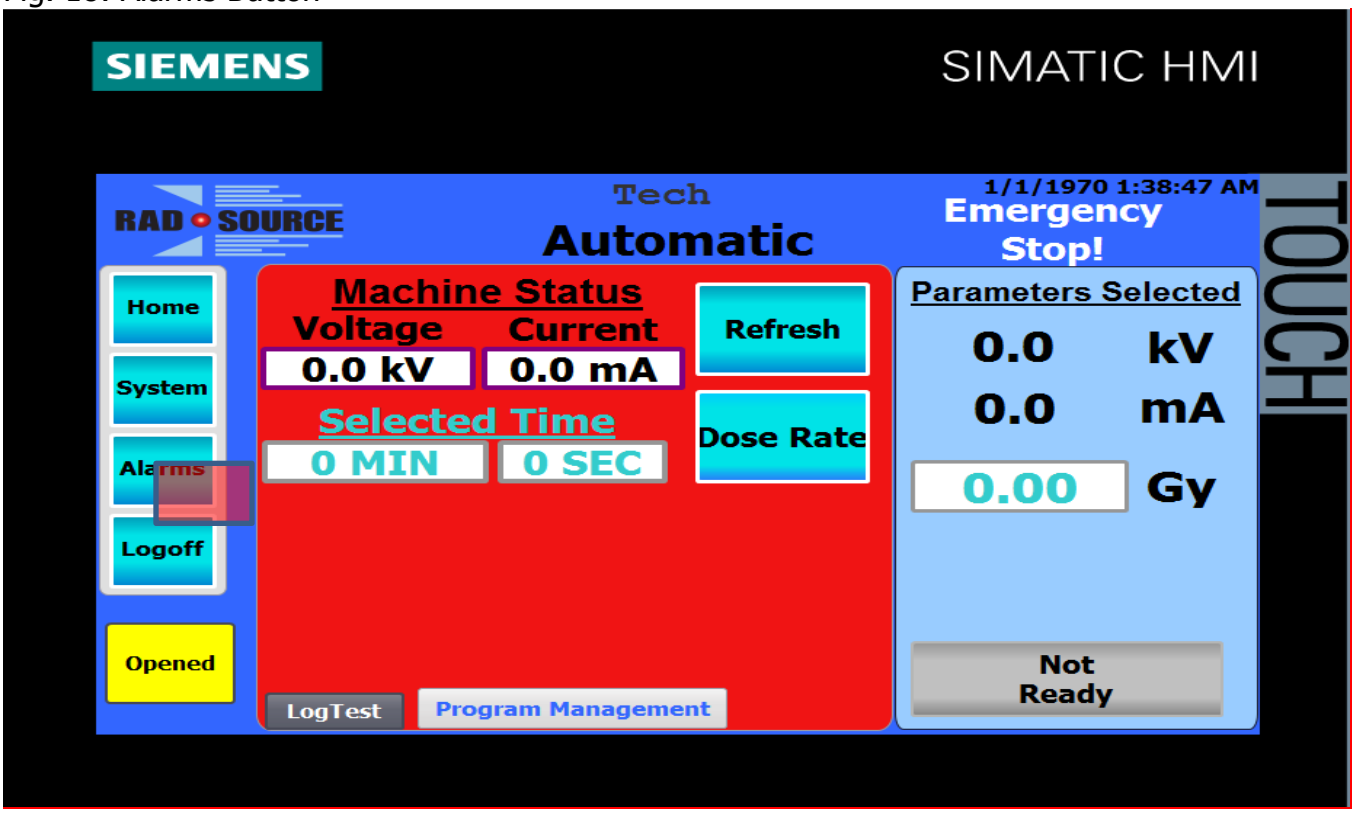
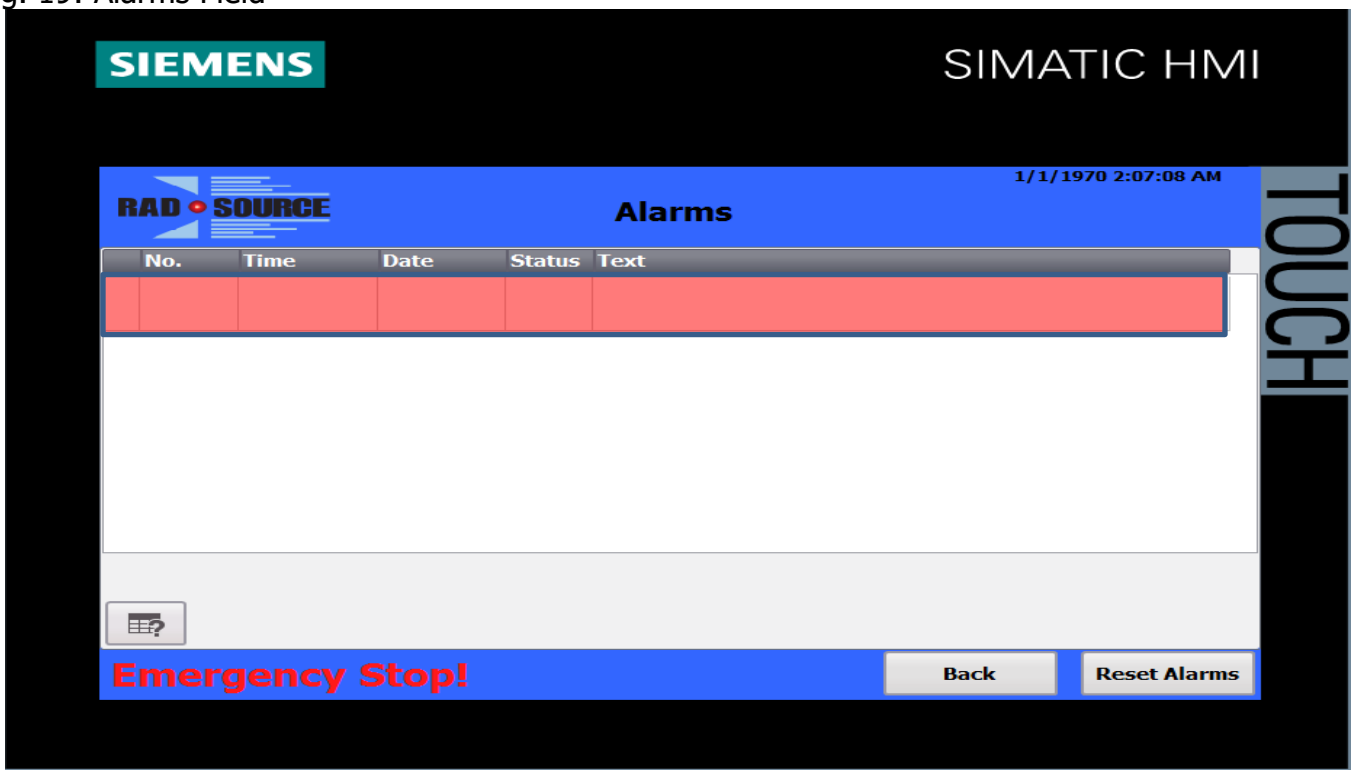


Fig. 19: Alarms Field



Inserting Product into the RS 420

Step 1. Prepare the Canister(s) by verifying the Canister bottom is securely in place and remove the Canister Lid with the handle, if it is in place, so that you have access to the Canister.

⚠ WARNING The RS 420 requires the use of Canisters as provided by Rad Source Technologies, Inc. NEVER substitute non-conforming Canisters.

Step 2. Take the Canister prepared per Step 1 and stand it upright or hold it in your hands and carefully and gently insert your product. To prevent Canister from rotating to one side, ensure the weight of the product is centered with the diameter of the Canister. NOTE: The Canister Lid Slots mark the volume lines for each Canister. This means that the products must fit between the Slots at each end of the Canister.

⚠ WARNING NO METAL OBJECTS SHOULD BE INCLUDED OR INSERTED INSIDE THE CANISTER. Metal objects can create scatter X-rays and affect the irradiation dose (e.g. paperclips).

Step 3. Once the products have been loaded, the Canister Lids must be attached to enclose the products properly into its "irradiation compartment"**.**

Step 4. Open the Chamber Door by selecting the Door Release Button on the Display Screen and pulling the Chamber Door Handle until the Chamber Door is open so that the Canister Holders are accessible.

Step 5. Visually inspect the Chamber. THERE SHOULD BE NOTHING INSIDE THE CHAMBER AND NOTHING IN ANY OF THE CANISTER HOLDERS.

⚠ WARNING The Chamber SHOULD NEVER BE USED FOR STORING ANY ITEMS WHATSOEVER. Nothing should ever be placed in the Chamber except for properly loaded Canisters within the Canister Holders.

Step 6. Place each loaded Canister into an available Canister Holder by slightly pushing the Canister Retaining Spring up (the Canister itself may be used for this purpose) and inserting the Canister all the way into the Canister Holder so that the Canister Retaining Spring returns to its original position, gently securing the Canister in the Canister Holder. NOTE: For easier removal, orient the Canister so that the Canister Lid Slots are NOT located at the Canister Retaining Spring (the Spring may sometimes catch on the Slots when removing the Canister).

NOTE: Loaded Canisters may be placed in any configuration, regardless of the number of Canisters used. Do not place empty Canisters in the Chamber. Use only properly loaded Canisters within the Canister Holders (See Step 5).

⚠ WARNING The Canister must be inserted fully into the Canister Holder in order for the products to be in the proper irradiation field. The Canister Retaining Spring should never be compromised in any way and must ALWAYS be present.

⚠ WARNING Assure the Canister Lid is properly seated prior to loading the Canister into the Canister Holder.

Step 8. Once all Canisters have been loaded perform **Step 5** and **STEP 6** once again (Except, of course, the loaded Canisters will be in the Canister Holders). Ensure the Canister Retaining Spring on each Canister is in a horizontal position.

Step 9. Close the Chamber Door gently ensuring the Door Latching Magnet engages to lock the Door closed.

⚠ WARNING The Chamber Door should be operated gently and NEVER SLAMMED or RAPIDLY OPENED OR RAPIDLY CLOSED.

Step 10. Verify the Cycle Time Display is illuminated on the Display Screen.

Step 11. Press the Start Button. At this point, the X-ray Indicator Lights will illuminate together indicating the RS 420 is checking components for proper operation. This will occur for a few seconds and then the X-rays will begin and the X-ray Indicator Lights will flash throughout the Cycle. The Cycle Time Display will count down seconds and display the seconds remaining until the Cycle is complete.

⚠ WARNING Never interrupt a Cycle once it has been started (Except in the event of an emergency). An interruption will result in an incomplete Cycle and the products will not have been fully irradiated, and therefore cannot be used as irradiated products.

Step 12. The Cycle has successfully completed only when the Buzzer sounds. If this does not occur, the Cycle has not properly completed.

⚠ WARNING The Buzzer is a positive indicator for Cycle completion. If this are NOT PRESENT, the Cycle should be considered failed and the products should not be used as an irradiated products.

⚠ WARNING Refer to the "Fault" section for instructions on how to handle a fault that occurs during a Cycle.

Step 13. The Buzzer will indicate completion of the cycle. Once the operator opens the Chamber Door to retrieve the irradiated products by selecting the Door Release Button and pulling the Chamber Door Handle, the Cycle Time Display resets.

Step 14. Remove ALL Canisters from the Chamber and assure the Chamber is empty. Gently close the Chamber Door.

Step 15. Remove all of the products from all of the Canisters, inspect irradiation indicators and process per your institution's protocols and set aside Canisters for future use.

Fault

The RS 420 monitors multiple internal operations. When the system detects that any of the internal operations are functioning outside of their set parameters a fault may result. The Fault Light will illuminate when a fault occurs and the Fault Buzzer will sound. The Fault Buzzer and Light will remain "on" until the operator follows the instructions below on how to turn the Buzzer and Light "off" (See the "Resume Feature" section).

When the Key is in Cycle Mode, if the Door Latching Magnet is not fully engaged when the Start Button is pressed, then the Fault Light will illuminate and sound, the Cycle Time Display will not illuminate, and the device will not produce X-rays. If a fault occurs during a Cycle and the Cycle Time Display is counting down the remaining time, the timer will pause and the Fault Light will illuminate (See "Resume Feature" section for how to proceed).

Resume Feature

In the event a fault occurs during a Cycle, the operator can attempt to complete the Cycle. This can only be done if nothing has been disturbed to permanently terminate the Cycle (e.g., opening the Chamber Door, shutting the device off, pushing the E-Stop Button, etc.). If nothing has been disturbed, then the operator should allow at least 30 seconds to pass after the Fault Light illuminates and then press the Start Button to Resume the Cycle. When this is done, the device will first check monitored components (this may take a few seconds). The X-Ray Indicator Lights will both come on during this period (~ 5-10 seconds) and the Cycle Time Display will remain static until all items are checked by the device at which point it will then begin to complete the Cycle and the Cycle Time Display will resume. In the event a fault occurs and the "Resume Feature" is not utilized or completed, the Fault Light will remain "on".

⚠ CAUTION Operators should refrain from using the "Resume Feature" more than three times within a single Cycle to avoid possible damage to the device. With each fault, operators should allow at least 30 seconds to pass after the Fault Light illuminates before pressing the Start Button.

⚠ WARNING If the RS 420 faults four times within a single Cycle or cannot complete a Cycle at any time, contact Rad Source Technologies, Inc. at (678) 765-7900 or email service@radsource.com.

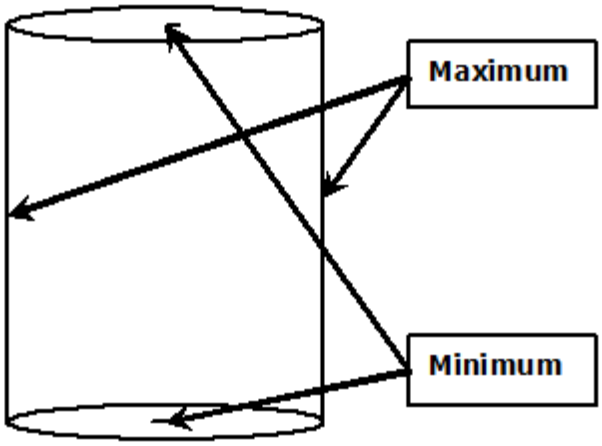
⚠ WARNING If the device has not completed a Cycle, then the products will not have been fully irradiated in accordance with the device's "Indications for Use". All products and canisters should be removed from the Chamber after attempting to use the "Resume Feature" three times. These products should be handled according to the institution's protocol.

Dosimetry

The X-ray Source in the RS 420 creates a "cloud" of irradiation emitted longitudinally along its axis. The dose of irradiation produced to the Canisters is moderated by the rotation about the X-ray Source. Fig. 23 is illustrative of the distribution of the irradiation to the Canister. The maximum dose will generally be the middle surface of the Canister and the minimum dose will generally be delivered to the central ends of the Canister.

The standard volume configuration of the RS 420 holds 5 Canisters of approximately 3 liters per Canister (fully enclosed with lids attached). The Maximum to Minimum dose ratio in this configuration is about 1.5.

Fig. 20: Radiation Dose to Canister



Dosimetry is recommended to be performed every 6 months.

Maintenance

A. User maintenance The RS 420 is designed to require minimum maintenance. However, there are areas of the system that the user should check periodically.

Door Interlock mechanism - This should be inspected by the user at least monthly. Verify that the Interlock "tongue" attached to the Chamber Door has no obvious faults (cracks or missing hardware) and that it inserts into the Door Interlock freely and properly. (See Fig. 3)

Power Cord – Visually inspect – it should not appear worn to the extent that it is frayed or there are cuts or failures in the insulation. This should be done monthly.

B. Cleaning When cleaning, use a mild detergent or disinfectant, such as TB Spray. Do not allow cleaners or water to drip into panels or chamber. Only use damp cloth with mild soaps for cleaning. Do NOT spray or pour liquid onto the machine. Do NOT use caustic chemicals.

If you have further questions, please contact Rad Source Technologies, Inc. at (678) 765-7900 or email service@radsource.com.

RS 420 Specifications

Weight……	2,160 lbs. /1,111 kg
Dimensions (English)……	75 in Height, 47 in Width, 34 in Depth
Dimensions (Metric)……	191 cm Height, 120 cm Width, 86 cm Depth
Coolant Type……	Clean, Filtered/Purified Water
Coolant Volume……	30 Gallons or more
Standard Number of Canisters……	5 Canisters
Standard Canister Volume (each)…….	~3 Liter
Electric Power……	6 kW PS – 3 phase, 50/60 Hz, 220 VAC/Phase ±10%, 40 Amps
Thermal Output (during operation)	86 BTU per minute
Noise Level……	~73db
Max running kV……	160 kV
Max running mA……	37.5 mA
End of Cycle Audible & Visual Indicator	Yes
Fault Audible & Visual Alert……	Yes

APPENDIX I

RAD SOURCE TECHNOLOGIES, INC.
INITIAL WARRANTY

Subject to the terms and conditions of this Initial Warranty, if the Product is determined to be defective, Rad Source Technologies, Inc. ("Rad Source") will, at its sole discretion, (i) replace the defective Product or defective parts, at no charge to the original owner, (ii) repair the defective Product or defective parts, at no charge to the original owner, or (iii) refund to the customer the amount actually paid to Rad Source for the defective Product.

1. COVERAGE. Rad Source will provide this Initial Warranty for the following Product (model and serial #): _____.

2. TERM. Subject to our receipt of payment in full, the term of this Initial Warranty begins on the date of delivery and expires on the one year anniversary of the delivery date. Any claims under this Initial Warranty which are not asserted in writing by the customer within the term shall be deemed to be waived by the customer.

3. LIMITATIONS OF COVERAGE. THIS INITIAL WARRANTY DOES NOT COVER:
   a. non-functional parts (such as trim) and cosmetic defects; or
   b. repair or replacement of any Product which is damaged or malfunctioning due to causes beyond Rad Source's control, including, but not limited to, repairs necessitated by operator or owner negligence or misuse, rust caused by atmospheric conditions, abuse, theft, fire, flood, wind, lightning, freezing, power failure, power reduction or unusual atmospheric conditions.

4. TIME AND PLACE OF SERVICE. Initial Warranty service will be performed during Rad Source's normal business hours. To arrange for service, contact Rad Source at (866) 301-3986.

5. LIMITATION OF LIABILITY. NEITHER RAD SOURCE, NOR ITS AFFILIATES, AGENTS, CONTRACTORS, OR LICENSEES WILL BE LIABLE FOR ANY INCIDENTAL, SPECIAL, INDIRECT OR CONSEQUENTIAL DAMAGES ARISING FROM THIS EXTENDED WARRANTY OR IN CONNECTION WITH THE USE OF THE PRODUCT, INCLUDING, BUT NOT LIMITED TO, PROPERTY DAMAGE, LOST PROFITS OR REVENUES, LOST TIME, LOSS OF USE OF COVERED PRODUCT(S) OR ANY OTHER DAMAGES RESULTING FROM THE BREAKDOWN OR FAILURE OF COVERED PRODUCT(S) SERVICED UNDER THIS INITIAL WARRANTY, DELAYS IN SERVICING OR THE INABILITY TO SERVICE ANY COVERED PRODUCT(S), REGARDLESS OF WHETHER RAD SOURCE HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES. IN NO EVENT SHALL RAD SOURCE'S LIABILITY WITH REGARD TO THE PRODUCT EXCEED THE AMOUNT PAID BY THE CUSTOMER FOR THE PRODUCT GIVING RISE TO SUCH LIABILITY.

6. ARBITRATION. Any and all claims or disputes arising out of, in connection with, or in relation to the interpretation, performance or breach of this Initial Warranty shall be resolved, on an individual basis, by final and binding arbitration. However, this arbitration provision does not apply to any claim or dispute relating to the financing of or payment for this Initial Warranty, any claim or dispute relating to any security interest in goods or services or any agreement or disclosure relating to any financing, payment or security interest. All arbitrations shall be held at the office of the American Arbitration Association ("AAA") in closest proximity to your facility. All arbitrations shall be administered by the AAA in accordance with its Commercial Arbitration Rules. The Federal Arbitration Act, 9 U.S.C. Sections 1, et. Seq. shall govern all arbitrations under this Initial Warranty.

7. LIMITATION OF WARRANTY. EXCEPT AS EXPRESSLY PROVIDED HEREIN, RAD SOURCE DOES NOT MAKE, AND HEREBY EXPRESSLY DISCLAIMS, ANY AND ALL OTHER WARRANTIES WITH REGARD TO THE PRODUCT, WHETHER EXPRESSED, IMPLIED, OR OTHERWISE, INCLUDING, WITHOUT LIMITATION, ANY IMPLIED WARRANTY OF MERCHANTABILITY, IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE, WARRANTY OF NONINFRINGEMENT OF THIRD PARTY RIGHTS, OR WARRANTY THAT THE PRODUCTS MEET THE REQUIREMENTS OF THE CUSTOMER.

8. CHOICE OF LAW. This Initial Warranty is governed by the laws of the State of Georgia, without regard for conflict of laws principles.

EXHIBIT 3

CANNABIS IRRADIATOR

RS™ 420•M Operators Manual

RAD SOURCE

About This Manual

The information in this publication is provided for reference only. All information contained in this publication is believed to be accurate and complete. Rad Source Technologies, Inc. shall not be liable for errors contained herein, nor incidental or consequential damages in connection with the furnishing, performance, or the use of this material.

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Manufacturer's Address:
Rad Source Technologies, Inc
4907 Golden Parkway
Suite 400
Buford, GA 30518

RS 420•M Operator's Manual
MKT-025
Revision 3
Effective Date: 17 August 2018
Copyright: 2018

Table of Contents

User Responsibility

In order to operate properly, this product must be installed, operated, and maintained in accordance with the procedures described herein.

Periodic inspection of the RS 420•M will aid in detecting anything that may cause problems with the unit's operating performance. If any part is found to be worn, broken, or damaged in any way, immediately contact Rad Source Technologies, Inc.

Only Rad Source Technologies, Inc. authorized persons should perform repair procedures.

Any alteration to the RS 420•M not in accordance with the procedures set forth by Rad Source Technologies, Inc. places sole responsibility on the user for any malfunction resulting from faulty maintenance, improper repair, damage, or alteration by any person other than Rad Source Technologies, Inc. authorized persons.

⚠ WARNING The RS 420•M should only be operated by AUTHORIZED PERSONNEL who have thorough knowledge of the proper use of the device. The key for the unit should be accessible only by AUTHORIZED PERSONNEL.

Questions about its use should be addressed to Rad Source Technologies, Inc. at (678) 765-7900 or email service@radsource.com.

System Description and Indication for Use

The RS 420•M is a cabinet x-ray device with a single X-ray Source. It is used to irradiate mold and fungus. The RS 420•M utilizes proprietary, patented technology. (Patents 9,484,177 and other patents pending)

Indications for Use

The RS 420•M is intended for the irradiation of mold and fungus remediation in cannabis.

Safety Information and Symbols Used

Specific notations are used in this manual to call attention to conditions that could potentially result in injury, damage to equipment, or require special attention.

Warning, Caution, and NOTE may be used throughout this manual and on the RS 420•M to emphasize important and critical information. You must read these statements to help ensure safety and to prevent product damage.

⚠ WARNING Indicates a potentially hazardous situation which if not avoided could result in death or serious injury.

⚠ CAUTION Indicates a potentially hazardous situation which if not avoided could result in minor or moderate injury. It may also be used to alert against unsafe practices.

NOTE: Used to notify people of installation, operation, or maintenance information that is important, but not hazard-related.

IMPORTANT SAFETY INSTRUCTIONS

Also note the additional SAFETY instructions will be found throughout this manual and ALL must be heeded.

⚠ WARNING This unit is to be installed only by factory-authorized personnel. DO NOT ATTEMPT to install or otherwise apply or attach any electric power to the unit prior to contacting Rad Source Technologies, Inc. at service@radsource.com or call (678) 765-7900.

⚠ WARNING The machine is extremely heavy and movement should only be done AFTER CONSULTING WITH the manufacturer. NEVER attempt to move the machine once it has been installed BEFORE contacting the manufacturer. Sudden movement, or movement over uneven floors, inclines, or declines may result in tipping. A level floor is required for installing this unit.

⚠ WARNING This unit is to be serviced by trained personnel only. Do not remove any covers or adjust any screws, bolts, or related fasteners.

⚠ WARNING This manual instructs how to use the RS 420•M. If you disregard the instructions or information in the manual, you could be assuming responsibility for damages, costs, or injury incurred by such disregard.

⚠ WARNING This device is equipped with safety interlocks incorporated into the chamber door and X-ray tube access panel to prevent the unit from operating when the chamber is open. Overriding, modifying, adjusting, or in any way defeating these interlocks is hazardous.

⚠ WARNING If any obvious mechanical damage is detected or suspected, cease use immediately, and contact Rad Source Technologies, Inc. at (678) 765-7900.

⚠ CAUTION Please keep unit dry. When cleaning, do not allow cleaners or water to drip into panels or chamber. Only use damp cloth with mild detergents for cleaning.

⚠ CAUTION Do not use the top of the unit as a storage area, or place any heavy items or items containing liquids or materials that may harm the unit if leaked or spilled on top or inside.

System Components

Illustrations of the RS 420•M components and item descriptions are found in this section and in the following sequence:

Fig. 1 – Front View of the RS 420•M
Fig. 2 – Rear View of the RS 420•M
Fig. 3 – Front View with Chamber Door Removed

Fig. 1: Front View of the RS 420•M

1. **X-ray Indicator Light** – During the time that X-rays are being produced, the Rainbow Switch will flash red. On the screen you will notice that *X-Ray on* will flash in an alternating fashion between yellow and red on the lower left side of the screen, and *X-ray on* in red at the top center of the screen.

   NOTE: Failure of light during operation will result in that particular light not operating and the Alarm Fault will indicate on the HMI and the unit will stop working. This will not pause the Cycle in progress; however, the failed light should be replaced immediately and so the X-ray Indicator Light operated normally.

2. **Chamber Door** – This is a heavy door made primarily of shielding material in the form of lead which shields the X-rays in the irradiation Chamber (See Fig. 3). It is held in the closed position by a magnetic latch that is released only by pressing the Door Release Button on the Control Panel.

   ⚠ CAUTION The Chamber Door should be operated gently and NEVER SLAMMED or RAPIDLY OPENED or RAPIDLY CLOSED.

3. **Chamber Door Hinge** – Holds the Chamber Door and allows it to operate freely. It is adjustable only by the manufacturer.

4. **Chamber Door Handle** – Used to open and close the Chamber Door using the non-mechanical magnetic latch. The handle itself does not operate any mechanical latch mechanism, but is used only for ease of operating the Door itself.

5. **Control Panel** – Contains operating and display controls and indicators.

6. **Load Staging Shelves** – Removable shelves may be used to stage Canisters for loading or unloading into the Chamber.

7. **Front Forklift Access Opening** – This allows forklift access for lifting machine only for manufacturer authorized transport.

8. **Casters** – Allow for movement of the machine within a location and ONLY ON LEVEL floors.

9. **Rubber Padded Foot -** Is lowered from its base to mitigate movement.

Fig. 2: Rear View of the RS 420•M

1. **Top Vents** – For allowing heat to escape interior of cabinet. It should never be covered or restricted.

2. **Top Rear Panel** – For maintenance access only.

3. **Panel Attachment Screws** – For retaining all access panels.

4. **Lower Rear Panel** – For maintenance access only.

5. **Main Power Breaker Switch** – Supplies main power to the machine. Should not be shut off unless required for relocating or otherwise removing the machine.

⚠ CAUTION The RS 420•M at rest still requires power for its low voltage vacuum power supply which is used for continuous maintenance of the X-ray Source. By shutting off this switch ALL power is removed, including the vacuum power supply and this will cause deterioration or destruction of the X-ray Source over a period of time.

6. **Main Power Plug** – The main power plug, once installed, should never be removed and should periodically be inspected for proper seating. Also, see 5 above.

7. **Lower Vents** – For allowing heat to escape interior of cabinet. It should never be covered or restricted. (Its optional feature for RS 420•M version)

8. **Rear Forklift Lifting Holes** – Allows full insertion of forklift lifting tines from front of machine through the rear of the machine.

Fig. 3: Front View with Chamber Door Removed

1. **Door Interlock** – The Door Interlock is a safety mechanism designed to terminate power if the Chamber Door is opened during X-ray operation. The Door has a "tongue" which is aligned to insert into this when the Door is closed, thereby activating the Door Interlock circuit.

⚠ WARNING Never insert anything into the interlock switch or otherwise alter or override the interlock in any way.

2. **Door Latching Magnet** – The Chamber Door utilizes a non-mechanical latching mechanism which is magnetic. The Magnet is de-activated by selecting Door Release on the control panel to allow the Door to be opened. The default state for this mechanism is "on" so that the Door, if closed, will be in a latched mode. Always keep this Magnet clear of small magnetic objects since they can interfere with the normal operation of the Door.

3. **Chamber** – This houses the X-ray Source and is made primarily of shielding material in the form of lead.

4. **X-ray Source** – The X-ray Source is cylindrical and emits radiation outwardly, irradiating the Canisters as they rotate around it. This should not be touched.

⚠ WARNING No objects should EVER be stored inside the Chamber. Nothing should ever inhibit or interfere with the rotation of the Canister Holders.

5. **Key Switch** – The Key Switch has 2 positions. On and Off and press Rainbow button for Reset. When turned all the way to the left, the unit is in the Off mode and is completely non-operational (aka. "at rest"). This would be its position during long down times (days, e.g.). When turned once to the right (clockwise), the Key Switch is in On, its Standby mode when we press rainbow button once and release it, the rainbow button change color. This is the time system is on position and the Blue Led turn ON.

6. **Emergency Stop or E-Stop Button** – When pressed, all processes are immediately stopped. The E-Stop Button should remain depressed until the emergency is resolved. Investigate the reason the E-Stop Button was pressed before resuming normal operation. If the E-Stop Button is pressed for any reason during a Cycle, turn the Key to the Off position, turn the E-Stop Button clockwise to release it, and turn the Key to the On position to resume normal operation.

⚠ CAUTION The E-Stop Button does not remove all power to the machine. The X-ray tube vacuum pump power supply, relay K1, and safety relay remain powered.

⚠ CAUTION Whenever the E-Stop Button is pressed, either accidently or due to an emergency, ALWAYS turn the Key to the Off position before resetting the E-Stop Button.

Installation and Site Requirements

Physical Requirements

The RS 420•M requires an area approximately 3 feet wide by 3.5 feet deep. It requires a height clearance of 7 feet. The rear of the machine should never be up against a wall and should allow free movement of air. Do not place the machine closer than 8 inches to the rear wall.

Each side of the machine also requires the free movement of air and therefore, should be no closer than 6 inches to any wall or device. Because the cooling system relies on cool, ambient air, any restriction in air flow will result in restricted operation or no operation due to an inability to cool the machine.

The unit is mounted on casters and when it is in place, the locks on each wheel will be set to mitigate movement.

Floors on which the unit will be located must be capable of bearing its load. The unit weighs approximately 1,350 pounds and is caster mounted.

⚠ WARNING A level floor is required for installing this unit. The unit is heavy and tipping or movement may result in a dangerous situation.

Electrical

Since a power cord will be connected to the RS 420•M, it is recommended that a fuse disconnect switch be available within 6 feet of the RS 420•M's location. The RS 420•M 4 kW Unit requires 208-240 VAC, single Phase, 50/60Hz, 40Amp, 100% Duty Cycle.

⚠ WARNING Risk of electric shock. Exterior panels should only be removed by Rad Source authorized maintenance personnel.

⚠ WARNING Unit must be connected only to supply voltage rating marked on the unit and receptacle must be of GROUNDED TYPE (true earth ground is required).

⚠ CAUTION The plug on the rear of the RS 420•M should never be forced or otherwise pressed up against a wall. Sufficient clearance should be allowed so that the plug is never at risk for being compromised because of physical stress.

⚠ CAUTION If your facility performs generator tests, then the user must turn the Key to the Off position before the generator test is performed. After the test is over, the user may turn the Key to the On position and resume normal operation.

Environmental Conditions

Indoor Use in an air-conditioned environment:

- Max Temp (F): 82
- Min Temp (F): 62
- Humidity Range: 30% - 90%

Humidity above 50% may result in reduced cooling efficiency.

Cooling

The end user will provide a turn-key Water Cooling Chiller that will be safe, have rugged construction, and is easy to transport, install and maintain in accordance with all pertaining Standards and Codes specific to this kind of equipment. The water cooling system will be used for the removal of heat generated by the X-ray Tube in the irradiator.

Cooling System requirements

Flow Rate : 5.0 Gal/Min

Max Temp(F) : 95 (35°c) "note:104 °F is high cut off temperature"

Min Temp(F) : 68 (20°c) "note:61 °F is low cut off temperature"

Note: It's important to use only stainless steel, aluminum or Plastic component on cooling system connection since the use of Brass, copper or any yellow metal will corrode the X-Ray tube.

The water chiller must be filled with DISTILLED WATER ONLY.

⚠ CAUTION The cooling vents on the back of the unit should be clear of any obstruction to allow free airflow when the irradiator is operating. Do not place the machine closer than 8 inches to the rear wall. Each side of the machine also requires the free movement of air and therefore, should be no closer than 6 inches to any wall or device.

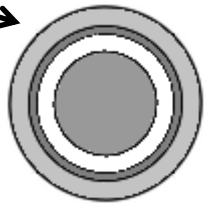
Make sure environmental conditions are good and clean for chiller and there are no restrictions on the water chiller.

1. First Power On

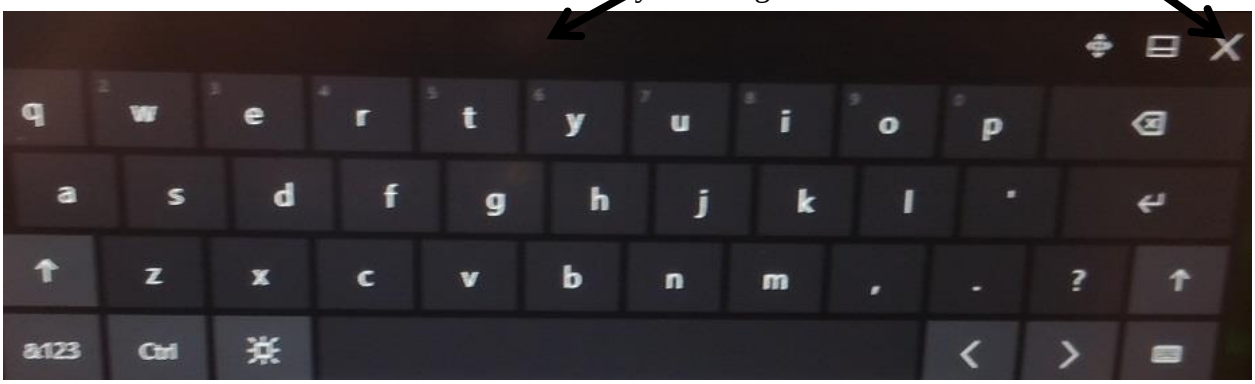
When power is applied to the RS 420•M the system for the first time it goes through a onetime initialization that takes just under two minutes. The system will not respond to any user input during this time.

1.1 Password

When the key switch is first turned to the ON position the rainbow button will appear white and the HMI will start a power on sequence after which a password screen will be shown.



Touching the User name input box will pop up a keyboard. The keyboard can be dragged around the screen by touching and holding the top **bar** and dragging the keyboard off any input prompts. It can be closed by touching the X



2. Systems Overview

2.1 Action Buttons

Actions are initiated by touching a top row buttons, examples;

2.1.1 Dose

Starts an irradiation cycle that will prompt the user for the desired Dose.

2.1.2 Run Program

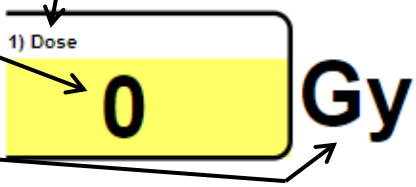
Starts a pre-programmed irradiation cycle.

2.1.3 Warm-up

Starts a warm up, which is required after the tube has not been used for 24 or more hours.

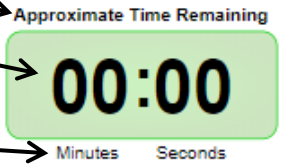
2.2 Enter Value Fields

Fields with open left borders are *Enter Value Fields.* The **field name** is shown above the background color, and the current **field value** is shown on the background color. Touching the background will prompt the user to enter a new value.
Unit of measure is shown to the right or above the field.



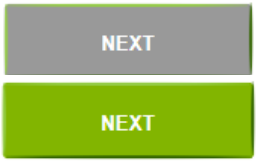
2.3 Display Value Fields

Fields with solid light border are *Display Value Fields*. The **field name** is shown above the field. These fields show **computed values** and cannot be directly changed by the user.
Unit of measure is shown below or to the right of the rectangle.



2.4 Next Button

The *Next* button will be grey until the *Approximate Time Remaining* field shows at least one minute. Adjust *Dose* and/or *Power* to change this value. Press green *Next* to continues irradiation cycle.

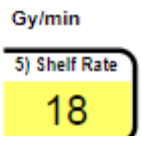


2.5 Admin Fields

Some *Display Value Fields* become *Enter Value Fields* when logged in as admin. Press an action button to reach screens that display these fields then touch the field to enter data.

The default password for admin is admin.

User 1

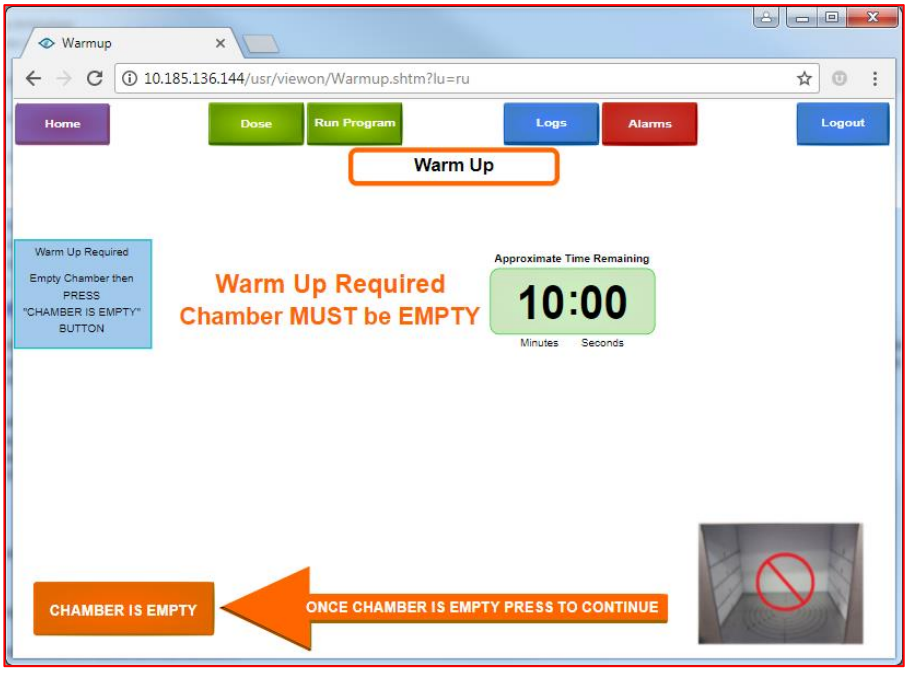


Admin

3. Warmup

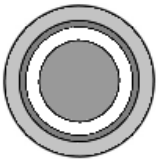
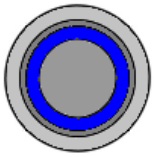
Warmup is required anytime the system has not been run for 24 or more hours.

1) Press the Warmup button on the home screen.
2) Empty the chamber.
3) Press the Chamber is Empty button



4) Close the door, the rainbow button will become green.
5) Once the green rainbow button is pressed the system will run a 10 min warmup.
6) If the unit not used for 72 HR the system will run a 20 min warm up instead of 10 min.

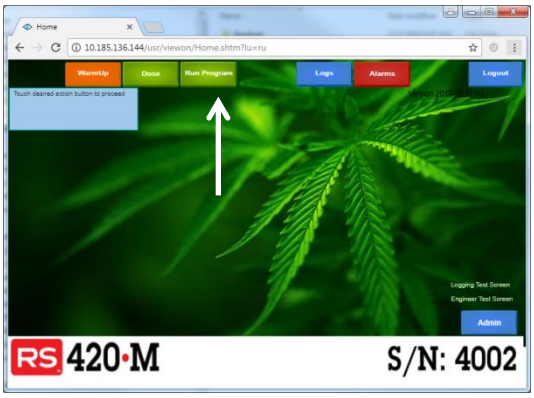
4. Irradiation Cycle

4.1 Run Program

4.1.1 From Key Off

1) Turn Key to ON, rainbow button turns white.
2) Press rainbow button and release. The rainbow button turns Cyan and then blue.
3) Wait for the logon screen to be displayed.
4) Touch inside "User name" input box > Key board will popup.
5) Move key board as necessary to view input field by dragging the top of keyboard.
6) Enter users name; Example "user1".
7) Touch inside "Password" input box.
8) Enter password; Example "password1".
9) Home Screen Appears.



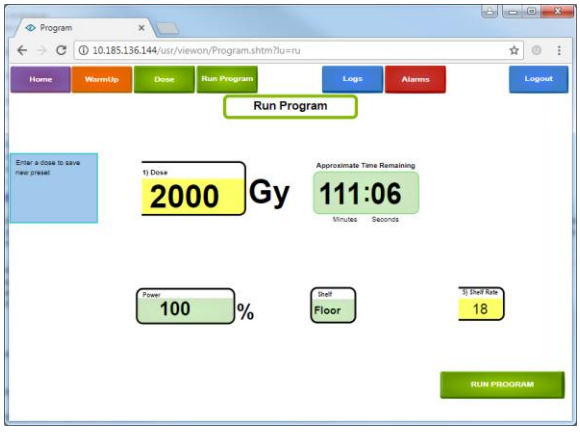
4.1.2 From Home Screen

1) Place item to be irradiated into chamber.
2) Close the door.
3) Touch *Run Program* button > *Enable Irradiation* screen is displayed.

4.1.3 Admin

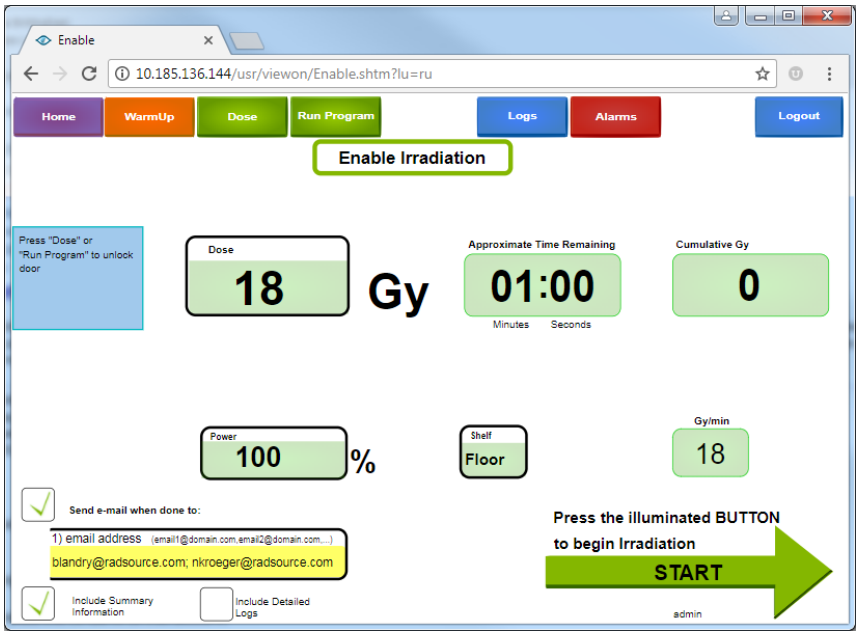
When admin is logged the *Run Program* screen is displayed instead of *Enable Irradiation* screen.

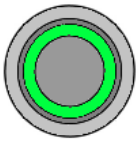
1) On this screen admin can set the default Dose for Run Program and set the Gy/min rate by touching the appropriate yellow field.
2) One the defaults are updated, admin can execute the program by touching the *Run Program* button > *Enable Irradiation* screen is displayed.



4.1.4 Enable Irradiation Screen

1) If the door is open the lower right corner will show the **DOOR OPEN** icon and the rainbow button will be OFF.
2) Once the door is closed, the lower right corner will show a green START arrow and the rainbow button will be Green.





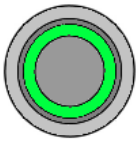
3) You can only review the irradiation information on this screen.
If you need to make any changes, or unlock the door, touch the Dose button to return to the Dose Entry screen. The values will be cleared and the door will be unlocked.

4.1.4.1 E-MAIL

Once the unit is connected to the internet it can be set up to automatically send an e-mail when the irradiation cycle completes for stops for any reason. It can also send a summary of the irradiation cycle, or a full log.

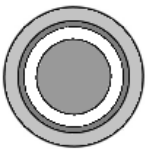
1) If you want send an e-mail touch the e-mail field. A keyboard and popup window will be displayed. Move the keyboard as necessary to see the data entry field near the top of the screen. Separate e-mail addresses with a colon.
2) To enable e-mail check one or more of the displayed check boxes.

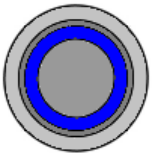
4.1.4.2 START IRRADIATION



Press the Green rainbow switch. The *Pre Warn* screen will be displayed.

See section **0 4.3 Pre Warn** Screen

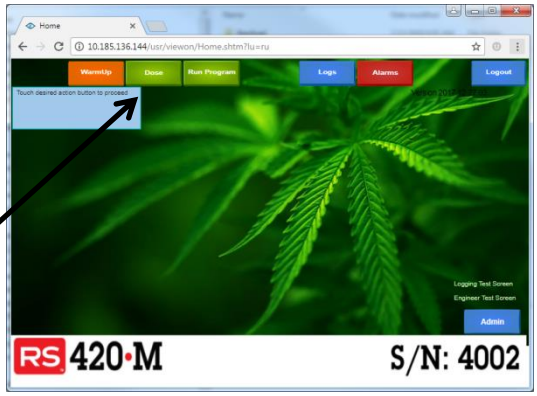




4.2 Dose (Manual Input)

4.2.1 From Key Off

10) Turn Key to ON, rainbow button turns white.
11) Press the rainbow and release it, it will change rainbow button to Cyan and then blue color.
12) Wait for the logon screen to be displayed.
13) Touch inside "User name" input box > Key board will popup.
14) Move key board as necessary to view input field by dragging the top of keyboard.
15) Enter users name; Example "user1".
    1) Touch inside "Password" input box.
    2) Enter password; Example "password1".
    3) Home Screen Appears.

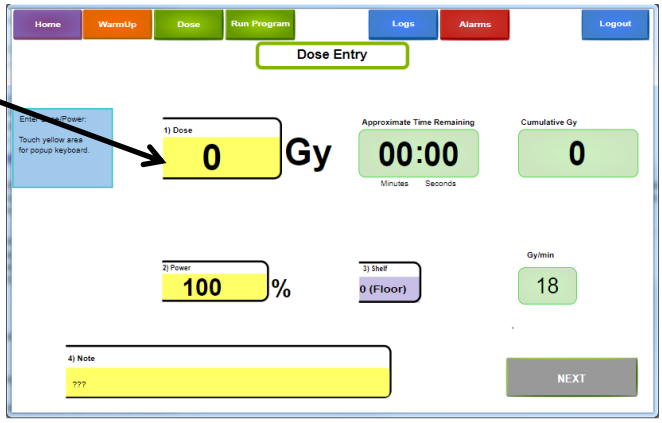


4.2.2 From Home Screen

1) Place item to be irradiated into chamber.
2) Close the door.
3) Touch *Dose* button > *Enable Irradiation* screen is displayed.
4) Touch *Dose* button > *Dose Entry* screen is displayed.

4.2.3 Dose Entry Screen

1) Place item to be irradiated into chamber.
2) Touch *Dose* entry field > keyboard pops up
3) Enter desired dose. > Next button become Green provided *Approximate Time Remaining* greater than 1 min.
4) **If desired**, reduce power by touching *Power* entry field and entering a power between 10% and 100% of full power.
5) **If desired,** add a note to be associated with this run cycle by touching the Note field and typing a note.
6) Confirm item to be irradiated is in chamber and close the door.
7) Press green *Next* button > Door magnet is engaged > Enable Irradiation screen is displayed.

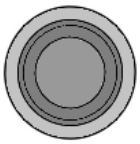


4.2.4 Admin

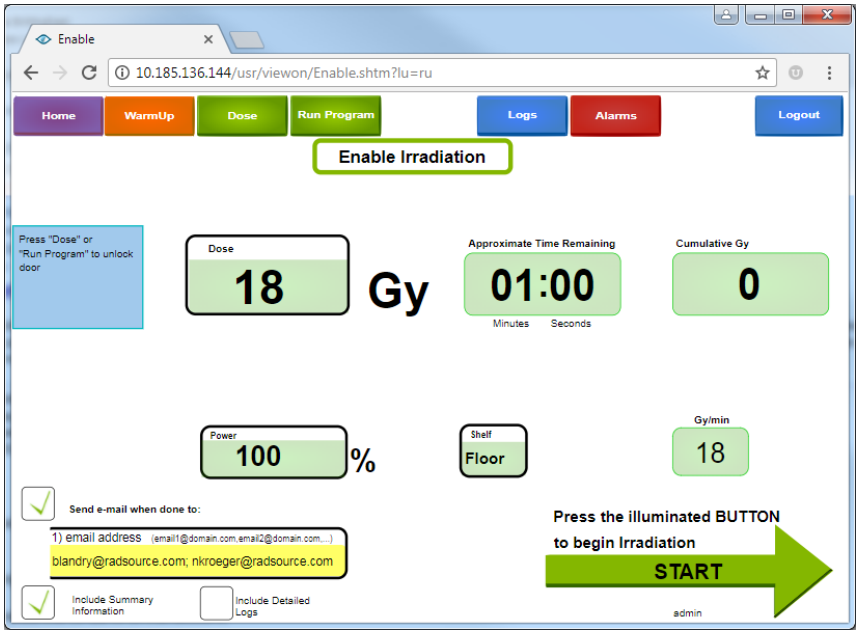
When logged in as admin the Gy/min field will have a yellow background and the value can be updated. There is a separate value stored for each Shelf. So to enter Gy/min do the following;

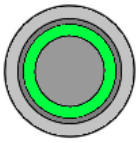
1) Touch the Shelf selector > List of available shelfs will be displayed.
2) Select the desired shelf > Current Gy/min value for that shelf is displayed.
3) Touch the Gy/min field > Numeric keyboard will popup.
4) Enter the Gy/min value and touch Enter.
5) The new Gy/min value will be displayed.
6) Repeat as necessary for each Shelf

4.2.5 Enable Irradiation Screen



1) If the door is open the lower right corner will show the **DOOR OPEN** icon and the rainbow button will be OFF.
2) Once the door is closed, the lower right corner will show a START arrow and the rainbow button will be Green.





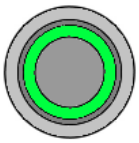
3) You can only review the irradiation information on this screen.
   If you need to make any changes, or unlock the door, touch the Dose button to return to the Dose Entry screen. The value will be cleared and the door will be unlocked.

4.2.5.1 E-MAIL

Once the unit is connected to the internet it can be set up to automatically send an e-mail when the irradiation cycle completes for stops for any reason. It can also send a summary of the irradiation cycle, or a full log.

3) If you want send an e-mail touch the e-mail field. A keyboard and popup window will be displayed. Move the keyboard as necessary to see the data entry field near the top of the screen. Separate e-mail addresses with a colon.
4) To enable e-mail check one or more of the displayed check boxes.

4.2.5.2 START IRRADIATION

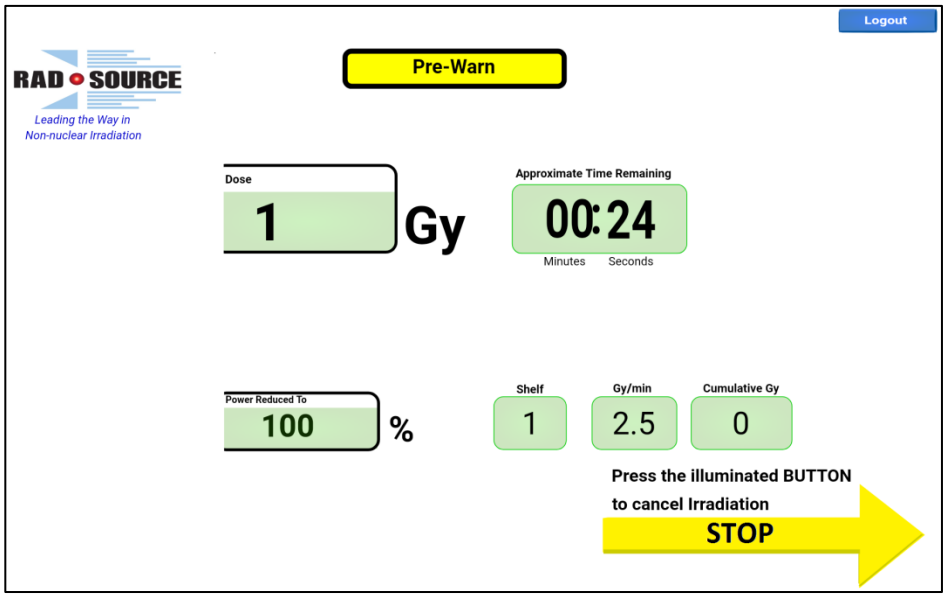


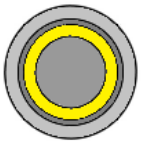
Press the Green rainbow switch. The *Pre Warn* screen will be displayed.

4.3 Pre Warn Screen

Before irradiation is started the *Pre-Warn* screen will be displayed with a yellow STOP arrow pointing at a yellow rainbow button. Pressing the rainbow button stop the cycle.

1) After 10 seconds the system will automatically start irradiating and display the *X-RAYs ON* screen.





4.3.1 Aborting

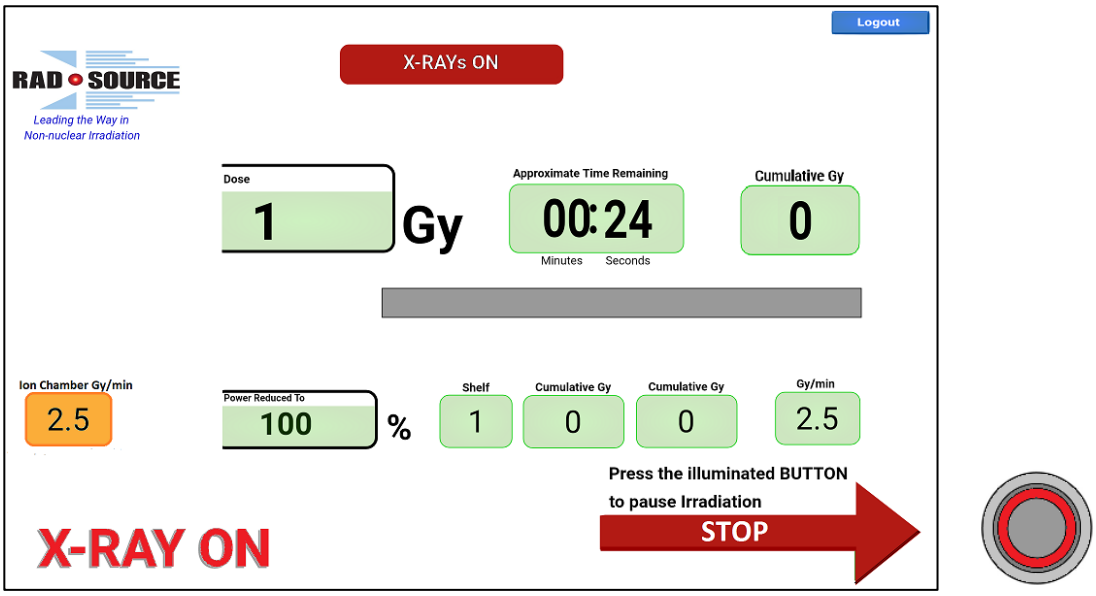
To abort the irradiation cycle, press the yellow rainbow button.

4.3.2 Logging Out

The current user can logout by touching the *Logout* button. The system will continue to run but a new irradiation cycle cannot be started until someone logs in.

4.4 Irradiation Screen

1) While the system is irradiating the rainbow switch will flash red. The only time the rainbow switch flashes, is when the system is irradiating.
2) The words X-RAY ON will be alternating between yellow and red in the lower left corner of the display.
3) The words X-RAYs ON will be highlighted in red at the top of the display.
4) While the cycle is running the Cumulative Gy value will increase until the requested *Dose* value is reached.
5) The *Approximate Time Remaining* value will decrease until it reaches 0.
   Some alarms are automatically handled by the system. While these are being handled the *Approximate Time Remaining* value will freeze. The count down will automatically resume once the alarm has been handled.
6) If the optional ion chamber is installed, the instantaneous Gy/min reading, at the ion chambers position, will be displayed in an orange box on the lower left side.
7) When the cycle is complete the *Dose Complete* screen will be displayed.

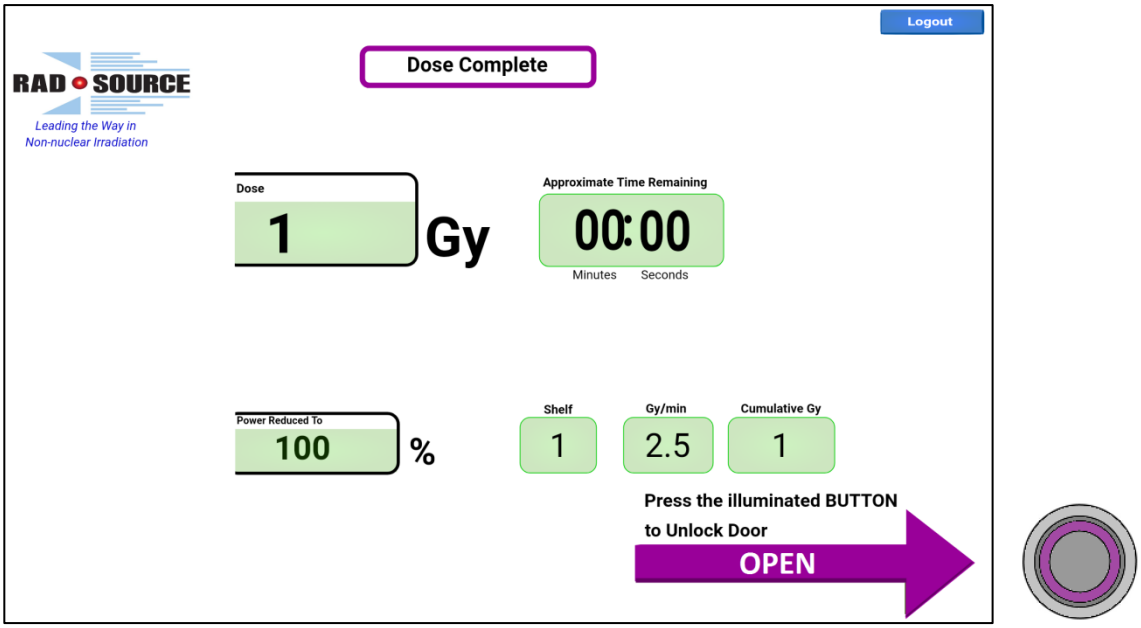


4.4.1 Logging Out

The current user can logout by touching the *Logout* button. The system will continue to run but a new irradiation cycle cannot be started until someone logs in.

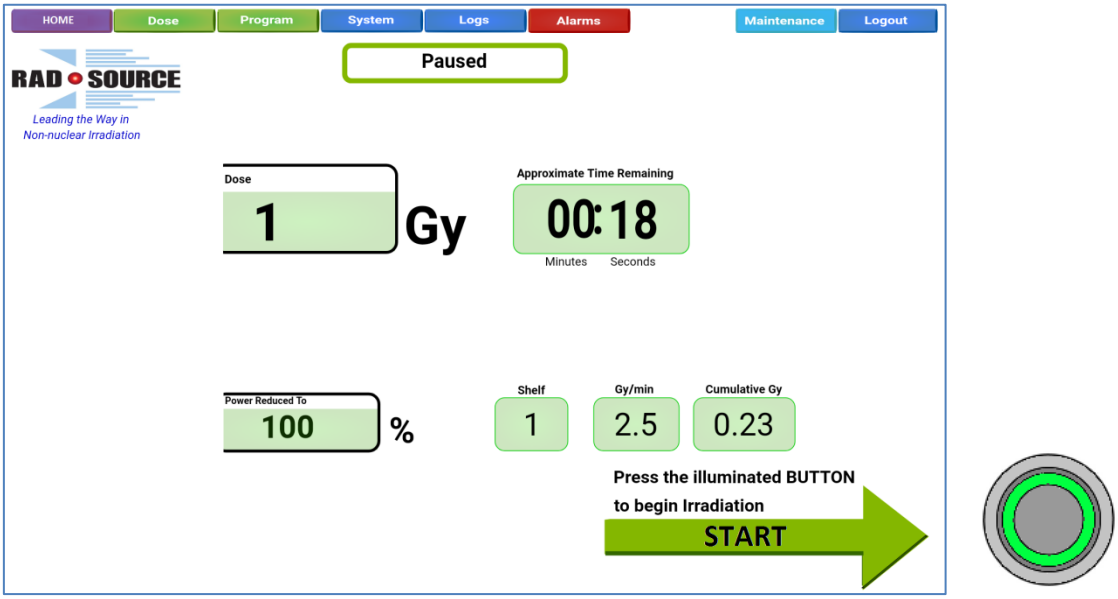
4.5 Complete Screen

1) When the cycle is complete the *Dose Complete* screen will be displayed with a purple OPEN arrow pointing to the purple rainbow switch.
2) The door remains locked until the purple rainbow switch is pressed.
3) Once the door is open the system returns to the Enable Irradiation screen with the same values used for the previous irradiation cycle and the rainbow button turns blue.
4) The user can place new product in the chamber and close the door at which point the rainbow button turns green, the door locks and all navigation buttons are displayed.
5) To repeat the previous cycle press the green rainbow button.
6) To start a new cycle or to just unlock the door press any of the action buttons including *Home*, *Dose* or *Run Program*.



4.5.1 Pause

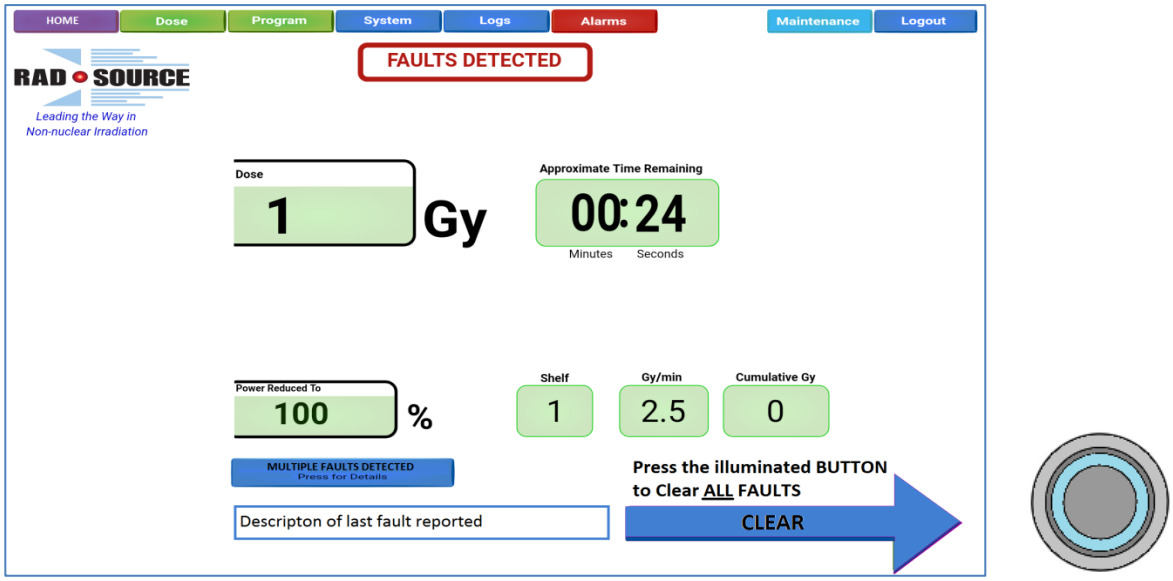
To pause the irradiation cycle, press the red rainbow button. The *Paused* screen will be displayed, the door will be unlocked and the rainbow button will turn green as long as the door remains closed. While the door is open the rainbow button will be off.



4.6 Alarm Screen

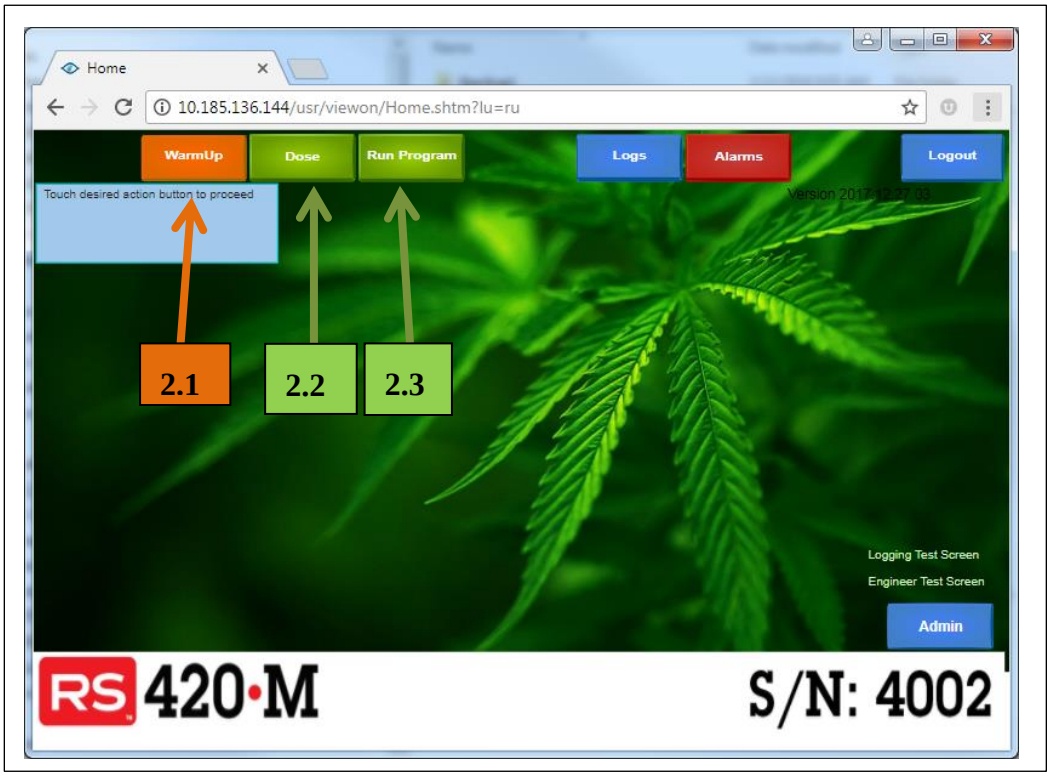
When a fault is detected an alarm will sound and the system will show the Faults Detected screen with a cyan CLEAR arrow pointing to a cyan rainbow button.

1) The name of the first alarm will be displayed at the bottom of the screen.
2) Once the cause of the fault is cleared the alarm can be reset by pressing the rainbow button.
3) If the fault is not cleared, pressing the rainbow button accomplishes nothing.



4) An arc fault will be cleared automatically and the system will automatically cycle back to the *Pre-Warn* and then the *X-RAYs ON* screens.

5. Home Screen Overview



5.1 Warmup

When the unit has been off for more than 8 hours a Warm-up cycle should be done before is the irradiator used for Dosing. This is initiated by touching the Warm-up button.

5.2 Dose

To initiate a user settable Dosage touches the Dose button.

5.3 Run Program

To initiate the preprogrammed Dosage cycle touch the Run Program button.

5.4 Logs

This system maintains numerous logs which are saved in a comma delimit format compatible with excel™. These logs can be e-mailed at the end of each cycle or down loaded to a thumb drive.

5.5 Logout

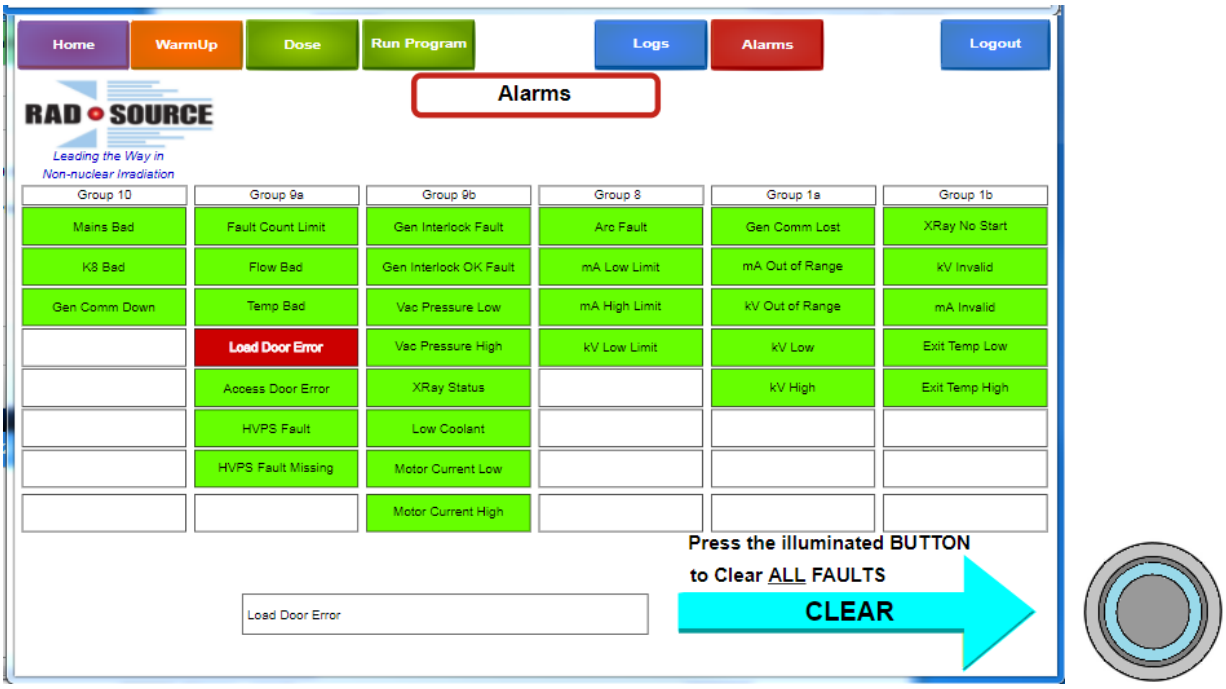
When done using the irradiator touch the Logout button.

5.6 Alarm

To display details of which alarms are preventing operation touch the Alarm button.

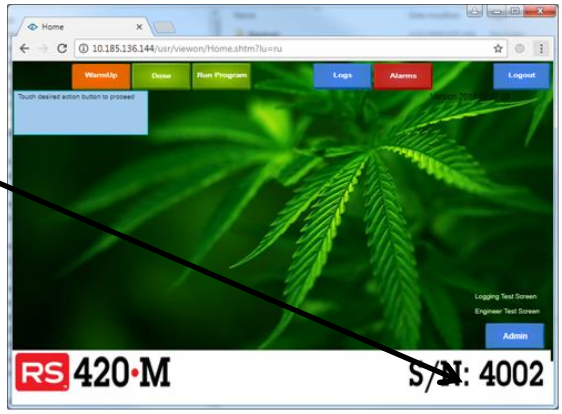
All possible alarms are displayed.

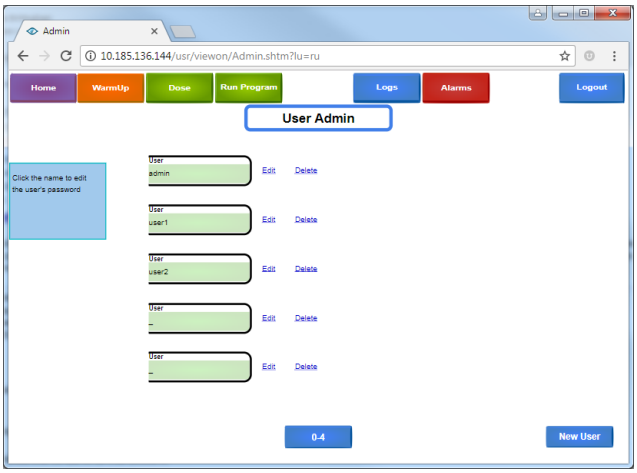
1) No alarm is indicated by black text on a green background.
2) Alarms are indicated by white text on a red background
3) Once the cause of the alarm is cleared the warning can cleared by pressed the cyan rainbow button.



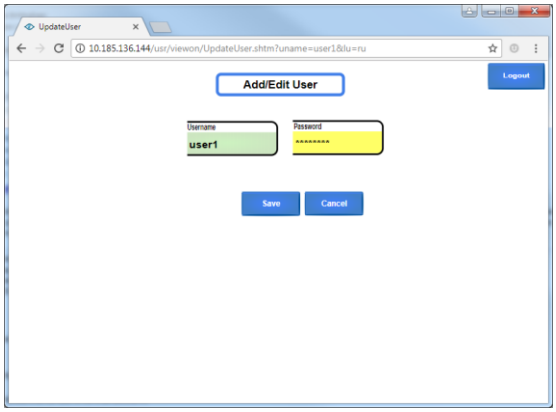
5.7 Admin

1) When admin is login the *Home* screen will show an Admin button on the lower right.
2) Pressing the Admin button will display the *User Admin* screen.





3) User and passwords can be added, changed or deleted on these screens by touching the Edit or Delete text next to the desired user.



4) Once the edit are complete press the Save button.

EXHIBIT 4

RS 420•XL

Cannabis Irradiator

Operator's Manual

RAD SOURCE

1. About This Manual

The contents within this manual are applicable for the RS 420•XL machine.

The information in this publication is provided for reference only. All information contained in this publication is believed to be accurate and complete. Rad Source Technologies, Inc. shall not be liable for errors contained herein, nor incidental or consequential damages in connection with the furnishing, performance, or the use of this material.

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Rad Source Technologies, Inc.
4907 Golden Parkway
Suite 400
Buford, GA 30518

MKT-027
Revision 2
Effective Date: 01 Mar 2019

1.1 User Responsibility

In order to operate properly, the RS 420•XL must be installed, operated, and maintained in accordance with the procedures described herein.

Periodic inspection of the RS 420•XL will aid in detecting anything that may cause problems with the unit's operating performance. If any part is found to be worn, broken, or damaged in any way, immediately contact Rad Source Technologies, Inc.

Only Rad Source Technologies, Inc. authorized persons should perform repair procedures.

Any alteration to the RS 420•XL not in accordance with the procedures set forth by Rad Source Technologies, Inc. places sole responsibility on the user for any malfunction resulting from faulty maintenance, improper repair, damage, or alteration by any person other than Rad Source Technologies, Inc. authorized persons.

⚠ WARNING The RS 420•XL should only be operated by AUTHORIZED PERSONNEL who have thorough knowledge of the proper use of the device. The key for the unit should be accessible only by AUTHORIZED PERSONNEL.

Questions about its use should be addressed to Rad Source Technologies, Inc. at (1) 678-765-7900 or email service@radsource.com.

The information in this document is confidential, subject to change without notice and may be legally privileged. It is intended solely for the end user. While we have taken reasonable precautions to assure the accuracy of the information in this document, we shall not accept liability for any damages which you sustain as a result of use of this document.

2. Safety Information

This section identifies the symbols and specific notations used to call attention to conditions that could potentially result in injury, damage to equipment, or require special attention.

DANGER, WARNING, CAUTION, NOTE, and the symbols below may be used throughout this manual and on the RS 420•XL to emphasize important and critical information. You must read these statements to help ensure safety and to prevent product damage.

2.1 Danger

⚠ DANGER - Indicates an imminently hazardous situation which, if not avoided, will result in death or serious injury. This signal word is to be limited to the most extreme situations.

2.2 Warning

⚠ WARNING - Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.

2.3 Caution

⚠ CAUTION - Indicates a potentially hazardous situation which, if not avoided, could result in minor or moderate injury. It may also be used to alert against unsafe practices.

2.4 Notes

NOTE: – Used to notify people of installation, operation, or maintenance information that is important, but not hazard-related.

2.5 Reference

- This symbol may be found on the RS 420•XL, or on the units Control Unit, and is used to refer the user to reference the manual for further information.

2.6 X-rays On

- This symbol is found on the RS 420•XL and is used to notify the observer that X-rays are produced by this machine when energized.

3. Introduction

3.1 Causes of Exposure Using X-ray

1) Putting fingers in X-ray beam to change sample
2) Aligning X-ray beam visually
3) Modification of shielding
4) Failure to read & follow manufacturers operating instructions

⚠ WARNING Any of these actions could cause an unnecessary exposure and a potential negative effect.

3.2 Unsafe conditions

Examples of unsafe conditions:

1) Load door interlocks do not work.
2) Shielding has been damaged.
3) Viewing window (if installed) is cracked.
4) Evidence of machine tampering.

⚠ WARNING IF AN UNSAFE CONDITION ARISES WITH YOUR X-RAY DEVICE

1) Stop work immediately!
2) Push in the red Emergency Stop Button. (This will remove power from the High Voltage Power Supply, X-ray Emitter, and the Cooling System. An X-ray device requires power to produce radiation.)
3) Notify your Principal Investigator.

3.3 Electrical Hazard

⚠ CAUTION Another serious hazard from an X-ray instrument is electrical shock. The X-ray generator is a highly regulated DC power supply that operates at an applied voltage of up to 160 kV in order to achieve an optimum flux of X-rays.

3.4 General X-ray Equipment Safety Procedures

⚠ CAUTION No unauthorized personnel may defeat or override any safety features on the X-ray Emitters, the safety enclosure, or the control system without the permission of the manufacturer.

3.5 IMPORTANT SAFETY INSTRUCTIONS

Also note the additional SAFETY instructions will be found throughout this manual and ALL must be heeded.

⚠ WARNING This unit is to be installed only by factory-authorized personnel. DO NOT ATTEMPT to install or otherwise apply or attach any electric power to the unit prior to contacting Rad Source Technologies, Inc. at service@radsource.com or call (1) 678-765-7900.

⚠ WARNING The machine is extremely heavy and movement should only be done AFTER CONSULTING WITH the manufacturer. NEVER attempt to move the machine once it has been installed BEFORE contacting the manufacturer. Sudden movement, or movement over uneven floors, inclines, or declines may result in tipping. A level floor is required for installing this unit.

⚠ WARNING This unit is to be serviced by trained personnel only. Do not remove any covers or adjust any screws, bolts, or related fasteners.

⚠ WARNING This manual instructs how to use the RS 420•XL. If you disregard the instructions or information in the manual, you could be assuming responsibility for damages, costs, or injury incurred by such disregard.

⚠ WARNING This device is equipped with safety interlocks incorporated into the chamber door and X-ray tube access panel to prevent the unit from operating when the chamber is open. Overriding, modifying, adjusting, or in any way defeating these interlocks is hazardous.

⚠ WARNING If any obvious mechanical damage is detected or suspected, cease use immediately, and contact Rad Source Technologies, Inc. at (1) 678-765-7900.

⚠ CAUTION Please keep unit dry. When cleaning, do not allow cleaners or water to drip into panels or chamber. Only use damp cloth with mild detergents for cleaning.

⚠ CAUTION Do not use the top of the unit as a storage area, or place any heavy items or items containing liquids or materials that may harm the unit if leaked or spilled on top or inside.

3.6 System Components

Illustrations of the RS 420•XL components and item descriptions are found in this section.

3.6.1 Front View

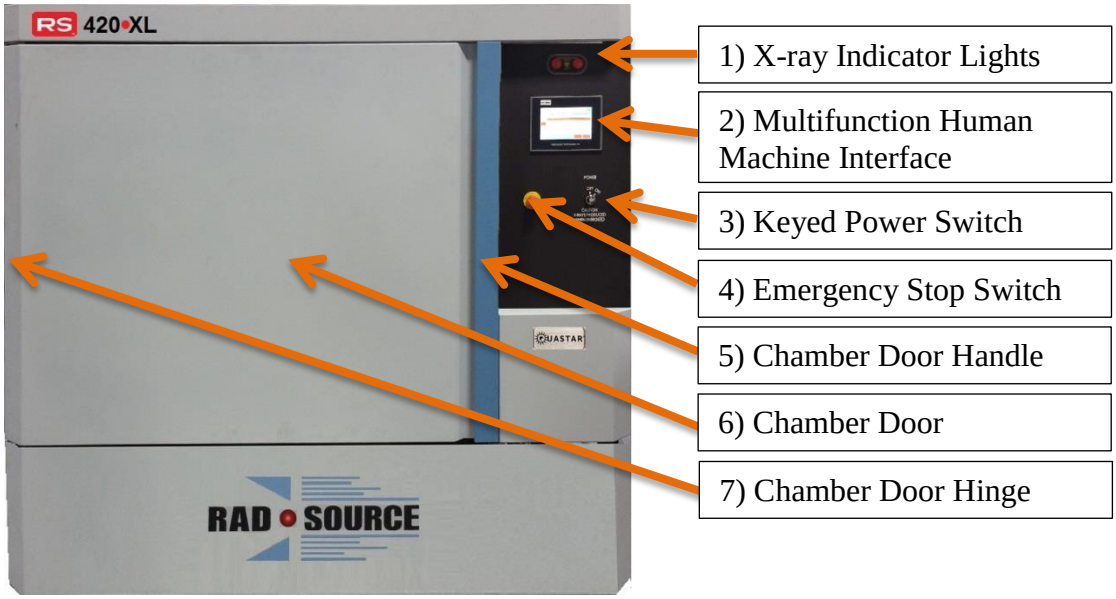


Figure 1 Front View of the RS 420•XL

1) **X-ray Indicator Light** – Two red lights. They will flash in an alternating fashion to indicate when X-rays are being produced. Both red lights will illuminate momentarily while the device is evaluating conditions prior to turning on X-rays.
2) **Multifunction Human Machine Interface** – Contains operating and display controls and indicators which are described later in this manual.
3) **Keyed Power Switch -** The Key Switch has 2 positions. On and Off. When turned all the way to the left, the unit is in the Off mode and is completely non-operational (aka. "at rest"). This would be its position during long down times (days, e.g.). When turned to the right (clockwise), the Key Switch is in On, its Standby mode. Key distribution must be limited only to authorized individuals.

4) **Emergency Stop Switch -**– When pressed, all processes are immediately stopped. The E-Stop Button should remain depressed until the emergency is resolved. Investigate the reason the E-Stop Button was pressed before resuming normal operation. If the E-Stop Button is pressed for any reason during a Cycle, turn the Key to the Off position, turn the E-Stop Button clockwise to release it, and turn the Key to the On position to resume normal operation.
5) **Chamber Door Handle -** Used to open and close the Chamber Door. The handle itself operate a mechanical latch mechanism and must be in the open position to close the door.
6) **Chamber Door** – This is a two part inner and outer door with the inner door being a heavy door made primarily of shielding material in the form of lead which shields the X-rays in the irradiation Chamber. It is held in the closed position by a latch that is released by pulling out on the Chamber Doo Handle.

⚠ CAUTION The Chamber Door should be operated gently and NEVER SLAMMED or RAPIDLY OPENED or RAPIDLY CLOSED.

7) **Chamber Door Hinge** – Holds the Chamber Door and allows it to operate freely. It is adjustable only by the manufacturer.

4. Installation and Site Requirements

4.1 Physical

The RS 420•XL require an area approximately 78"W x 53"D x 83"H. The rear of the device should never be up against a wall and should allow free movement of air. The RS 420•XL must have sufficient clearance on the sides of the device to prevent restriction of air flow. Do not place the devices closer than 6 inches to the rear wall.

⚠ CAUTION At least 36 inch clearance should be allowed on the RS 420•XLs right side to allow for the opening of side panels for maintenance.

⚠ CAUTION Sufficient clearance must exist for the 56 inch wide front door to open on the left to 150°.

Each side of the machine also requires the free movement of air and therefore, should be no closer than 6 inches to any wall or device. Because part of the cooling system relies on cool, ambient air, any restriction in air flow will result in restricted operation or no operation due to an inability to cool the machine.

⚠ WARNING These devices are extremely heavy and should never be moved on an incline of or tipped greater than 10 degrees.

Floors on which the device will be located must be capable of bearing its load. The device weighs approximately 6,300 pounds and is leveler mounted.

⚠ WARNING A level floor is required for installing this device. The device is heavy and tipping or movement may result in a dangerous situation.

Earthquake Zones: Floor mount is required in Earthquake Zones. Reference Rad Source does not provide or support earthquake anchoring equipment. Please follow your local building codes for anchoring your machine to meet earthquake safety protocol.

Europe/CE Earthquake Requirement: Floor mount is required for CE compliance and according to IEC regulation. Rad Source does not provide or support earthquake anchoring equipment. Please follow your local building codes for anchoring your machine to meet earthquake safety protocol.

Note: Rad Source Technologies, Inc. does not provide the anchoring system for your facility. Each customer is responsible for removing and replacing the anchoring system any time Rad Source Technologies, Inc. services your device.

4.2 Electrical

Input power requirements are:

RS 420•XL: Single Phase, 50/60 Hz, 208-240VAC, 60 Amps (L1, L2/N, GND)

Installation of the power supply cable to the power box is the responsibility of the customer. It should be performed by a qualified licensed electrician or construction personnel.

Once the power cord is connected, turn the mains power on, and turn the main machine breaker (located in the rear near the power entry) to the ON position.

A 60 Amp wall mounted Lockable Mains Disconnect Switch (provided by the customer) must be mounted within 6 feet (2 meters) of the rear of the device. The disconnect switch must be non-shorting, be capable of disconnecting L1 and L2/N simultaneously, be easily accessible by the operator and capable of being locked in the "Off" position. The Disconnect Switch must be protected by a Standard 60 Amp Double Pole Mod C Branch Breaker, such as a THQB (Thermal Magnetic) 10kA 240 volts A/C, or equivalent. The use of fuses is discouraged.

A power cord permanently connected to the rear of the device and approximately 7 feet long will be provided by Rad Source Technologies, Inc. The power cord will be 6 AWG (13.3 mm^2) with three copper conductors using 133/27 stranding surrounded by an unshielded Carolprene® black jacket with a nominal diameter of 0.980 inches (24.89mm). The power cord is only replaceable by Rad Source Technologies, Inc.

Power cord compliance:
UL Flexible Cord – Subject 62
CSA Flexible Cord – C22.2-49
MSHA Approved
RoHS Compliant

A mains ground stud will be provided for secondary grounding when required. The stud should be connected to earth ground by the customer.

⚠ WARNING To avoid risk of electric shock, the exterior panels should only be removed by Rad Source AUTHORIZED PERSONNEL

⚠ WARNING Unit must be connected only to supply voltage rating marked on the unit (see label on back of unit and ratings noted above) and any power receptacle must be of GROUNDED TYPE.

⚠ CAUTION The cable on the rear of the RS 420•XL should never be forced or otherwise pressed up against a wall. Sufficient clearance should be allowed so that the cable is never at risk for being compromised because of physical stress.

⚠ CAUTION If your facility performs generator tests, then the user must turn the Key to the Off position before the generator test is performed. After the test is over, the user may turn the Key to the On position and resume normal operation.

4.3 Electromagnetic

To minimize the effects of electromagnetic interference only operate the machine with all panels installed. The RS 420•XL will not be adversely affected by other machines likely to be used in the same location. The RS 420•XL will not generate electromagnetic phenomena that will adversely affect other machines likely to be used in the same location.

4.4 Environmental

Environmental Conditions and limitations for operating this equipment:

1) Indoor Use in an air-conditioned environment
2) Altitude up to 5000 Meters
3) Temperature 50°F (10°C) to 104°F (40°C)
4) Maximum relative humidity 80% for temperatures up to 86°F (30°C) decreasing linearly to 50% relative humidity at 104°F (40°C)
5) Internal water tank requires 9 Gallons of Distilled water.
6) RS 420•XL requires external chilled water that supplies min 30,000 BTU External Cooling with 5 GPM flow rate, @ between 24°±6°C/75°±11°F.
7) Mains supply voltage fluctuations up to +/-10% of the nominal voltage

NOTE: The device will not operate properly outside the environmental conditions stated above.

4.5 Cooling

The RS 420•XL pumps distilled water around the X-ray tubes and through a water to water heat exchangers for cooling. An external chiller or other chilled water source is required to keep the internal water cool. External chilled water that supplies a min of 30,000 BTU

External Cooling with 5 GPM flow rate, at 40 to 60 psi @ approx. 24°±6°C/75°±11°F is required.

⚠ CAUTION Please consult the Safety Data Sheets (SDS) when chemicals are used. If a technician does happen to interact with the water, they should keep their hands out of their eyes and mouth and wash them when work is completed.

If a disinfectant is required, isopropyl alcohol or ethanol may be added to the water systems internal tank.

⚠ CAUTION The cooling vents on the back of the unit should be clear of any obstruction to allow free airflow when the irradiator is operating. Do not place the machine closer than 6 inches to the rear wall. Each side of the machine also requires the free movement of air and therefore, should be no closer than 6 inches to any wall or device.

If the "Cooling Required" warning on the Display Screen is frequently active, it may be due to an overly warm operating environment. Make sure environmental conditions are acceptable and that there are no restrictions on the water chiller.

5. Operation

5.1 RS 420•XL Intended Use

This is an industrial cabinet X-ray device and is not approved for use on humans. It is for use only by properly trained operators for cannabis irradiation or for research laboratory or other specialty applications where ionizing radiation is required.

⚠ WARNING Any use of this equipment not for its intended use may result in an unsafe condition. Do not insert any flammable or potentially explosive materials into the unit, or apply toxic or corrosive chemicals.

If you have any questions about its use, please contact Rad Source Technologies, Inc. at (1) 678-765-7900 or email to info@radsource.com prior to using.

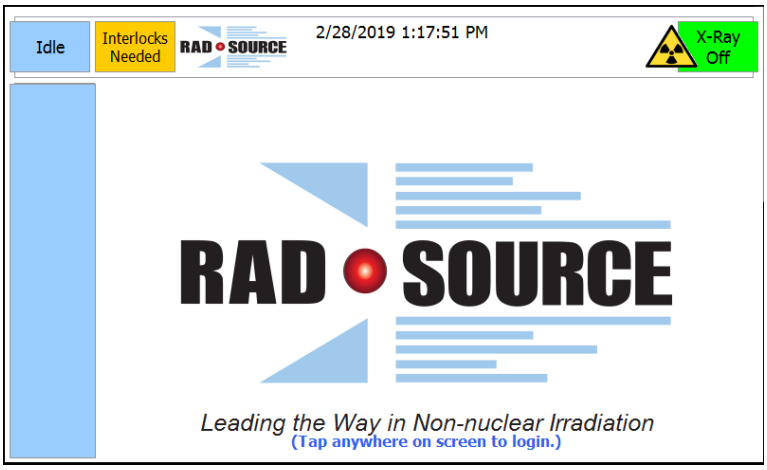
5.2 Getting Started

To prepare for operation of the RS 420, pull on the left side of the *CHAMBER DOOR HANDLE* and open the *CHAMBER DOOR*. Insert product or empty the chamber and while holding the *CHAMBER DOOR HANDLE* in the open position, close the *CHAMBER DOOR*

NOTE: Safety interlocks are incorporated into the unit to only allow operation if the door is properly closed.

If the *EMERGENCY STOP SWITCH* is engaged, verify that it is safe to use the machine, then release the *EMERGENCY STOP SWITCH* by twisting the knob clockwise and letting it pop back out. A yellow ring should be visible at the base of the red *EMERGENCY STOP SWITCH*.

Turn the *KEYED POWER SWITCH* to the right and wait for the *MULTIFUCTION HUMAN MACHINE INTERFACE* to boot up and the following screen to be displayed.



5.3 Logging In

1) Touch the screen to bring up the Login window.
2) If this is the first use of the system, login using the following:
   User name: admin
   Password: password
3) Touch the box for each field and type in the appropriate value for that field followed by the Enter key (↵) using the on-screen keyboard that will appear.

NOTE: The Administrator should change their password once logged in (see USER INFORMATION).

5.4 Machine Operation

5.4.1 Login Group/Access Levels

1) Each person who is provided with a Login must also be assigned a User Group. There are three User Groups, each with different permissions as shown in the table below. The permissions allow various operation of the irradiator as described in the remaining paragraphs of this section.

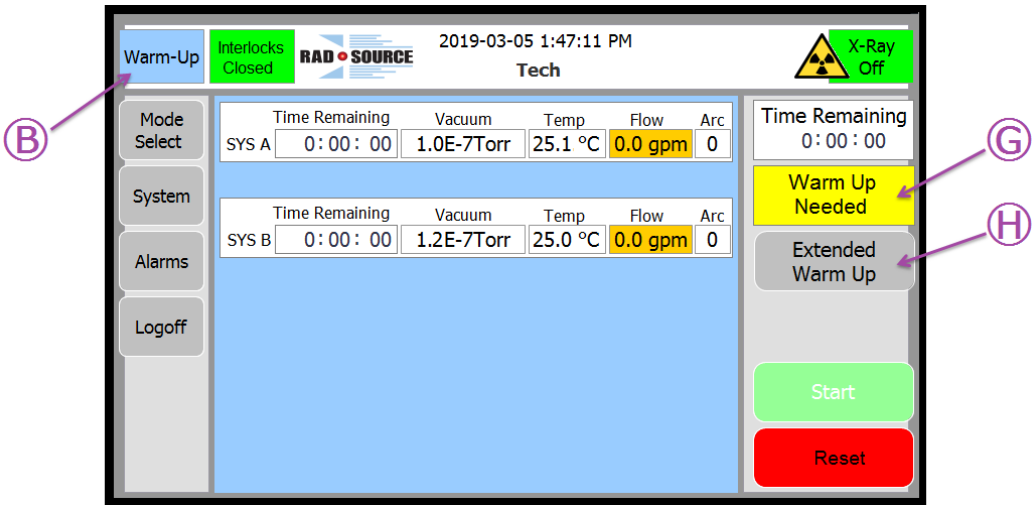
Permissions \ User Group	Admin	Writer	Selector
Performing an X-ray Tube Warm-up	X	X	X
Writing Automatic Programs	X	X	
Editing an existing Program	X	X	
Running Automatic Programs	X	X	X
Pausing Automatic Programs	X	X	X
Manual Mode	X	X	
User Administration	X		
Adding New Users	X		
System Information	X	X	X
Changing logged in password	X	X	X

2) The above permissions allow various operation of the irradiator as described in the remaining paragraphs of this section.

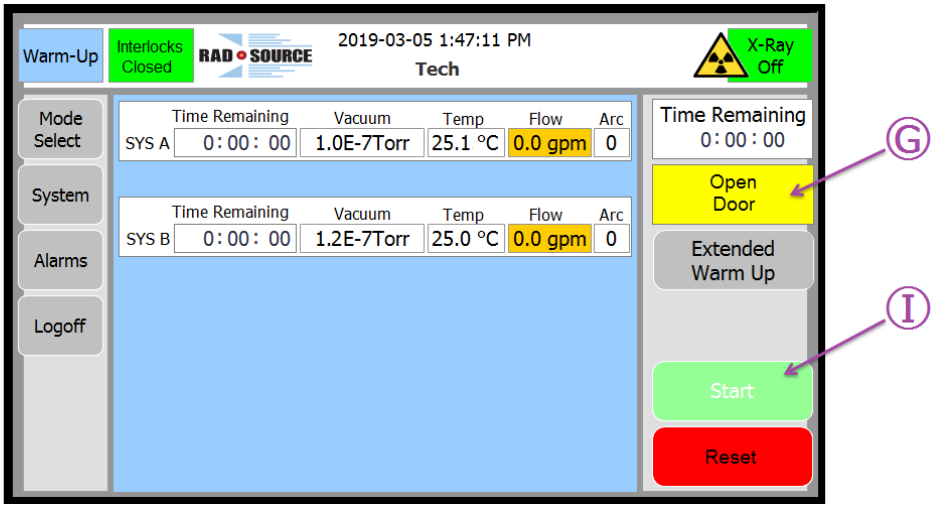
5.4.2 Warm-Up Required

This section applies to Admin, Writer and Selector.

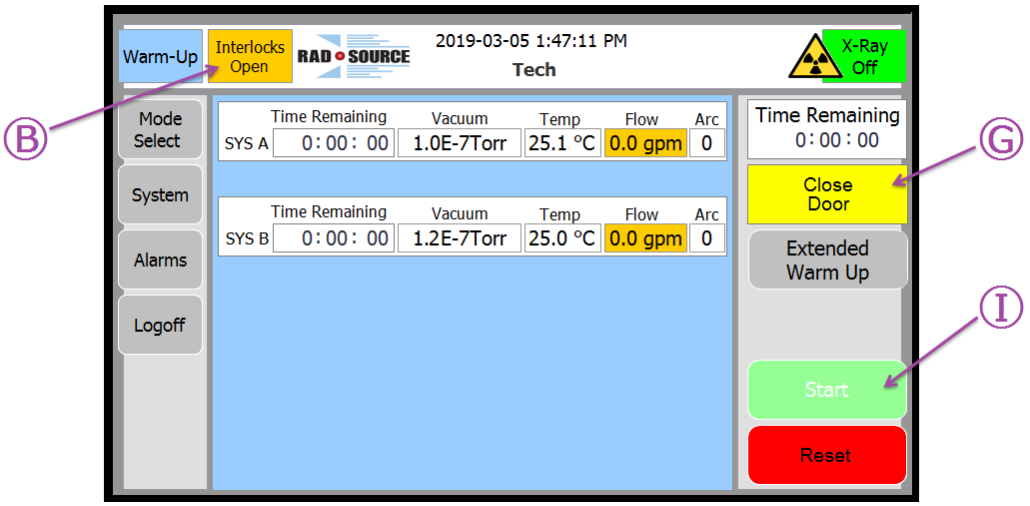
1) If X-rays have not been generated in the previous 24 hours the mode will automatically be set to "Warm-Up" Ⓑ. The yellow Instruction Box will display "Warm-Up Needed" Ⓖ. Pressing the grey "Warm-Up" button Ⓗ willswitch between "Normal Warm-Up" and "Extended Warm-up". It is recommended that if X-rays haven't been generated in the last 72 hours an "Extended Warm-Up" be performed.



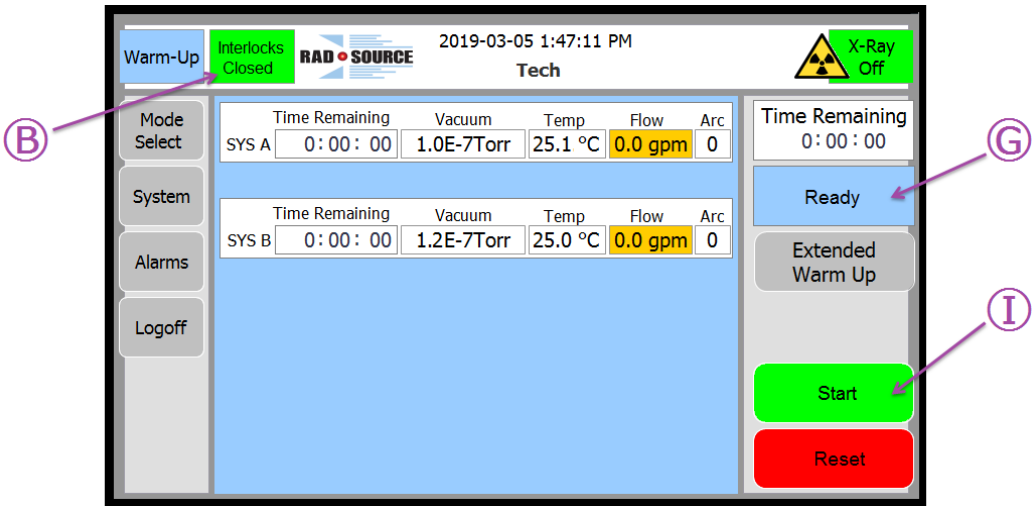
2) The operator MUST confirm that the chamber is empty. The yellow Instruction Box will display "Open Door" Ⓖ until the door has been opened. The Start Button Ⓘ will be a light green indicating the system is not ready to start a "Warm-Up" until the door has been opened.



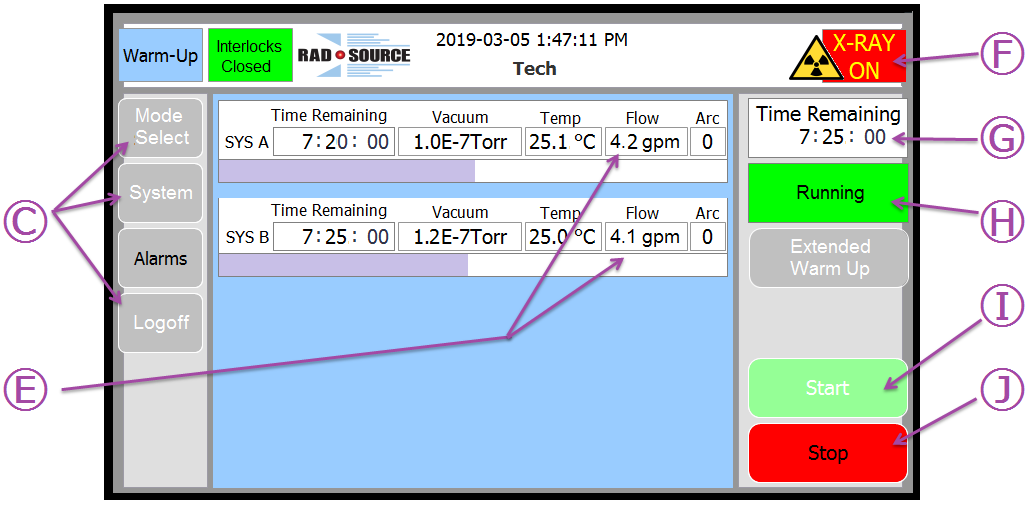
3) While the door is open the Interlocks Indicator's background will be Orange and it will display "Interlocks Open" Ⓑ. The yellow Instruction Box will display "Close Door" Ⓖ. The Start Button Ⓘ will remain a light green.



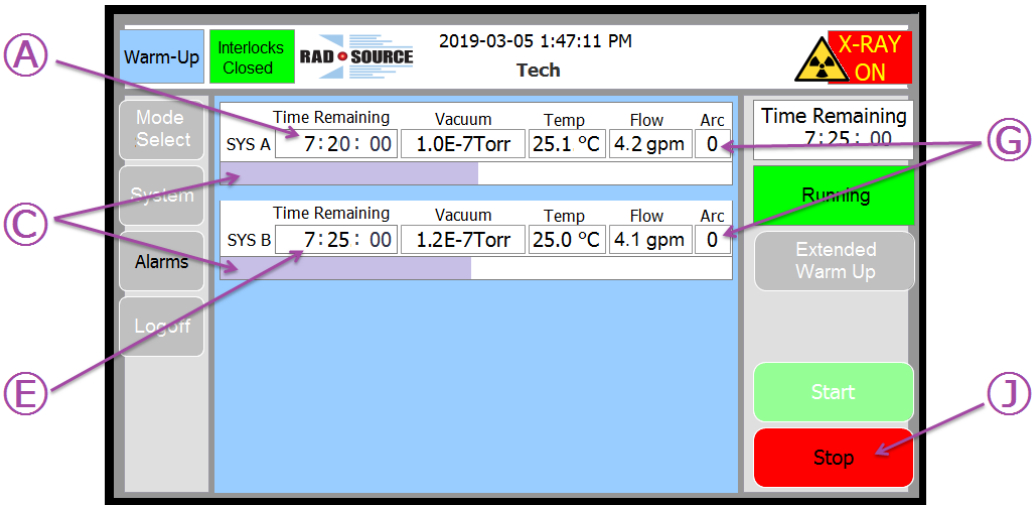
4) Unless some other interlock is open, once the door is closed the, Interlocks Indicator's background will become Green and it will display "Interlocks Closed" Ⓑ. The yellow Instruction Box will be replaced by as light blue System Status Box which will display "Ready" Ⓖ. The Start Button Ⓘ will be a sold green indicating the system is ready to run "Warm Up"



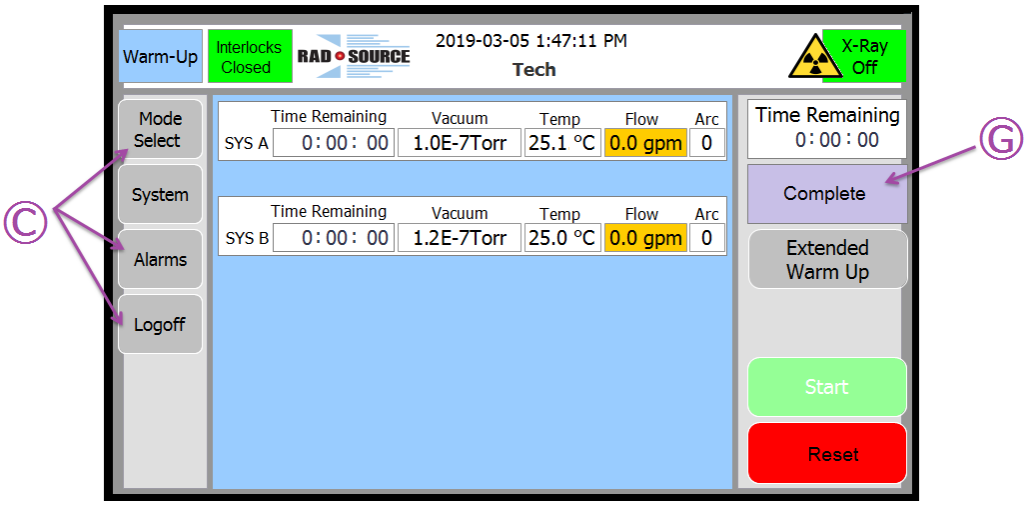
5) Press the Start button to initiate the Warm Up. The X-ray On Indicator Ⓕ will toggle between Yellow and Red. The approximate Time Remaining Ⓖ.will count down. The blue System Status Box will be replaced by a green system Running box Ⓗ. The Start Button Ⓘ and other controls Ⓒ will be disabled. Flow Ⓔ values will indicate the cooling water circulation rate. A Stop Button Ⓙ will be displayed.



6) During Warm Up each tube is slowly ramped up to full power. Normal takes at least 8 minutes while Extended takes at least 16 minutes. As power ramps from zero to full the appropriate *POWER LEVEL WINDOW* Ⓒ will fill in from left to right. Once at full power the system will run an additional 2 minutes in Normal and 4 minutes in Extended. Should an Arc occur the Arc Count Ⓖ. will be incremented and the power reduced. The power for the tube that arced will be reduce and the appropriate *TUBE TIME REMAINING*, Ⓐ or Ⓔ, will increase. The Warm Up cycle can be stopped at any time by pressing the Stop Button



7) When the Warm Up cycle has completed successfully, the green System Running box is replaced with a purple cycle Complete Ⓖ box. Controls Ⓒ that had been disabled during Warm Up are restored.



8) The door MUST be opened before additional operations can be performed.

5.4.3 Loading Canisters into Chamber

1) Open load door by pulling the handle.
2) To rotate the canisters tray Ⓙ into a desired position, turn a canister holder Ⓔ by hand several times unit the canister the desired canister holder(s) is/are in position for easy access.
3) Remove any canister already in position, and place filled canister(s) onto holder(s).

4) Repeat steps 2 & 3 as necessary.

5.4.4 Operational Concepts

This section applies to Admin, Writer and Selector.

When running the irradiator manually, or writing automatic programs, the following concepts are used to enter information into the irradiator control system to obtain the desired results;

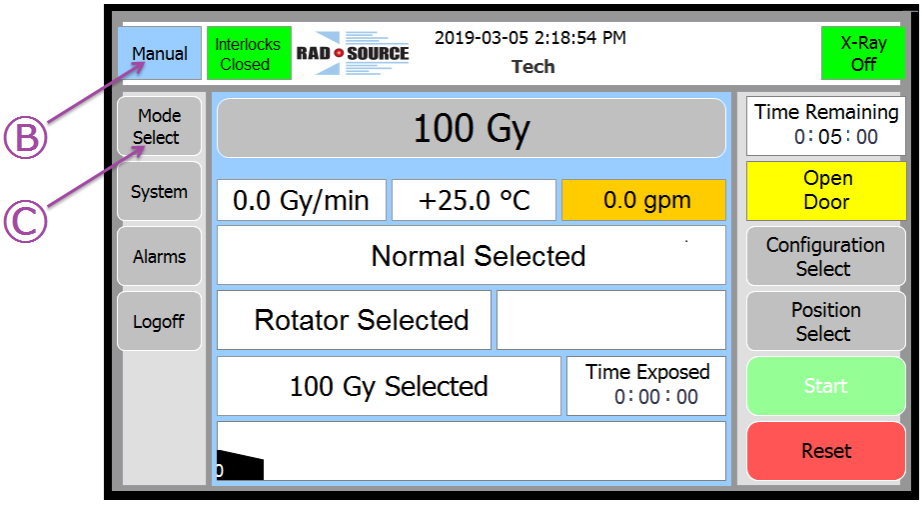
1) Dose (Gy) – The amount of energy to be delivered to the object being irradiated.
2) Position Number – The default position is Rotor.
3) Configuration – During installation a numbered collection that represents how the object will be held in the irradiator, and its orientations, are stored in the control system. Each number is also assigned a name. The operator selects the predefined Configuration that matches how the object will be positioned.
4) Program – Programs are shortcuts that allow the operator to save a Dose, Position Number and Configuration set and to assign that set a Name. To use that set of values again the operator only needs to select the appropriate Program Name.

NOTE: – Screen shots are examples only. The actual screens may be different.

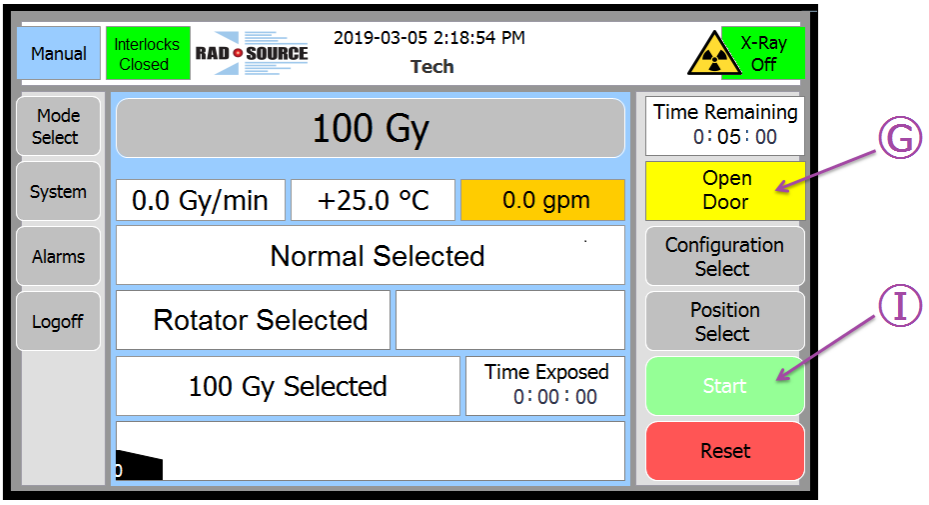
5.4.5 Manual Mode

This section applies to Admin and Writer only.

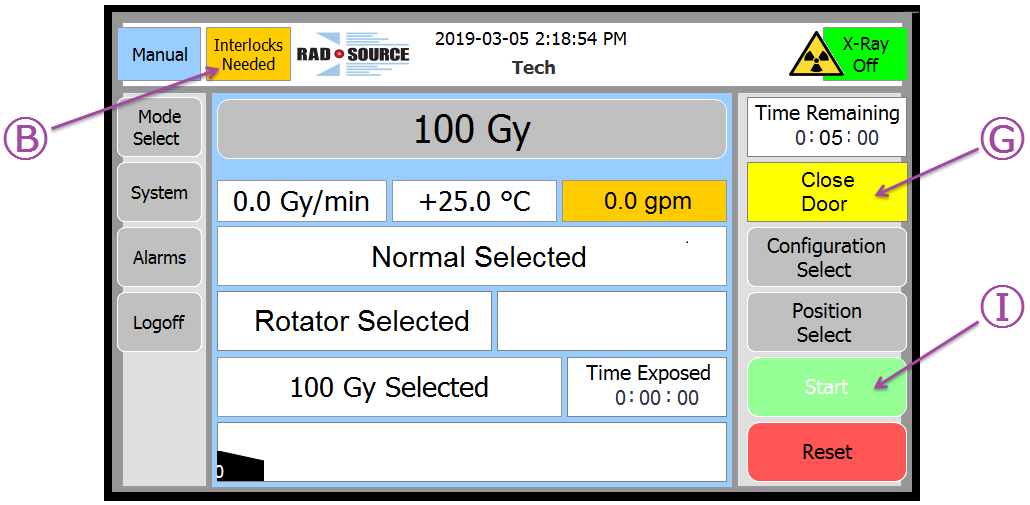
1) Tap Mode *Select* Ⓒ to cycle through modes until Manual Ⓑ is displayed.



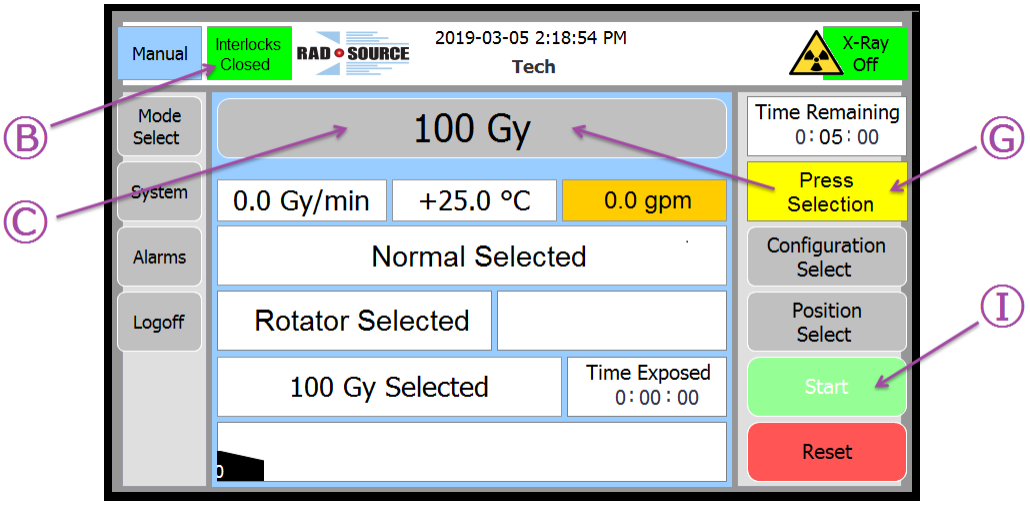
2) The operator MUST confirm that the product is properly loaded.. The yellow Instruction Box will display "Open Door" Ⓖ until the door has been opened. The Start Button Ⓘ will be a light green indicating the system is not ready to start until the door has been opened.



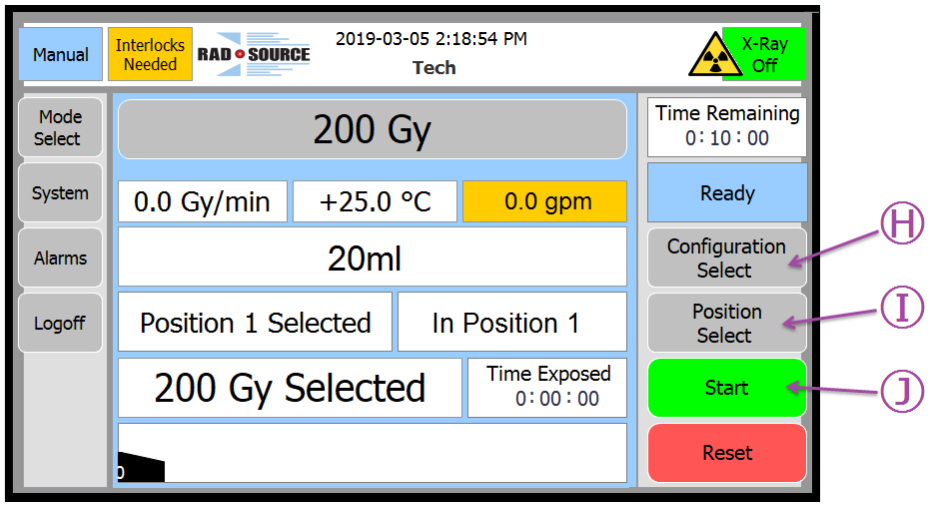
3) While the door is open the Interlocks Indicator's background will be Orange and it will display "Interlocks Open" Ⓑ. The yellow Instruction Box will display "Close Door" Ⓖ. The Start Button Ⓘ will remain a light green.



4) Unless some other interlock is open, once the door is closed the, Interlocks Indicator's background will become Green and it will display "Interlocks Closed" Ⓑ. The yellow Instruction Boxshows Press Selection Ⓖ indicating that the operator MUST confirm or change the Gy value by Tapping the Gy Value Selection box Ⓒ. The Start Button Ⓘremains a light green.

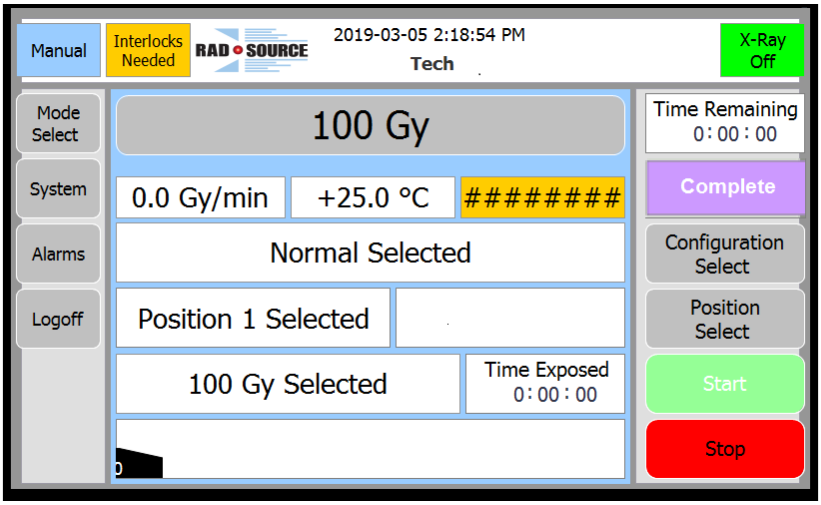


5) Select the correct configuration by touching the *Configuration Select* Ⓗ button to cycle through the available configurations. Touch the *Position Select* Ⓘ button to select the desired position. Press *Start* Ⓙ to begin the cycle.



NOTE: The Time Remaining display will automatically adjust the cycle time according to the selections made.

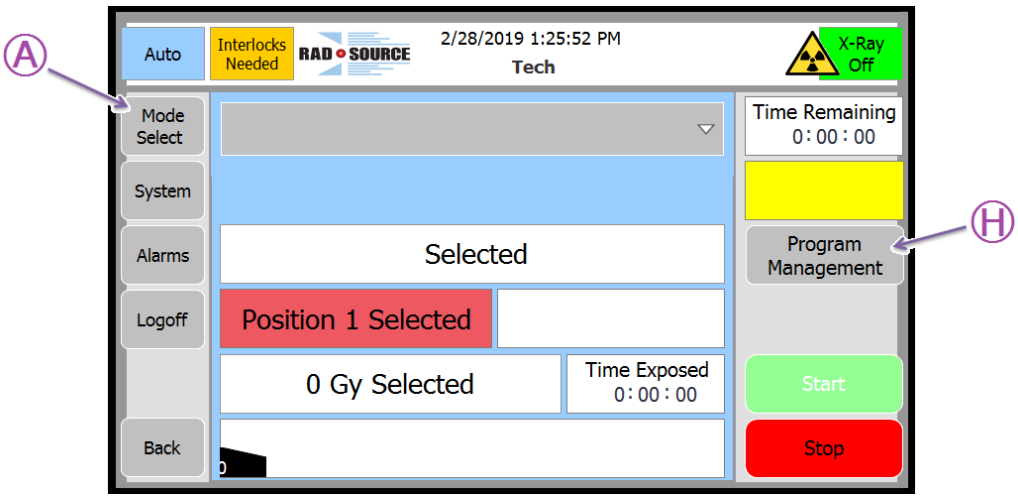
6) When complete, open the door, remove the product, close the door, and press *Reset.*



5.4.6 Writing Automatic Programs

This section applies to editing an existing program and can only be done by Admin and Writer.

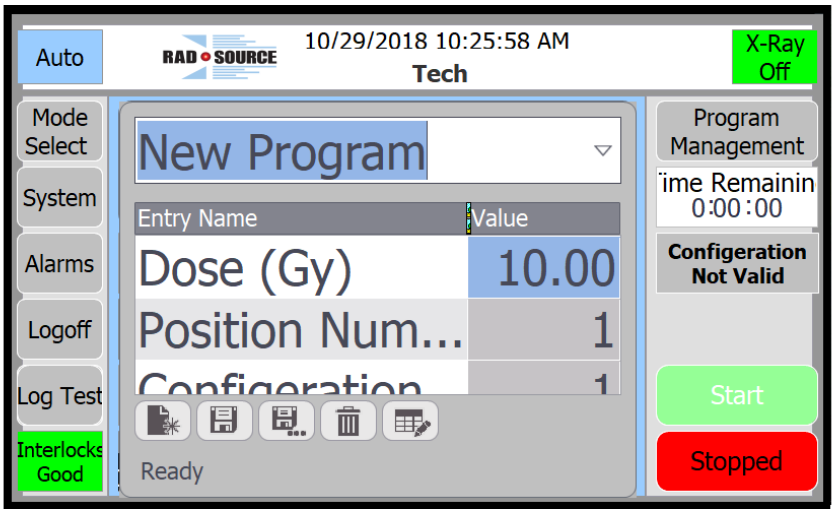
1) Use the Mode Select button Ⓐ to go to the Auto screen. On the right side of the screen, touch the Program Management button Ⓗ to bring up the Program Management screen.



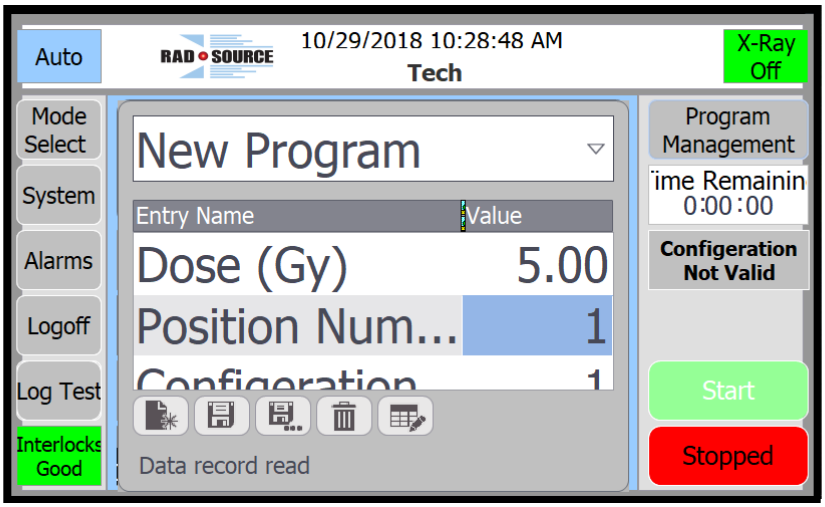
2) Touch the New Program icon to create a new program. Touch within the empty dropdown box and a keyboard will appear on screen to allow the user to input the program name, and confirming it with the Enter button. The new name will now appear in the dropdown box.

3) Or, to edit an existing program, select it and then touch on the program name.

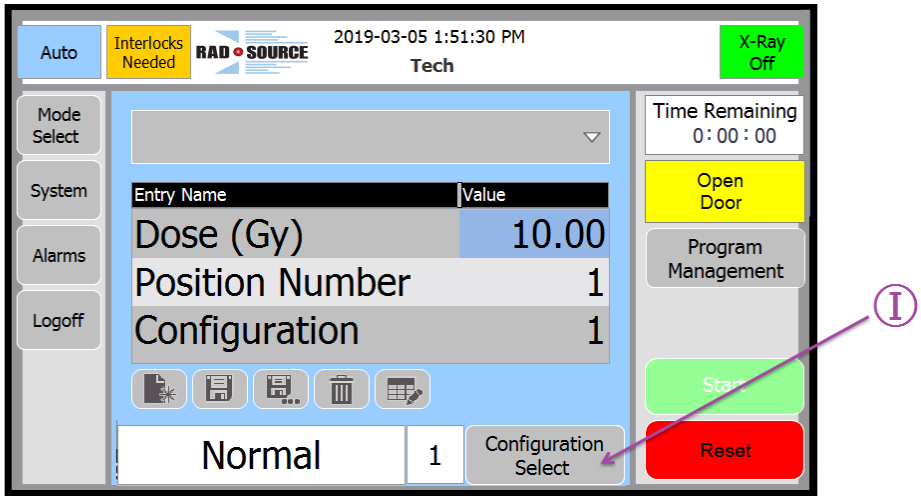
4) Input the desired total dose value in Gray (Gy) into the Dose (Gy) field using the on-screen keyboard pop-up after touching its Value field



5) Position Number – For the RS 420•XL the position is always "Rotator"



6) Press the Configuration Select button Ⓗ to cycle through the available configurations, then, enter the corresponding number into Value column next to Configuration

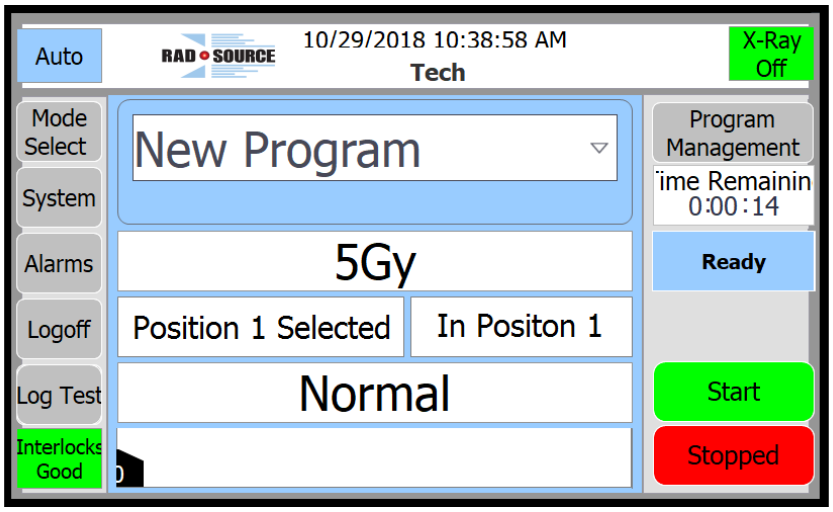


Press the *Save* icon (Additional Icons available)

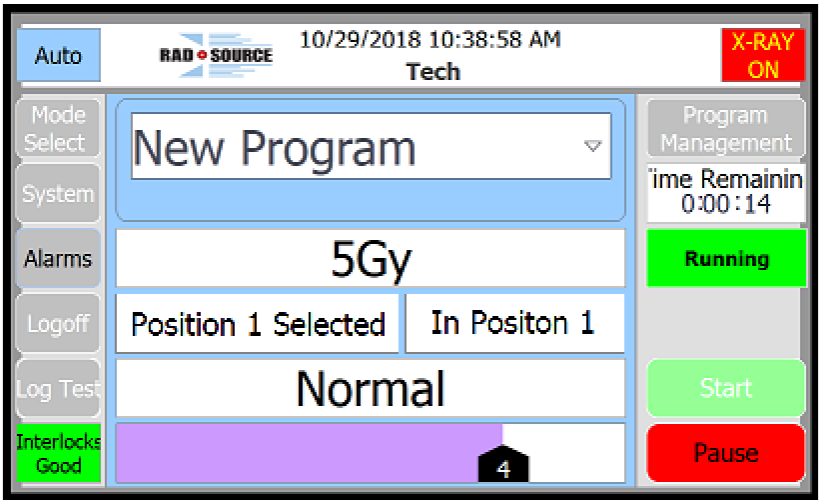
5.4.7 Running Automatic Programs

This section applies to Admin, Writer, and Selector.

1) To run a previously programmed Automatic Program, press the Mode Select button* until the Automatic Program screen is visible, as indicated by *Auto** displayed in the Mode Status box.
2) At the top of the screen, select the desired program from the drop down menu*.
3) Open the door, load the product, and close the door completely. A sensor verifies that the door is completely closed and this verification is displayed at the top of the screen with the words "Interlocks Closed,"* at which point the system is ready to run. Press Start*.



4) During X-ray generation a variety of buttons will turn white, indicating that they are unavailable for selection, a Progress Bar* displaying the total Grays (Gy) produced will run from left to right across the bottom of the screen, the X-ray On indicator* will flash, and the status indicator will display "Running."*

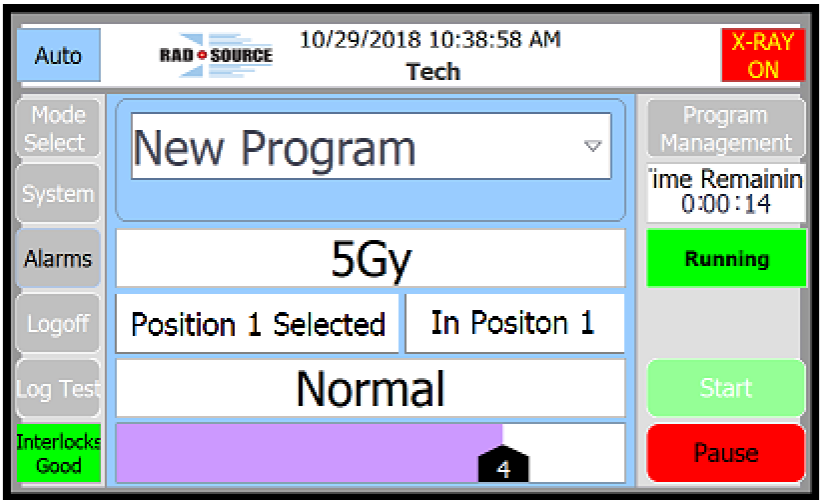


5) When the exposure is complete the buzzer will sound and the status indicator will change from "Running" to "Complete*." Open the door, remove the product, and close the door.

5.4.8 Interrupting Automatic Programs

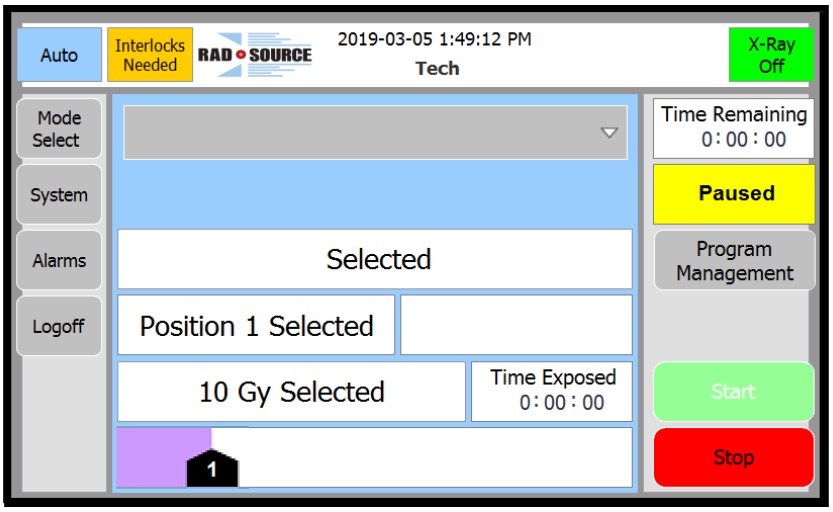
This section applies to Admin, Writer and Selector.

1) To either pause or cancel a running cycle, press the Pause button *.



.

2) When the machine has been paused, you may either resume the cycle by pressing Resume*, or cancel the cycle by pressing Stop*



5.4.9 User Administration

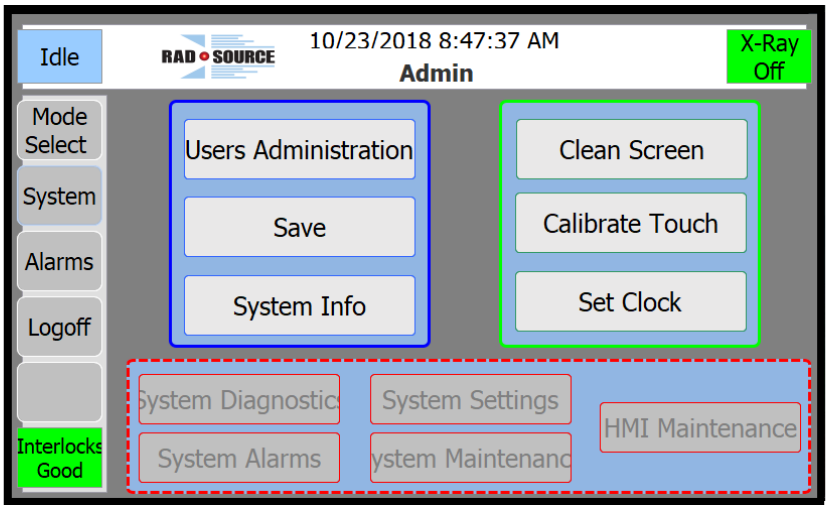
This section applies to Admin only.

1) Touch the *System* button to access the System screen, then touch the *Users Administration* button to enter the User Administration screen.
2) Adding New Users: To add a new user, touch the empty field under the User column and enter the user's name using the keypad that appears on screen. Then, touch the empty field to the right of that new user's username under the password column and setup the password using the Change Password dialogue box that appears on screen. Finally, change the user's privilege group from Unauthorized by assigning the user to one of the three User Groups.
3) User Groups: There are three User Groups available to be assigned to a user with the following differences;
4) Selector: Authorized to run the machine in Warm-Up mode, as well as run pre-programmed cycles in the Auto mode
5) Writer: Authorized to run the machine in Warm-Up mode, Auto mode, Manual mode, and define new cycles using the Program Management screen.
6) Administrator: Authorized to run the machine in Warm-Up mode, Auto mode, Manual mode, define new cycles using the Program Management screen and setup new users using the User Administration screen.

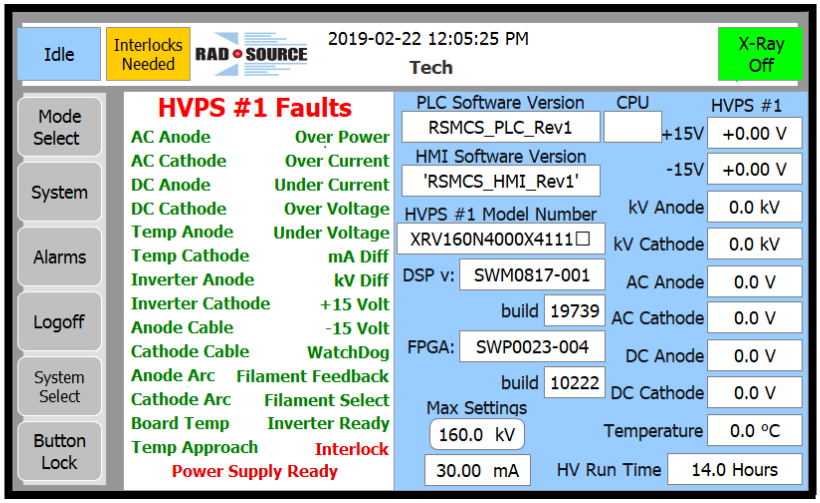
5.4.10 System Information

This section applies to Admin, Writer and Selector.

1) To view the HVPS information, touch System Navigation Key.



2) To switch between HVPS1 and HVPS2, tap the *System Select* button.

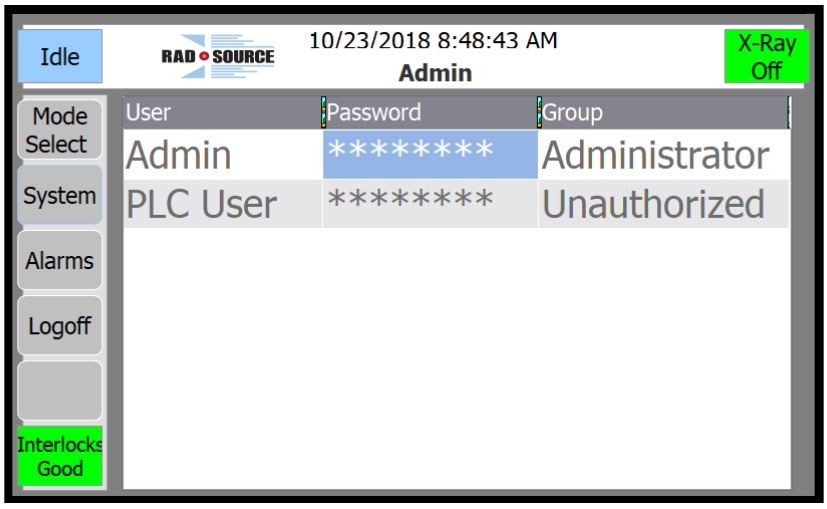


5.5 User Information

5.5.1 Changing logged in password

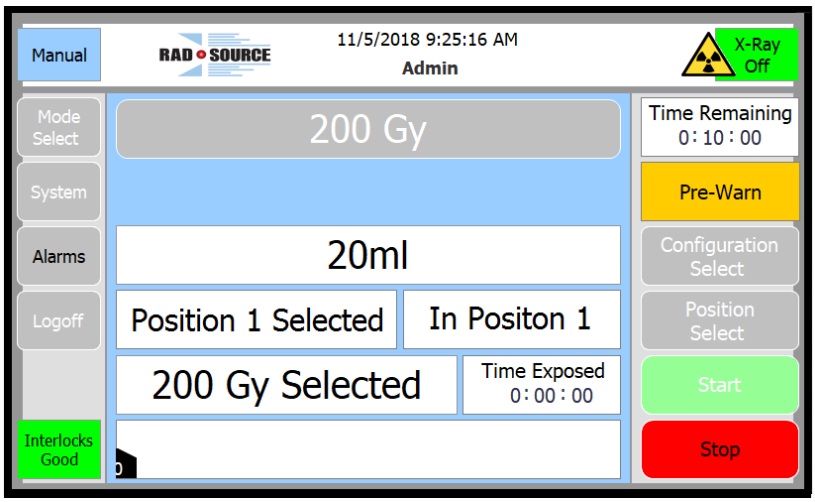
This section applies to Admin, Writer and Selector.

1) Once logged in, a user may change their password from the User Administration Screen.
2) Touch the System button, followed by the User Administration button.
3) Touch the asterisks in the Password column and use the Change Password dialogue box that appears on screen to complete the password change.
4) Use the navigation keys to perform additional operations
5) Press *OK*, then touch anywhere on the screen again when done.



5.6 Warning and X-ray Tube On Lamps

During Pre-Warn, after *Start* has been pressed and before X-rays are produced, the System Status box will turn Orange and display "Pre-Warn" as a warning prior to X-ray generation. Whenever X-rays are being produced, the red X-ray On Lamps will be lit.



5.7 Internet Connection

The RS 420•XL supports a secure internet connection that allows remote monitoring and technical support.

Inside the RS 420•XL is a router with a fully secure SSL-based VPN tunnel that can communicate via an encrypted SSL (2048-bit key) allowing only authenticated users to connect. This router provides segregation between your WAN and the LAN inside the irradiator. This segregation means that our support team can communicate only with the hardware inside the irradiator and has no access to any other part of the connected network.

Because no incoming connections are made, there is typically no need to change firewall settings, routing policies, open ports or add exceptions. Little to no IT involvement is required.

The internal router initiates a VPN tunnel to an Industrial Cloud VPN server by making an outbound connection across the LAN using ports that are commonly enabled (HTTPS port 443 or UDP port 1194).

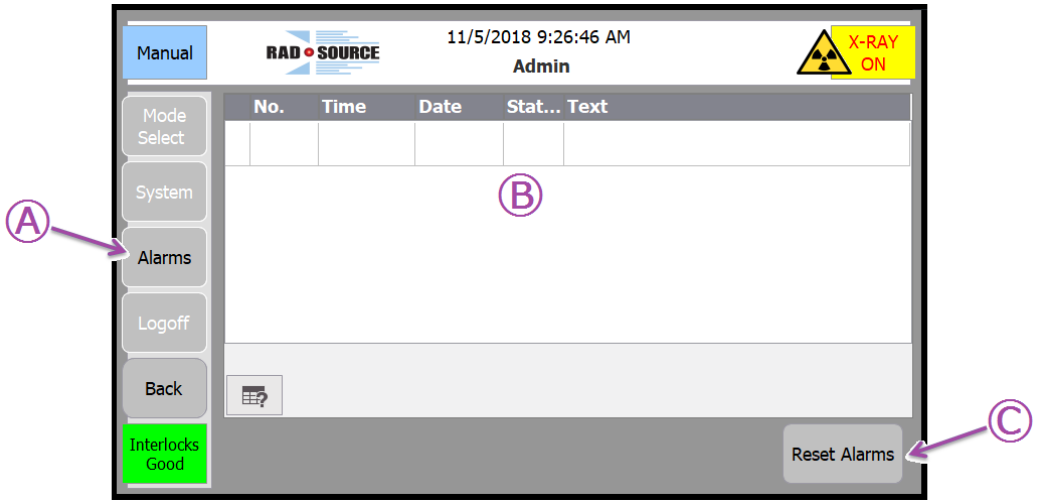
To use this feature the Ethernet cable coming out the back of the unit needs to be connected to your company network or to a WiFi router that you supply. The WiFi router can use your internal network or your guest network.

Once connected, our support team can provide remote technical support by observing the internal operation of the RS 420•XL and answering question about its operation. This connection can also be used to upload requested software modifications and/or improvements that control the irradiator operation.

5.8 Alarms

If the alarm sounds or the Alarms button changes color to indicate an alarm condition, press Alarms Ⓐ on the left and read the information displayed in the Alarms screen Ⓑ. Press Reset Alarms Ⓒ in the bottom right of the screen to clear all alarms that are no longer active. Any alarm that is still active will have to be resolved before the alarm before can be cleared.

The possible alarms and the corrective actions are given in the following table. A Warning will not cause the machine to stop operation but is an indication that a problem may exist and should be investigated before it gets worse. A Non-Critical Fault will cause an operation to pause and, in Automatic or Warm-Up modes, the machine will automatically attempt to resume operation after a short delay. A Critical Fault will stop any in-progress operation and operation cannot resume nor be started until the fault is cleared.



5.8.1 WARNINGS:

Table 2: Alarm Descriptions and Possible Corrective Actions

ID	Warning	Description / Corrective Action
5	X-rays On Lamp One Failure	Replace Light Bulb. Check Lamp Failure Detection Circuit.
6	X-rays On Lamp Two Failure	Replace Light Bulb. Check Lamp Failure Detection Circuit.
11	Tube #1 Coolant Temperature Too Low	The Coolant Temperature Measured at the X-ray Tube is Very Low. Check Sensor.
12	Tube #1 Coolant Temperature Low	The Coolant Temperature Measured at the X-ray Tube is Below Normal Operating Range.
13	Tube #1 Coolant Temperature High	The Coolant Temperature Measured at the X-ray Tube is Above Normal Operating Range. Check Cooler.
14	Tube #1 Coolant Temperature Too High	The Coolant Temperature Measured at the X-ray Tube is Very High. Check Sensor.
17	No High Voltage from HVPS #1	Power Supply Not Generating High Voltage. Check Power to the Generator.
18	HVPS #1 High Voltage Out of Range	Tube Arc
19	HVPS #1 kV Monitor Does Not Equal Command	Control System Malfunction
20	HVPS #1 mA Monitor Does Not Equal Command	Control System Malfunction
21	HVPS #1 Failed To Start	An X-ray On Command Was sent to the Generator But an X-ray Status was Not Returned.
26	HVPS #1 Requested kV Out of Range	An Incorrect kV Value Was Entered, Try Again.
27	HVPS #1 Requested mA Out of Range	An Incorrect mA Value Was Entered, Try Again.
30	X-rays On Lamp One Detection Failure	Check Lamp Failure Detection Circuit.
31	X-rays On Lamp Two Detection Failure	Check Lamp Failure Detection Circuit.
38	HVPS #1 Communications Lost	Check Data Cable and Auxiliary Power Connections to High Voltage Power Supply.

ID	Warning	Description / Corrective Action
41	Tube #2 Coolant Temperature Too Low	The Coolant Temperature Measured at the X-ray Tube is Very Low. Check Sensor.
42	Tube #2 Coolant Temperature Low	The Coolant Temperature Measured at the X-ray Tube is Below Normal Operating Range.
43	Tube #2 Coolant Temperature High	The Coolant Temperature Measured at the X-ray Tube is Above Normal Operating Range. Check Cooler.
44	Tube #2 Coolant Temperature Too High	The Coolant Temperature Measured at the X-ray Tube is Very High. Check Sensor.
45	No High Voltage from HVPS #2	Power Supply Not Generating High Voltage. Check Power to the Generator.
46	HVPS #2 High Voltage Out of Range	Tube Arc
47	HVPS #2 kV Monitor Does Not Equal Command	Control System Malfunction
48	HVPS #2 mA Monitor Does Not Equal Command	Control System Malfunction
49	HVPS #2 Failed To Start	An X-ray On Command Was sent to the Generator But an X-ray Status was Not Returned.
50	HVPS #2 Requested kV Out of Range	An Incorrect kV Value Was Entered, Try Again.
51	HVPS #2 Requested mA Out of Range	An Incorrect mA Value Was Entered, Try Again.
52	HVPS #2 Communications Lost	Check Data Cable and Auxiliary Power Connections to High Voltage Power Supply.
73	Software Version Mismatch	Check PLC CPU & HMI Software Versions in System Info Screen. Reprogram with latest release.
74	Tube #1 Coolant Flow Rate Low	The Measured Flow Rate of Coolant through the X-ray Tube is Low. Check Frequency of VFD, Speed of Pump Motor, and for any Blockage in Coolant Line.
75	Tube #2 Coolant Flow Rate Low	The Measured Flow Rate of Coolant through the X-ray Tube is Low. Check Frequency of VFD, Speed of Pump Motor, and for any Blockage in Coolant Line.
76	Tube #1 Coolant Flow Rate High	The Measured Flow Rate of Coolant through the X-ray Tube is High. Check Frequency of VFD, Speed of Pump Motor, and for any Loose Coolant Line.

ID	Warning	Description / Corrective Action
77	Tube #2 Coolant Flow Rate High	The Measured Flow Rate of Coolant through the X-ray Tube is High. Check Frequency of VFD, Speed of Pump Motor, and for any Loose Coolant Line.
78	Tube #1 Vacuum Pressure High	Check Vacuum Pump Power Supply and Cable. If Arcs have Occurred, Wait for Vacuum to Recover.
79	Tube #2 Vacuum Pressure High	Check Vacuum Pump Power Supply and Cable. If Arcs have Occurred, Wait for Vacuum to Recover.

5.8.2 NON-CRITICAL FAULTS

ID	Non-Critical Fault	Description
10	HVPS #1 High-Voltage Arc	Power Supply Arc Fault. (Most often caused by a Tube Arc or a High Voltage Connection Problem.)
15	HVPS #1 No or Too Low High-Voltage Current	Power Supply Under-Current Fault. May Indicate an Open Filament.
16	HVPS #1 High-Voltage Current Above Maximum	Power Supply Over-Current Fault. (Most often caused by a Tube Arc or a High Voltage Connection Problem.)
40	HVPS #1 No High Voltage	Power Supply Not Generating High Voltage. Check Power to the Generator.
66	HVPS #2 High-Voltage Arc	Power Supply Arc Fault. (Most often caused by a Tube Arc or a High Voltage Connection Problem.)
67	HVPS #2 No or Too Low High-Voltage Current	Power Supply Under-Current Fault. May Indicate an Open Filament.
68	HVPS #2 High-Voltage Current Above Maximum	Power Supply Over-Current Fault. (Most often caused by a Tube Arc or a High Voltage Connection Problem.)
69	HVPS #2 No High Voltage	Power Supply Not Generating High Voltage. Check Power to the Generator.

5.8.3 CRITICAL FAULTS

ID	Critical Fault	Corrective Action
1	Coolant Flow through Tube #1 Out of Range	Check That Cooling System is Turned On and Properly Adjusted. Check Coolant Flow Sensor.
2	Tube #1 Coolant Temperature Out of Range	Let Cooler Run without X-rays On to cool down Coolant. Check Thermocouple. Check ambient temperature.

ID	Critical Fault	Corrective Action
3	Loading Door Open	Close Front Loading Door. Check That Door Prox Sensor is being Activated when the Door is Closed.
4	Access Door Open	Close Maintenance Access Door. Check That Door Prox Sensor is being Activated when the Door is Closed.
7	Failure of Both X-rays On Lamps	Replace Both Light Bulbs. Check Lamp Failure Detection Circuit.
8	High Voltage Power Supply #1 Fault	Power Supply Fault: See System Info, and Check Circuit Breakers. Refer to Power Supply Manual.
9	High Voltage Power Supply #1 Interlock Fault	Power Supply Interlock Fault: Check Power Supply Data Cable, System Info screen, and LEDs on Side of Power Supply. Refer to Power Supply Manual.
22	Vacuum Leak in Tube #1	Check Vacuum Pump Power Supply. Ensure That High Voltage On Indicator is Lit. Check Vacuum Pump Cable.
23	Vacuum System #1 Malfunction	Check Vacuum Pump Cable. Check Vacuum Pump Power Supply. Ensure That High Voltage On Indicator is Lit.
24	HVPS #1 X-ray Status Inconsistent	Check High Voltage Power Supply Data Cable connection, System Info screen, and LEDs on Side of Power Supply. Refer to Power Supply Manual.
25	Number of Arc Faults from HVPS #1 Exceeded Maximum Value	Re-Run Warm-Up / Conditioning Routine.
28	Positioning Motor Over Current	Check Positioning Motor for Binding.
29	Positioning Motor Under Current	Check Positioning Motor for Disconnection (Electrical or Mechanical).
32	High Voltage Power Supply #1 Fault Missing	Power Supply Fault Signal Not Detected: Check High Voltage Power Supply Data Cable, System Info screen, and LEDs on Side of Power Supply. Refer to Power Supply Manual.
33	High Voltage Power Supply #1 Interlock OK Fault	Power Supply Interlock OK Fault: Check Interlock Outputs from PLC, Power Supply Data Cable, System Info screen, and LEDs on Side of Power Supply. Refer to Power Supply Manual.
34	Failure of Both X-rays On Lamp Detectors	Check Lamp Failure Detection Circuit.
35	Low Coolant Level	Check Coolant Tank Level Float Sensor.

ID	Critical Fault	Corrective Action
36	HVPS #1 X-ray Status Relay Bad	Check High Voltage Power Supply X-rays On Status Relay.
37	HVPS #1 Main Contactor Bad	Check High Voltage Power Supply Main Contactor.
39	HVPS #1 Communications Error	Check Data Cable and Auxiliary Power Connections to High Voltage Power Supply. Check HVPS configuration. Refer to Power Supply Manual.
53	Coolant Flow through Tube #2 Out of Range	Check That Cooling System is Turned On and Properly Adjusted. Check Coolant Flow Sensor.
54	Tube #2 Coolant Temperature Out of Range	Let Cooler Run without X-rays On to cool down Coolant. Check Thermocouple. Check ambient temperature.
55	High Voltage Power Supply #2 Fault	Power Supply Fault: See System Info, and Check Circuit Breakers. Refer to Power Supply Manual.
56	High Voltage Power Supply #2 Interlock Fault	Power Supply Interlock Fault: Check Power Supply Data Cable, System Info screen, and LEDs on Side of Power Supply. Refer to Power Supply Manual.
57	Vacuum Leak in Tube #2	Check Vacuum Pump Power Supply. Ensure That High Voltage On Indicator is Lit. Check Vacuum Pump Cable.
58	Vacuum System #2 Malfunction	Check Vacuum Pump Cable. Check Vacuum Pump Power Supply. Ensure That High Voltage On Indicator is Lit.
59	HVPS #2 X-ray Status Inconsistent	Check High Voltage Power Supply Data Cable connection, System Info screen, and LEDs on Side of Power Supply. Refer to Power Supply Manual.
60	Number of Arc Faults from HVPS #2 Exceeded Maximum Value	Re-Run Warm-Up / Conditioning Routine.
61	High Voltage Power Supply #2 Fault Missing	Power Supply Fault Signal Not Detected: Check High Voltage Power Supply Data Cable, System Info screen, and LEDs on Side of Power Supply. Refer to Power Supply Manual.
62	High Voltage Power Supply #2 Interlock OK Fault	Power Supply Interlock OK Fault: Check Interlock Outputs from PLC, Power Supply Data Cable, System Info screen, and LEDs on Side of Power Supply. Refer to Power Supply Manual.
63	HVPS #2 X-ray Status Relay Bad	Check High Voltage Power Supply X-rays On Status Relay.

ID	Critical Fault	Corrective Action
64	HVPS #2 Main Contactor Bad	Check High Voltage Power Supply Main Contactor.
65	HVPS #2 Communications Error	Check Data Cable and Auxiliary Power Connections to High Voltage Power Supply. Check HVPS configuration. Refer to Power Supply Manual.
70	Position Out of Range	Check Mechanical Positioning Inside Chamber, Magnet, and Linear Magnetic Sensor.
71	Position Unstable	Check Mechanical Positioning Inside Chamber, Magnet, and Linear Magnetic Sensor.
72	Unable to Move Position	Check Positioning Motor for Disconnection (Electrical or Mechanical). Check Magnet and Linear Magnetic Sensor.

6. Technical Specifications

6.1 RS 420•XL

Parameter	Specification
Input Voltage	208/240 VAC, 1ϕ (single-phase) 50/60 Hz, grounded 3-Conductor (L1, L2/N, Gnd)
Input Current	60 Amps, Circuit Breaker Protected
Power Input Cable	Standard 6 AWG Color Coded 3-Condutor cable (Green wire connects to ground)
Ambient Temperature Range	50°F (10°C) to 104°F (40°C)
Internal Cooling System	Internal pumps require 9 gallons of distilled water and unobstructed air flow.
External Cooling System	Requires min 30,000 BTU External Cooling with 5 GPM flow rate, at 40 to 60 psi @ approx. 24°±6°C/75°±11°F
Maximum X-ray Power	8000 Watts
Output Radiation	(see included document for individual machine)
Maximum Dose Setting	Typically 9999 Gy (interface accepts up to 1,000,000 Gy)
Maximum Time	Typically 999 Minutes 59 Seconds (not directly settable, over 16 hours)
Time Resolution	1 Second
Duty Cycle	100% provided cooling specifications met.
Modes of Operation	Manual Mode (Dose), Automatic (Run Program) and System Warm-Up
Manual Mode	Dose in (Gray), Power (%), Shelf (Position), Text note and e-mail results.
Automatic Mode	Up to 9 groups, each with up a group leader plus up to 9 other members, each with up to 10 programs, for a total of 900 Programs. Programmable
System Warm-Up	Automatically prompted, based on time between exposures. Less than 24 hours (one day): no Warm-Up necessary; More than a day: Warm-Up routine of at least 10 minutes is required;
System Set-Up Screen (Technician use only)	Password Protected. System parameters (including maximum kV and mA values) may be entered in this screen, and a Warm-Up Routine requirement may be bypassed.
System Fault Detection	System Faults are monitored and displayed, including Power Supply Faults, Cooling Water Temperature and Flow Rate, Vacuum Level, Lamp Failure, Interlocks, etc.
Cabinet Size	Width 72", Depth 47", Height 77"
Cabinet Weight	6300 lbs.

7. Compliance

The RS 420•XL complies with the following standards:

7.1 FDA Standards

Code of Federal Regulations (CFR)
Title 21 – Food and Drugs Administration (FDA)
Chapter I – Department of Health and Human Services
Subchapter J – Radiological Health;
Part 1020 – Performance Standards for Ionizing Radiation Emitting Products
Part 1020.40 Cabinet X-Ray systems
Part 1010 Performance Standards for Electronic Products: General
Part 1000 to 1005 General

8. Maintenance

8.1 Owner maintenance

The RS 420•XL is designed to require minimum maintenance. However, there are areas of the system that the operator should check periodically.

4) **Door Interlock mechanism** – This should be inspected by the operator at least monthly. Verify that the Interlock "tongue" attached to the Chamber Door has no obvious defects (cracks or missing hardware) and that it inserts into the Door Interlock freely and properly. (See Section 3.6)
5) **Power Cord** – Visually inspect – it should not appear worn to the extent that it is frayed or there are cuts or failures in the insulation. This should be done monthly.
6) **Cleaning** When cleaning, use a mild detergent or disinfectant, such as TB Spray or Santi Wipes. Do not allow cleaners or water to drip into panels or chamber. Only use damp cloth with mild soaps for cleaning. Do NOT spray or pour liquid onto the device. Do NOT use caustic chemicals, such as bleach.
7) **Authorized Service Technician Maintenance** Refer to the Field Service Report or Annual Maintenance Service Report for a complete list of maintenance items that will be inspected during a Field Service or Annual Maintenance call. If you have further questions, please contact Rad Source Technologies, Inc. at (1) 678-765-7900 or email service@radsource.com.

NOTE: Forms can be provided upon request.

8.2 Service

In the event that service is required, the following cautions and warnings must be followed.

⚠ WARNING The RS 420•XL when in operation produces harmful levels of X-ray radiation and should only be serviced by Rad Source Technologies, Inc. AUTHORIZED PERSONNEL.

⚠ WARNING High voltage is used to generate X-rays and a residual voltage may be present after the device has been turned "off". Before servicing any high voltage component, discharge the high voltage cable by grounding the tip to an earth ground point.

⚠ CAUTION Line voltage is present throughout the power distribution assembly and cooling assembly. Use caution when servicing these components.

⚠ WARNING Pressing the Emergency Stop Button does not remove all power from the system. Power to the vacuum pump power supply and power on control circuit is still present.

NOTE: Rad Source Technologies, Inc. does not provide the anchoring system (Reference Section 4) for your facility. Each customer is responsible for removing and replacing the anchor system any time Rad Source Technologies, Inc. services your device.

9. Revision History

Rev	Date	By	Description of Change
1	15 May 2018	BJL	Initial Release
2	08 Mar 2019	BJL	Updated to support 2019 hardware updates.

EXHIBIT 5

2/13/2020

To Whom It May Concern,

I am writing on the merits of my doctoral degree in experimental nuclear physics, attained from the University of Kentucky. Over the course of my research, I have worked at Los Alamos and Oak Ridge National Laboratories, and presented at international conferences regarding my work, which was largely focused on the detection of ionizing radiation. I have utilized and developed detection equipment to measure neutrons, alpha particles (He^{2+}), protons, electrons, positrons (anti-electrons), X-rays and gamma rays. The sources for these include radioisotopes and man-made technologies, including both those provided by the facilities at the national labs and some that I built myself. In addition to my coursework and research efforts regarding the processes that create these radiations and their interactions with matter, I also received training from the labs to certify my knowledge as a radiological worker capable of routinely handling and working around ionizing radiation, and understanding the health risks associated with each type of radiation.

I was recently provided with the documents filed by both parties of Rad Source Technologies versus the State of Nevada Department of Taxation Marijuana Enforcement Division, including the Rad Source's motion and exhibits, the Department of Taxation's opposition, Rad Source's reply, and the Declaration of Karaline Cronkhite, as well as the Court's minute order from February 4, 2020. After reviewing the documents, particularly those presented by the Department, I realize that there are misconceptions about the nature of ionizing radiation, especially with regards to X- and gamma rays. I would like to take this opportunity to address the nature of X- and gamma rays, particularly on how they are alike and different, as well as the safety of their use for irradiation, particularly in regards to human consumables. I am hoping that these details will provide some clarity for this case, and hopefully mitigate some of the stigma surrounding the use of X-rays for irradiation.

Ionizing radiation is defined as any emission with sufficient energy to remove electrons from atoms and molecules, and can either be massive in nature, such as beta and alpha particles, or electromagnetic waves, such as X- and gamma rays. The energies of ionizing radiation are typically reported in units of electronvolts (eV), where 1 eV is the energy attained by an electron accelerated through a 1 V potential; thus, 1 eV is equivalent to 1.6×10^{-19} J (a very tiny amount of energy); as with other units, the metric prefixes are used to denote order of magnitude, so 1 keV = 1,000 eV, and 1 MeV = 1,000 keV = 1,000,000 eV. When considering electromagnetic radiation (more commonly known as light), the energy determines what type of light is being emitted; photons (quanta of light) with energies under 1 meV (0.000001 eV) are categorized as radio waves and photons with energy of 1.5-3 eV make up the visible spectrum. When discussing light, sometimes frequency and wavelength are used to characterize the type of light; frequency is proportional to energy (high energy = high frequency), while wavelength is inversely proportional (high energy = small wavelength).

X- and gamma rays are merely high-energy forms of light, with energies of ~1 keV to 10 MeV. Although textbook pictures of the electromagnetic spectrum often show X-rays as being lower in energy than gamma rays, this is misleading, as the only difference between the two is the origin of the light: X-rays are produced by the acceleration of charge, such as synchrotron and Bremsstrahlung radiations, while gamma rays originate from the radioactive decay of atomic nuclei, such as ^{60}Co and ^{137}Cs. As such, there are X-ray facilities that can produce ~10 MeV X-rays, just as there are <100 keV gamma ray sources. In spite of this difference, however, the interaction mechanisms with matter for photons (quanta of light) is identical for X- and gamma rays of the same energy, so their utilization is considered functionally equivalent by most governing bodies.

How photons deposit energy in a material depends on the energy of the photon and the material composition (elemental makeup, density, etc.); low energy microwaves, for example, will cause molecular vibrations, and thus deposit their energy has heat into the object. X- and gamma rays, however, can penetrate through material, and interact through one of three main mechanisms: photoelectric absorption, predominant at low energies, Compton scattering, more prevalent with increasing energy, and pair production, which can only happen when the incident photon's energy exceeds the rest mass of an electron-positron pair, or 1.022 MeV.

For the range of 1 keV to 1 MeV, where X-ray irradiators, such as those manufactured and sold by Rad Source Technologies, and gamma sources, like ^{137}Cs, reside, the photons can only interact with the electrons of atoms, and not the nuclei. Consequently, the material being irradiated will not become radioactive, as isotopic changes necessitate a modification of the number of protons or neutrons within the nucleus, and this does not happen. Furthermore, as X-ray irradiators do not utilize radioactive isotopes, there is no risk of contamination from the source material, so the likelihood of any subsequent radioactivity is non-existent. Meanwhile, the ionization of the molecules within the target material do little to change the chemical nature of it; as the United States Food and Drug Administration explains, "any changes made by irradiation are so minimal that it is not easy to tell if a food has been irradiated"[1]. Due to these details, many organizations around the globe including the United States Nuclear Regulatory

Commission, the United States Food and Drug Administration, and the International Atomic Energy Agency have concluded that the regulated use of X-rays for treatment does not cause radioactivity in food[2,3,4].

The use of irradiation for the processing of food has been in the works for nearly 100 years, evolving and improving alongside the development of new technologies[5]. Organizations such as the International Atomic Energy Agency (IAEA), the World Health Organization (WHO), and the Food and Agricultural Organization (FAO) of the United Nations have concluded that "the food irradiation process does not present any enhanced toxicological, microbiological, or nutritional hazard beyond those brought about by conventional food processing techniques"[6]. Just like ozone and radiofrequency (microwave) radiation, ionizing radiation is considered as a food additive (21 C.F.R § 173.368, 179.30, and 179.26, respectively), and due to its antimicrobial efficacy and nutrition preserving properties, has been approved for the treatment of foods including both meat and plants. Spices imported from other countries are routinely treated with irradiation[7], and even NASA employs irradiation to sterilize food for its astronauts[1].

In summary, X-ray irradiation is already a widely accepted practice for the treatment of food, and government agencies around the globe have welcomed its use for consumable material sterilization. For the purposes of food irradiation, X-ray irradiators and gamma sources are functionally equivalent. When used in the ranges specified, there X-ray irradiation causes no concern for activation of the target material or contamination by radioisotopes. With these two details in mind, X-ray irradiation is an extremely safe, and preferred method, for the treatment of human consumables; evidence of this statement is the abundance of government agencies which have regularly included it in literature detailing best food practices.

Sincerely,
Aaron Jezghani, PhD

[1] United States Food and Drug Administration. *Food Irradiation: What You Need to Know*. Jan. 2018. Accessed at https://www.fda.gov/food/buy-store-serve-safe-food/food-irradiation-what-you-need-know on Feb. 12, 2020.
[2] United States Nuclear Regulatory Commission. *Radiation Basics*. Oct. 2017. Accessed at https://www.nrc.gov/about-nrc/radiation/health-effects/radiation-basics.html on Feb. 11, 2020.
[3] Komolprasert, V., Bailey, A., Machuga, E., and Cianci, S. Regulatory Report on Irradiation of Food Packaging Material. Nov. 2017. Accessed at https://www.fda.gov/food/ingredients-additives-gras-packaging-guidance-documents-regulatory-information/regulatory-report-irradiation-food-packaging-materials on Feb. 12, 2020.
[4] International Consultative Group on Food Irradiation. *The Development of X-Ray Machines for Food Irradiation*. Oct. 1995. Accessed at http://www-naweb.iaea.org/nafa/fep/public/x-ray.pdf on Feb. 12, 2020.
[5] Tauxe RV. Food Safety and Irradiation: Protecting the Public from Foodborne Infections. *Emerging Infectious Diseases*. 2001;7(7):516-521. doi:10.3201/eid0707.017706.
[6] Diehl, J.F. Safety of Irradiated Foods, Marcel Dekker, Inc., New York, 1995, pp 283-289
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EXHIBIT 6

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An Assessment Related to RAD Tech and the State of Nevada Litigation

Introduction

I have been asked to provide my expertise, professional wisdom, and belief to the ongoing discussion between RAD Tech and the State of Nevada. I am a professional microbiologist. I received my undergraduate degree in Biology from the University of California San Diego and my Doctorate in Microbiology from the Plant Growth Lab at the University of California – Davis. In my professional career I spent twenty-two years as a scientist at NASA's Jet Propulsion Laboratory in Pasadena, California. While there my work was focused on the microbial cleanliness and sterilization of spacecraft to be sent to explore Mars. This meant that technical research and leadership was directed at developing technologies to ensure microbial cleanliness and performing tests and assays to ensure that the microbial bioburden of the spacecraft was minimized so that the planet Mars was not contaminated by terrestrial microbes and spores. Since my career at JPL, I have been a consultant in plant science, dealing especially with the issues related to cannabis (marijuana). I am the President and Co-Founder of Agate Biosciences, an agricultural consultancy that conducts technical assessments for cannabis companies.

Recognizing that time is of the essence, I write to render knowledge and professional wisdom to the discussion, knowing that research studies are planned and will be conducted to further address the concerns raised in the various briefs that have been submitted in this case. My role is to add scientific perspective and not legal opinion or non-scientific comment that can muddy the waters.

Microbial Safety Assessment

The three topics to be discussed, based on the brief from "Defendants Opposition to Plaintiff's Motion for Extraordinary Relief On Ordering Shortening Time" are: (1) RAD Tech Equipment provides a safe and effective method of destroying pathogens; (2) is safe for employees to operate; and (3) preserves the quality and integrity of the marijuana (cannabis). I will address each of these three special topics in the following paragraphs.

1. **<u>RAD Tech Equipment provides a safe and effective method of destroying pathogens:</u>**
    a. Most X-rays or Gamma-rays simply pass through the target plant material without interacting with it. The rays are like light through a window, to the largest extent.
    b. Those X-rays that do interact with biological material do so by directly, and irreversibly, damaging the cellular DNA rendering it non-viable. This the process that happens to the microbes within the plant sample being irradiated.

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c. Additional lethal damage is done to the microbes by interaction the cells' internal water content resulting in the generation of free radicals. These include hydroxyl radicals and superoxide radicals, as well as other oxidants such as hydrogen peroxide. It is worth noting that these are the same chemicals and associated mechanisms that hydrogen peroxide and ozone-based technologies for cannabis microbial reduction use.
d. All these methods are highly effective at reducing microbial contamination levels of to meet and exceed regulatory limits set by states where the sale of cannabis is legal. See ref.: R. Kern and J.R. Green, *Cannabis Science and Technology* 2(6), 15-19 (2019) Title: *It's Not Too Late: Post-Harvest Solutions to Microbial Contamination Issues*

2. <u>RAD Tech Equipment is safe for employees to operate:</u>

a. RAD Tech has Standard Operating Procedures (SOPs) and a rigorous worker training program, with ongoing mentoring, in place that is based on the last more-than-100 years of employees and researchers working with X-rays in professional settings. Their Safety Ed Program includes quarterly updates from regulatory agencies and annual testing for knowledge and accurate following of Standard Operating Procedures. Random Safety Audits are conducted without prior employee warning to ensure accurate worker protocol-following results. RAD Tech follows OSHA standards for workers in restricted and unrestricted work areas associated with irradiation sources. They follow the rules of Precautionary Procedures and Personal Monitoring as described in the OSHA standard: 1910-1096 – ionizing radiation. The RAD Tech machine chamber is lead lined and it is not possible for the operator to open the machine while it is operating. The lead lining prevents the escape of any ionizing radiation while the machine is operating. So, a safe environment exists in the workplace due the SOPs and the actual construction of the machine that prevents radiation leakage. Safety of the public and personnel is the primary concern at RAD Tech. Their SOPs, training, audits, and machine construction ensure the continual safety of employees and the public.

3. <u>RAD Tech preserves the quality and integrity of the marijuana:</u>

The University of California – Davis Center for Consumer Research writes significantly about the potential effects of irradiation of food and spice products. They conclude that x-ray irradiated consumables are safe and that no substantive changes take place due to irradiation due to residues, chemical changes, new chemical species, or harmful remains for consumers. Here is their set of comments:

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"Food can also be irradiated by X-rays. In this system an electron beam accelerator targets electrons on a metal plate. (See Answer 1, related to RAD Tech technique with its gold plate). Some energy is absorbed and the rest is converted to X-rays. Like gamma rays, X-rays can penetrate food boxes up to 15 inches thick or more, thus permitting food to be processed in a shipping container.

When food is irradiated, most of the radiation passes through the food without being absorbed. The small amount that is absorbed destroys any insects on grains, produce or spices, extends shelf life, and prevents fruits and vegetables from ripening too fast. Thus, food irradiation may replace chemical fumigants, sprout inhibitors, and post-harvest fungicides. Higher doses can kill Salmonella and other harmful bacteria that can contaminate meats and poultry and cause food borne diseases. Food irradiation is a "cold treatment" that achieves its effects without raising the food's temperature significantly, leaving the food closer to its original state. Even spices which are treated for … remain essentially at room temperature. By not using high temperatures, food irradiation minimizes nutrient losses and changes in food texture, color, and flavor.

The energy used in food irradiation is not great enough to cause food to become radioactive. During irradiation, energy passes through food much like a ray of light passes through a window. This energy destroys most of the bacteria that can cause disease, yet allows food to retain its high quality.

Irradiation pasteurizes food by using energy, just as milk is pasteurized using heat. At the level used, most harmful bacteria will be destroyed. Afterwards, surviving bacteria could start to multiply if the food were mishandled: such as, stored at an improper temperature. The level of irradiation used also does not kill certain spoilage organisms. This is for the protection of consumers. Spoilage bacteria will multiply and alert consumers not to use a product which has been improperly handled." *University of California – Davis, Center for Consumer Research*

Conclusion

My conclusion supports the approval of the introduction of this technology to the State of Nevada cannabis enterprise as one of the approved techniques for post-harvest decontamination of cannabis. It is my professional opinion, based upon my current knowledge of microbial safety that this technology is one of the few technologies ready and available to help ensure the safety of the consumers. It should be approved and allowed to be implemented as a supportive technology for microbial safety.

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EXHIBIT 7

frontiers in Pharmacology

ORIGINAL RESEARCH
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Evaluating the Effects of Gamma-Irradiation for Decontamination of Medicinal Cannabis

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In several countries with a National medicinal cannabis program, pharmaceutical regulations specify that herbal cannabis products must adhere to strict safety standards regarding microbial contamination. Treatment by gamma irradiation currently seems the only method available to meet these requirements. We evaluated the effects of irradiation treatment of four different cannabis varieties covering different chemical compositions. Samples were compared before and after standard gamma-irradiation treatment by performing quantitative UPLC analysis of major cannabinoids, as well as qualitative GC analysis of full cannabinoid and terpene profiles. In addition, water content and microscopic appearance of the cannabis flowers was evaluated. This study found that treatment did not cause changes in the content of THC and CBD, generally considered as the most important therapeutically active components of medicinal cannabis. Likewise, the water content and the microscopic structure of the dried cannabis flowers were not altered by standard irradiation protocol in the cannabis varieties studied. The effect of gamma-irradiation was limited to a reduction of some terpenes present in the cannabis, but keeping the terpene profile qualitatively the same. Based on the results presented in this report, gamma irradiation of herbal cannabis remains the recommended method of decontamination, at least until other more generally accepted methods have been developed and validated.

Keywords: medicinal cannabis, cannabinoids, terpenes, gamma-irradiation, quality control

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INTRODUCTION

Because medicinal cannabis is often used by chronically ill patients affected by a weakened immune system, pharmaceutical regulations in countries such as The Netherlands and Canada specify that these products must adhere to strict safety standards regarding microbial contamination. When harmful microbes or fungal spores are inhaled during e.g., vaporizing or smoking, they may directly enter the bloodstream and cause opportunistic infections. Such contamination risks are not merely hypothetical: cases of chronic pulmonary aspergillosis associated with smoking unsafe cannabis are well established in the scientific literature (Llamas et al., 1978; Sutton et al., 1986; Marks et al., 1996; Szyper-Kravitz et al., 2001; Kouevidjin et al., 2003; Cescon et al., 2008; Bal et al., 2010; Ruchlemer et al., 2015). For those with compromised immune systems, such lung diseases could be even fatal (Hamadeh et al., 1988).

To minimize contamination risks to patients, Dutch regulations demand that medicinal cannabis contains no more than 100 colony-forming units (CFUs) per gram of final product, which is close to sterility[1]. Under the Canadian program, limits are somewhat higher with a maximum of 1.000 CFUs per gram[2]. Following European or US Pharmacopoeia standards for inhaled preparations, certain specific pathogens must be completely absent, i.e., *Staphylococcus aureus*, *Pseudomonas aeruginosa*, and any bile-tolerant Gram-negative bacteria such as *E. coli* (EP, 2015; USP, 2015). Furthermore, the absence of fungal mycotoxins must be confirmed by additional quality control testing.

Decontamination of medicinal (herbal) cannabis is a necessity, as it has yet not been possible to grow cannabis plants under sufficiently sterile conditions to keep contamination levels below the required safety limits. Even if this were feasible, the multiple steps involved in harvesting, drying, processing and packaging cannabis buds would make it extremely hard to maintain near-sterile conditions throughout the entire production procedure. As a result, medicinal cannabis in The Netherlands as well as in Canada is treated by gamma irradiation before it becomes available to patients[1,2].

Methods of Decontamination

Reduction of microbes can be achieved by various treatments, as listed in **Table 1**. The optimal choice of decontamination depends on the nature of the product to be treated. For herbal materials such as cannabis, the only currently viable option for treatment is the use of ionizing radiation. Any of the other decontamination treatments would either affect chemical content or texture (i.e., heat, chemicals, pressure, steam; Ruchlemer et al., 2015) or would not penetrate beyond the surface of the dense cannabis flowers (i.e., UV-light).

Gamma irradiation involves exposing the target material to packets of light (photons) that are so highly energetic (gamma rays) that they damage the DNA strands present in microbes. As a result, the affected microbes cannot multiply, and consequently they will perish[3] . Because medicinal cannabis is a harvested and dried (i.e., non-living) product, this effect is not relevant for the condition of the cannabis plant cells.

Irradiation Safety and Concerns

Most commonly, the radioactive element cobalt-60 (^{60}Co) is used as the source for gamma irradiation. If administered at appropriate levels, irradiation can be used for the removal of decay-causing bacteria from many foods and herbs, and can prevent sprouting of fruit and vegetables to maintain freshness and flavor (EFSA Panel on Food Contact Materials Enzymes Flavourings Processing Aids-CEF, 2011; Arvanitoyannis et al., 2009). Decontamination or sterilization by gamma irradiation is also widely applied to medical instruments and medicines (Hasanain et al., 2014).

[1]https://www.cannabisbureau.nl/english/specication-sheets

[2]http://www.hc-sc.gc.ca/dhp-mps/marihuana/info/techni-eng.php

[3]http://www.cdc.gov/nczved/divisions/dfbmd/diseases/irradiation_food/#affect_foods

TABLE 1 | List of current main methods available for decontamination or sterilization of (food) products.

Type of decontamination	Main treatments
Heat:	Dry heat
	Steam (autoclave)
Chemicals:	Gas (ethylene oxide, ozone, nitrogen dioxide)
	Liquid (hydrogen peroxide, formaldehyde)
High pressure:	Pascalization
Filtration:	Micropore filter (*NB*: for liquids only)
Radiation:	Non-ionizing (UV-light)
	Ionizing (gamma-irradiation, X-rays, electron beam)

Over the years, the safety of irradiated foods has been confirmed in various animal as well as human studies. These include animal feeding studies lasting for several generations in several different species, including mice, rats and dogs (WHO, 1999; EFSA Panel on Food Contact Materials Enzymes Flavourings Processing Aids-CEF, 2011). NASA astronauts have been eating irradiated foods when they fly in space since the 1970s (Perchonok and Bourland, 2002). Irradiation-induced changes in food components are generally small and not significantly different from those reported in other conventional preservation processes, especially those based on thermal treatment (EFSA Panel on Food Contact Materials Enzymes Flavourings Processing Aids-CEF, 2011; Shahbaz et al., 2015). The changes in some components that are sensitive to irradiation, like some vitamins or micronutrients (Caulfield et al., 2008) may be minimized by using proper treatment conditions (Kilcast, 1994; WHO, 1999).

The safety of irradiated foods has been endorsed by the World Health Organization (WHO), the Food and Agriculture Organization of the United Nations (FAO), the U.S. Department of Agriculture (USDA), Health Canada (HC), the European Union (EU), and the Food and Drug Administration (FDA). Gamma irradiation is now permitted by over 60 countries with at least 400,000 metric tons of foodstuffs annually processed worldwide (EFSA Panel on Food Contact Materials Enzymes Flavourings Processing Aids-CEF, 2011). The regulations that dictate how food is to be irradiated, as well as which foods are allowed to be treated, may vary greatly from country to country[4].

Despite these developments, irradiation remains a somewhat controversial decontamination technique that can spark emotional debates among the general public. One specific concern with irradiation treatment is the formation of radiolytic compounds, in particular 2-alkylcyclobutanones (2-ACBs). These chemicals are formed in minute quantities when high fat containing foods (such as sesame seeds, pork meat, cheese, eggs, fish) are subjected to gamma irradiation, and their content increases with irradiation dose (Zanardi et al., 2007; Lee et al., 2008). Although some contradictory *in vitro* findings exist on the safety of these compounds, overall scientific consensus is that 2-ACBs are not an immediate cause for concern (EFSA Panel

[4]https://nucleus.iaea.org/ifa/

on Food Contact Materials Enzymes Flavourings Processing Aids-CEF, 2011).

Of course, consumers may also be concerned about the indirect effects of irradiation, such as the way it changes the way we relate to food or herbal medicine, or how the use of radioactive materials affect the environment during their mining, shipping and use. Furthermore, irradiation, like any form of treatment, adds to the final cost of a food product or medicine. All these concerns should be taken into consideration when determining whether gamma irradiation is the proper choice for decontamination of a product.

Evaluating the Effects of Gamma Irradiation on Medicinal Cannabis

Patients have occasionally expressed their concerns about the effects of irradiation treatment on medicinal cannabis. Some have claimed a change of taste or effect, while others worry about changes in the chemical composition or the quality of their medicine[5]. In response to such concerns, some Canadian licensed producers of medicinal cannabis initially pledged not to apply irradiation, but were forced to reconsider when their products could not meet microbial safety requirements. To cushion the impact on their customers, the obscuring term "cold pasteurization" was introduced when in fact gamma irradiation treatment was applied[6].

In fresh Cilantro leaves, gamma irradiation was shown to reduce the content of terpenes such as myrcene and linalool (Fan and Sokorai, 2002). Likewise, irradiation may perhaps have an effect on cannabis terpenes, which seem to play an important role in the synergistic effect and bioavailability of cannabinoids (Russo, 2011). Although an early study by our group on the effect of cannabis irradiation did not indicate changes in the cannabinoid profile (unpublished data), chromatographic analysis of cannabinoids has significantly improved over the years meaning that more detailed changes in the cannabinoid profile may now be visualized. The occurrence of 2-ACBs seems of limited relevance in the case of cannabis, because average daily cannabis consumption is very small compared to other irradiated products such as meats, fruits of vegetables. Also, cannabis flowers do not contain significant amounts of fat needed to form these radiolytic compounds in the first place.

To address the concerns that may exist around gamma irradiation of medicinal cannabis, we evaluated the effects of irradiation treatment of four different cannabis varieties covering different compositions (THC vs. CBD dominant types, Sativa vs. Indica types). Samples were compared before and right after standard gamma-irradiation treatment, by performing quantitative analysis of major cannabinoids, as well as qualitative analysis of full cannabinoid and terpene profiles. In addition, water content and microscopic appearance of the cannabis flowers was evaluated.

[5]http://www.hc-sc.gc.ca/fn-an/securit/irridation/cyclobutanone-eng.php
[6]http://www.leafscience.com/2014/05/01/tweeds-first-marijuana-orders-delayed-irradiated/

MATERIALS AND METHODS

Solvents and Chemicals

All organic solvents were HPLC or analytical grade. Acetonitrile was obtained from Boom labs BV (Meppel, The Netherlands). Ethanol and phosphorus pentoxide (P_4O_{10}) was purchased from VWR (Amsterdam, The Netherlands).

Cannabis Samples

Pharmaceutical-grade cannabis was obtained from the licensed Dutch cultivator, Bedrocan BV (Veendam, the Netherlands). Plants were grown from genetically identical clones under standardized indoor conditions. Flower tops were harvested and air-dried for 1 week under controlled temperature and humidity. Four different standardized varieties available in Dutch pharmacies were used for this study i.e., *Bedrocan*®, *Bediol*®, *Bedica*®, and *Bedrolite*®. Batch information and chemical composition of these products is listed in **Table 2**.

All cannabis batches used for this study were harvested in the period of late 2014–early 2015. Following standard procedure, each batch was packaged in portions of 250 grams in triple laminate foil bags with zip-lock closure (type Lamizip aluminum; Daklapack, The Netherlands) for gamma irradiation treatment at Synergy Health (Etten-Leur, The Netherlands). Each batch received an irradiation dose of (minimum) 10 kGy produced with a Cobalt-60 radiation source.

Of each cannabis variety a 10 gram sample was collected before (non-irradiated control) as well as after (irradiated sample) gamma irradiation, resulting in a total of 8 samples for this study [4 varieties × 2 treatments (before/after irradiation)]. Samples were homogenized by grinding in a blender until the material was about 5 mm in diameter. Ground samples were finally used for determination of water content, and for sample extraction for GC/UPLC analysis. Of variety *Bedrocan*, the most popular variety used by Dutch patients (Hazekamp and Heerdink, 2013), some non-homogenized samples were kept for microscopic analysis.

All samples were handled and stored under equivalent conditions. For each variety, irradiated and control samples were extracted and analyzed on the same day, so that any changes in chemical composition could only be attributed to the irradiation treatment. This study was carried out under a cannabis research license issued by the Dutch Health Department.

TABLE 2 | Cannabis type and batch information of the cannabis varieties used in this study.

Variety name	Batch #	THC/CBD type	Sativa/Indica type	Harvest date
Bedrocan	A1.01.45	THC	Sativa	11-12-2014
Bediol	A2.05.15	THC + CBD	Sativa	25-12-2014
Bedrolite	A2.08.13	CBD	Sativa	08-01-2015
Bedica	A2.07.20	THC	Indica	22-01-2015

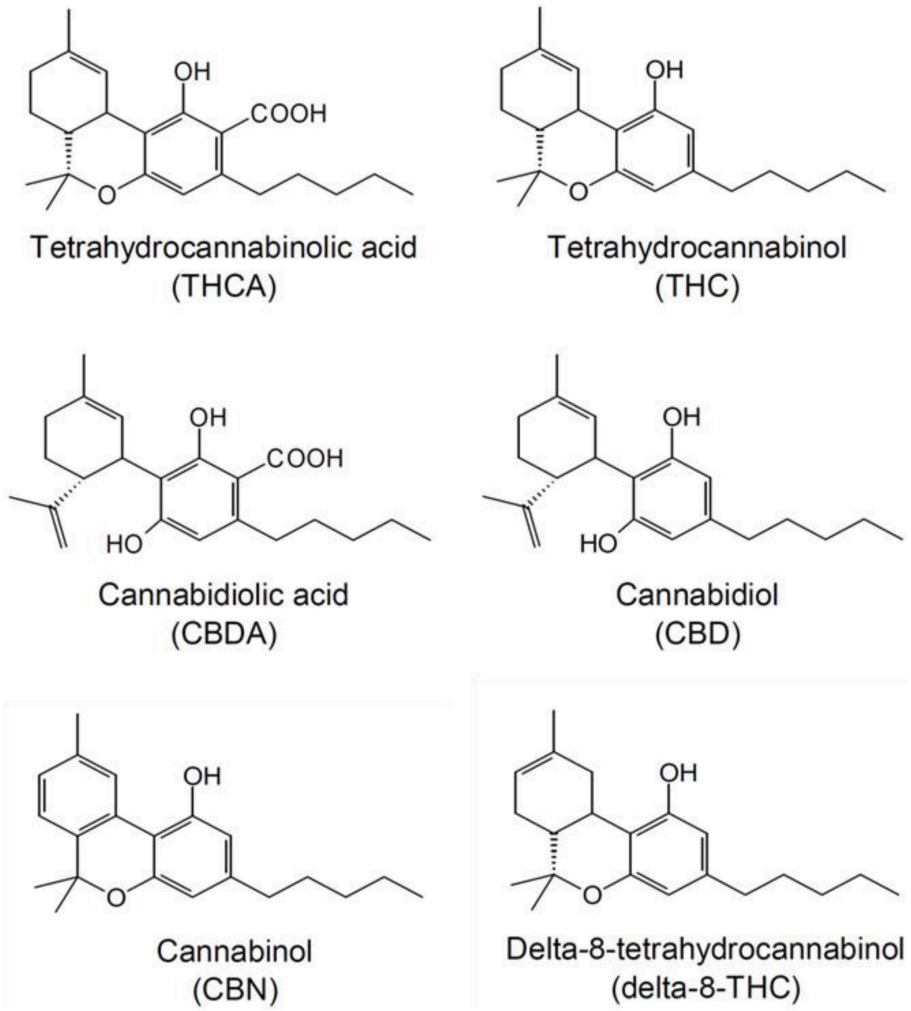

FIGURE 1 | Structures of the cannabinoids quantitatively analyzed by UPLC.

Water Content Determination

Water content of each homogenized sample was determined by using the Loss on Drying (LOD) method according to EP monograph 2.3.32 (method C). In short, 500 mg of each sample (in duplicate) was accurately weighed in small plastic containers, and dried for 24 h at 40°C under vacuum inside a desiccator containing the potent desiccant phosphorus pentoxide. Subsequently, all samples were weighed again. Water content (in percentage of initial weight) was determined by comparing weight before and after the procedure.

Sample Extraction

Ground cannabis samples were extracted for Gas Chromatography (GC) and Ultra-Performance Liquid Chromatography (UPLC) analysis as described in the Dutch Analytical Monograph for release testing of Cannabis Flos, version 7.1 (OMC, 2015)[7]. In short, 1000 mg of each homogenized sample (in duplicate) was extracted with 40 mL of absolute ethanol in plastic serum tubes (maximum content 50 mL) while mechanically shaking for 15 min at 300 rpm. Tubes were then centrifuged at 3000 rpm and clear supernatant was transferred to a 100 mL volumetric flask. For exhaustive extraction, the procedure was repeated twice more with 25 mL of ethanol, and supernatants were combined. Volumes were adjusted to 100 mL with ethanol, mixed well, and filtered through a 0.45 μm PTFE syringe filter to remove small particles. Filtrated extracts were used directly for GC analysis, or further diluted with acetonitrile/water (70:30, v/v) for analysis by UPLC.

Quantitative UPLC Analysis of Major Cannabinoids

The UPLC profiles were acquired on a Waters (Milford, MA) Acquity UPLC system consisting of a gradient pump, an autosampler, a column oven and a diode array detector (DAD). The device was controlled by Waters Empower software. Full spectra were recorded in the range of 200–400 nm. The analytical

[7]https://www.cannabisbureau.nl/medicinale-cannabis-artsen-en-apothekers-specificaties-en-analysevoorschriften

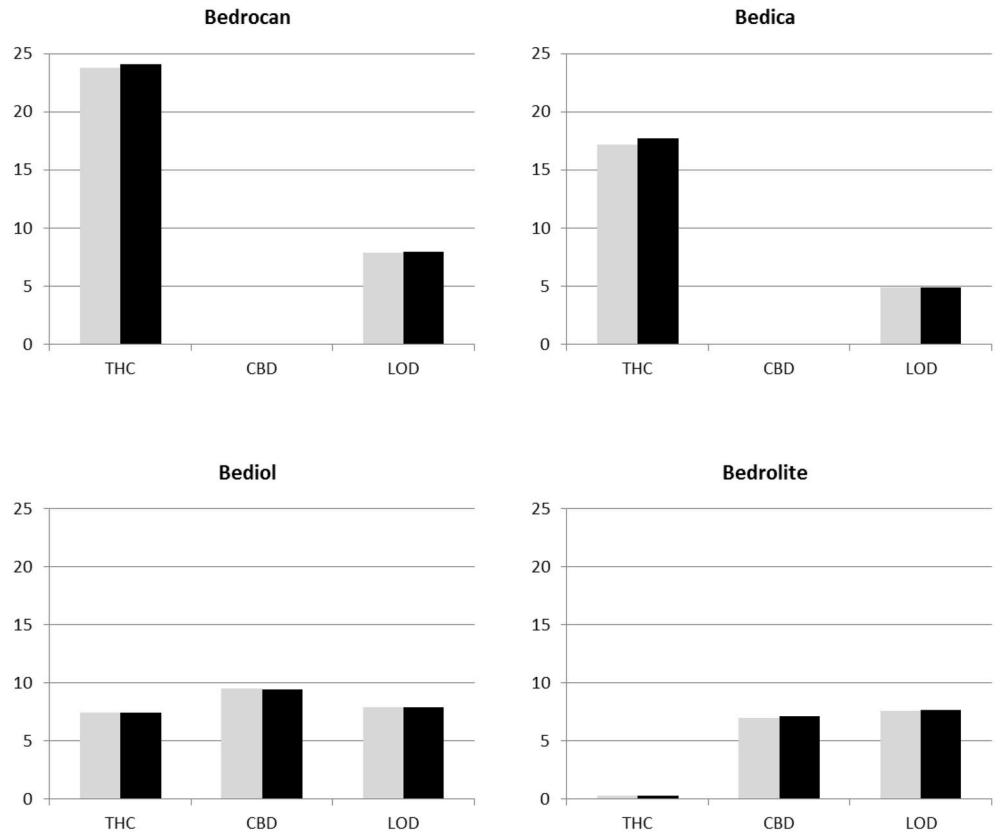

FIGURE 2 | Total THC and total CBD content (in % of dry weight) as determined by UPLC analysis, as well as water content (in % of total weight) as determined by Loss on Drying method (LOD) in all studied varieties *before* (gray bars) and *after* (black bars) irradiation treatment.

column was a Waters Aquity C_{18} (1.7 μm, 2.1 × 150 mm) equipped with a matching guard column. The mobile phase consisted of a gradient of acetonitrile (A) and water (B), both containing 0.1% formic acid. The gradient was programmed as follows: 0–6 min (hold at 70% A); 6–10.5 min (linear increase to 100% A); 10.5–11 min (hold at 100% A). The column was then re-equilibrated under initial conditions for 1.5 min, resulting in a total runtime was 12.5 min. Flow-rate was 0.4 mL/min. Injection volume was 10 μL. Chromatographic peaks were recorded at 228 nm. All determinations were carried out at 30°C. All samples were analyzed in duplicate.

Applying the standard protocol for release testing of medicinal cannabis (OMC, 2015)[7], the following cannabinoids were quantitatively determined: THC, THCA, CBD, CBDA, delta-8-THC, CBN. The structures of these compounds, including their full chemical names, are shown in **Figure 1**.

Qualitative GC Analysis of Cannabinoid and Terpene Profiles

Gas chromatography was used for the simultaneous qualitative analysis of monoterpenes, sesquiterpenes, and cannabinoids as previously reported (Hazekamp and Fischedick, 2012). An Agilent GC 6890 series (Agilent Technologies Inc., Santa Clara, CA, USA) equipped with a 7683 autosampler and a flame ionization detector (FID) was used. The instrument was equipped with a DB5 capillary column (30 m length, 0.25 mm internal diameter, film thickness 0.25 μm; J&W Scientific Inc., Folsom, CA, USA). The injector temperature was 230°C, with an injection volume of 1 μl, a split ratio of 1:20 and a carrier gas (N_2) flow rate of 1.2 ml/min. The temperature gradient started at 60°C and linearly increased at a rate of 3°C/min until the final temperature of 240°C which was held for 5 min resulting in a total run time of 65 min/sample. The FID detector temperature was set to 250°C. The device was controlled by Agilent GC Chemstation software version B.04.01.

Microscopic Visualization of Glandular Hairs

In order to visualize potential morphological changes in the glandular hairs (where cannabinoids and terpenes are produced) present in the cannabis flowers, microscopic analysis of cannabis variety *Bedrocan* was performed before and after gamma-irradiation treatment. Whole cannabis flowers were used, without homogenizing. A Leica (type MZ16FA) stereo-microscope was used. Images were captured at a magnification factor ranging from 20 to 120 times with a Leica (type DFC420C) camera, controlled by LAS software.

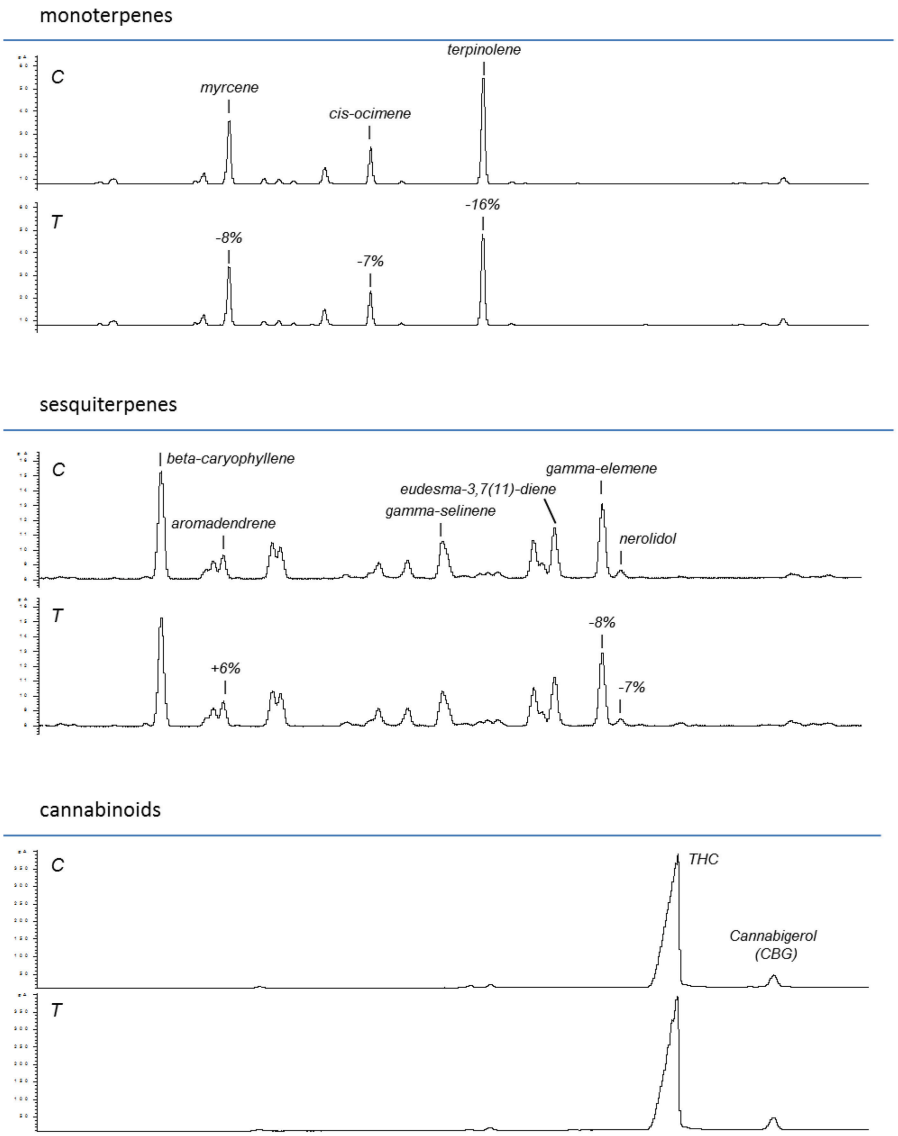

FIGURE 3 | Continued

RESULTS

Loss on Drying

Inhalation, either by smoking or vaporizing, is currently the main mode of administration used by patients (Hazekamp et al., 2013). Water content (humidity) seems to have significant impact on how consumers appreciate medicinal cannabis products during inhalation (Ware et al., 2006). Although gamma irradiation does not significantly heat up the treated product, water may be lost during the procedure either as a result of the irradiation itself (Yu and Wang, 2007) or because of shipping and handling of the product during the treatment. Release specifications for Bedrocan products require the water content to be no more than 10%. As shown in **Figure 2**, the actual water content of the analyzed varieties ranged between 5 and 8%, with no differences between treated and control samples.

UPLC Analysis

Six major cannabinoids were quantitatively analyzed by applying a validated UPLC methodology that is used as standard procedure for release testing of medicinal cannabis in The Netherlands. As customary, the sum of THC and its acidic precursor THCA is reported as "total THC content." Similarly, the sum of CBD and CBDA is reported as "total CBD content." It should be noted that delta-8-THC and CBN are not originally

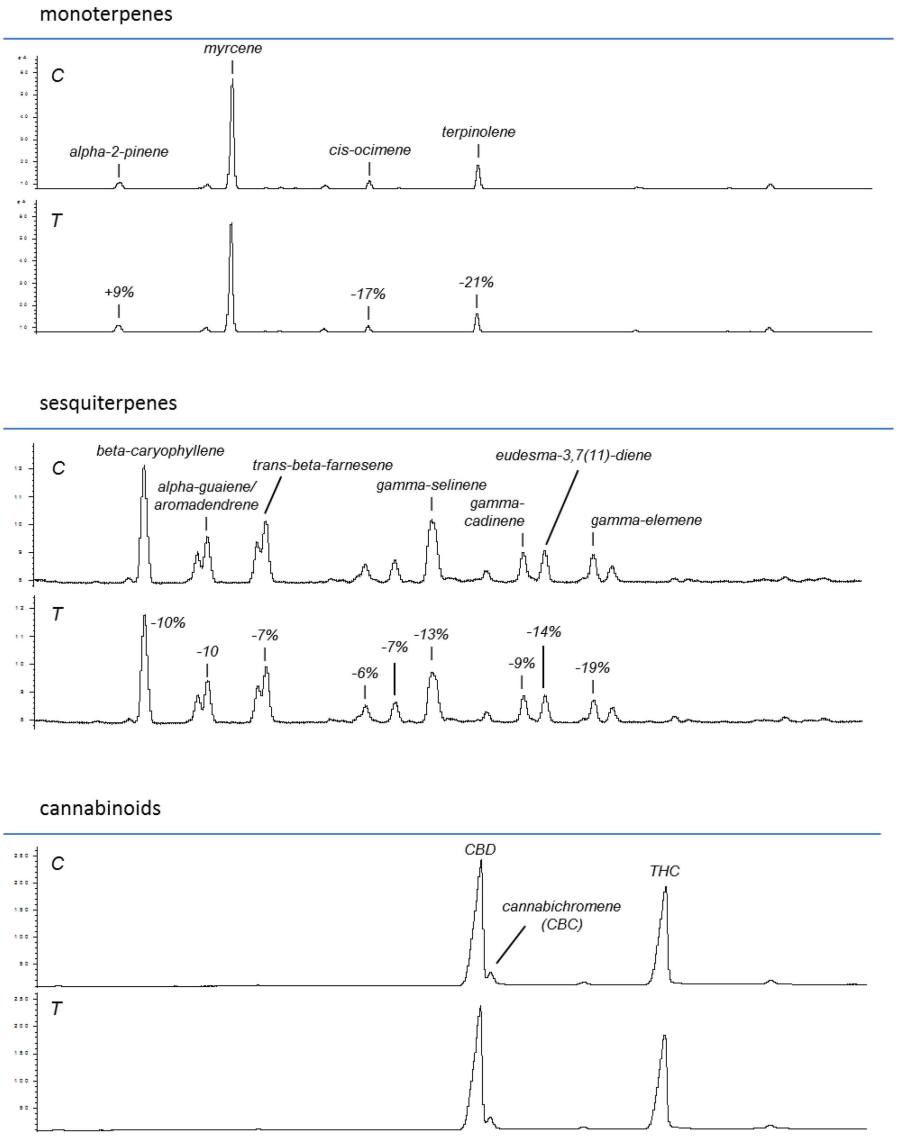

FIGURE 3 | Continued

produced by the cannabis plant, but are formed as degradation products of THC by exposure to heat or light, or by prolonged storage (Hazekamp et al., 2010).

Results of cannabinoid testing are shown in **Figure 2**, indicating that levels of total THC and/or CBD were not altered by irradiation treatment in any of the varieties studied. No delta-8-THC or CBN was detected in any of the samples (before or after irradiation) at levels over 0.1% (which equals 1 mg/gram of cannabis flower).

GC Analysis

Components visualized by GC analysis were not individually quantified because of the multitude of chromatographic peaks of interest (>50). Instead, the entire profiles of all visible peaks are presented in **Figure 3**. Because of the complexity of these profiles, the sections of the profile where monoterpenes, sesquiterpenes, and cannabinoids elute are displayed separately. For each variety, control (non-irradiated) samples, and treated (irradiated) samples are shown side by side, using the same vertical scale to allow direct comparison. The main peaks in each variety were identified based on previously published data (Hazekamp and Fischedick, 2012).

While the overall qualitative composition of the samples was unaltered, differences in several terpene components could be detected after irradiation in the cannabis varieties studied. Components that showed a clear reduction after irradiation

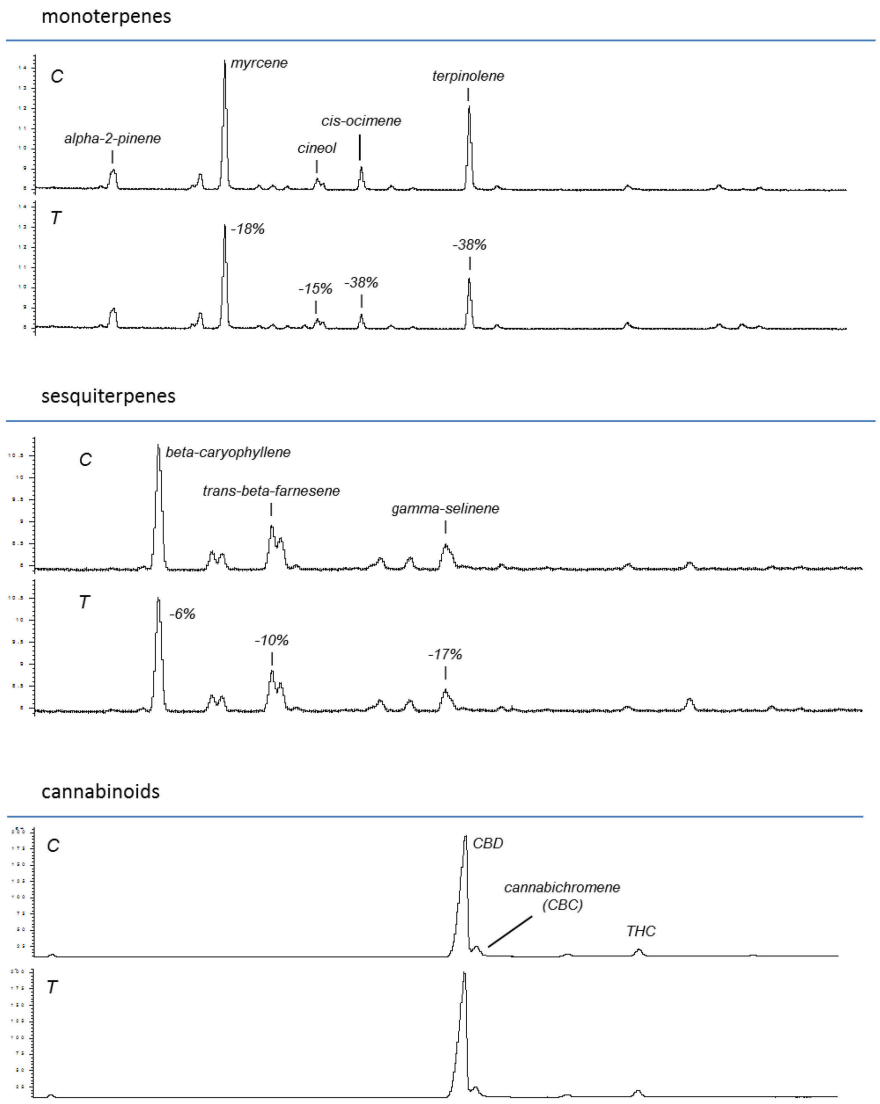

FIGURE 3 | Continued

treatment are indicated in **Figure 3** by showing the relative change (in %) compared to untreated sample. Because a small variability of terpene content between samples is to be expected, and is also observed between replicates of non-treated samples, changes that are smaller than +/– 5% are not indicated. The main components affected were the monoterpenes myrcene, cis-ocimene and terpinolene, and the sesquiterpenes gamma-selinene, eudesma-3,7(11)-diene and gamma-selinene. No new terpene peaks were formed as a result of treatment. No cannabinoids were altered or formed as a result of irradiation.

Microscopy

Multiple microscopic images were obtained of variety *Bedrocan* on flowers collected before and after treatment with gamma-irradiation, at a magnification of about 20–120 times. The trichomes (glandular hairs) where cannabinoid and terpenes are excreted by the cannabis plant are clearly visible, as shown in **Figure 4**. No clear differences in trichome structure, color, density, or shape could be observed between the control (non-irradiated) samples and treated (irradiated) samples.

DISCUSSION AND CONCLUSION

Gamma irradiation treatment of cannabis has become standard practice in the government-supported medicinal cannabis programs of The Netherlands as well as Canada. In the study presented here such treatment, at a radiation dose (10 kGy) sufficient to reduce microbial contamination (bioburden) to pharmaceutically acceptable levels, did not cause any changes in the content of THC and CBD, generally considered as the most important therapeutically active components of medicinal

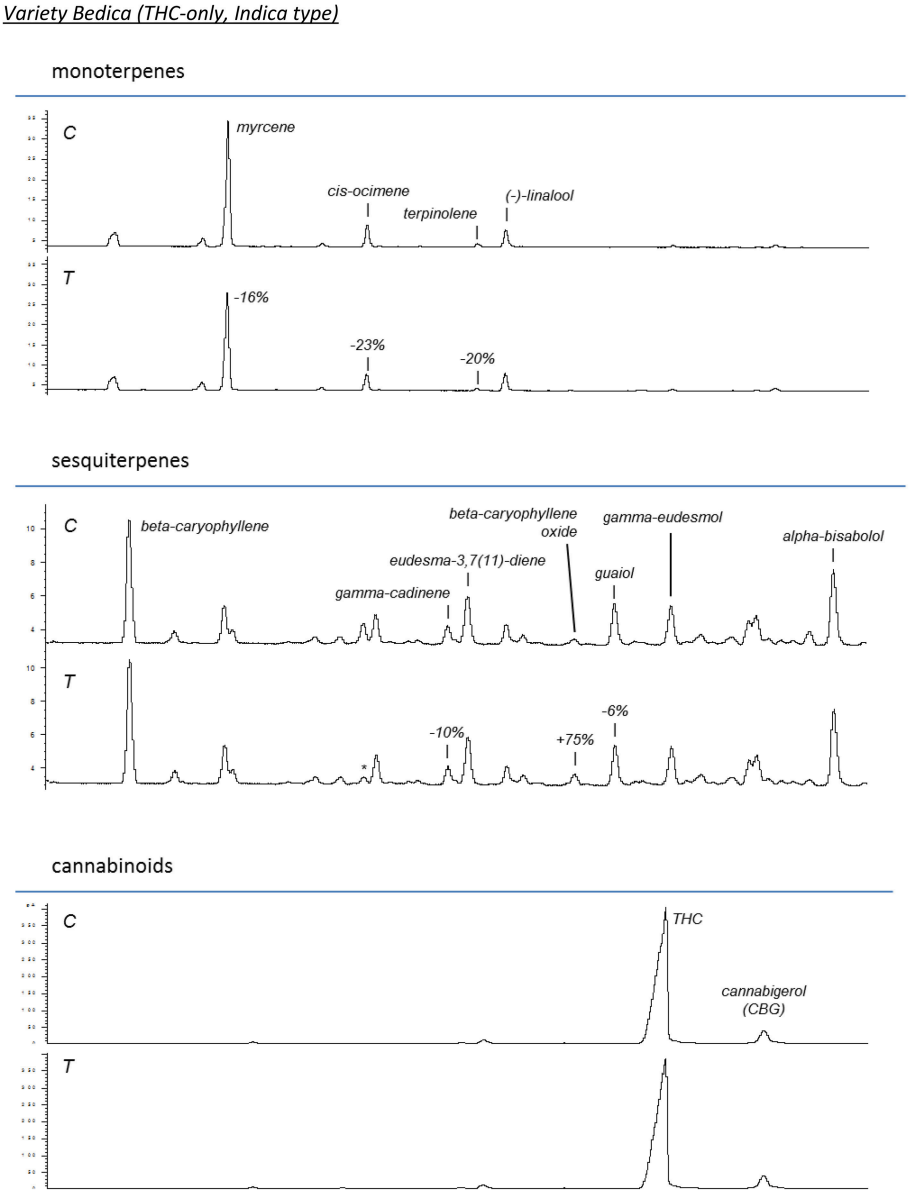

FIGURE 3 | GC profiles of four studied varieties showing monoterpenes, sesquiterpenes, and cannabinoids in separate sections. C, control (non-irradiated); T, treated (irradiated); *: artifact. Numbers indicate percentage of change in treated samples compared to non-treated controls.

cannabis (Grotenhermen and Müller-Vahl, 2012). Likewise, the water content and the microscopic structure of the dried cannabis flowers were not altered by standard irradiation protocol in four different cannabis varieties. The study included representative varieties of THC and CBD dominant types, as well as Sativa and Indica types.

In our study, irradiation had a measurable effect on the content of multiple cannabis terpenes, mainly on the more volatile monoterpenes. Reduction of affected terpenes was in general between 10 and 20%, but for some components this may be as much as 38%. In a previous study evaluating the effect of gamma irradiation on fresh Cilantro, a decrease in terpene content was also described (Fan and Sokorai, 2002). However, the authors concluded that the observed loss of terpenes such as myrcene and linalool was insignificant compared to the losses that occurred by evaporation during refrigerated storage of Cilantro. Also in orange juice the effect of irradiation on terpenes was found to be non-significant in comparison to changes induced by refrigerated storage (Fan and Gates, 2001). Likewise, the slight terpene reduction observed in the current study is comparable to the effect that short term storage in a paper bag had on cannabis samples, in a study performed by (Ross and ElSohly, 1996). A likely explanation therefore seems that gamma irradiation

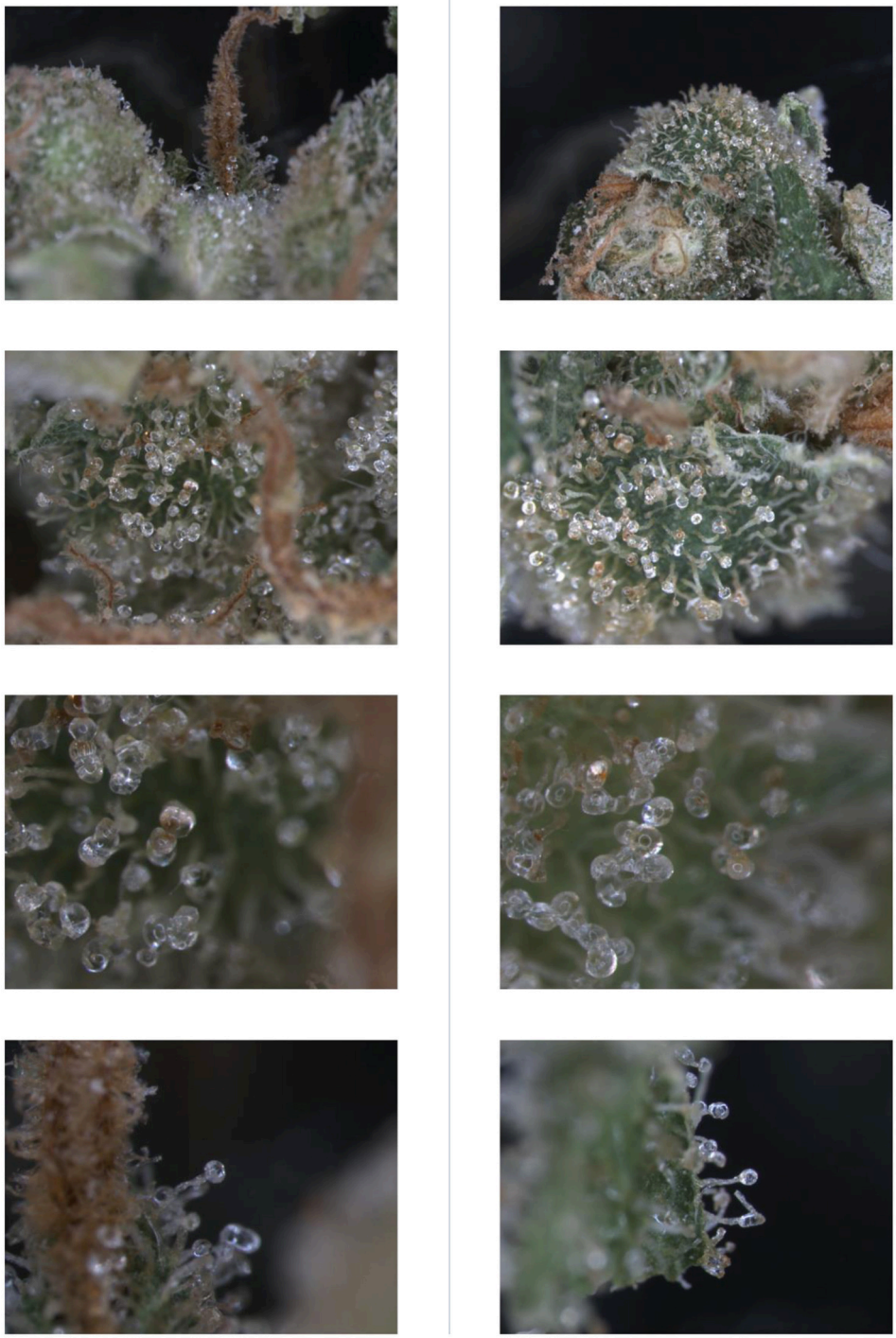

FIGURE 4 | Microscopic images of trichomes (glandular hairs) before and after treatment with gamma-irradiation. Cannabis variety *Bedrocan* was used. Magnification ± 20–120 times.

slightly accelerates the evaporation of some of the more volatile terpenes. This idea is supported by the fact that no degradation products or additional chromatographic peaks were found to account for the lost terpenes, with the exception of some beta-caryophyllene oxide formed in the irradiated sample of variety *Bedica*. Interestingly, terpenes were not affected to the

same degree in all varieties, e.g., myrcene content was clearly reduced in varieties *Bedica* and *Bedrolite* but not in variety *Bediol*. Perhaps this indicates a protective effect that cannabis components may have on each other when present in specific proportions.

Some cannabis users have claimed that irradiation changes the taste and/or smell of cannabis during smoking or vaporizing (personal observation by the author). Unfortunately, such opinions may be hard to substantiate because the same cannabis is usually not available to consumers in both its irradiated and non-irradiated form to allow direct comparison, meaning there is no "base-line" product to quantify the magnitude of the change. Nevertheless, the taste and smell of cannabis mainly depends on its terpene (essential oil) content (Russo, 2011). While the current study indicated quantitative changes in some of the terpenes upon irradiation, a subtle change in smell or taste may indeed be possible as a result of such treatment. Despite these changes, the overall terpene profile of each variety remained clearly recognizable.

Gamma irradiation remains controversial among some consumers of medicinal cannabis. However, weighing the risks vs. the benefits currently keeps pointing toward the use of this decontamination procedure. After all, cannabis plants cannot (yet) be grown and processed under conditions aseptic enough to meet pharmaceutical standards, while infection risks are well documented in the medical literature and can be harmful or even fatal to seriously ill patients. Meanwhile, the main harm of gamma-irradiation seems to be limited to a reduction of some terpenes present in the cannabis, leading to a small quantitative effect, but keeping the terpene profile qualitatively essentially intact.

Based on the results presented in this report, gamma irradiation of herbal cannabis remains the recommended method of decontamination, at least until other more generally accepted methods have been developed and validated. This is especially important when cannabis is prescribed to seriously ill and possibly immune-deprived patients, with an increased risk of suffering from microbial infection. Meanwhile, the development of improved hygienic standards for cultivation and processing of medicinal cannabis may ensure that irradiation doses can be reduced to an absolute minimum. In time, gamma-irradiation may eventually be replaced with other, more generally accepted, forms of reliable decontamination.

AUTHOR CONTRIBUTIONS

The author confirms being the sole contributor of this work and approved it for publication.

ACKNOWLEDGMENTS

The Dutch Office of Medicinal Cannabis (OMC) and pharmaceutical quality control laboratory Proxy Labs (Leiden, The Netherlands) are gratefully acknowledged for their support in performing this study. A big thanks to Gerda Lamers (Leiden University) for preparing the microscopic images.

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Conflict of Interest Statement: The author is full time employed by Bedrocan BV, the licensed company that provided the medicinal grade cannabis used for this study.

EXHIBIT 8

USDA
United States Department of Agriculture

Phytosanitary Irradiation: Technology and Efficacy

Andrea Beam

Supervisory Biological Scientist
CPHST Miami Lab

Science and Technology
Plant Protection and Quarantine
Animal and Plant Health Inspection Services
United States Department of Agriculture

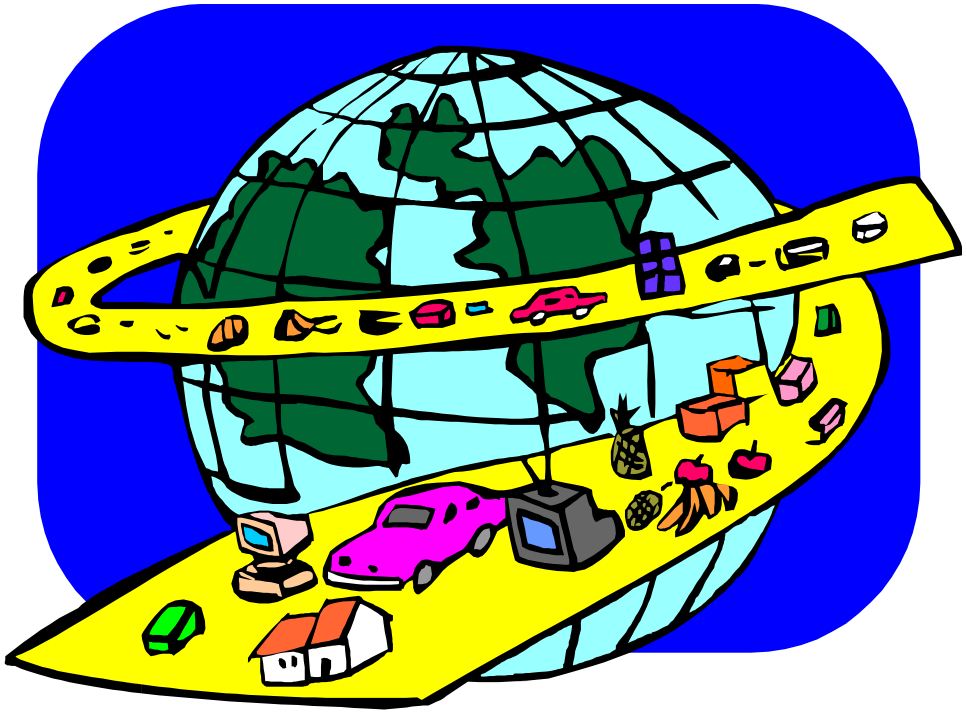
Outline

- Irradiation Technology
- Insect Efficacy
- Phytosanitary Irradiation History
- Mite Generic Dose Development

Background

Global trade of commodities

- New products for US consumers
- New export markets for US producers
- Exotic pests



PPQ Mission

Plant Protection and Quarantine (PPQ)
Animal and Plant Health Inspection Services
United States Department of Agriculture

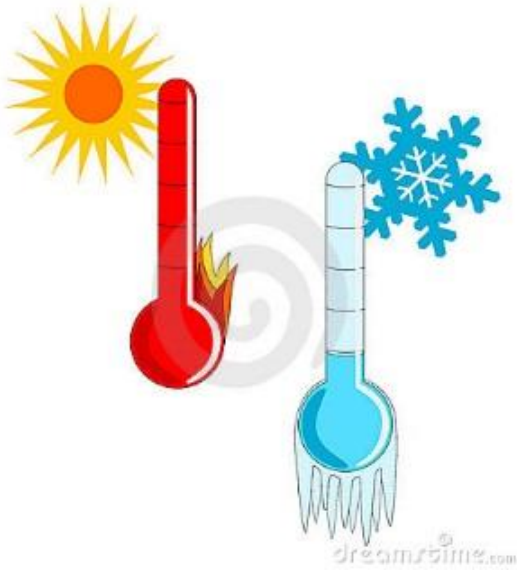
APHIS

Safeguard U.S. agriculture and natural resources against the entry, establishment, and spread of economically and environmentally significant pests, and facilitate the safe trade of agricultural products.

Definitions & Concepts

Phytosanitary Treatment- Regulatory measure intended to prevent the introduction or spread of quarantine pests by killing or sterilizing pests with high efficacy

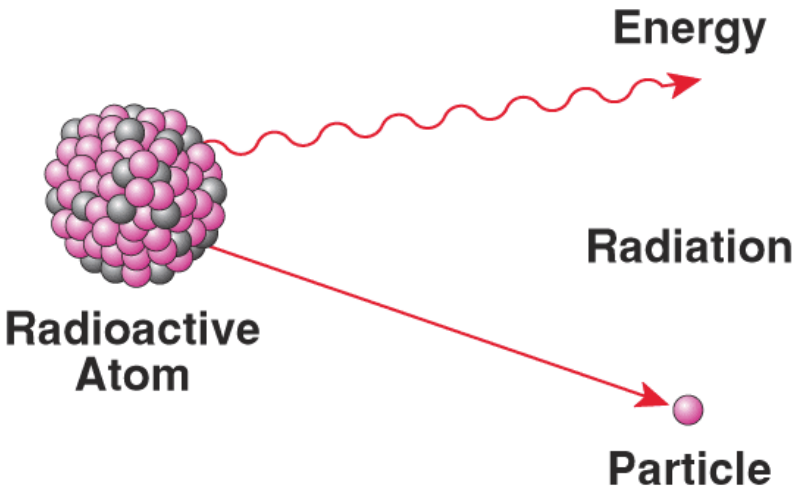
Examples of Treatments:
Irradiation
Heat (44-48 °C)
Cold (0-2 °C)
Fumigation



Definitions & Concepts

Irradiation- The exposure of a substance to ionizing energy (radiation) for the purpose of achieving some desired technical benefit

- Food and agricultural products
  - phytosanitary treatment, shelf life extension, sprout inhibition, pathogen reduction
- Sterilization of medical products
- Materials modification
  - semiconducters, gemstone coloration, polymers



Irradiation (gamma, e-beam, X-ray) at typical energies for radiation processing WILL NOT cause any of the irradiated products to become radioactive or leave any radioactive residue.

Definitions & Concepts

Dose vs Absorbed Dose- Dose refers to the amount of ionizing radiation delivered; Absorbed dose refers to the quantity of radiating energy (in *Gray*) absorbed per unit of mass of a specified target

Gray (Gy)- a unit of absorbed dose where 1 Gy is equivalent to the absorption of 1 joule per kilogram of the specified material (1 Gy = 1 J/kg)

Typical Absorbed Dose Requirements

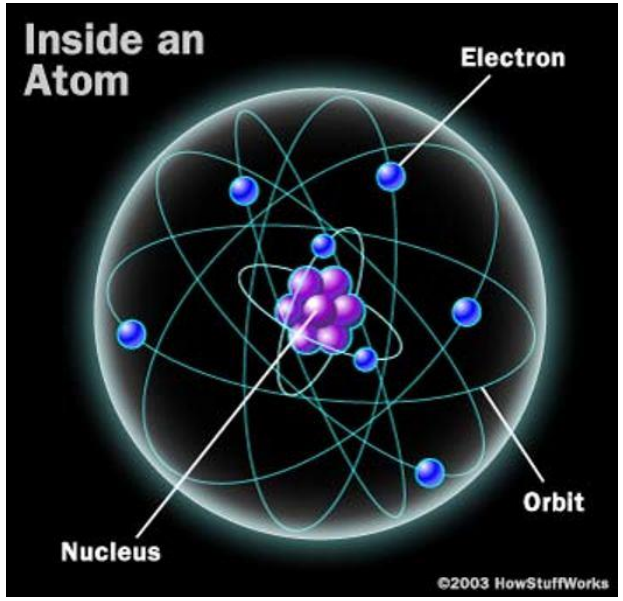
Purpose	Dose (Gray)
Inhibit Sprouting	50
Phytosanitary Irradiation	60-400
Pathogen Reduction (Meat and Poultry)	1,500
Spice Sanitation	6,500
Medical Device Sterilization	25,000
Food Sterilization (NASA)	46,000

Approved Irradiation Sources

Gamma: Cobalt 60 or Cesium 137 emits photons during decay

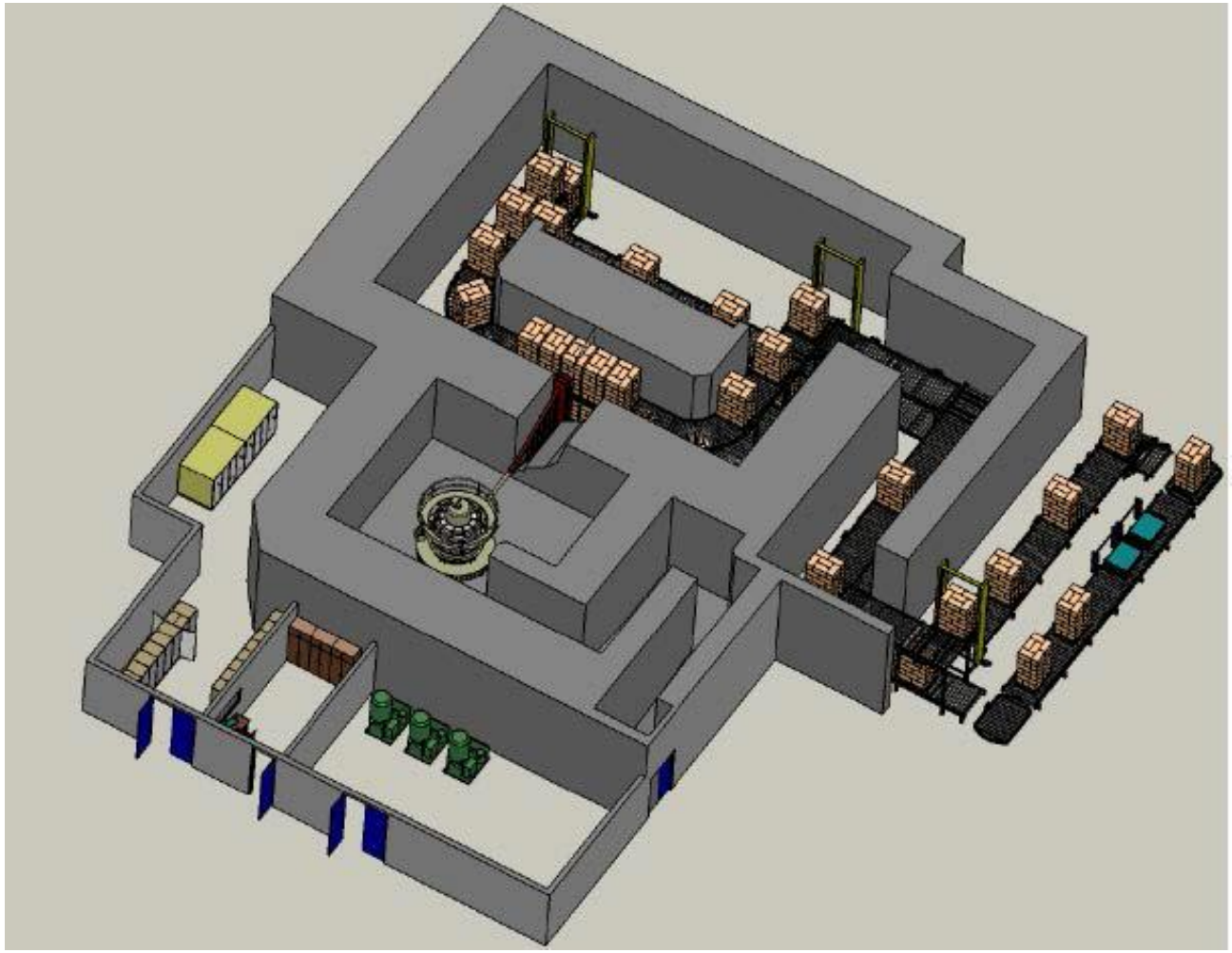
E-beam: High energy electrons propelled (particle beam) from an electron gun

X-ray: High energy electrons are converted to X-rays (photons)



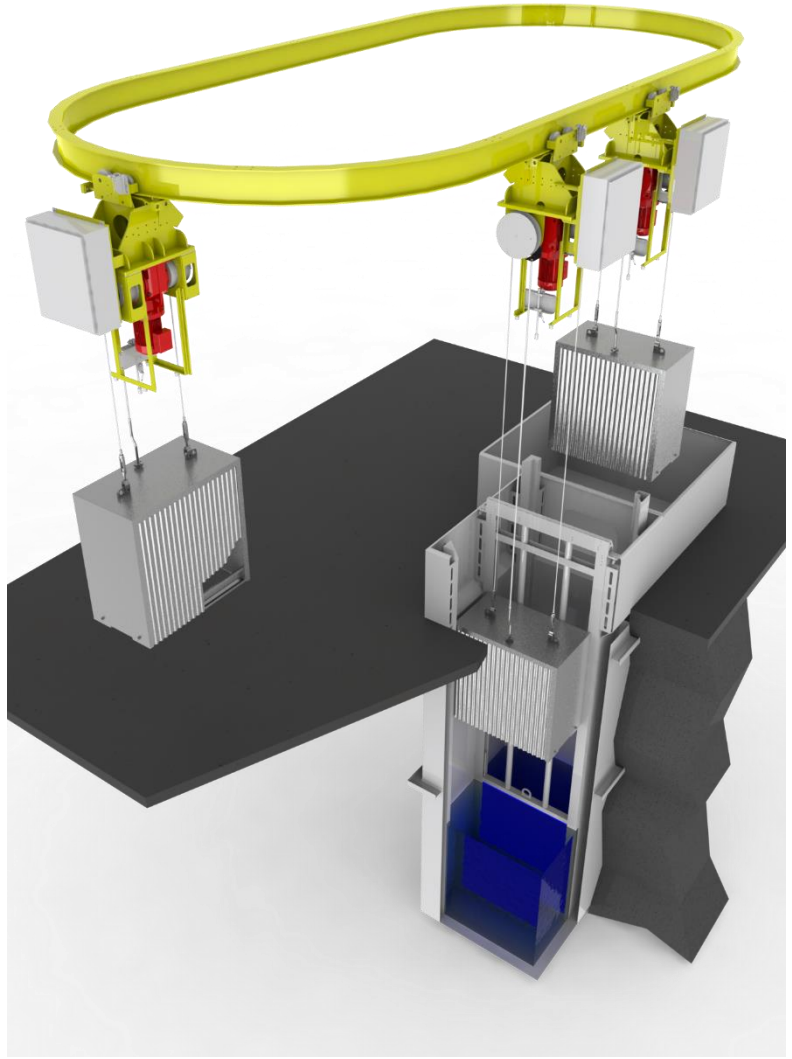
Components of Irradiation Facilities

- Radiation source
  (gamma, x-ray, e-beam)
- Biological shield
- Product transport system
- Control and safety equipment



X-Ray Facility Image Credit: IAEA

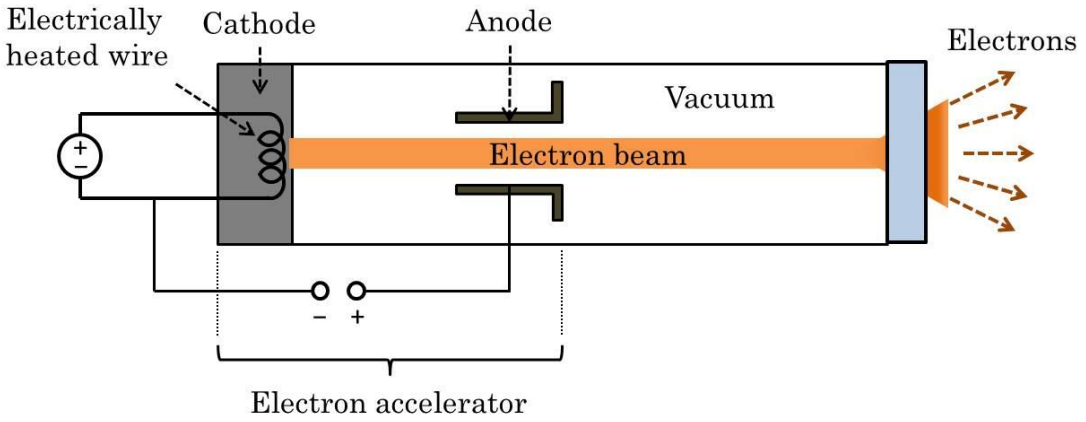
Gamma Irradiator (Cobalt 60)



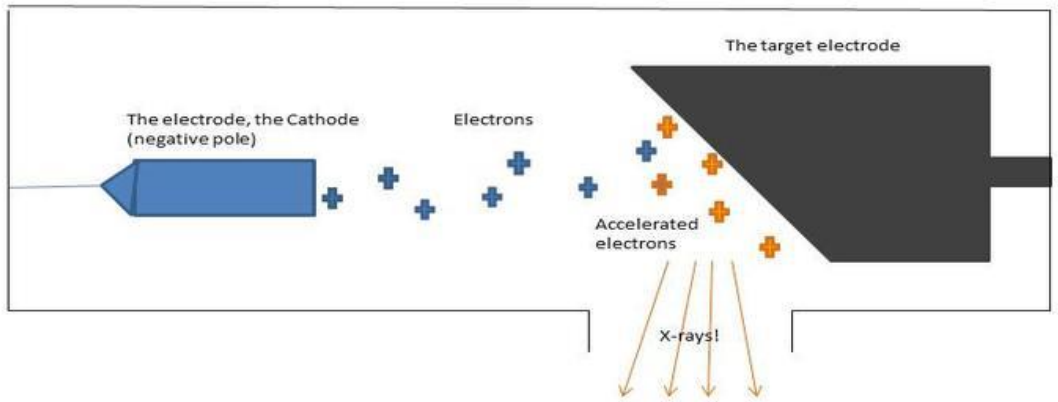
Cherenkov radiation

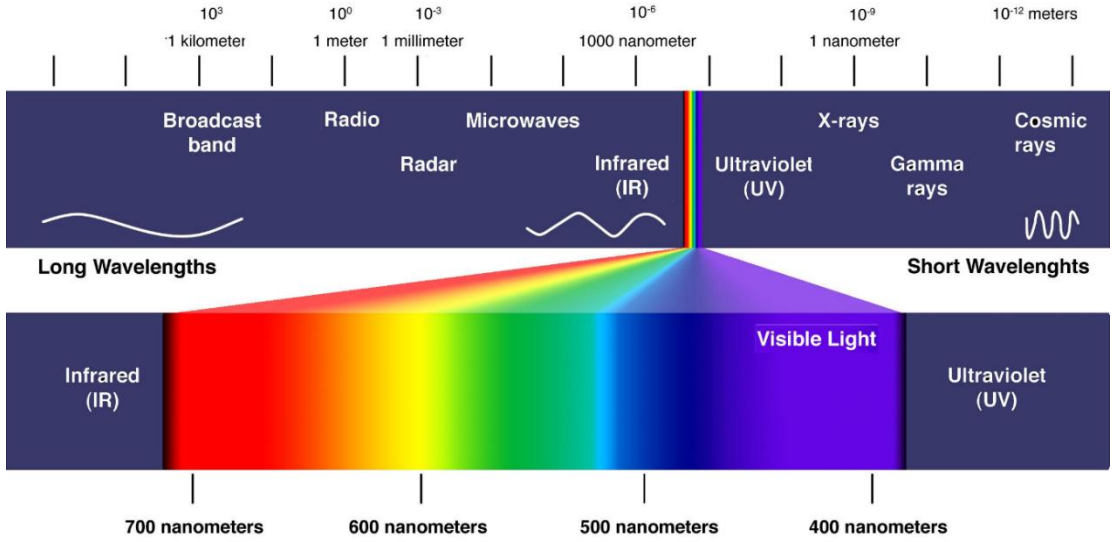
E-beam Irradiator

Image Credit: IAEA



X-Ray Irradiator

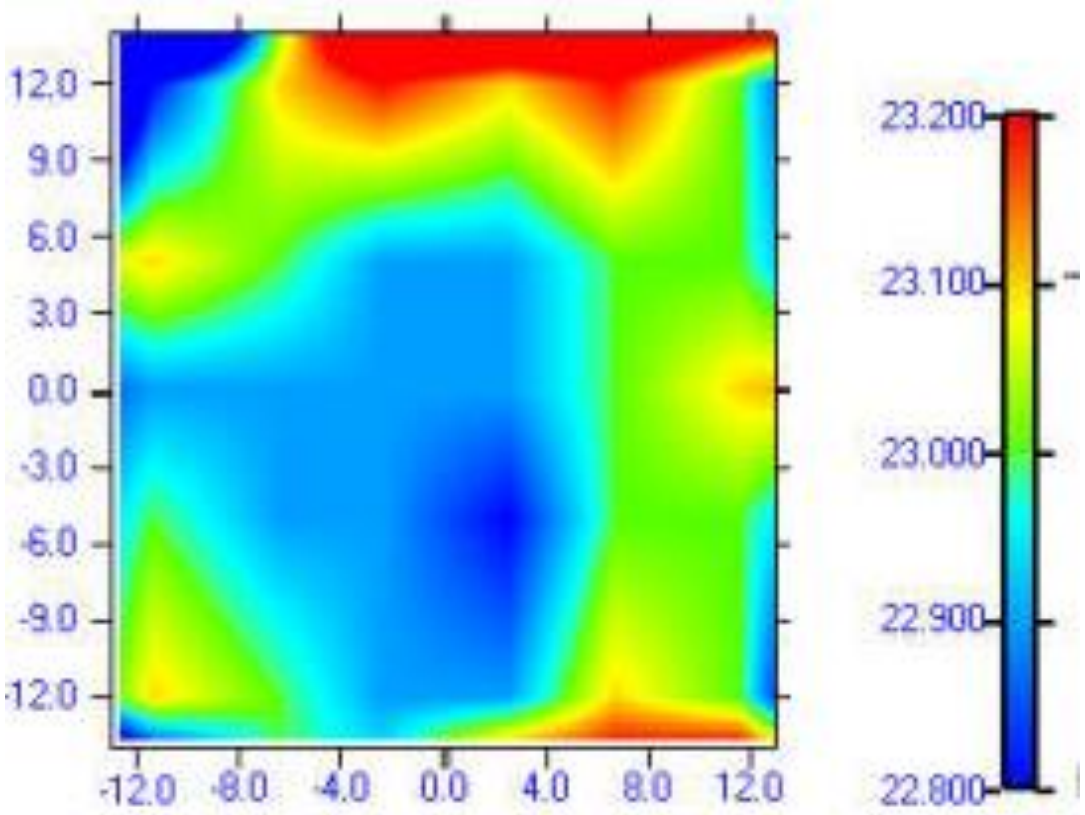




Definitions & Concepts

Dose Distribution- The spatial variation of absorbed dose throughout the process load, the dose having the extreme values *D*max and *D*min.

Note: FDA limits fresh fruit and vegetable treatments to 1000 Gy



From www.teasystems.com/WhitePapers/WeirPW_DoseUniformity.htm

Insect Efficacy

The objective of using irradiation as a phytosanitary measure is to prevent the introduction and spread of plant pests

This can be realized by achieving certain responses in the target pest(s) such as:

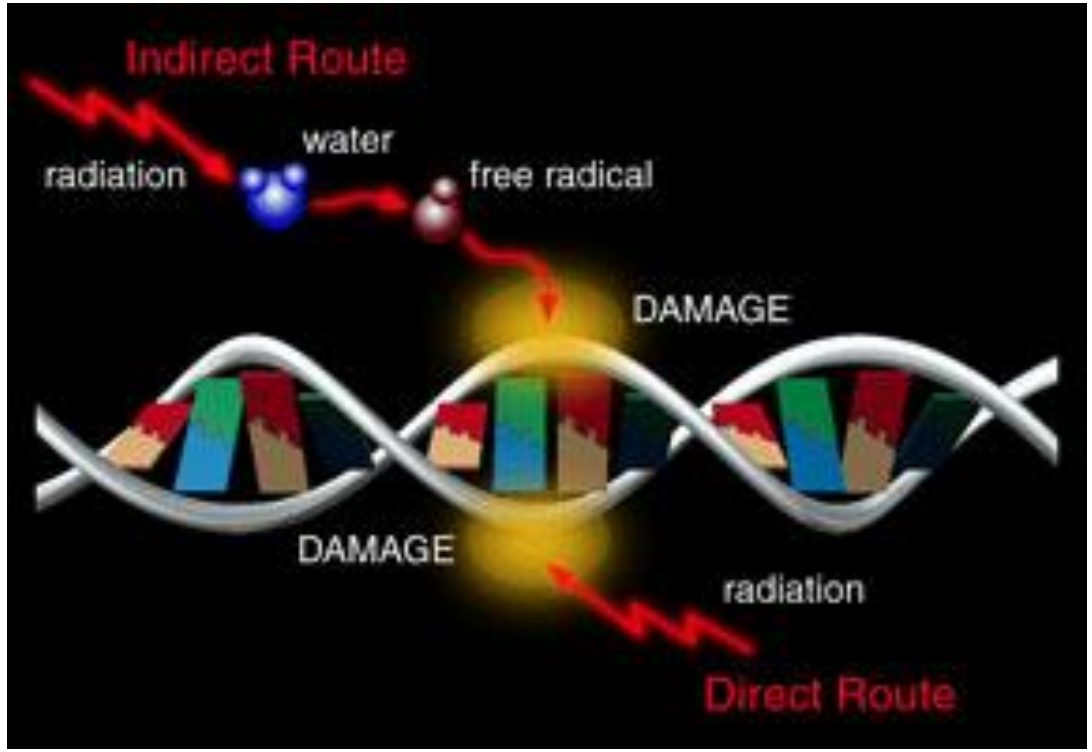
- mortality
- preventing development
- sterility
- inactivation

Mortality is usually not the target response for APHIS irradiation treatments and live insects may remain after treatment

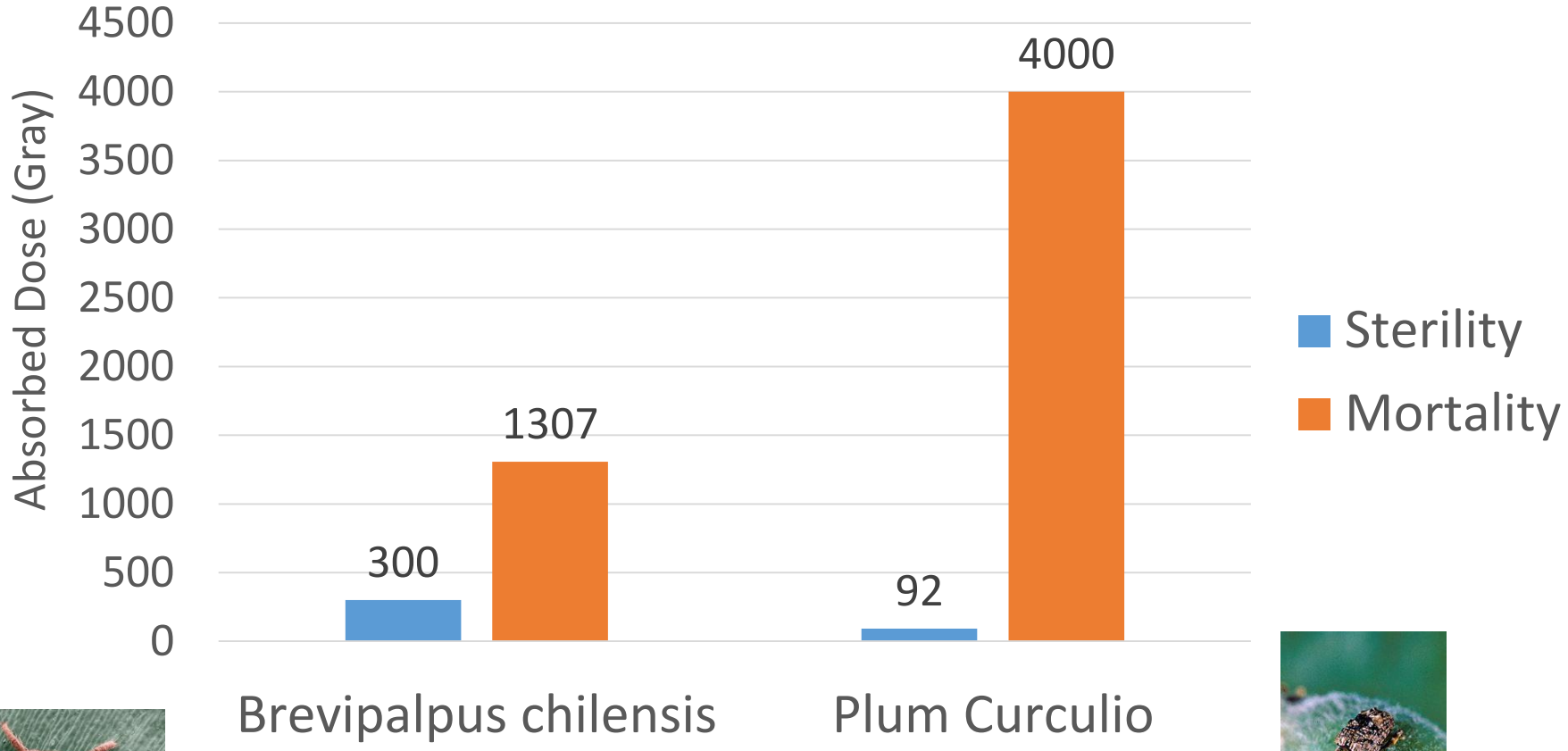
Insect Efficacy

Effects of ionizing radiation on insect pests:

- Free radicals cause tissue damage
- Broken chemical bonds
- DNA damage can be fatal or prevent reproduction



Absorbed Doses Required for Sterility vs. Mortality



From Castro et al., 2004 and Hallman, 2003.

Phytosanitary Irradiation History

- 1986. US FDA approves irradiation of fruits and vegetables for insect disinfestation
- 1989. Approval of Hawaii papaya
- 1995. Hawaii produce exported with special permit
- 1996. USDA APHIS approves phytosanitary irradiation against fruit flies on any commodity

Phytosanitary Irradiation History

2002. Irradiation approved for all admissible fruits and vegetables from all countries to US

2004. Australian mangos to New Zealand

2006. USDA APHIS approves generic doses

2007. Thai mango to United States

2011. First Upon Arrival Irradiation Treatment

2015. First US exports of irradiated fruit

Generic vs. Specific Treatment

Generic

- Treatment covers multiple pests and commodities
- Subset of insects from group are tested

Specific

- Treatment applies to a single pest
- Often commodity-specific
- Single pest tested

APHIS Approved Irradiation Treatments

Pest	Dose (Gy)
All fruit flies of the family Tephritidae	150
All insects except adults and pupae of the order Lepidoptera	400
Eggs and larvae of the family Tortricidae	290

Pest	Dose (Gy)
Rhagoletis pomonella	60
Anastrepha ludens, Anastrepha obliqua, Anastrepha suspensa	70
Conotrachelus nenuphar	92
Anastrepha serpentina, Bactrocera jarvisi, Bactrocera tryoni, Ceratitis capitata, Copitarsia declora	100
Aspidiotus destructor, Cylas formicarius, Euscepes postfasciatus, Omphisa anastomosalis, Pseudaulacaspis pentagona, Bactrocera cucurbitae, Bactrocera dorsalis	150
Sternochetus frigidus	165
Cydia pomonella, Grapholita molesta, Epiphyas postvittana	200
Cryptophlebia ombrodelta, Cryptophlebia illepida	250
Brevipalpus chilensis, Sternochetus mangiferae	300

Generic Treatments in Use

Trading Partners	Commodity	Dose
Mexico to US	Citrus, manzano pepper, mango	150 Gy
India & Pakistan to US	Mango	400 Gy
Mexico to US	Guava	400 Gy
Vietnam to US	Dragonfruit	400 Gy
Australia to New Zealand	Mango, papaya	250 Gy
Australia to New Zealand	Lychee	350 Gy

Hallman, G., 2012. Generic phytosanitary irradiation treatments. Radiation Physics and Chemistry. 81:861–866.

USDA
United States Department of Agriculture

Dose Development - Mites

- Mites
  - Quarantine pests for many fresh commodities
  - Vectors for plant diseases
- Limited phytosanitary treatment options
  - Not covered by generic 400 Gy insect dose
- Australia and New Zealand
  - 400 Gy for Tetranychidae
  - 500 Gy for all other mites

Joseph Berger, Bugwood.org

USDA United States Department of Agriculture

Dose Development - Mites

Objective

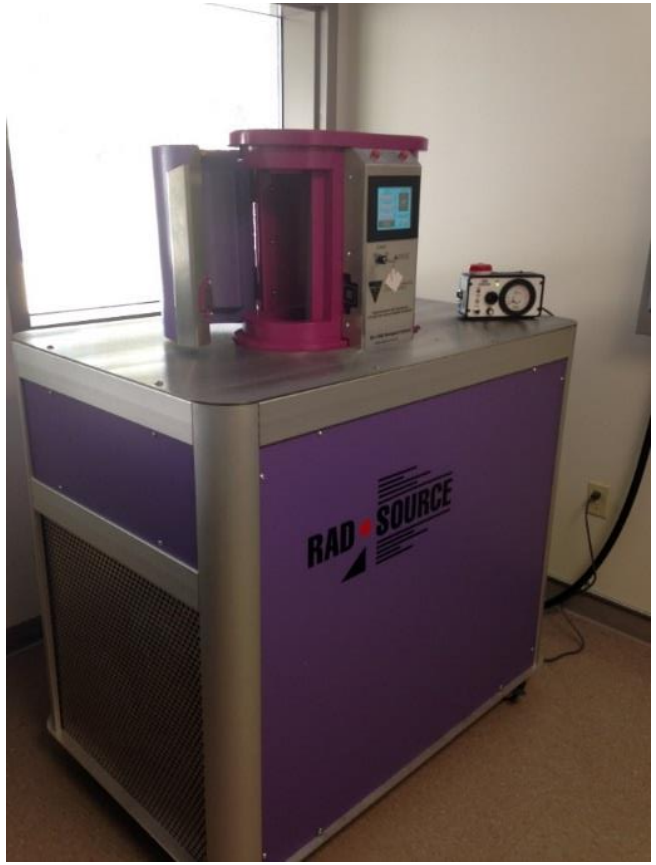
- Determine irradiation dose that prevents reproduction of *Brevipalpus yothersi*
  - Endpoint = prevent F1 egg hatch

- Contribute to the body of literature required to establish a generic dose for mites

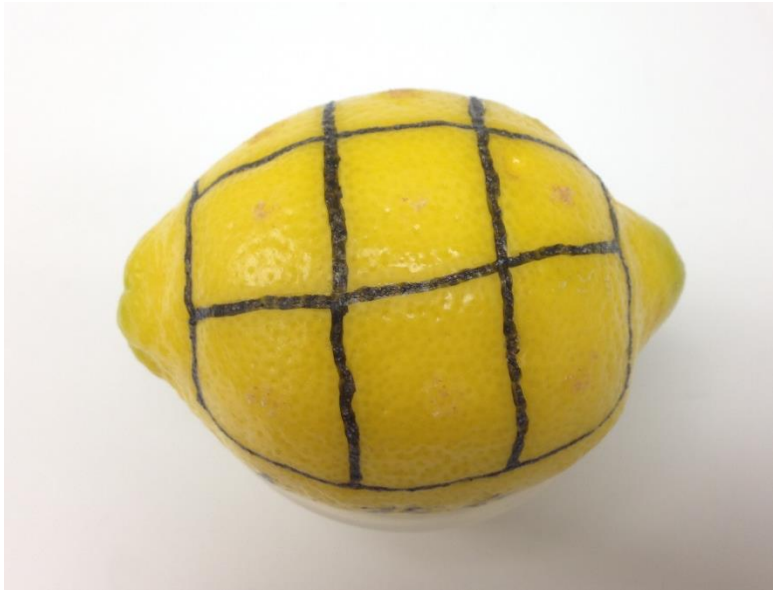
Brevipalpus yothersi

USDA United States Department of Agriculture

Methods



X-ray irradiator at Miami CPHST lab



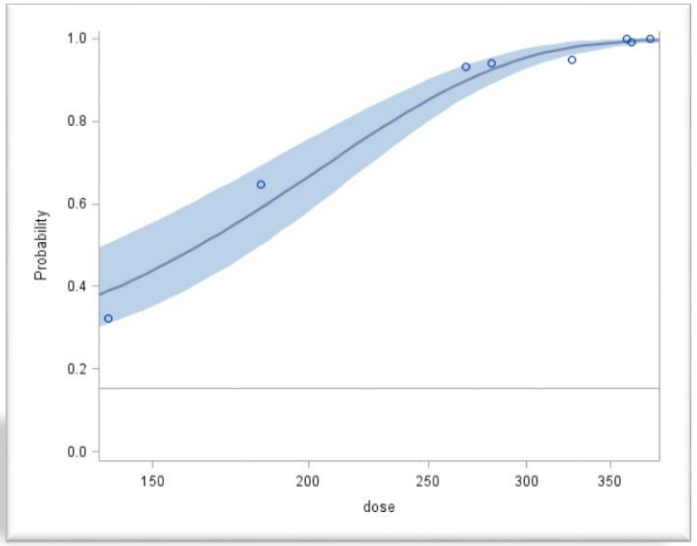
Lemon with arenas for individual mites

Brevipalpus mites on lemon

USDA
United States Department of Agriculture

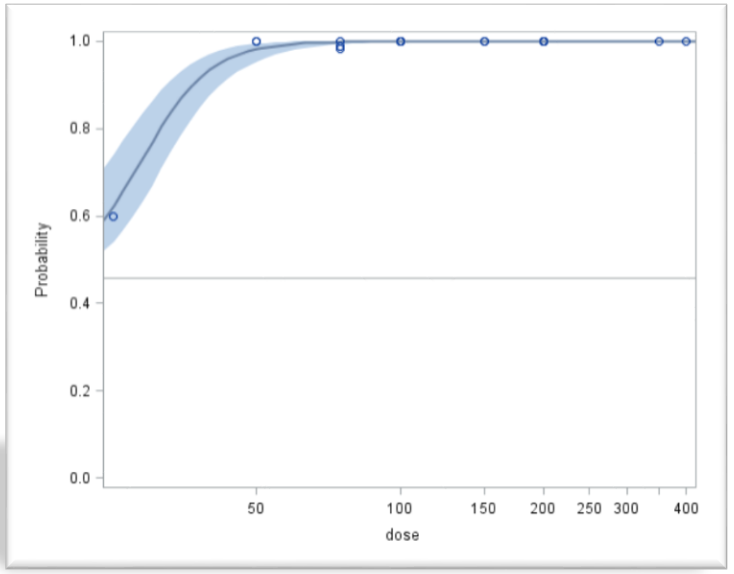
Preliminary Results

Adult (n=577)



Egg (n=1921)

insectimages.org



Life Stage	SD-99	SD-99.9	Model
Adult	352 (327-387)	406 (371-461)	Gompertz
Egg	61 (51-82)	90 (70-140)	Logistic

Concluding Thoughts

Benefits of PI

- Effective for many types of pests
- Minimal impact on commodity quality
- May be applied at diverse points post-harvest

Question for you:

What commodities could be added to the US irradiation program?

Questions?

Andrea.l.beam@aphis.usda.gov
(305) 278-4888

EXHIBIT 9

APHIS
Animal and Plant Health Inspection Service

PPQ Irradiation Program: Research and Future Directions

Laura Jeffers

USDA-APHIS-PPQ
Center for Plant Health Science and Technology

APHIS
Animal and Plant Health Inspection Service

Outline

- Irradiation as a MB Alternative
- Benefits from Irradiation
- Generic Doses
- Modified Atmosphere Packaging

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Animal and Plant Health Inspection Service

What are we treating?

Table 5-2-13 Origin and Approved Commodity List for 150 Gy

Origin	Commodity
Hawaii	Abiu, Atemoya, Banana, Breadfruit, *Capsicum* spp., Carambola, *Cucurbita* spp., Dragon fruit, Eggplant, Jackfruit, Litchi, Longan, Mangosteen, Melon, Moringa pods (Drumstick), Papaya, Pineapple, Rambutan, Sapodilla, Sweet Potato, and Tomato
Mexico	Carambola, Clementine/Mandarin/Tangerine (*Citrus reticulata*), Grapefruit (*Citrus paradisi*), Mango, Manzano Pepper (*Capsicum pubescens*), Sweet lime (*Citrus limettoides*), Sweet Orange (*Citrus sinensis*), Tangelo (*Citrus tangelo*)

Table 5-2-15 Origin and Approved Commodity List for 300 Gy

Origin	Commodity
Hawaii	Mango

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What are we treating?

Table 5-2-14 Origin and Approved Commodity List for 400 Gy

Origin	Commodity
Ghana	Eggplant, Okra, Pepper
Hawaii	Banana, Breadfruit, Cowpea (pod), Curry Leaf, Dragon fruit, Guava, Jackfruit, Mangosteen, Melon, Moringa pods (Drumstick), and Sweet Potato
India	Mango
Malaysia	Papaya, Rambutan
Mexico	Guava
Pakistan	Mango
South Africa	Grape, Persimmon
Thailand	Dragon Fruit, Litchi, Longan, Mango, Mangosteen, Pineapple, Rambutan
Viet Nam	Dragon Fruit, Rambutan

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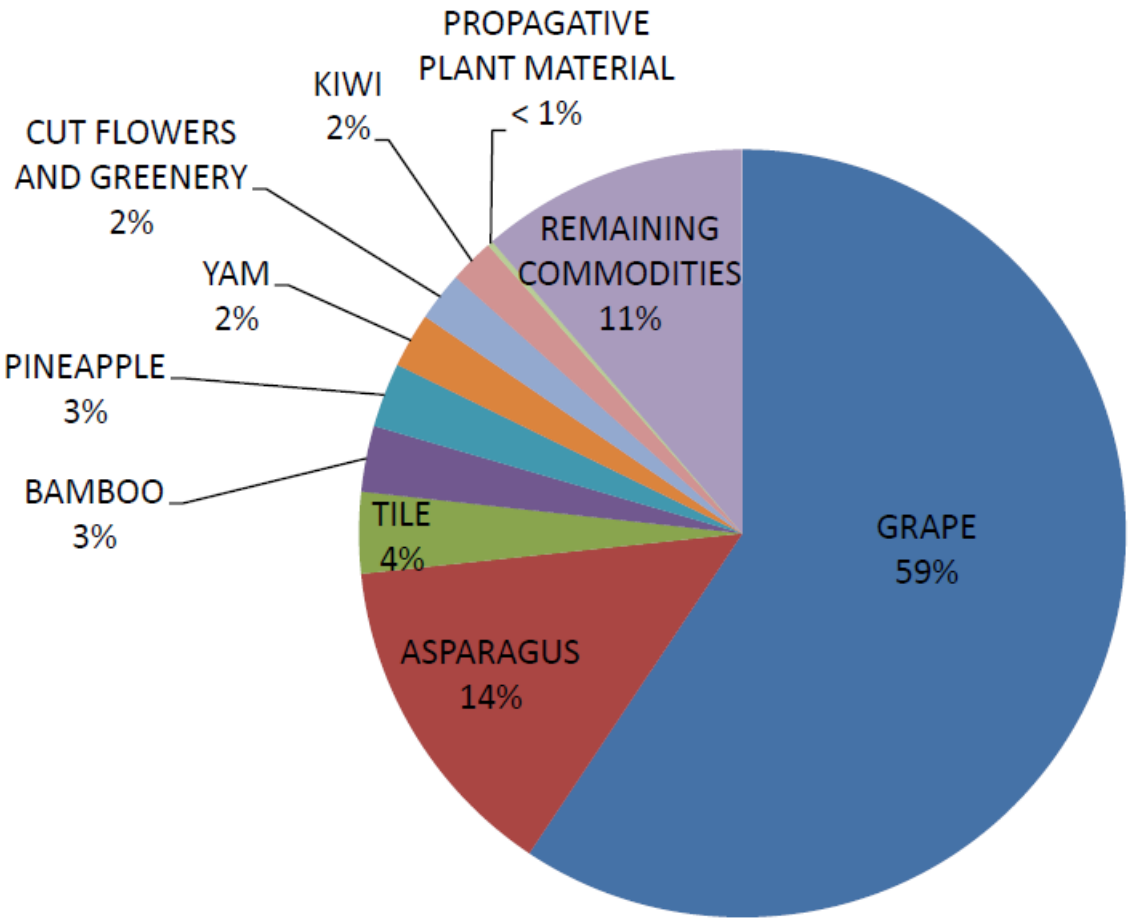
2010 Import MB Usage



Total Usage
680,000 lbs

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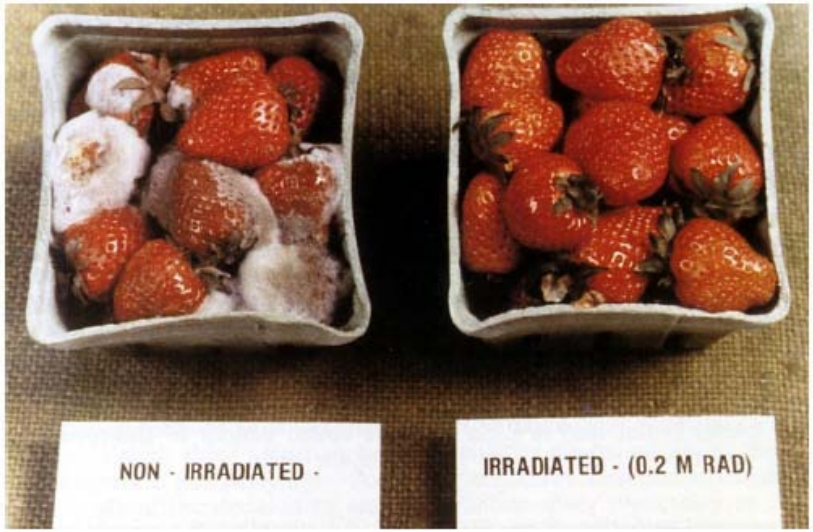
Benefits from Irradiation



Most fruit can be irradiated with 150-600 Gy with no adverse effects

- Increased shelf life
- Improved quality

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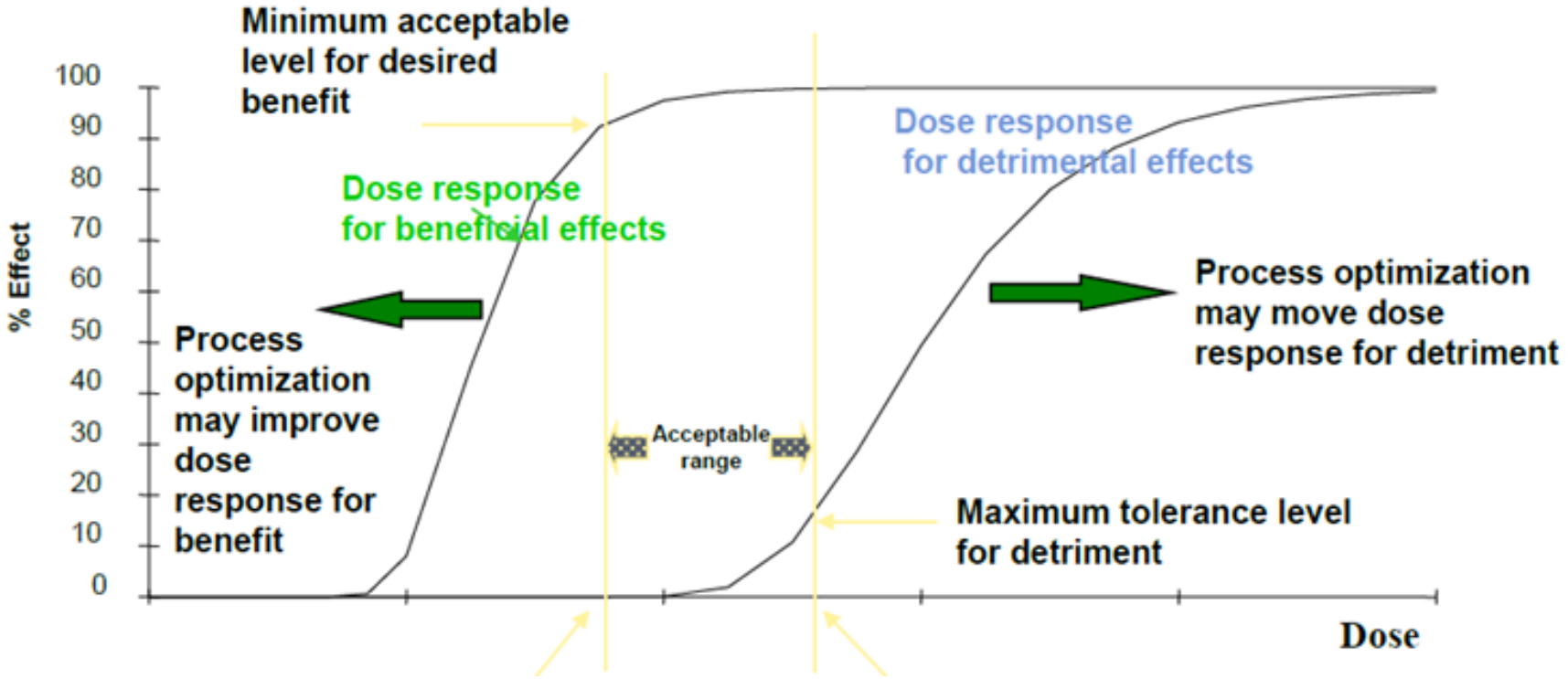
Desired Dose Range for Treatment



Joseph Borsa, MDS Nordion

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Animal and Plant Health Inspection Service

Irradiation of Stone Fruit Exports

Joint Project (Chapman University, FTSI, and PPQ)

- Peaches irradiated 250, 400, 700, and 1000 Gy in FL
- Peaches trucked to CA
- Analysis 1,7,and 14 days after arrival
- Shelf life, pH, Brix, and weight loss
- Appearance, aroma, texture, and flavor

Irradiation of Stone Fruit Exports

Irradiation positively affected the liking/acceptability of all peach varieties tested

Shelf life, pH, Brix, and weight loss are not negatively affected by irradiation
(variety and age play a bigger role)

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Generic Absorbed Doses

Table 5-2-12 Pest-Specific Minimum absorbed dose (Gy)

Scientific Name	Common Name	Minimum Absorbed Dose (Gy)
Cryptophlebia illepida	Koa seedworm	250
Cylas formicarius elegantulus	Sweet potato weevil	150
Cydia pomonella	Codling moth	200
Euscepes postfasciatus	West Indian sweet potato weevil	150
Grapholita molesta	Oriental fruit moth	200
Omphisa anastomosalis	Sweet potato vine borer	150
Pseudaulacaspis pentagona	White peach scale	150
Rhagoletis pomonella	Apple maggot	60
Sternochetus mangiferae	Mango seed weevil	300
	All other fruit flies of the family Tephritidae which are **not** listed above	150
	Plant pests of the class Insecta **not** listed above, except pupae and adults of the order Lepidoptera	400

Pest-Specific Absorbed Dose

Generic Absorbed Dose

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Generic Absorbed Doses

Generic Absorbed Doses Facilitate Trade

If a risk analysis of a new commodity demonstrates that no pupae or adult Lepidoptera follow a pathway, then export approval can happen without further research

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Generic Absorbed Doses

- Development of specific doses for quarantine Lepidoptera not covered by the generic treatment
- Reduction of dose levels for specific pests and commodities to shorten treatment time and minimize deleterious effects
- Development of generic doses below 400 Gy for important groups of quarantine arthropods (other than fruit fly)

Follett, 2009

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Generic Absorbed Doses

Table 4–Possible generic doses that might provide control of various quarantine pest groups.

Pest group[a]	Measure of efficacy	Possible generic dose (Gy)
Aphids	Prevent reproduction of adult	100
Whiteflies	Prevent reproduction of adult	100
Dried seed weevils	Prevent reproduction of adult	100
Fruit fly larvae	Prevent adult emergence	150[b]
Fruit weevils	Prevent reproduction of adult	150
Thrips	Prevent reproduction of adult	250
Lepidoptera larvae	Prevent adult emergence	250
Scale insects	Prevent reproduction of adult	250
Mealybugs	Prevent reproduction of adult	250
All insects except pupae and adults of Lepidoptera[c]	Prevent reproduction of adult or development to adult by eggs, nymphs and larvae	250
Lepidoptera pupae	Prevent reproduction from subsequent adult	350
Mites	Prevent reproduction of adult	350
All arthropods except adults of Lepidoptera	Prevent reproduction of adult	350

Hallman, 2011

Modified Atmosphere Packaging

MAP is a process that alters the gas composition surrounding a commodity

- prolongs the shelf-life of perishable goods
- Retards development of aerobic microorganisms
- low O_2 environments are created by displacing O_2 in the packaging with other gases (e.g. N_2 or CO_2)

In the past few years, requests to use MAP for phytosanitary treatments have dramatically increased.

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Modified Atmosphere Packaging

Commodity	Temperature [°C]	Humidity [%]	Modified atmosphere % O_2	CO_2
Fruit				
Apricot	0-5	90	2-3	2-3
Orange	3-9	90-95	5-10	0-5
Banana	13-15	90-95	2-5	2-5
Persimmon	0-5	90-95	3-5	5-8
Cherry, sweet	0-5	90-95	3-10	10-15
Strawberry	0-5	90-95	4-10	15-20
Apple	0-5	90	1-3	1-3
Blueberry	0-5	90-95	5-10	15-20
Peach	0-5	90-95	1-2	3-5
Pear	0-5	90-95	2-3	0-1
Vegetables				
Asparagus	0-5	95-100	aria	5-10
Broccoli	0-5	95-100	1-2	5-10
Cauliflower	0-5	95-98	2-5	2-5
Cucumber	8-12	90-95	3-5	0
Lettuce	0-5	95-100	1-5	0
Corn, sweet	0-5	95-98	2-4	10-180
Green pepper	8-12	90-95	3-5	2-8
Tomato, partly	8-12	90-95	3-5	0-3
Spinach	0-5	95-98	7-10	5-10

Table 8: MAP recommended conditions for fresh fruit and vegetable

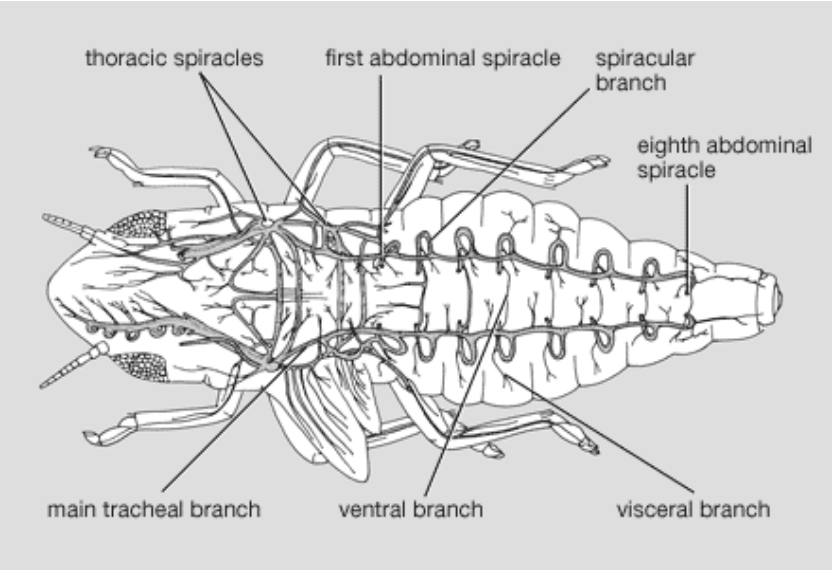
BPI Dansensor

Modified Atmosphere Packaging

Most MAP creates a low O_2 environment

Respiration slows, resulting in reduced O_2 concentrations in the hemolymph

In hypoxic environments, absorbed doses need to be greater to achieve same physiological effects



Modified Atmosphere Packaging

Mexican Guava
Spring Valley Fruits

- Simulate packing house and treatment facility conditions
- Record the O_2 concentrations before and after “treatment”

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Modified Atmosphere Packaging

Before Treatment

19.8%

After Treatment

5.6%

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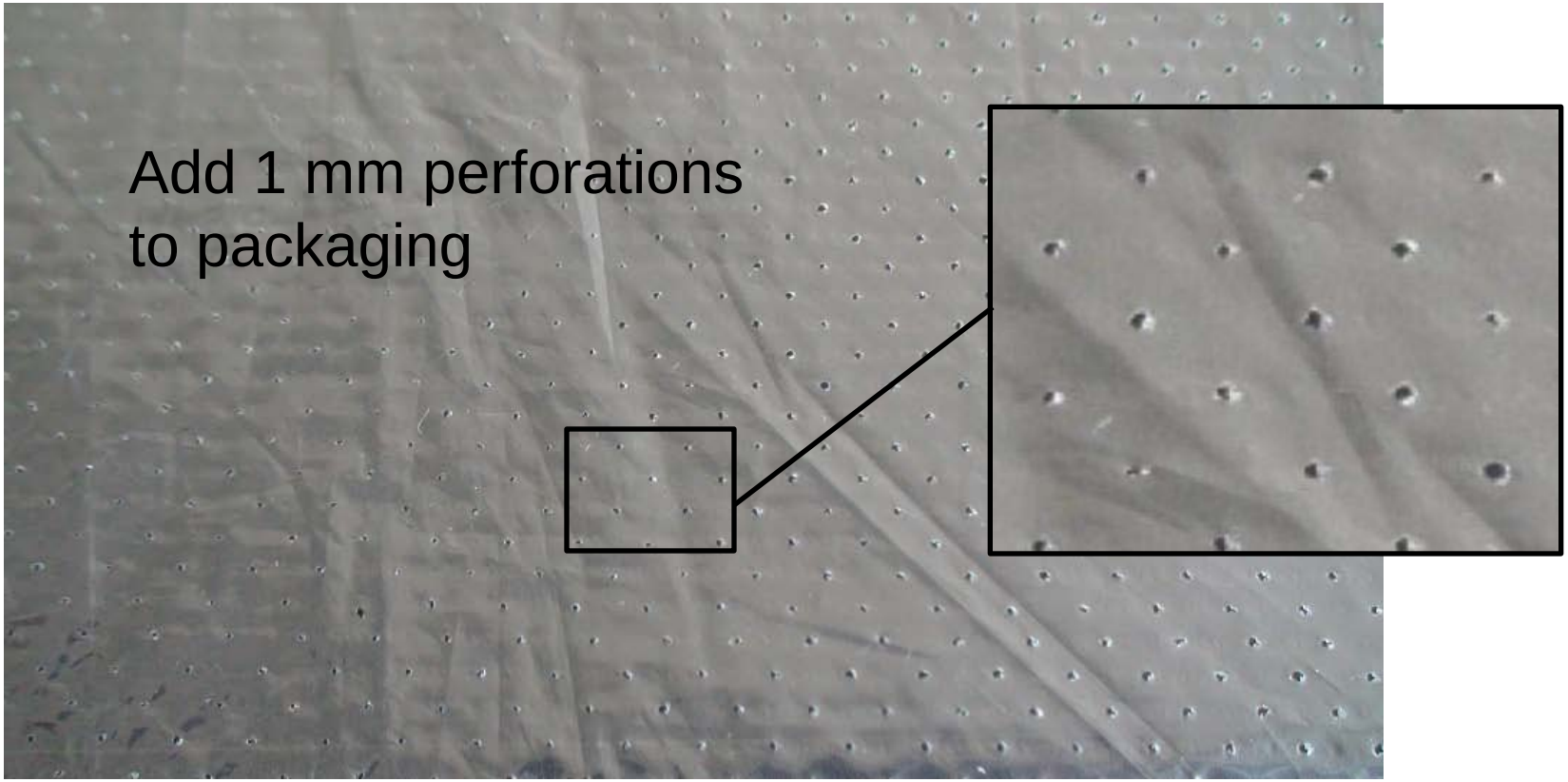
Modified Atmosphere Packaging



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Modified Atmosphere Packaging

Before Treatment

20.9%

After Treatment

20.9%

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Final Thoughts

Questions?

EXHIBIT 10

APHIS PPQ Phytosanitary Irradiation Program

Laura A. Jeffers

National Operations Manager

Field Operations
Plant Protection and Quarantine
Animal and Plant Health Inspection Services
United States Department of Agriculture

Outline

- APHIS PPQ Overview
- General Information
- Regulatory Overview
- Program Types

PPQ Mission

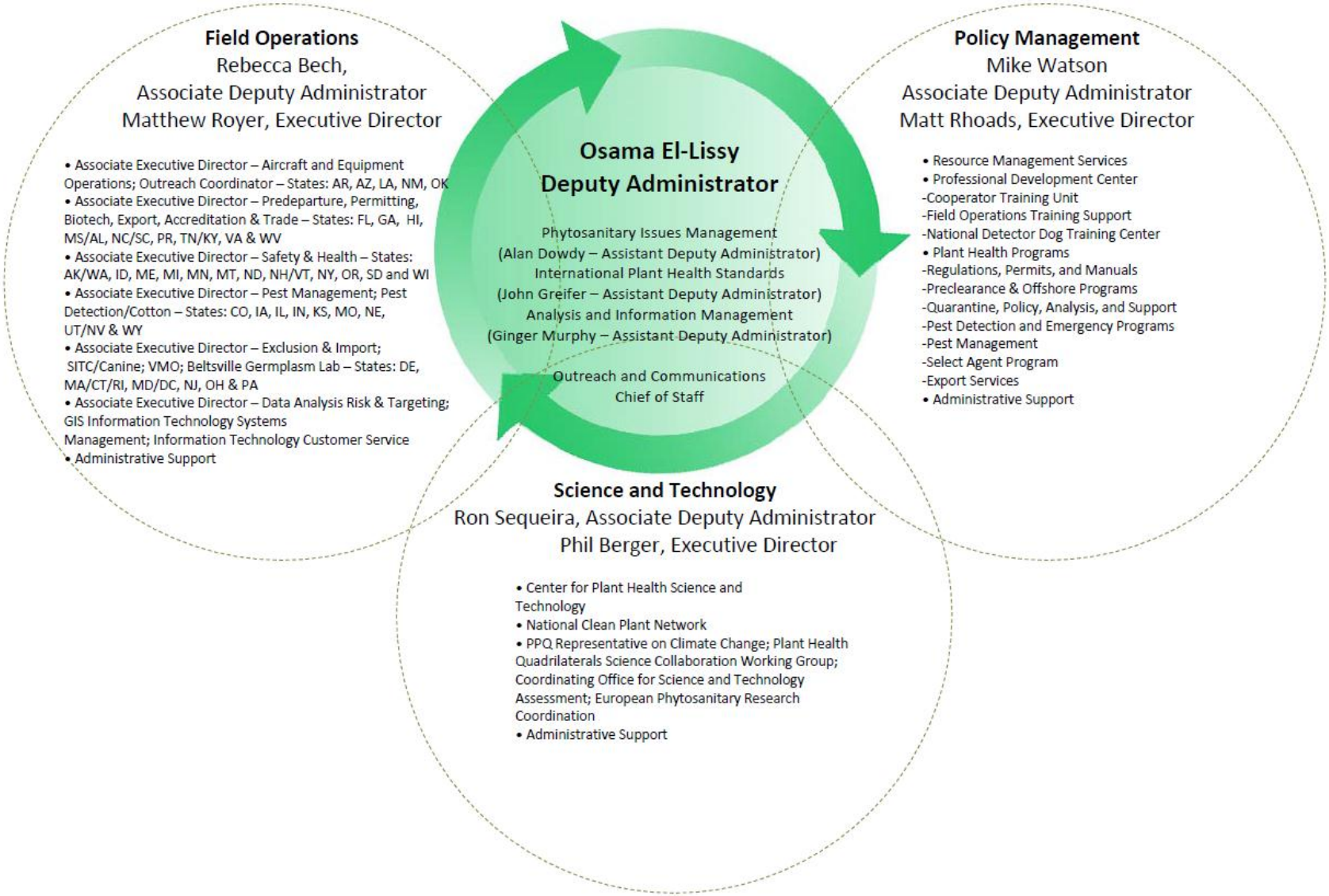
Regulate the movement of any commodity capable of harboring invasive, threatening plant pests, including noxious weeds, in order to protect the “agriculture, environment, and economy of the United States”

Facilitate import, export, and interstate commerce of agricultural products and other commodities that pose a risk of harboring certain plant pests

Plant Protection Act of 2000

Plant Protection and Quarantine Organizational Structure

Current as of September 2015



Approved Source Types

Gamma: ^{60}Cobalt or ^{137}Cesium emits photons during decay

E-beam: High energy electrons propelled from an electron gun

X-ray: High energy electrons are converted to X-rays (photons)

Phytosanitary Irradiation

APHIS treatments require minimum absorbed doses between 60-400 Gy

FDA limits fresh fruit and vegetable treatments to 1000 Gy

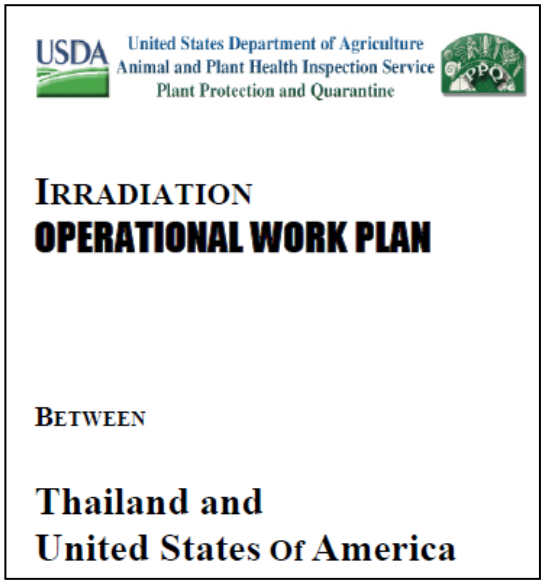
Radura must be visible at the point of sale for fresh fruits and vegetables

Pest Proof Packaging

As mortality is not the target response for APHIS treatments, live insects may remain after treatment

Regulatory Summary

- Market access granted
- Framework equivalency work plan signed
- Trust fund established
- Operational work plan signed
- Commodity-specific addendum signed


USDA United States Department of Agriculture
Animal and Plant Health Inspection Service
Plant Protection and Quarantine

IRRADIATION
OPERATIONAL WORK PLAN

BETWEEN

Thailand and
United States OF America

Regulatory Summary

- Facility plan approved
- Facility certified
- Importer compliance agreement signed
- Importer permit granted
- Packaging approved
- Process configuration approved

Irradiation Program Types

Preclearance and Offshore Programs
Offshore irradiation of US imports 

Port of Entry Program
Domestic irradiation of US imports 

Domestic Quarantine Program
Irradiation for domestic movement 

Export Program
Irradiation of US exports

Preclearance: India

Krushak

- First certified overseas facility
- Certified 2007
- ^{60}Co

Preclearance: Thailand

Synergy Health Ltd

- Certified 2008
- ^{60}Co

Thai Irradiation Center

- Certified 2007
- ^{60}Co

Preclearance: Vietnam

An Phu Irradiation

- Certified 2009
- ^{60}Co

Son Son Corporation

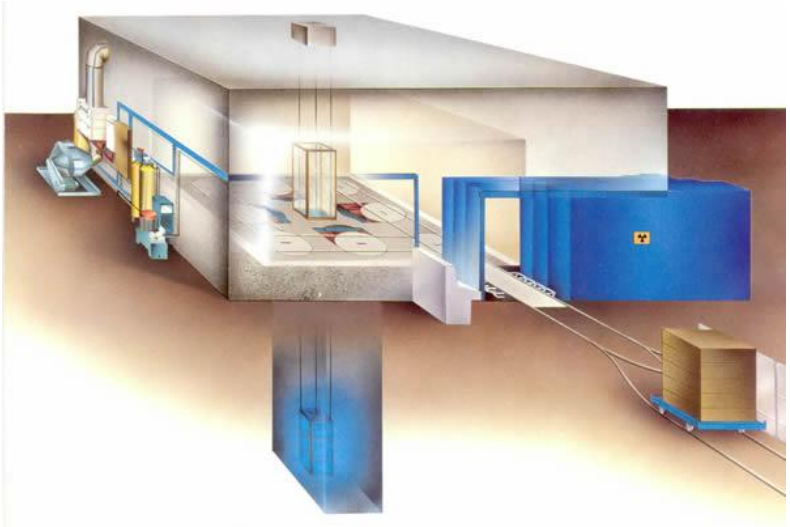
- Certified 2008
- E-beam

Preclearance: Mexico

Sterigenics
- Certified 2008
- ^{60}Co

Benebión
- Certified 2011
- ^{60}Co

Preclearance: South Africa



High Energy Processing (HEPRO)

- Certified 2012
- ^{60}Co

Preclearance Totals

(in kg)

	India	Mexico	South Africa	Thailand	Vietnam	Total
2007	0	0	0	195,000	0	195,000
2008	276,000	262,000	0	2,440,000	121,000	3,099,000
2009	132,000	3,559,000	0	2,247,000	117,000	6,055,000
2010	94,000	5,672,000	0	1,540,000	754,000	8,060,000
2011	80,000	5,539,000	0	743,000	1,445,000	7,807,000
2012	217,500	8,349,500	16,500	937,500	1,764,500	11,286,500
2013	283,000	9,526,000	16,500	1,060,500	1,967,500	12,853,500
2014	265,500	10,119,500	0	843,000	2,293,000	13,617,500

Offshore Program

Australia Mango and Lychee Irradiation Pilot Program- 3 years

Steritech

- Certified 2015
- ^{60}Co
- Fruit exports to New Zealand

Port of Entry

Sadex Corporation

- Certified 2009
- Sioux City IA
- E-beam

Southern Tier Rule

http://www.gpo.gov/fdsys/pkg/FR-2012-07-20/pdf/2012-17725.pdf

Southern Tier Rule

As of July 2012, establishment of port of entry phytosanitary irradiation facilities are allowed in the Southern U.S. states.

Additional Requirements:

- Approval by State Representative to the National Plant Board (State Plant Regulatory Official)
- Refrigerated Conveyance of Commodity
- Maps of Surrounding Agricultural Production Areas
- Pest Trapping or Monitoring
- Additional Facility Safeguarding

Southern States: Port of Entry

NCEBR

- Certified 2012
- College Station TX
- E-beam

Gateway America

- Certified 2013
- Gulfport MS
- ^{60}Co

Southern States: Port of Entry

Issues

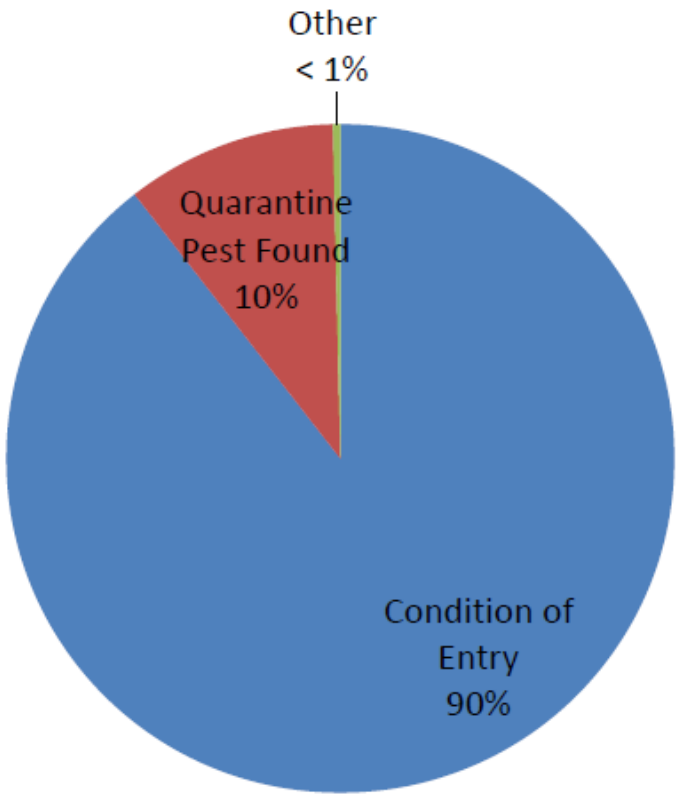
- Additional safeguarding at the facility
- Pre-approve packaging
- **Process configuration approval upon arrival**

Process Configuration Testing

Condition of Entry Treatment

↓

Emergency Action



US Imports: 2014 MB Usage

Domestic Movement

Hawaii Pride

- 1st PPQ-certified facility
- X-ray

Pa'ina Hawaii

- Certified 2012
- ^{60}Co

PPQ Irradiation Treatment Site

USDA APHIS → Plant Health → Import into the US → Quarantine Treatments → Irradiation

USDA United States Department of Agriculture
Animal and Plant Health Inspection Service

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Plant Health / Import into the U.S. / Quarantine Treatments

- Plant Health
- Program Overview
- Pests and Diseases
- Import into the U.S.
- Export from the U.S.
- International
- Manuals

Irradiation Treatment

Last Modified: Jun 26, 2015 | Print

In order to meet U.S. entry requirements, certain fresh fruits and vegetables require the application of a quarantine treatment to mitigate pests that may pose a phytosanitary risk to US agriculture and natural resources. Irradiation is a viable option utilized for this purpose in some instances.

Click the links below for information to determine if an irradiation treatment is an option, and if applicable, the requirements to utilize irradiation treatments.

I want to use irradiation as a treatment to import a commodity. Where do I start?

Before a fresh fruit or vegetable becomes eligible for irradiation treatment into the U.S. it must first be approved for importation into the U.S. and listed in the Fruits and Vegetables Import Requirements Database (FAVIR). If a commodity is not listed in FAVIR then it is not currently eligible for entry and must be approved for importation via the Animal and Plant Health Inspection Service (APHIS) commodity import approval process. This process begins with a request from the Plant Protection Organization of the originating country. For more concerning the commodity import approval process, view the Commodity Import Request Process APHIS web page.

I checked FAVIR. The commodity is eligible for entry, but irradiation is not listed as an approved treatment. What do I do?

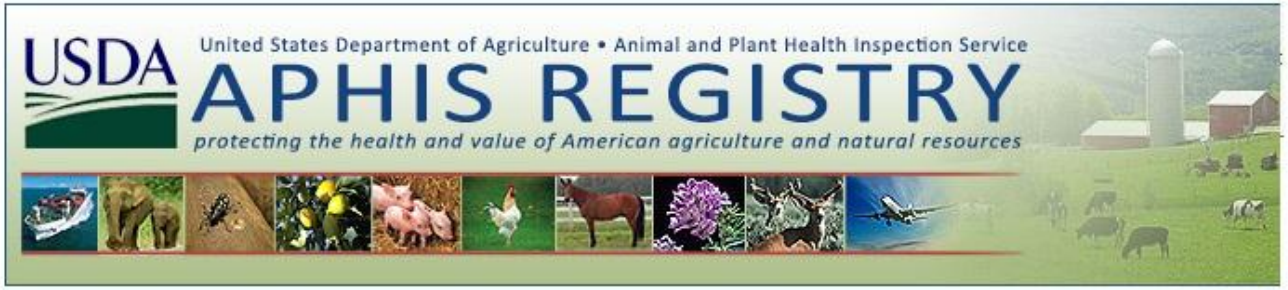
I checked FAVIR. The commodity is eligible for entry, and irradiation is an approved treatment. What are my options?

Are there non-phytosanitary import requirements that I should be aware of?

I am interested in having an irradiation facility certified by APHIS to apply quarantine treatments for fresh fruits and vegetables. Where can I get more information?

PPQ Stakeholder Registry

https://public.govdelivery.com/accounts/USDAAPHIS/subscriber/new



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PPQ Stakeholder Registry

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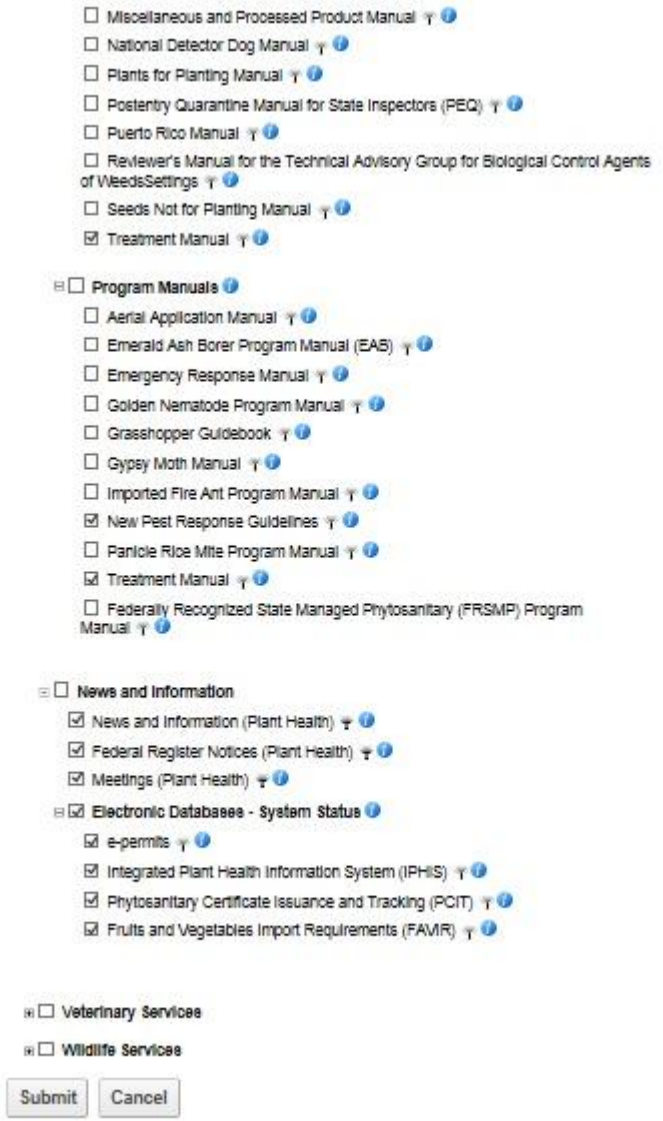
  - ☑ Importation into the US
  - ☑ Exportation from the US
  - ☑ Plant Health in the US (Domestic)
  - ☐ Manuals Updates
    - ☐ Import Inspection Manuals
      - ☑ Agricultural Quarantine Inspection Monitoring (AQIM) Handbook
      - ☐ Animal Product Manual
      - ☐ Canadian Border Agricultural Clearance Manual
      - ☐ CITES I-II-III Timber Species Manual
      - ☑ Cut Flowers and Greenery Import Manual
      - ☑ Export Program Manual (XPM)
      - ☐ Federally Recognized State Managed Phytosanitary (FRSMP) Program Manual
      - ☑ Fruits and Vegetables Import Requirements (FAVIR) database
      - ☑ Fresh Fruits and Vegetable Manual
      - ☑ Hawaii Manual
      - ☐ Japanese Beetle Program Manual for Airports
      - ☑ Manual for Agricultural Clearance
      - ☐ Mexican Border Job Aid



PPQ Stakeholder Registry

Final Thoughts and Questions

"Any policy is a success by sufficiently low standards and a failure by sufficiently high standards." -Thomas Sowell

EXHIBIT 11

Journal of Food Protection, Vol. 69, No. 7, 2006, Pages 1561–1564

Effect of X-Ray Irradiation on Reducing the Risk of Listeriosis in Ready-to-Eat Vacuum-Packaged Smoked Mullet†

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MS 05-536: Received 31 October 2005/Accepted 21 February 2006

ABSTRACT

Listeria monocytogenes can pose a serious threat in several areas of the nation's food supply including ready-to-eat seafood products. Use of irradiation processing can potentially reduce the risk of listeriosis caused by consumption of ready-to-eat seafood products. This study measured the effect of X-ray irradiation on reducing the population of *L. monocytogenes* on ready-to-eat, vacuum-packaged smoked mullet. Smoked mullet were inoculated with a five-strain mixture of *L. monocytogenes* (10^4 CFU/g), vacuum packaged, and irradiated (0, 0.5, 1.0, 1.5, and 2.0 kGy). The packaged fish were then stored at 3 and 10°C for 90 and 17 days, respectively. Radiation doses of 0.5, 1.0, and 1.5 kGy reduced the initial population of *L. monocytogenes* by 1.1, 1.6, and 2.1 log CFU/g, respectively. The 2.0-kGy dose reduced *L. monocytogenes* to undetectable levels with no recovery growth at either temperature. Compared to the control, irradiation at 1.5 kGy demonstrated 1.0 and 1.7 log CFU/g less growth at 3°C after 60 days and 10°C after 17 days, respectively. Sensory flavor analysis was conducted to determine if a difference existed between irradiated samples. Panelists indicated that there were no differences among treated and untreated samples. An X-ray dose of 2 kGy effectively eliminated 10^4 CFU/g *L. monocytogenes* on smoked mullet without changing sensory quality.

Ready-to-eat seafood products are a potential source of pathogens for the consumer *(7).* Pathogens may conceivably contaminate foods during processing or through cross contamination during regular handling and packaging. Among pathogens of concern, *Listeria monocytogenes* is widely distributed in nature and virtually contaminates every food source prior to harvest *(5, 12).* With the ubiquitous nature of this pathogen, it is routinely brought into food processing plants where it can be housed in equipment, on floors and walls, and form biofilms on direct food contact surfaces. Seafoods used to produce ready-to-eat products are among those exposed to *L. monocytogenes* prior to harvest and during processing, and thus are subject to being surface contaminated prior to packaging *(12, 13).* In the United States, contamination of domestic and imported seafoods with *L. monocytogenes* has been reported in 5 and 6% of the cases, respectively *(13).* The bacterium has been found on cooked shrimp, crabmeat, and surimi, and on hot- and cold-smoked fish, squid, eel, and mussels *(13).* Despite this occurrence, there have been few cases of listeriosis linked to the consumption of ready-to-eat seafood, none of which occurred in the United States *(10).* The bacterium has been linked to a case of listeriosis in New Zealand due to consumption of smoked mussels *(13)* and to an outbreak of febrile gastroenteritis in Finland caused by consumption of cold-smoked rainbow trout *(10).* Smoked seafood is considered the sixth riskiest food category in terms of relative risk for causing listeriosis in intermediate-aged individuals *(10).*

With the potential for *L. monocytogenes* contamination in ready-to-eat smoked fish, it is imperative to investigate methods to reduce the risk of infection. One of the newest technologies available to food researchers and ultimately to food processors is a high-intensity food-grade X-ray irradiator. Irradiation food processing has typically focused on inactivation of foodborne pathogens in a variety of food products. These processes (high-energy electron beams or gamma rays) have been available for some time but have met with consumer reluctance to embrace the technology. Because consumers are familiar with medical X rays there is hope that X-ray–treated foods would meet with more enthusiasm. X-ray food irradiation has not been widely studied to establish dose levels that control pathogens while maintaining sensory qualities acceptable to consumers *(9).*

With the exception of raw molluscan shellfish *(19),* seafood products are not currently approved for commercial irradiation in the United States. However, studies have shown that ionizing radiation levels of 1 to 3 kGy are most commonly utilized for shelf-life extension and pathogen reduction *(1, 2, 17, 18).* The effectiveness of irradiation on *L. monocytogenes* varies depending on several factors such as the strain, substrate, irradiation type and dose, and plating medium *(3, 4, 8).* Therefore, many studies have produced conflicting results. Savvaidis et al. *(18)* demonstrated

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that the growth of *L. monocytogenes* in vacuum-packaged trout was suppressed by 0.7 and 2 log CFU/g by irradiation at 0.5 and 2 kGy, respectively, when stored at 4°C for 18 days. In the same study, *L. monocytogenes* was suppressed by 0.9 and 2 log CFU/g at 0.5 and 2 kGy at 10°C. Other studies have demonstrated that *L. monocytogenes* can be effectively eliminated with doses as low as 2 kGy when initial inoculum levels were below 10^4 CFU/g *(2, 4, 11).* Others, however, have shown that greater inoculum levels of *L. monocytogenes* can recover and proliferate at the same dose *(3).* Andrews et al. *(4)* reported that a 10^3-CFU/ml population of *L. monocytogenes* suspended in tryptic soy broth could be inactivated with a dose of 2 kGy. Due to high water activity ($a_w > 0.95$) and lack of competitive chemical activity or bacteria, broth media provides better conditions for irradiation inactivation than solid foods *(4).* On the other hand, irradiation is less efficient in dry foods such as smoked fish *(1).*

The commercial success of irradiated foods depends greatly on consumer satisfaction of sensory quality. Several studies have examined the sensory quality of a variety of irradiated seafoods, focusing on attributes such as appearance, odor, and taste *(1, 6, 16–18).* However, few studies have focused on the effect of irradiation on smoked fish sensory quality. While there are many types of sensory evaluation tests that can be utilized when evaluating seafood, the present study used the difference-from-control test. The difference-from-control test determines whether a difference exists between control and test samples and also estimates the magnitude of difference. With this test, panelists are presented with a control sample plus one or more test samples. Panelists are asked to rate the magnitude of difference between each sample and the control on a provided scale *(15).*

The objectives of this research were to evaluate the effects of X-ray radiation dose on the reduction of *L. monocytogenes* in ready-to-eat smoked mullet and to evaluate the sensory quality of the smoked fish following X-ray processing.

MATERIALS AND METHODS

Smoked mullet. Approximately 10 kg of fresh mullet (*Mugil cephalus*) was obtained from commercial harvesting vessels in Pascagoula (Mississippi) and held on ice prior to use. Individual mullet, weighing approximately 0.23 to 0.34 kg, were deheaded, gutted, and butterflied by hand. The fish were washed, soaked in a 10% salt solution for 4 h, rinsed, and draped on racks belly up in a smoker. Salted fish were hot smoked (82 to 85°C) using hickory wood in 9 to 13.5 kg batches for 4.5 to 5 h *(14),* resulting in a muscle pH of 5.5 and a_w of 0.87. The pH was measured using a probe-type pH meter (Orion 290A, Orion Research Inc., Boston, Mass.). Water activity was measured using an electric hygrometer (thermoconstanter TH200, Novasina AG, Zurich, Switzerland). The smoked fish were frozen at −20°C until used and thawed at 4°C for 24 h prior to use.

Preparation of inoculum. *L. monocytogenes* strains ATCC 15313, 51414, 43256, 19115, and 7644 (American Type Culture Collection, Manassas, Va.) were used to make a cocktail for inoculation. Frozen stock cultures of each of the five strains were individually inoculated into 200 ml of Trypticase soy broth with 0.6% yeast extract (Becton Dickinson, Sparks, Md.) and grown overnight at 28°C. After incubation, 2 ml of each strain was added to a single sterile test tube and vortexed for 10 s, creating a five-strain 10-ml cocktail of approximately 10^8 CFU/ml. One milliliter of this cocktail was then diluted into 9.0 ml phosphate-buffered saline (0.01 M PBS; Sigma, St. Louis, Mo.), producing approximately 10^7 CFU/ml. Two milliliters of this inoculum was distributed into 2.5 liters of PBS, producing an immersion solution of approximately 10^4 CFU/ml *L. monocytogenes.*

Inoculation of smoked mullet. The frozen smoked mullet was thawed overnight at 4°C. Under aseptic conditions, the mullet was aseptically broken by gloved hands into approximately 20-g pieces under a laminar flow hood. A total of 950 g of smoked mullet pieces was then placed into each of two sterile 3-liter steamer baskets (Progressive International, Kent, Wash.). One basket was placed in a control bucket containing only 2.5 liters of sterile PBS, while the other basket was placed in a bucket containing 2.5 liters of PBS containing 10^4 CFU/ml *L. monocytogenes.* The baskets remained in the two solutions under constant agitation by hand. After 5 min, the baskets containing smoked fish were removed and allowed to drain on sterile paper towels for 10 min. After the inoculation procedure, the pH of the smoked mullet remained at 5.5 while the a_w dropped slightly to 0.86. Due to case hardening after smoking, it was not unexpected that the smoked fish pH and a_w values remained unchanged after immersion inoculation.

Packaging. Cryovac (Duncan, S.C.) B2650 bags (20.3 by 16.5 cm) possessing water vapor transmission properties of 0.5 to 0.6 g/254 cm^2 at 37.8°C, 100% relative humidity per 24 h, and oxygen transmission properties of 3 to 6 ml/m^2/24 h at 4.4°C were used to package the smoked mullet. Aseptically, 20 g of inoculated smoked mullet pieces was transferred to the bags. The bags were then vacuum sealed (Multivac model A300/16, Kansas City, Mo.) at 999 mbar vacuum for 1 s with a 2.5-s seal.

Irradiation. Three replications of vacuum-packaged smoked mullet were irradiated on separate days using an RS 2000 X-ray irradiator (Rad-Source Technologies, Boca Raton, Fla.). The fish, surrounded by ice packs, were irradiated at approximately 3°C in batches of 240 g at five different dosage levels (0, 0.5, 1.0, 1.5, and 2.0 kGy). This was achieved at a rate of 1 kGy/50 min. Irradiator operating conditions were at 145 kV with 19 mA. Dose rate from top to bottom of chamber was 20.1 (top), 26.3 (middle), and 20.0 (bottom) Gy/min. Calculations for time of exposure were based on the maximum time to achieve the desired dose rate. Calibration was achieved by placing an Inovision model 451P calibration dosimeter (Cardinal Health Inc., Cleveland, Ohio) in different places throughout the X-ray chamber.

Bacterial enumeration. The irradiated vacuum-packaged smoked mullet were stored at two separate temperatures of 3 and 10°C. The fish stored at 3°C were analyzed monthly for three months, while the fish stored at 10°C were analyzed biweekly for 17 days. Microbial analyses included aerobic plate counts, psychrotrophic plate counts, and *L. monocytogenes* plate counts. Samples were diluted 1:1 wt/vol in PBS in stomacher bags and homogenized for 30 s using a stomacher (Tekmar, STO-400, Cincinnati, Ohio). Serial dilutions of the homogenized fish were made in PBS and plated onto duplicate modified Oxford agar (MOX; Becton Dickinson) and quadruplicate plate count agar (PCA; Becton Dickinson) utilizing a model D spiral plater (Spiral Biotech, Norwood, Mass.). The MOX plates were incubated at 32°C for 48 h to allow for growth of *L. monocytogenes* colonies. Two PCA plates per sample were incubated at 32°C for 48 h to allow for

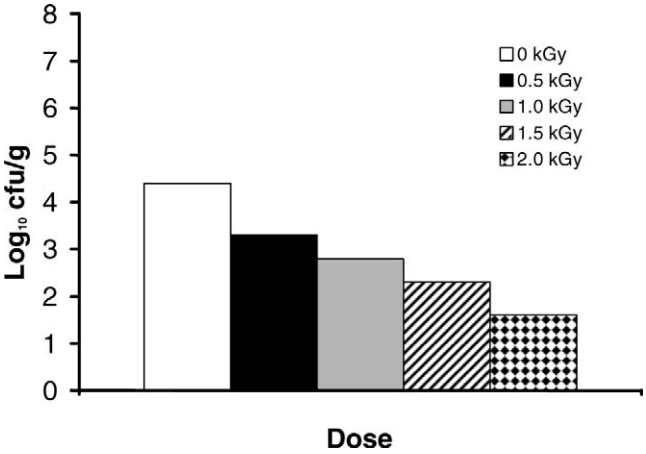

FIGURE 1. *Effect of radiation dose on the initial population of* L. monocytogenes *on vacuum-packaged smoked mullet stored at 3 and 10°C.*

growth of aerobic bacteria and two PCA plates were incubated at 7°C for 10 days to allow for the growth of psychrotrophic bacteria. All plates were counted using the procedures described in the model D spiral plater manual.

Sensory analysis. Uninoculated irradiated smoked fish samples (10 kg) were vacuum packaged as previously described and stored for 1 week at 3°C. After storage, wearing sterile gloves, the fish were removed from the package and broken into approximately 28-g pieces. The fish were immediately served to panelists in small plastic cups appropriately coded with a random three-digit number. An untrained panel of 45 people, including faculty, staff, and students from the Department of Food Science, Nutrition, and Health Promotion at Mississippi State University were each presented a control sample (0 kGy) plus five test samples (0, 0.5, 1.0, 1.5, and 2.0 kGy). Each panelist was given a scale and asked to rate the magnitude of difference between each sample and the control *(15).* On the scale, there were five degrees of difference (none, slight, moderate, much, and extreme), where 0 indicated ''none'' or no difference and 4 indicated ''extreme'' or extreme difference. The fish were evaluated for flavor quality based on the degree of difference from the control.

Statistical analysis. A 2×5 factorial design with three replications was used to test the effects ($P < 0.05$) of storage temperature, radiation dose, and temperature $\times$ radiation dose interaction on *L. monocytogenes,* aerobic bacteria, and psychrotrophic bacteria populations (general linear methods [GLM] procedure, SAS version 8.2; SAS, Cary, N.C.). Duncan's multiple range test (SAS) was utilized to separate treatment means when differences ($P < 0.05$) occurred among treatments.

For sensory analysis, a randomized complete block design with three replications was utilized to determine differences ($P < 0.05$) in fish due to radiation dose level (GLM, SAS).

RESULTS AND DISCUSSION

Effect on *L. monocytogenes*. The effect of irradiation on the growth of *L. monocytogenes* in vacuum-packaged smoked mullet at 3 and 10°C is shown in Figures 1 through 3. Results for aerobic plate count and psychrotrophic plate count are not shown due to lack of a significant difference from *L. monocytogenes* counts, which means that these counts were exclusively due to the inoculated *L. monocytogenes.* In addition, control samples that were not inoculated had no *L. monocytogenes* growth, indicating that no *L. monocytogenes* was present in the smoked mullet before use.

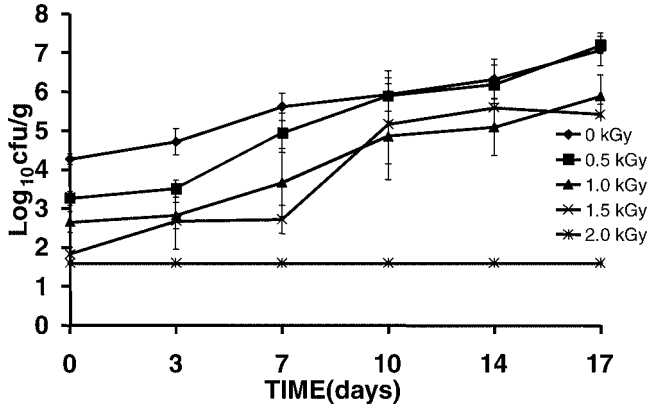

FIGURE 2. *Effect of radiation dose on the growth of* L. monocytogenes *on vacuum-packaged smoked mullet stored at 3°C.*

The initial population of *L. monocytogenes* in the inoculated, untreated control sample (0 kGy) had a mean value of 4.4 log CFU/g at 3 and 10°C. Figure 1 displays the effect of radiation dose on the initial population of *L. monocytogenes* in vacuum-packaged smoked mullet. Radiation levels of 0.5, 1.0, and 1.5 kGy reduced the initial population of *L. monocytogenes* by 1.1, 1.6, and 2.1 log CFU/g, respectively. However, 2.0 kGy proved to be the most effective ($P \leq 0.05$) by reducing *L. monocytogenes* below levels of detection (1.6 log CFU/g). As demonstrated in Figures 2 and 3, samples treated with 2.0 kGy supported no *L. monocytogenes* growth during storage at 3 and 10°C.

These results are similar to those of Andrews and Grodner *(2),* who demonstrated that 2 kGy of gamma radiation was sufficient to eliminate 10^4 CFU/g *L. monocytogenes* on crawfish tail meat, while further suppressing growth at 4°C. They also found that *L. monocytogenes* was able to recover and grow when irradiated at levels less than 2.0 kGy. Foong et al. *(8)* obtained similar results in reducing *L. monocytogenes* on vacuum packaged smoked turkey. In their study, 25 g of smoked turkey was inoculated with approximately 10^5 CFU/g *L. monocytogenes,* vacuum packed, and stored at 4°C for 24 h prior to irradiation. Us-

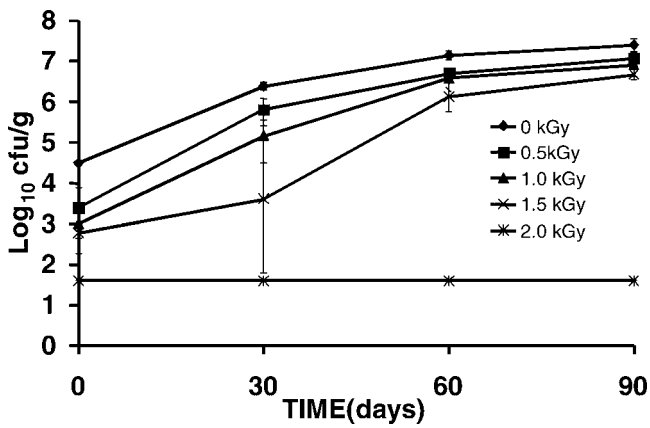

FIGURE 3. *Effect of radiation dose on the growth of* L. monocytogenes *on vacuum-packaged smoked mullet stored at 10°C.*

ing an electron beam source, a 3-log CFU/g reduction of *L. monocytogenes* was attained at 1.5 kGy and a 5-log CFU/g reduction was obtained with 2.5 kGy. Foong et al. *(8)* also studied the survival and growth of *L. monocytogenes* on select ready-to-eat meats after irradiation at 2 and 4 kGy and storage at 4 and 10°C for 12 weeks. A dose of 2 kGy successfully reduced the numbers of *L. monocytogenes* and suppressed the growth of the bacterium for about five weeks at 4°C. However, after 5 weeks of storage, numbers began to increase. At 10°C, numbers increased much faster. On the other hand, no survivors were observed for samples irradiated at 4 kGy at either temperature over the entire 12 week storage period *(8).*

Effect on smoked mullet flavor. Results of the sensory difference from control study were interesting. Ironically, the panelists found the untreated sample (0 kGy) to be most different from the control (0 kGy) with a mean score of 1.9, followed by 1.5 kGy, 2.0 kGy, and 1.0 kGy. The sample found least different from the control by the panelists was the sample treated with 0.5 kGy with a mean score of 1.2. Because none of these differences were statistically significant, these results clearly indicate that the panelists were unable to differentiate irradiated from nonirradiated samples. According to the panelists' comments, the most common difference between the fish samples was the degree of smoke flavor. This suggests that the small difference in samples was most likely caused by variations in smoke deposition and not by irradiation.

In summary, X-ray irradiation proved to be an effective treatment to control *L. monocytogenes* on smoked mullet without adversely affecting sensory quality. Doses of 2 kGy appear to be effective to eliminate 10^4 CFU/g levels of *L. monocytogenes.*

ACKNOWLEDGMENTS

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EXHIBIT 12

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Reduction of *Vibrio vulnificus* in pure culture, half shell and whole shell oysters (*Crassostrea virginica*) by X-ray☆

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ABSTRACT

The purpose of this investigation was to study the inactivation effect of X-ray treatments on inoculated *Vibrio vulnificus* in pure culture, half shell and whole shell oysters to achieve a 5.0 log reduction, which is recommended by the Interstate Shellfish Sanitation Conference and the Food and Drug Administration. A mixed culture of three *V. vulnificus* strains was used to prepare the pure culture and inoculated oysters. The pure culture and inoculated oysters were treated with 0.0, 0.1, 0.5, 0.75, 1.0, 1.5, 2.0, and 3.0 kGy X-ray at 22 °C and 50–60% relative humidity. Surviving bacterial populations in the pure culture and inoculated oysters were enumerated using overlay-plating method [with a non-selective media (trypticase soy agar) followed by a selective medium (Modified Cellobiose-Polymyxin B-Colistin) and most probable number (MPN) method. Greater than a 6-log reduction of *V. vulnificus* was achieved with 0.75, 1.0 3.0 kGy X-ray in pure culture, half shell and whole shell oysters, respectively. Treatment with 0.75 kGy X-ray significantly ($p<0.05$) reduced the inherent microorganisms in half shell oysters, to less than the detectable limit (<1 log CFU/g). The maximum dose (3.0 kGy) of X-ray treatment did not affect the survivability of live oysters.

1. Introduction

The U.S. oyster industry produced approximately 16 million kg of oysters with value of $ 126.9 million in 2007. The Gulf of Mexico region led in oyster landings with 63% of the national total; the Coastal Gulf of the State of Mississippi on the Gulf of Mexico traditionally has a commercial oyster industry with an economic impact of approximately $20 million annually (NOAA, 2007).

Eating raw oysters is popular among the consumers worldwide (DePaola et al., 1983; Gelli et al., 2001; Lopez-Caballero et al., 2000; Kural and Chen, 2008). However, raw oysters can serve as vehicles for many foodborne pathogenic microorganisms including *Vibrio* (Kelly and Dinuzzo, 1985; Ruple and Cook, 1992; Altekruse et al., 1999; Feldhusen, 2000; Levine and Griffin, 1993; Oliver, 1989; National Academy of Sciences, 1991; Wright et al., 1986; Kaysner et al., 1987; Hoi et al., 1998; Shapiro et al., 1998). Seafood, including oysters, was the first leading vehicle in foodborne disease outbreaks, accounting for 488 outbreaks between 1998 and 2002 (CDC, 2006). Oysters filter large volume of seawater during their feeding activities that concentrate bacteria such as *Vibrio* spp. in their body (Calci et al., 2005; Cliver, 1995; Olafsen et al., 1993; Hartland and Timoney, 1979). The presence of the pathogens in oysters has a serious impact on public health and international trade (Ristori et al., 2007). The US Public Health Service estimated that 6.5–81 million cases of diarrhoeal diseases with approximate 9000 deaths occur in the US each year due to pathogenic bacteria including *Vibrio* spp. (Lee, 1994).

V. vulnificus is a gram-negative bacterium, occurring naturally in warm estuarine environments, such as the Gulf Coast water where the majority of the US oysters are harvested (Azanza et al., 1996; Kilgen and Hemard, 1996; Andrews, 2004; Cook et al., 2002; Oliver, 2005; Wirth and Minton, 2004). *V. vulnificus* was first described as a cause of human illness in 1979 (Blake et al., 1979; Oliver, 1989). It is the leading causes of foodborne illness associated with the consumption of raw oysters in the United States (Mead et al., 1999; Ulusarac and Carter, 2004). *V. vulnificus* has the highest fatality rate (40–50%) among food-borne pathogens in the United States (Shapiro et al., 1998; Kural and Chen, 2008; Linkous and Oliver, 1999; Mead et al., 1999). *V. vulnificus* can cause death to individuals with underlying diseases especially liver disease (Oliver, 1989; CDC, 1993; Kilgen and Hemard, 1996). The CDC estimated that 8028 *Vibrio* infections occur annually in the US (Mead et al., 1999). No outbreaks-associated illnesses of *V. vulnificus* have been documented except for cases of sporadic illness. The CDC estimates 47 foodborne illnesses of *V. vulnificus* yearly in the U.S., with 18 deaths (Tajkarimi, 2007).

In the last decade, several post-harvest techniques have been proposed to reduce *V. vulnificus* and *Vibrio parahaemolyticus* in live and processed oysters. These techniques included cold treatments (Ruple and Cook, 1992; Cook and Ruple, 1992; Kilgen and Hemard, 1996; Melody et al., 2008), high temperature (Hesselman et al., 1999), vacuum packaging (Parker et al., 1994), UV treatments (Tamplin and Capers, 1992), electrolyzed water (Ren and Su, 2006) and high-pressure treatments

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(Calik et al., 2002; Cook, 2003). Most of these techniques have low log reduction on *V. vulnificus* and/or kill oysters. Therefore, to improve the safety and quality of oyster, highly effective new technologies are needed to meet consumers' demands and to be suitable for the oyster industry. The standard set by the ISSC and FDA is a 5-log reduction of *V. vulnificus* (FDA, 1995; Kural and Chen, 2008; Cook, 2003).

The US Food and Drug Administration has approved ionizing radiation for many foods including seafood (IAEA, 1995; Henkel, 1998). Irradiation is particularly valuable as an endproduct decontamination procedure (Andrews et al., 2003). Radiation can effectively eliminate potentially pathogenic bacteria on food products (Farkas, 1998). X-ray is a novel technology for seafood decontamination, which has not yet been thoroughly studied (Mahmoud and Burrage, in press). The RS 2400 (Rad Source Technologies Inc.), which produces X-radiation at energy of 5 MeV, was used in this study. The RS 2400 is a food-grade X-ray irradiator alternative to the gamma ray irradiator for decontamination of oysters. The objective of this investigation was to establish the X-ray dose needed to reduce *V. vulnificus* by 5-log reduction in half shell and whole shell live oysters.

2. Materials and methods

2.1. Oysters (Crassostrea virginica)

Live, freshly harvested Atlantic oysters (*C. virginica*) were obtained from Seafood Market (Desporte & Sons, Biloxi, MS) and transported immediately in a cooler with cubed ice to the MSU Experimental Seafood Processing Laboratory in Pascagoula, MS. The oysters were washed with tap water to remove mud from the shells and acclimated to warm conditions (25 °C) in polyethylene tank (249 by 130 by 29 cm) containing recirculating artificial seawater (salinity, 18–20 ppt) until use.

2.2. Bacterial strains and growing conditions

A cocktail of three *V. vulnificus* strains (ATCC 27562, AF 1053-08 and AF 1056-08) was used. The last two strains were kindly provided by Dr. Darrell Jay Grimes, Gulf Coast Research Laboratory, (GCRL), University of Southern Mississippi. Each bacterial culture was grown in trypticase soy broth with 1% NaCl (TSB-1% NaCl) and incubated at 37 °C for 18–24 h with continuous agitation (100 rpm) on a MaxQ 2000 platform shaker (Barnstead Lab-line, Melrose, IL, USA). The cultures were streaked onto individual plates of trypticase soy agar (Difco, Becton Dickinson, Sparks, MD) supplemented with 1.0% NaCl (TSA-1% NaCl) and incubated at 37 °C for 18 to 24 h. A single colony was selected from the TSA-1% NaCl plate and enriched in TSB-1% NaCl at 37 °C for 18–24 h (approximately 10^{7-8} CFU/ml).

2.3. Preparation of pure culture and inoculated oysters

a) Pure culture: Each bacterial strain culture was centrifuged at 1100 ×g (BD 420104 Dynac III Centrifuge, Aria Medical Equipment, San Antonio, TX) for 10 min. The supernatant was discarded and the cell pellet was washed and resuspended in 10 ml sterile alkaline peptone water (APW). The three strains of *V. vulnificus* were then combined at an equal volume to produce a culture cocktail of approximately 107–8 CFU/ml.
b) Oysters: Oysters were transferred from the main polyethylene tank (in pilot plant) to laboratory polyethylene tank (33 by 21.6 by 25.4 cm) containing recirculating 10 litter of artificial seawater (salinity, 18–20 ppt) and containing *V. vulnificus* culture (approximately, 10^{7-8} CFU/ml) at room temperature (20–22 °C) for 12–18 h before X-ray treatments.

2.4. Description of RS 2400 radiator and generation of X-ray

Specific irradiation dose (0.1, 0.5, 0.75, 1.0, 1.5, 2.0 and 3.0 kGy) were generated using the RS 2400 (Rad Source Technologies, 2007). The RS 2400 is an industrial cabinet X-ray irradiator. The total dimensions of the cabinet are 160 cm by 78.7 cm by 76.2 cm. The dimensions of exposure chamber are 91.4 cm by 60.0 cm by 63.5 cm. The RS 2400 irradiator requires 208-volt AC, three-phase, 50/60 Hz, 40-amp input. The operating range of the X-ray tube varies from 25 to 150 kV and 2 to 45 mA. The X-ray generating tube consists of a tungsten filament running down the center of a 10.2 cm diameter stainless steel cylinder. This is housed within a larger 11.4 cm diameter stainless steel cylinder. A layer of gold, 12 μm thick, is plated inside the inner cylinder. As the tungsten filament is heated, electrons are released from the surface. At higher currents (mA), more electrons leave the filament. An electric potential difference (kV) is applied between the filament and the inner tube, attracting the electrons toward the inner tube. A vacuum is drawn between the filament and the inner tube so the electrons do not interact with gas molecules. The electrons gather energy equal to the potential difference; the higher the potential difference, the more energy the electrons gather. When the electrons reach the gold target plated inside the inner tube, they interact with the gold atoms and emit photons called X-rays. The X-ray doses in the treatment chamber were determined using dosimeter (Rad Sources Technology. Inc., GA).

2.5. Treatment of pure culture and inoculated oysters with X-ray

a) Pure culture: Four glass tubes (16×150 mm), each containing 5.0 ml of the suspension of *V. vulnificus*, were prepared as mentioned above. Two of the tubes were used to determine the initial numbers of viable cells (control). The other two tubes were placed in the canister (in this study, the canister was cut in the center to two parts and placed close to the X-ray tube to increase the exposure doses from 37 Gy for the normal whole canister to 63 Gy min^{-1} for the half canister) and irradiated with 0.0, 0.1, 0.5, and 0.75, kGy X-ray.
b) Oyster: Four half shell and four whole shell oysters (7–9 cm length, 20–25 g meat) were used. Two of each of the oyster types were used to determine the initial numbers of viable cells (control) before exposure to X-ray. The other two oysters were placed in the canister (half canister was used as above) inside the exposure chamber and treated with different doses of X-ray (0.0, 0.1, 0.5, 0.75, 1.0, 1.5, 2.0, and 3.0 kGy).

2.6. Microbial enumeration

a) Pure culture: At each examined dose, two tubes of pure culture were removed from the exposure chamber. Serial 10-fold dilutions were prepared in APW. Bacterial populations were enumerated using overlay plating method in brief; 0.1 ml of the dilutions were spread plated onto TSA-1.0%NaCl agar plates and incubated at 37 °C for 4–6 h (to resuscitate injured cells). Then a layer of selective agar (mCPC) was poured on the top of the resuscitated cells and incubated for another 18–20 h. Colonies were counted and results expressed as log CFU/ml. And by the three tubes MPN Method, all sample dilutions were individually inoculated into three tubes of APW. Serial 10-fold dilutions were prepared in APW. Inoculated APW tubes were incubated at 35–37 °C for 18 h and one loopful of enriched APW from the top 1.0 cm of a turbid tube was streaked onto individual mCPC for *V. vulnificus* detection. All plates were incubated at 37 °C for 24 h. Formation of colonies that are round (2–3 mm diameter) and yellow on mCPC are considered positive for *V. vulnificus*. Results were expressed by converting numbers of APW tubes that were positive for *V. vulnificus* to log MPN/ml, using an MPN table.
b) Oysters: At each examined dose, two half shell and two whole shell oysters were removed from the exposure chamber. Whole and half

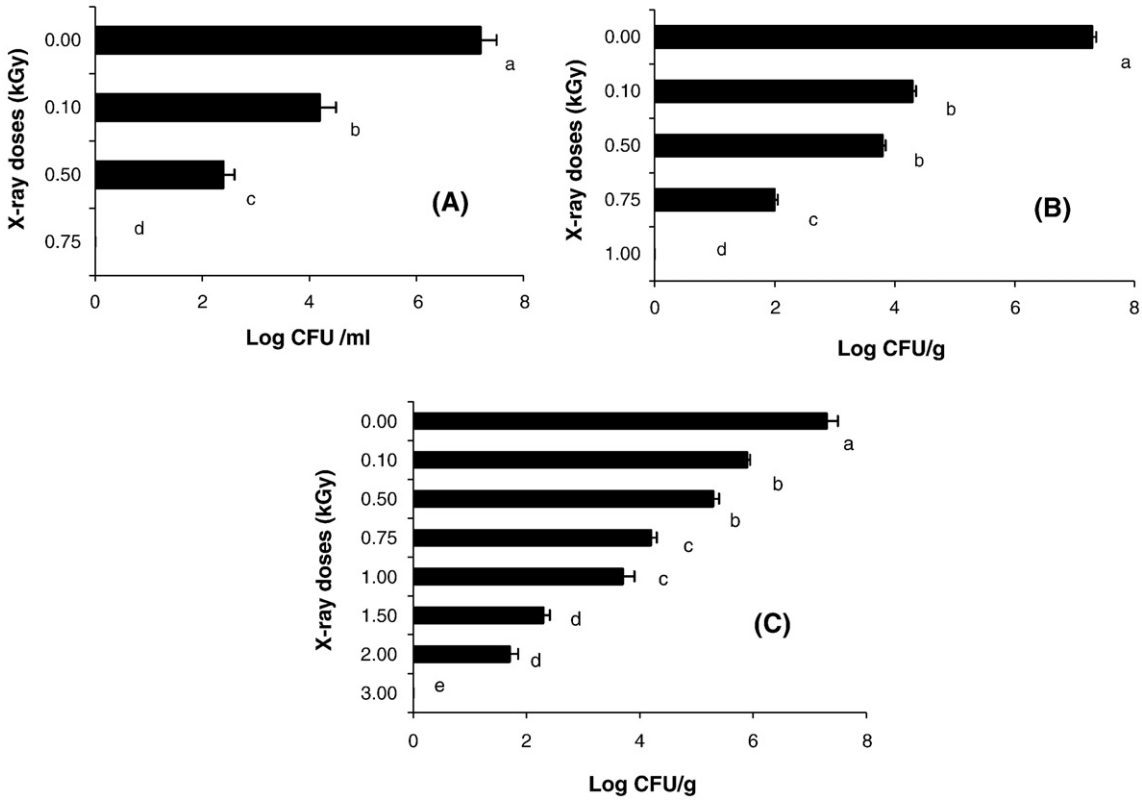

Fig. 1. Effect of X-ray doses on *V. vulnificus* inoculated in pure culture (A), half shell oysters (B) and whole shell oysters (C).

shell oysters were shucked with a sterile shucking knife in a sterile tray. 25.0 g of shucked oyster meat was placed in a sterile Whirl-Pak bag, followed by addition of 225 ml of sterile APW. The oyster samples were homogenized for 2 min using a Stomacher 80 Lab-blender. Serial 10-fold dilutions were prepared in APW. Bacterial populations were enumerated using overlay-plating method (as above). Colonies were counted and results expressed as log CFU/g, and by three tube MPN Methods (as above) and results expressed as log MPN/g.

2.7. Effect of X-ray on the inherent microflora on oysters

Five non-inoculated half shell oysters were exposed to same X-ray doses as above. Oysters were shucked using a sterile shucking knife in a sterile tray. Then 10 g of shucked oysters meat was homogenized in 90 ml peptone water for 2 min using a Stomacher 80 Lab-blender. Serial dilutions were prepared and 100 µl of each dilution were spread on TSA plates and incubated at 37 °C for 48 h.

2.8. Evaluation of X-ray treatment on the survivability of oysters

Non-inoculated live oysters were exposed to different doses of X-ray (0.1–3 kGy) to test the lethality of X-ray treatment. Live irradiated oysters were kept at the refrigerator temperature (5 °C) for up to 7 days, and their survival was determined daily. The survivability of treated oysters was determined on the basis of difficulty to open the valves during storage.

2.9. Statistical analysis

All experiments were replicated three times using two samples per experiment for a total of six data points per treatment. Data were pooled and the mean values and standard deviations were determined and a Student's *t*-test (Microsoft Excel; Microsoft Windows XP) was used to compare significant differences between samples which considered to be significant differences when $p<0.05$.

3. Results

3.1. Inactivation of V. vulnificus in pure culture

The population of *V. vulnificus* was significantly ($p<0.05$) reduced from 7.2±0.3 to 4.2±0.3, and 2.4±0.2, log CFU/ml after treatment with 0.1, and 0.5 kGy X-ray, respectively (Fig. 1A). Exposure to 0.75 kGy X-ray reduced the population of *V. vulnificus* in pure culture to below the detection limit (<1.0 log/ml). Meanwhile, treatment with 0.75 kGy X-ray significantly ($p<0.05$) decreased the MPN of *V. vulnificus* in pure culture from 7.0±0.0 to <0.5 log MPN ml^{-1} (Table 1).

Table 1
Effect of X-ray doses on *V. vulnificus* (log MPN/g or ml) inoculated in pure culture, half and whole shell oysters

	Initial counts	0.1 kGy	0.5 kGy	0.75 kGy	1.0 kGy	1.5 kGy	2.0 kGy	3.0 kGy
Whole shell	7.0±0.0A	5.7±0.6B	5.0±0.0B	4.5±0.2C	3.8±0.0C	2.5±0.5D	2.0±0.0D	<0.5±0.0E
Half shell	7.0±0.0A	4.8±0.2B	2.8±0.2C	2.1±0.2C	<0.5±0.0D	–	–	–
Pure culture	7.0±0.0A	2.5±0.4B	2.2±0.3B	<0.5±0.0C	–	–	–	–

Data are the means of 6 determinations±SD. Mean values with different letters in the same row are significantly different $p<0.05$).

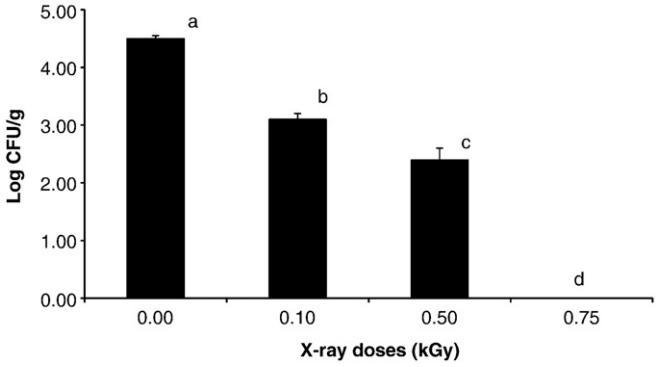

Fig. 2. Effect of X-ray doses on the inherent microflora on half shell oysters.

3.2. Inactivation of V. vulnificus in half shell oysters

The population of *V. vulnificus* was significantly ($p<0.05$) decreased from 7.3±0.06 to 4.3±0.05, 3.8±0.05, and 2.0±0.06 log CFU/g after treatment with 0.1, 0.5, and 0.75 kGy X-ray, respectively (Fig. 1B). Treatment with 1.0 kGy X-ray reduced the population of *V. vulnificus* in half shell oysters to undetectable limit (<1.0 log CFU/g). Furthermore, treatment of inoculated *V. vulnificus* in half shell oysters with 1.0 kGy X-ray significantly ($p<0.05$) reduced the MPN from 7.0±0.0 to <0.5 log MPN/g (Table 1).

3.3. Inactivation of V. vulnificus in whole shell oysters

The population of *V. vulnificus* was significantly ($p<0.05$) reduced in whole shell oysters from 7.0±0.2 to 5.9±0.05, 5.3±0.1, 4.2±0.1, 3.7±0.2, 2.3±0.1 and 1.7±0.15 log CFU g^{-1} after treatment with 0.1, 0.5, 0.75, 1.0,1.5 and 2.0 kGy X-ray, respectively (Fig. 1C). Treatment with 3.0 kGy X-ray reduced the population of *V. vulnificus* in whole shell oysters to undetectable limit (<1.0 log/g). Furthermore, treatment of inoculated *V. vulnificus* in whole shell oysters with 3.0 kGy X-ray significantly ($p<0.05$) reduced the MPN from 7.0±0.0 to <0.5 log MPN/g (Table 1).

3.4. Effect of treatment with X-ray doses on the inherent microflora in half shell oysters

Changes in the microflora in half shell oysters after treatment with 0.0, 0.1, 0.5, and 0.75 kGy X-ray are shown in Fig. 2. Treatment with 0.1, 0.5 and 0.75 kGy significantly ($p<0.05$) reduced the total microbial counts in half shell oysters from 4.7±0.2 to 3.1±0.1, 2.4±0.2 and <1.0 log CFU/g, respectively.

3.5. Evaluation of X-ray treatment on the survivability of oysters

The survivability of live oysters was not affected after treatment with X-ray and during storage at refrigerator temperature (5 °C) for up to 7 days. The survivability of treated oysters was determined daily on the basis of difficulty to open the valves during storage.

4. Discussion

It is important for the industry to identify effective sanitation processes for pathogenic bacteria on oysters that lead to achieve a 5 log CFU reduction, as recommended by the Interstate Shellfish Sanitation Conference, ISSC (Cook, 2003: Kural and Chen, 2008). Consumers demand safe, minimally processed fresh-like characteristics of oysters that led us to use ionizing irradiation. X-ray irradiation is an alternative that has certain advantages over other current approved ionizing irradiation used in the food industry, such as gamma rays. The X-ray irradiator does not have a radioactive source (Janatpour et al., 2005). In this investigation we used X-ray as a new technology to replace other current technologies including the gamma ray for the oysters industry.

The inactivation effect of X-ray on *V. vulnificus* increased with increasing X-ray doses, as expected. The X-ray doses needed to reduce the population of *V. vulnificus* in whole shell oysters was higher than those needed in pure culture and half shell oysters because the oyster shells were found to reduce the maximum deliverable dose rate by about 35% (Mahmoud and Burrage, in press). The populations of *V. vulnificus* were significantly reduced by 3.0, 2.7 and 1.4 log CFU ml^{-1}/g^{-1} after treatment with 0.1 kGy X-ray for pure culture, half shell and whole shell oysters, respectively. The populations of *V. vulnificus* in pure culture, half shell and whole shell oysters were significantly reduced to undetectable limit (<1 log CFU/ml or g) after treatment with 0.75, 1.0 and 3.0 kGy X-ray, respectively. The populations of *V. vulnificus* were significantly reduced by 4.5, 2.2 and 1.3 log MPN/ml or g after treatment with 0.1 kGy X-ray for pure culture, half shell and whole shell oysters, respectively. The reduction of *V. vulnificus* increased by increasing the exposure doses, the MPN reduced from 7.0 log to <0.5 log MPN/ml or g after treatment with 0.75, 1.0 and 3.0 kGy for pure culture, half shell and whole shell oysters, respectively. These results are in the same trend as those obtained by (Mahmoud and Burrage, in press) who reported that a greater than a 6.0 log reduction of *V. parahaemolyticus* was observed with 1.0, 2.0 and 5.0 kGy X-ray for pure culture, half shell and whole shell oysters, respectively. Also, these results are in agreement with those obtained by Anderws et al. (2003) who found that 1.0 kGy gamma irradiation reduced *V. vulnificus* population on oyster meat by more than 3 log reduction. A radiation dose of 1 kGy is adequate to eliminate *V. vulnificus* in oysters (Mallett et al., 1991). Jakabi et al. (2003) have reported that 3.0 kGy gamma ray delivers a 5-log reduction in *Vibrio* spp. in unshucked oysters.

In this study *V. vulnificus* was found to be more sensitive to X-ray treatment than *V. parahaemolyticus* as determined in a previous study by Mahmoud and Burrage (in press). The doses needed to reduce the population of *V. vulnificus* in pure culture, half shell and whole shell oysters to undetectable limit (<10 CFU/ml or g) were achieved with 0.75, 1.0 3.0 kGy X-ray, respectively. The doses needed to reduce the population of *V. parahaemolyticus* in pure culture, half shell and whole shell oysters to undetectable limit (<10 CFU/ml or g) were achieved with 1.0, 2.0 and 5.0 kGy X-ray, respectively (Mahmoud and Burrage, in press). These findings are also in agreement with those obtained by (Cook, 2003) who reported that the *V. parahaemolyticus* was more resistant to high-pressure processing compared with any other *Vibrio* spp. Ren and Su (2006) reported that *V. parahaemolyticus* was more resistant to electrolyzed water than *V. vulnificus*. Andrews et al. (2003) found that *V. vulnificus* was more sensitive than *V. parahaemolyticus* to gamma irradiation. Irradiations at doses of 1.5 and 2.0 kGy, respectively, were required to reduce populations of *V. vulnificus* and *V. parahaemolyticus* in pure broth cultures from 7 log CFU/ml to undetectable levels. Koo et al. (2006) reported that *V. vulnificus* was more sensitive than *V. parahaemolyticus* to high-pressure treatment. Berlin et al. (1999) and Hu et al. (2005) reported that *V. vulnificus* was more sensitive to pressure treatments than *V. parahaemolyticus*.

Treatment of half shell oysters by 0.1, 0.5 and 0.75 kGy X-ray significantly reduced the inherent microflora from 4.7 to 3.1, 2.5 and undetectable limit (<1.0 log CFU/g), respectively. These results are in agreement with previous results (Mahmoud and Burrage, in press) where treatment with 1.0 kGy significantly reduced the inherent microflora in whole shell oysters to undetectable limit (<1.0 log CFU/g). The survivability of treated oysters was determined on the basis of difficulty to open the valves during storage at 5 °C for 7 days. Oysters open their valves only during feeding or after death. The survivability of treated oysters with X-ray was not affected even with the highest dose 3.0 kGy X-ray. These findings are in agreement with those obtained by (Gelli et al., 2001; Mahmoud and Burrage, in press).

In summary, this is the first report that describes reduction of *V. vulnificus* in half shell and whole shell oysters by X-ray. From the results in this study a 6-log reduction of *V. vulnificus* in half shell and whole shell oysters were achieved with 1.0 and 3.0 kGy, respectively. The main advantage of using X-ray for reducing *V. vulnificus* in oysters is that the X-ray treatment did not kill the oysters even with the highest dose (3.0 kGy).

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EXHIBIT 13

X-ray machines help kill bacteria in food

By Karen Templeton
MSU Ag Communications

PASCAGOULA – It is not surprising to see an X-ray machine at a physician's or dentist's office, but research at Mississippi State University may help make them commonplace at seafood processing facilities and commercial produce operations.

Barakat Mahmoud, an assistant professor of food safety and microbiology with the Mississippi Agricultural and Forestry Experiment Station and spokesman for the Institute of Food Technologists, is researching X-ray machines as a way to decontaminate food products. He conducts his work at MSU's Experimental Seafood Processing Laboratory in Pascagoula.

His research shows X-ray doses can kill dangerous bacteria that make people sick, such as salmonella, E. coli, vibrio, shigella and listeria. The process simply removes harmful bacteria and does not alter the food product in any other way. In 1963, the Food and Drug Administration deemed the irradiation of food to be a safe practice.

"Vibrios are the bacteria in raw oysters that can make them dangerous to eat," Mahmoud said. "This technology completely eliminates the naturally occurring bacteria, making the delicacy safe to consume. The X-rays do not kill the oysters; they stay alive throughout the entire process."

Mississippi State University assistant professor of food safety and microbiology Barakat Mahmoud uses the RS 2400 X-ray machine to rid seafood and produce of harmful bacteria. Here, he places fresh produce carefully wrapped in plastic into the machine. In a matter of a few minutes, the food is irradiated and ready to eat. (Photo by MSU Ag Communications/Karen Templeton)

The technology is also being used on fresh produce, such as spinach, lettuce and tomatoes.

"The salmonella and E. coli outbreaks in fresh produce over the last few years have really brought attention to the importance of food safety," Mahmoud said. "What I've been working on is a way to get rid of food-borne illnesses without affecting the quality and freshness of the food."

Gary Bachman, assistant MSU Extension horticulture professor at the Coastal Research and Extension Center in Biloxi, worked with Mahmoud on some of the research.

"I helped select the vegetables that would benefit most from the X-ray process," Bachman said. "Given the issues leafy greens have had with contamination, they were a good choice."

Bachman participated in evaluating the treated vegetables and found the quality stayed consistent.

"The process doesn't seem to affect quality," he said. "The technology is reliable, and as a result, the vegetables are free of pathogens."

Mahmoud uses an RS 2400 X-ray machine to do his work. He carefully wraps the food items in plastic before putting them into the machine. In a matter of a few minutes, the food is irradiated and ready to eat. The final product looks no different than when it first entered the X-ray machine.

"The freshness of the food remains the same," he said. "There is minor loss of vitamins A and C, but they always are reduced in any type of food processing."

Mahmoud and his colleagues found that not only does the X-ray technique kill pathogenic bacteria, but it also extends the shelf life of irradiated food. Spinach, lettuce and other fresh vegetables last 30 days longer after the spoilage bacteria are eliminated.

Processes using chlorine dioxide gas have been used in the past to rid leafy greens of dangerous bacteria, but the gas diminished the quality of the lettuce and spinach, Mahmoud said. He also said gamma rays are often used for food irradiation, but X-ray is a more familiar technology for consumers.

“X-ray machines are more common, and their use can help consumers feel more secure,” Mahmoud said.

Now, Mahmoud and his colleagues are working to show the seafood and produce industries how useful X-ray machines will be in their operations.

“We want the industry to adopt this technique as a way to make food safer,” he said.

The research is being presented at industry and academic meetings across the country.

“This technique can be effectively used in large-scale commercial operations,” Mahmoud said. “Ridding food of dangerous bacteria before it reaches grocery store shelves can certainly help instill better consumer confidence.”

-30-

Released: April 15, 2010
Contact: Dr. Barakat Mahmoud, (228) 762-7783 x304

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EXHIBIT 14

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Attorneys for Plaintiff
RAD Source Technologies, Inc.

EIGHTH JUDICIAL DISTRICT COURT

CLARK COUNTY, NEVADA

RAD SOURCE TECHNOLOGIES, INC., a Florida Corporation, Plaintiff, vs. THE STATE OF NEVADA *ex rel.* DEPARTMENT OF TAXATION, MARIJUANA ENFORCEMENT DIVISION, Defendant.	Case No.: A-19-805074-W Dept. 29 **AMENDED COMPLAINT AND PETITION FOR WRIT OF CERTIORARI, MANDAMUS, PROHIBITION, DECLARATORY JUDGMENT, INTENTIONAL INTERFERENCE WITH CONTRACTUAL RELATIONS, AND INTENTIONAL INTERFERENCE WITH PROSPECTIVE ECONOMIC ADVANTAGE** **AND REQUEST FOR HEARING** (Exempt from Arbitration – Seeks Extraordinary and Injunctive Relief; Damages in Excess of $50,000)

Plaintiff RAD Source Technologies, Inc. ("RAD Source"), by and through its counsel of record, H1 Law Group, as and for its Amended Complaint and Petition against Defendant the State of Nevada, Department of Taxation, Marijuana Enforcement Division ("the Department"),

states and alleges as follows:

THE PARTIES, JURISDICTION, VENUE

1. RAD Source is and was at all relevant times hereto a foreign corporation, duly organized and existing under the laws of the State of Florida, and which has applied for and received authority to conduct business in the State of Nevada, and has its principal offices in Buford, Georgia.

2. The Department is an agency of the State of Nevada. The Department is responsible for licensing and regulating both medical and recreational marijuana businesses in Nevada.

3. This Court has jurisdiction over this matter pursuant to Nev. Const. art. 6, § 6, NRS § 34.020, NRS § 34.160, NRS § 34.330, and NRS § 41.031(2).

4. Venue is proper in this Court pursuant to NRS § 13.020(2)-(3).

GENERAL ALLEGATIONS

RAD Source Is a World-Renowned Manufacturer of Irradiators

5. RAD Source was founded in 1997 with the purpose of creating safer irradiation methods than those used at the time, which involved radioactive gamma sources. For over 20 years, RAD has been the industry leader in manufacturing renewable, non-isotope, ionizing radiation products worldwide.

6. RAD Source's patented and proprietary QUASTAR® technology produces high output X-ray radiation efficiently and reliably for a wide variety of irradiation applications including blood, cell and tissue, insects, biological research, and viral inactivation.

7. RAD Source's equipment is utilized in these various applications throughout the United States and worldwide.

8. Currently, RAD Source's equipment resides in hundreds of major pharmaceutical labs, healthcare institutions, and renowned universities worldwide. RAD Source's impressive and extensive client list includes the American Red Cross, the Mayo Clinic, and the U.S. Food and Drug Administration's National Center for Toxicological Research, to name a few.

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Irradiation Is a Safe, Widely-Utilized, and Well-Studied Process

9. Irradiation is the process by which an object is exposed to radiation, i.e., energy transmitted in waves or streams of particles. Types of electromagnetic radiation include visible light, radio frequency, microwaves, infrared light, ultraviolet light, X-rays and gamma rays.

10. RAD Source is the developer of the RS 420 Line of X-ray Irradiators.

11. The RS 420 Line is used for the safe and effective treatment of marijuana, as described herein.

12. Irradiation is a safe, widely utilized, and well-studied process that is used in marijuana decontamination, sterilization, blood transfusion, immunology and oncology research, and agriculture, among others.

13. RAD Source's RS 420 Line of equipment operates within parameters prescribed by FDA under existing regulations to treat food products and is a safe alternative to gamma source irradiators and other processes used to treat marijuana.

14. Ionizing radiation has been used for more than a decade in Canada and the Netherlands specifically for the treatment of marijuana.

15. Food irradiation is endorsed by FDA, the World Health Organization (WHO), the Centers for Disease Control and Prevention (CDC), and the U.S. Department of Agriculture (USDA) to treat products for human consumption.

16. Specifically, irradiation is beneficial for prevention of foodborne illness, preservation, control of insects, delay of sprouting and ripening, and sterilization that may be present in untreated product for human consumption.

RS 420 Line of X-Ray Irradiators for Treatment of Marijuana Is a Safe and Preferred Method for Treating Marijuana.

17. The use of X-ray photons or emitters for ionizing radiation is the preferred method for the treatment of marijuana because radioactive isotopes (gamma sources) pose an environmental and security risk.

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18. The RS 420 Line uses RAD Source's proprietary, patented QUASTAR® X-Ray technology.

19. Within the United States, the RS 420 Line has been allowed to treat marijuana under California, Colorado, Illinois and Michigan's regulated marijuana markets.

Public Health and Safety Concerns Related to Untreated Marijuana

20. Given the multiple steps involved in harvesting, drying, processing, and packaging marijuana, it can be difficult to maintain perfectly sterile conditions throughout the entire marijuana production process. In order to ensure the safety of the product ultimately delivered to the consumer, growers utilize decontamination processes in the everyday processing of marijuana product and in converting quarantined product into safe, useable product.

21. For example, RAD Source has numerous test results from multiple states, including Nevada, that show its use of X-ray treatment on marijuana has little to no impact on THC, terpenes, or moisture, and that there is no change to the core characteristics of the product after treatment.

22. Moreover, just like cultivating any other crop, marijuana is subject to a wide range of potential contaminants including yeast, mold, insects, and other pathogens.

23. The most concerning pathogen in the marijuana industry is *Aspergillus*. There have been documented cases of medicinal marijuana patients who have died from aspergillosis, a condition caused by inhaling *Aspergillus* spores.

24. The Department recently issued a public health and safety advisory warning concerning the presence of Aspergillus in Nevada marijuana, highlighting the importance of this issue and the significance of potential impact on the health and safety of Nevada citizens and consumers.

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Voter Concern About Public Health and Safety When Passing the Ballot Initiative

25. Nevada voters have also demonstrated concern about public health and safety related to untreated marijuana.

26. During Nevada's 2016 General Election, the voters approved an initiative petition to legalize the recreational use of marijuana by persons 21 years of age or older. This initiative petition was codified as Chapter 453D of the Nevada Revised Statutes (the "Ballot Initiative").

27. In the Ballot Initiative, voters agreed that

> *In the interest of public health and public safety*, and in order to better focus state and local law enforcement resources on crimes involving violence and personal property, the People of the State of Nevada find and declare that the use of marijuana should be legal for persons 21 years of age or older, and its cultivation and sale should be regulated similar to other legal businesses.

NRS 453D.020(1) (emphasis added).

28. Therefore, public health and safety was a central concern of Nevada voters when they enacted the Ballot Initiative.

29. Further, Nevada voters agreed that

> The People of the State of Nevada proclaim that marijuana should be regulated in a manner similar to alcohol so that:
>
> …
>
> (c) Cultivating, manufacturing, testing, transporting and selling marijuana will be strictly controlled through state licensing and regulation; [and]
>
> …
>
> (g) Marijuana sold in the State will be tested and labeled.

NRS 453D.020(3).

30. Therefore, the safe treatment, and ultimately consumption, of marijuana was likewise an express and implied concern of the voters.

31. In the Ballot Initiative, the voters mandated that the Department establish regulations as follows:

> Not later than January 1, 2018, the Department shall adopt all regulations necessary or convenient to carry out the provisions of this chapter. *The regulations must not prohibit the operation of marijuana establishments, either expressly or through regulations that make their operation unreasonably impracticable*. The regulations shall include:
>
> …
>
> (f) Requirements for the testing and labeling of marijuana and marijuana products sold by marijuana establishments.

NRS 453D.200 (emphasis added).

32. Thus, under the express language of the Ballot Initiative, the Department was forbidden from creating regulations that made the operation of recreational marijuana establishments unreasonably impracticable. This would include, among other things, improperly excluding certain treatment processes, such as the RS 420 line of equipment, that effectively treat marijuana, protecting both the public health and welfare, as well as promoting the economic health of the industry.

The RS 420 Line Was in Use for Two Years Prior to the Department's Ban

33. From March 2017 through March 2019, Nevada marijuana growers utilized the RS 420 Line in everyday processing of marijuana to reduce yeast, mold (e.g., *Aspergillus*), and other pathogens and in converting quarantined product into safe, useable marijuana product.

34. During this time, the Department was aware that growers were using RAD Source's technology to treat marijuana and did not raise concerns regarding its use. In fact, there have never been any concerns raised related to the use of the RS 420 Line and the product safely and effectively treated by the machines.

The Department Shuts Down the RS 420 Line and Provides a 6-point Checklist to Obtain Approval

35. Earlier this year, without any notice to RAD Source or any legitimate justification, the Department banned RAD Source customers from using the RS 420 Line of equipment.

36. RAD Source immediately and consistently engaged in good faith communications with the Department in an effort to resolve any concerns the Department may have regarding its technology.

37. On April 9, 2019, Dave Witkowski, DOT Inspector II, communicated to RAD Source a list of six criteria that the Department required in order to approve the use of irradiation instrumentation utilizing ionizing radiation to treat marijuana and marijuana products.

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38. The following week, the Department acknowledged that RAD Source had addressed all but one of the six criteria to its satisfaction, specifically, certification from the U.S. Food and Drug Administration ("FDA") or a letter of exemption from FDA (the "FDA Requirement").

The Single Remaining Item on the Checklist, the FDA Requirement, Is Impossible to Obtain

39. Marijuana and anything made with marijuana, such as edible marijuana products, do not constitute "food" regulated by FDA.

40. Marijuana is a controlled substance under the Controlled Substances Act ("CSA") and its production, possession, and distribution are federally proscribed. 21 U.S.C. § 801 *et seq.* Therefore, it is not possible for RAD Source, nor any end user or any other party, to obtain FDA approval for devices used to process marijuana.

41. In its effort to appease the Department, RAD Source reached out to FDA to inquire as to the possibility of obtaining some form of certification or letter of exemption per the Department's request and requirement for the same. In response, a representative of FDA informed RAD Source that: (i) the request being made by the Department is impossible as marijuana products do not constitute food; and (ii) FDA, as a federal agency, will not review or issue any certification or letter of exemption on a marijuana product because it is not legally permitted under federal law.

42. RAD Source has gone to great lengths to resolve the FDA Requirement to the Department's satisfaction, including multiple discussions with the Department representatives and counsel, in person and over the phone, and providing documentation explaining (1) marijuana is not a "food" and therefore is not subject to FDA oversight, and (2) as marijuana is a federally controlled substance, it is impossible to satisfy the FDA Requirement.

43. However, the Department continues to ban the RS 420 Line based on the inapplicable, and impossible, FDA Requirement.

44. The FDA Requirement is not embodied, or in any way referenced, in any Nevada Revised Statute or Nevada Administrative Code provision. Instead, the Department appears to

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have created the FDA Requirement outside of the Department's standard process of enacting rules and regulations.

45. The Department does not require other marijuana treatment processes or equipment to meet the FDA Requirement. In short, the Department approved competitors of RAD Source who have not had their processes or machines approved by the FDA for use with marijuana.

The Department Approves Similarly Situated Competitor Devices Including Irradiation Devices

46. Despite the Department refusing to approve the RS 420 Line without the FDA Requirement, the Department approved one of RAD Source's competitors, Ziel, which also treats marijuana with irradiation, without requiring Ziel or its customers to satisfy the FDA Requirement.

47. Ziel's technology, just like RAD Source's, uses a form of irradiation to treat marijuana. Ziel advertises on its website that "Ziel's food safety technology uses *RF photons* to energize (activate) molecules in the host commodity and its pests, inducing thermal effects that lead to disinfection (pasteurization), disinfestation, enzyme inactivation and drying effects." *The System,* Ziel, https://zielps.com/system/ (accessed November 1, 2019) (emphasis added).

48. Ziel further advertises on its website that "Ziel's process uses *electromagnetic energy waves* to energize molecules in commodities and pests." *How It Works,* Ziel, https://zielps.com/how-it-works/ (accessed November 1, 2019) (emphasis added).

49. To be clear, "RF" refers to Radio Frequency (RF) Radiation, one of the several types of radiation that comprises the electromagnetic spectrum. While Ziel may not use the word "irradiation," its technology most certainly is a form of irradiation.

50. The technology utilized by RAD Source is X-ray irradiation, another form of radiation on the electromagnetic spectrum.

51. Neither RF radiation nor Ziel's device are approved by the FDA for use in treatment of marijuana.

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52. The Department's approval of one irradiation device and not another is unequal treatment, and is arbitrary and capricious.

53. The Department also approves other treatment processes and devices, including an ozone-based treatment process used by Willow, another competitor of RAD Source.

54. Neither ozone treatment nor Willow's device are approved by the FDA for use in treatment of marijuana.

55. The Department's approval of one or more non-FDA approved treatment processes, but not another, is unequal treatment, and is arbitrary and capricious.

56. Given that the FDA Requirement is impossible to satisfy, the Department must have waived this requirement for Ziel, Willow, and its customers. Yet the Department still requires RAD Source and its customers to comply with the impossible FDA Requirement as a pre-requisite to obtaining approval. This unequal treatment of similarly situated competitors is unlawful.

57. Further, given voter concerns about public health and safety in the Ballot Initiative, and given the Department's recently issued public health and safety advisory warning concerning the presence of *Aspergillus* in Nevada marijuana, it is in the public interest to approve the RS 420 Line and return it to use.

58. This is especially true given that X-ray irradiation, as used by RAD Source, is a safe and preferred method for the treatment of marijuana. In fact, at no time has the Department ever questioned the safety of using X-ray irradiation to treat marijuana.

59. Rather, the Department has banned the RS 420 Line based on the inapplicable, and impossible, FDA Requirement.

RAD Source Sends Multiple Requests to the Department to Withdraw Its Unlawful FDA Requirement

60. Immediately after the Department banned the RS 420 Line, RAD Source sent the Department a letter on April 10, 2019, through its counsel at the time, that explained the inapplicability of the FDA Requirement.

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61. Over the next weeks and months, RAD Source worked extensively with the Department to resolve the issue regarding the inapplicable, and impossible, FDA Requirement.

62. Given the Department's unwillingness to withdraw the FDA Requirement, on August 23, 2019, RAD Source sent the Department a white paper with detailed exhibits and references.

63. Despite this detailed explanation, the Department still refused to withdraw the FDA Requirement. So, in a final effort to resolve this issue outside of a legal action, RAD Source sent another letter, on November 1, 2019, to Steven Shevorski, head of complex litigation at Nevada's Office of Attorney General.

64. This final letter explained in detail that (1) the RS 420 Line was in use for two years prior to the Department's ban; (2) the FDA Requirement is inapplicable and impossible; (3) the Department has approved similar devices without requiring them to meet the FDA Requirement; and (4) the Department has acted arbitrarily and capriciously.

65. Despite these many letters and detailed explanations, the Department has refused to resolve this matter and insists on the RS 420 Line meeting the inapplicable, and impossible, FDA Requirement.

RAD Source Has Suffered, and Will Continue to Suffer, Significant Harm

66. Due to the Department's unlawful ban of the RS 420 Line, five (5) clients of RAD Source in Nevada have 11 machines that have been shut down. Collectively, these 5 clients paid more than $2 million for their 11 machines, and the Department's ban has rendered the machines effectively unusable. Understandably, RAD Source's clients are dissatisfied with this situation.

67. In addition, at the time of the Department's unlawful ban, RAD Source was in negotiations for the sale of additional RS 420 machines with prospective customers. At a minimum, RAD Source lost twelve (12) prospective machine sales. For just the costs of the units, and not factoring in additional revenues from add-on items and services or renewed warranties, this has resulted in $2,395,000.00 of lost sales.

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68. RAD Source customers historically have been highly satisfied with the effectiveness of the RS 420 products, and as a result have purchased multiple machines. The Department's unlawful ban has precluded all such sales.

69. In addition, RAD Source anticipates further lost sales from other industry participants that had expressed interest in and/or that are familiar with the RS 420 Line, but whom have learned of the unlawful ban. RAD Source estimates $2 million to $4 million in lost potential sales from these prospective customers if the ban is not lifted.

70. Further, this estimate is a minimum because the longer the ban is in place, the greater RAD Source's lost potential sales will be.

71. The Department also has allowed Ziel and Willow's similarly situated products but banned RAD Source's RS 420 Line. Because of this, RAD Source is losing, and has lost, significant market share as well as its competitive advantage for its superior and preferable products.

72. Moreover, the Department's ban has caused RAD Source to lose customer goodwill and business reputation.

73. Money damages are inadequate to compensate RAD Source's loss of market share, competitive advantage, goodwill, and reputation.

74. Further, the longer the ban remains in place, the greater the harm will be to RAD Source's sales, market share, competitive advantage, goodwill, and reputation.

75. The Department has informed RAD Source that it has no right to appeal its decisions and actions.

CLAIMS FOR RELIEF

FIRST CAUSE OF ACTION

(Writ of Certiorari)

76. Plaintiff incorporates all allegations of the Complaint herein by reference.

77. The Department has exceeded its authority by, among other things:

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a. Banning RAD Source's RS 420 Line of X-ray irradiators, even though x-ray irradiation is a safe and preferred method for treating marijuana;

b. Requiring RAD Source to meet an impossible FDA Requirement before its RS 420 Line can be approved;

c. Applying different standards to similarly situated competitors, e.g., requiring RAD Source's irradiation products to meet the FDA Requirement, but not requiring Ziel's irradiation products to meet the FDA Requirement; and,

d. Applying different standards to similarly situated competitors, e.g., requiring RAD Source's treatment method to meet the FDA Requirement, but not requiring the Ziel or Willow methods to meet the FDA Requirement.

78. The Department has informed RAD Source that it has no right to appeal these decisions and actions. Therefore, RAD Source does not have any plain, speedy, and adequate remedy to challenge the Department's improper actions.

79. RAD Source petitions this Court for a writ of certiorari to (1) prohibit the Department's continued arbitrary and capricious ban of the RS 420 Line, (2) overturn the Department's impossible-to-meet FDA Requirement, and (3) direct the Department to treat RAD Source equally to its similarly situated competitors, like Ziel and Willow, and requests that this Court undertake such review of the Department's conduct as it deems necessary and appropriate.

80. RAD Source requests an immediate hearing on this matter.

SECOND CAUSE OF ACTION

(Writ of Mandamus)

81. Plaintiff incorporates all allegations of the Complaint herein by reference.

82. The Department violated NRS 453D.200(f) and failed to perform acts which the law compels it to perform by:

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a. Banning the RS 420 Line, which is a safe and preferred method for treatment of marijuana;

b. Creating impossible standards for RAD Source to meet, namely requiring FDA certification or an FDA letter of exemption in order to lift the ban on the RS 420 Line;

c. Applying different standards to similarly situated competitors, specifically, requiring RAD Source's irradiation products to meet the FDA Requirement, but not requiring Ziel's irradiation products to meet the FDA Requirement; and,

d. Applying different standards to similarly situated competitors, e.g., requiring RAD Source's treatment method to meet the FDA Requirement, but not requiring the Ziel or Willow methods to meet the FDA Requirement.

83. To the extent the Department's actions were an exercise of discretion, the Department has acted arbitrarily and capriciously by:

a. Banning RAD Source's RS 420 Line, which is a safe and preferred method for treating marijuana;

b. Requiring RAD Source to meet the impossible requirement of obtaining an FDA certification or FDA letter of exemption before approving the RS 420 Line for treating marijuana;

c. Applying different standards to similarly situated competitors, namely, requiring RAD Source's irradiation products to meet the FDA Requirement, but not requiring Ziel's irradiation products to meet the FDA Requirement; and

d. Applying different standards to similarly situated competitors, e.g., requiring RAD Source's treatment method to meet the FDA Requirement, but not requiring the Ziel or Willow methods to meet the FDA Requirement.

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84. RAD Source was denied a right to appeal the Department's decisions and actions. Therefore, there is no plain, speedy, and adequate remedy in the ordinary course of law to correct the Department's failure to perform the acts required by law or to correct the Department's arbitrary and capricious use of discretion.

85. RAD Source therefore petitions this Court to issue a writ of mandamus to the Department compelling it to (1) lift the ban on the RS 420 Line and approve of its use for the treatment of marijuana; (2) cease and desist requiring the RS 420 Line to meet the impossible FDA Requirement; and (3) apply the same standards to similarly situated competitors, like RAD Source, Ziel, and Willow.

86. RAD Source requests an immediate hearing on this matter.

THIRD CAUSE OF ACTION

(Writ of Prohibition)

87. Plaintiff incorporates all allegations of the Complaint herein by reference.

88. The Department has exceeded its authority by, among other things:

a. Banning RAD Source's RS 420 Line, which is a safe and preferred method for treating marijuana;

b. Requiring RAD Source to meet the impossible FDA Requirement;

c. Applying different standards to similarly situated competitors, namely, requiring RAD Source's irradiation products to meet the FDA Requirement, but not requiring Ziel's irradiation products to meet the FDA Requirement; and

d. Applying different standards to similarly situated competitors, e.g., requiring RAD Source's treatment method to meet the FDA Requirement, but not requiring the Ziel or Willow methods to meet the FDA Requirement.

89. The Department has informed RAD Source that it has no right to appeal these actions. Therefore, RAD Source does not have any plain, speedy, and adequate remedy for the Department's improper actions.

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90. RAD Source therefore petitions the Court to issue a writ of prohibition that prohibits the Department from (1) banning the RS 420 Line, (2) requiring the RS 420 Line to meet the impossible FDA Requirement, and (3) applying different standards to similarly situated competitors, like RAD Source, Ziel, and Willow.

91. RAD Source requests an immediate hearing on this matter.

FOURTH CAUSE OF ACTION

(Declaratory Judgment)

92. Plaintiff incorporates all allegations of the Complaint herein by reference.

93. The Department has acted unlawfully by, among other things:

a. Banning RAD Source's RS 420 Line, which is a safe and preferred method for treating marijuana;

b. Requiring RAD Source to meet the impossible FDA Requirement;

c. Applying different standards to similarly situated competitors, namely, requiring RAD Source's irradiation products to meet the FDA Requirement, but not requiring Ziel's irradiation products to meet the FDA Requirement; and

d. Applying different standards to similarly situated competitors, e.g., requiring RAD Source's treatment method to meet the FDA Requirement, but not requiring the Ziel or Willow methods to meet the FDA Requirement.

94. RAD Source therefore requests declaratory judgment declaring that it was unlawful for the Department to (1) ban the RS 420 Line, (2) require the RS 420 Line to meet the impossible FDA Requirement, and (3) apply different standards to similarly situated competitors, like RAD Source, Ziel, and Willow.

95. RAD Source also requests declaratory judgment declaring that (1) the RS 420 Line is allowed for the treatment of marijuana in Nevada, (2) the RS 420 Line does not have to meet the FDA Requirement, and (3) any standards applied to RAD Source's products must also be applied to similarly situated competitors.

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96. RAD Source further requests injunctive relief as a supplemental remedy. NRS § 30.100.

97. As shown herein, RAD Source is likely to succeed on the merits of its claims.

98. RAD Source has suffered, and will suffer irreparable injury, for the Department banning its RS 420 Line in Nevada, while its competitors' products are allowed in Nevada for the treatment of marijuana.

99. RAD Source's injuries include lost market share, competitive advantage, customer goodwill, and business reputation.

100. RAD Source will further suffer irreparable injury if its products are held to different standards than its competitors.

101. Compensatory damages are an inadequate remedy.

102. RAD Source therefore requests preliminary and permanent injunctive relief compelling the Department to (1) lift the ban on the RS 420 Line and approve of its use for the treatment of marijuana; (2) cease and desist requiring the RS 420 Line to meet the impossible FDA Requirement; and (3) apply the same standards to similarly situated competitors, like RAD Source, Ziel, and Willow.

FIFTH CAUSE OF ACTION

(Intentional Interference with Contractual Relations)

103. Plaintiff incorporates all allegations of the Complaint herein by reference.

104. RAD Source had valid and existing contracts with its Nevada customers who used the RS 420 Line to treat marijuana.

105. The Department knew of these contracts, or at least could have reasonably inferred the existence of these contracts, when it banned RAD Source's customers from using the RS 420 Line products that they had purchased.

106. The Department took intentional acts intended or designed to disrupt RAD Source's contractual relationships, namely through banning the use of the RS 420 Line,

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creating the impossible-to-meet FDA Requirement for the RS 420 Line, and applying different standards to similarly situated competitors like RAD Source, Ziel, and Willow.

107. Actual disruption of RAD Source's contracts occurred. RAD Source's customers are no longer allowed to use the RS 420 Line in their treatment of marijuana.

108. The Department's actions regarding RAD Source and its products did not involve personal deliberation, decision, or judgment.

109. The Department's decisions and actions regarding RAD Source and its products were not based upon considerations of social, economic, or political policy.

110. The Department did not exercise due care.

111. The Department acted and continues to act in bad faith.

112. RAD Source has suffered significant damages.

113. RAD Source estimates its monetary damages for these lost contracts at a minimum of $2 million. These damages will continue to grow as long as the ban is in place.

114. Therefore, RAD Source requests monetary damages in an amount in excess of $15,000, the specific amount to be proven at trial.

115. RAD Source has also suffered non-monetary damages such as lost market share, competitive advantage, goodwill, and reputation.

116. These damages will continue to grow as long as the ban is in place.

117. As such, RAD Source has suffered irreparable harm for which there is no adequate legal remedy.

118. RAD Source therefore also requests a preliminary and permanent injunction compelling the Department to (1) lift the ban on the RS 420 Line and approve of its use for the treatment of marijuana; (2) cease and desist requiring the RS 420 Line to meet the impossible FDA Requirement; and (3) apply the same standards to similarly situated competitors, like RAD Source, Ziel, and Willow.

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SIXTH CAUSE OF ACTION

(Intentional Interference With Prospective Economic Advantage)

119. Plaintiff incorporates all allegations of the Complaint herein by reference.

120. RAD Source had prospective contractual relationships with customers in Nevada who treat marijuana.

121. The Department knew of these prospective relationships.

122. The Department intended to harm RAD Source by preventing these relationships, namely through banning the RS 420 Line, creating the impossible-to-meet FDA Requirement, and applying different standards to similarly situated competitors like RAD Source, Ziel, and Willow.

123. The Department's actions are not justified.

124. The Department's decisions and actions regarding RAD Source and its products did not involve personal deliberation, decision, or judgment.

125. The Department's decisions and actions regarding RAD Source and its products were not based upon considerations of social, economic, or political policy.

126. The Department did not exercise due care.

127. The Department acted and continues to act in bad faith.

128. RAD Source has suffered actual harm from the Department's conduct.

129. RAD Source estimates its lost negotiations at the time of the ban at around $2.3 million. RAD Source's also has lost on multiple machine purchases from these potential customers. Further, RAD Source estimates lost sales from other industry participants at $2 million to $4 million, which damages will continue to grow the longer the ban is in place.

130. Therefore, RAD Source requests monetary damages in an amount in excess of $15,000, the specific amount to be proven at trial.

131. RAD Source has also suffered non-monetary damages such as lost market share, competitive advantage, goodwill, and reputation.

132. These damages will continue to grow as long as the ban is in place.

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133. As such, RAD Source has suffered irreparable harm for which there is no adequate legal remedy.

134. RAD Source therefore also requests a preliminary and permanent injunction compelling the Department to (1) lift the ban on the RS 420 Line and approve of its use for the treatment of marijuana; (2) cease and desist requiring the RS 420 Line to meet the impossible FDA Requirement; and (3) apply the same standards to similarly situated competitors, like RAD Source, Ziel, and Willow.

PRAYER AND REQUEST FOR RELIEF

Wherefore, RAD Source seeks, prays for, and requests judgment against the Department, and in RAD Source's favor, as follows:

a. For a writ of certiorari reviewing (1) the Department's ban of the RS 420 Line; (2) the Department's impossible FDA requirement; and (3) the Department's unequal treatment of similarly situated competitors, like RAD Source as compared to, e.g., Ziel and Willow;

b. For a writ of mandamus to the Department compelling it to (1) lift the ban on the RS 420 Line and approve of its use for treating marijuana; (2) cease and desist requiring the RS 420 Line to meet the impossible FDA Requirement; and (3) apply the same standards to similarly situated competitors, like RAD Source as compared to, e.g., Ziel and Willow;

c. For a writ of prohibition which prohibits the Department from (1) banning the RS 420 Line, (2) requiring the RS 420 Line to meet the impossible FDA Requirement, and (3) applying different standards to industry competitors, like RAD Source as compared to, e.g., Ziel and Willow;

d. For declaratory relief that it was unlawful for the Department to (1) ban the RS 420 Line, (2) require the RS 420 Line to meet the impossible FDA Requirement, and (3) apply different standards to similarly situated competitors;

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e. For declaratory relief that (1) the RS 420 Line is allowed for the treatment of marijuana in Nevada, (2) the RS 420 Line does not have to meet the FDA Requirement, and (3) any standards applied to RAD Source's products must also be applied to similarly situated competitors;

f. For monetary relief in an amount in excess of $15,000, the specific amount to be proven at trial;

g. For preliminary and permanent injunctive relief compelling the Department to (1) lift the ban on the RS 420 Line and approve of its use for the treatment of marijuana; (2) cease and desist requiring the RS 420 Line to meet the impossible FDA Requirement; and (3) apply the same standards to similarly situated competitors, such as Ziel and Willow; and,

h. For any other relief the Court deems just and proper.

Dated this ___ day of December 2019.

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EXHIBIT 15

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EIGHTH JUDICIAL DISTRICT COURT

CLARK COUNTY, NEVADA

RAD SOURCE TECHNOLOGIES, INC., a Florida Corporation, Plaintiff, vs. THE STATE OF NEVADA *ex rel.* DEPARTMENT OF TAXATION, MARIJUANA ENFORCEMENT DIVISION, Defendant.	Case No.: A-19-805074-W Dept. 29 **RAD SOURCE TECHNOLOGIES, INC.'S: (1) MOTION FOR ORDER TO SHOW CAUSE WHY A WRIT OF CERTIORARI, MANDAMUS, AND/OR PROHIBITION SHOULD NOT ISSUE; (2) ALTERNATIVE MOTION FOR PRELIMINARY INJUNCTION; AND (3) APPLICATION FOR ORDER SHORTENING TIME** **HEARING REQUESTED**

RAD Source Technologies, Inc. ("RAD Source"), by and through counsel, hereby moves:

(1) Pursuant to Nevada Revised Statutes ("NRS") §§ 34.030, 34.190, and 34.340, for entry of and Order to Show Cause Why a Writ of Certiorari, Mandamus, and/or Prohibition Should Not Issue, in the form submitted herewith as **Exhibit 1**;

(2) In the alternative, pursuant to NRS §§ 33.010 and 30.100, for a preliminary injunction; and

(3) Pursuant to Eighth Judicial District Court Rule ("EDCR") 2.26, for an order shortening time on the hearing of this Motion.

This Motion is based upon the following Memorandum of Points and Authorities and supporting exhibits, including the Declaration of William Hartman attached hereto as **Exhibit 2** and the supporting exhibits thereto; the papers and pleadings already on file herein, including RAD Source's *Amended Complaint and Petition for Writ of Certiorari, Mandamus, Prohibition, Declaratory Judgment, Intentional Interference with Contractual Relations, and Intentional Interference with Prospective Economic Advantage* filed December 12, 2019 (the "Amended Complaint"); and the Declaration of Joel Schwarz (the "Schwarz Declaration") submitted in compliance with Eighth Judicial District Court Rule ("EDCR") 2.26.

DECLARATION OF JOEL Z. SCHWARZ IN SUPPORT OF APPLICATION FOR ORDER SHORTENING TIME

I, JOEL Z. SCHWARZ, hereby declare as follows:

1. I am an attorney duly licensed to practice law in the State of Nevada, and I am a member of the law firm of H1 Law Group, counsel for Plaintiff in the above matter.

2. I have personal knowledge of the matters set forth herein and know them to be true.

3. Pursuant to EDCR 2.26, good cause exists for an order shortening time for a hearing on RAD Source's motion for an order to show cause and alternative motion for a preliminary injunction.

4. In particular and as set forth more fully below, the Department of Taxation (the "Department") has banned the use of RAD Source's RS 420 Line of X-Ray irradiators in Nevada, has failed to articulate any rationale for its unlawful ban, has refused to consider data and other information provided by Rad Source, and has refused and continues to refuse to engage with Rad Source in good faith.

5. Due to the Department's unlawful ban of the RS 420 Line, RAD Source estimates its current monetary damages at more than $2 million. As long as the ban is in place, these damages are ongoing and increasing.

6. However, while the Department has banned RAD Source's RS 420 Line, it has allowed other marijuana treatment products to be sold and used in Nevada by RAD Source's

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primary competitors.

7. Because of this, RAD Source is losing, and has lost, significant market share as well as its competitive advantage for its superior and preferable products.

8. RAD Source has also suffered, and continues to suffer, loss of customer goodwill and business reputation.

9. Moreover, the longer the Department's ban on RAD Source's products remains in place, the greater the loss is to RAD Source's market share, competitive advantage, goodwill, and reputation.

10. For these reasons, good cause exists for an order shortening time and the Court should grant such an order.

I declare under penalty of perjury under the laws of the State of Nevada that the forgoing is true and correct.

Executed this 13th day of December 2019.

JOEL Z. SCHWARZ

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MEMORANDUM OF POINTS AND AUTHORITIES

I. INTRODUCTION

RAD Source is entitled to an order directing the Department to show cause why a writ of certiorari, mandamus, or prohibition should not issue. RAD Source is an experienced and respected world-wide manufacturer of irradiation products. RAD Source's RS 420 Line of X-ray irradiators is a proven safe, effective, and preferable method for decontaminating and treating marijuana for human consumption. Despite this, the Department—for no apparent reason other than to give RAD Source's competitors a leg up—has banned RAD Source's RS 420 Line of X-ray irradiators from being used in Nevada. Exacerbating its actions, the Department has set an impossible-to-meet standard in order to lift this ban. Specifically, the Department is requiring RAD Source to obtain an FDA certification or exemption letter for the irradiators, even though

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(1) marijuana is not a "food" and thus not regulated by the FDA and (2) marijuana is a federally controlled substance and therefore no such FDA certification or exemption can issue.

While the Department imposed an arbitrary ban and has set an impossible-to-meet standard for RAD Source, the Department has taken no such actions with respect to RAD Source's competitors. These competitors are currently allowed to sell and use their marijuana treatment products in Nevada with no restrictions, which is unequal and unfair to RAD Source. For these reasons, RAD Source is entitled to an order directing the Department to show cause why a writ of certiorari, mandamus, or prohibition should not issue.

In the alternative, RAD Source unequivocally can demonstrate a likelihood of success on the merits of each and every claim in its Amended Complaint because the Department has unlawfully (1) banned RAD Source's RS 420 Line of X-ray irradiators, even though X-ray irradiation is a safe and preferred method for treating marijuana; (2) required RAD Source to meet an impossible FDA requirement before the RS 420 Line can be approved; (3) applied different standards to similarly situated competitors.

RAD Source is suffering irreparable harm, for which there is no adequate remedy at law. RAD Source has, and will, suffer lost sales, market share, competitive advantage, customer goodwill, and business reputation. Money damages, which are statutorily capped at $100,000, are woefully inadequate to compensate RAD Source for the harm caused by the Department and will not restore the lost market share and customer goodwill resulting from the Departments unlawful ban.

The balance of the hardships weighs heavily in favor of RAD Source. RAD Source is, and will continue, to suffer greatly for lost sales, market share, competitive advantage, customer goodwill, and business reputation. In contrast, no harm will result to the State.

Finally, public policy favors a preliminary injunction. There are serious health and safety concerns with untreated marijuana, including the potentially deadly *Aspergillus* spores. RAD Source's X-ray irradiators are a safe and preferable method for treating marijuana. As such, public policy favors a preliminary injunction and one should be granted by this Court.

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II. STATEMENT OF RELEVANT FACTS

RAD Source Is a World-Renowned Manufacturer of Irradiators

1. RAD Source was founded in 1997 with the purpose of creating safer irradiation methods than those used at the time, which involved radioactive gamma sources. For over 20 years, RAD has been the industry leader in manufacturing renewable, non-isotope, ionizing radiation products worldwide. Hartman Decl., ¶ 4.

2. RAD Source's patented and proprietary QUASTAR® technology produces high output X-ray radiation efficiently and reliably for a wide variety of irradiation applications including blood, cell and tissue, insects, biological research, and viral inactivation. *Id.* ¶ 5.

3. RAD Source's equipment is utilized in these various applications throughout the United States and worldwide. *Id.* ¶ 6.

4. Currently, RAD Source's equipment resides in hundreds of major pharmaceutical labs, healthcare institutions, and renowned universities worldwide. RAD Source's impressive and extensive client list includes the American Red Cross, the Mayo Clinic, and the U.S. Food and Drug Administration's National Center for Toxicological Research, to name a few. *Id.* ¶ 7.

Irradiation Is a Safe, Widely Utilized, and Well-Studied Process

5. Irradiation is the process by which an object is exposed to radiation, i.e., energy transmitted in waves or streams of particles. Types of electromagnetic radiation include visible light, radio frequency, microwaves, infrared light, ultraviolet light, X-rays and gamma rays. *Id.* ¶ 8.

6. RAD Source is the developer of the RS 420 Line of X-ray Irradiators. *Id.* ¶ 9

7. The RS 420 Line is used for the safe and effective treatment of marijuana, as described herein and in the Hartman Declaration. *Id.* ¶10.

8. Irradiation is a safe, widely utilized, and well-studied process that is used in marijuana decontamination, sterilization, blood transfusion, immunology and oncology research, and agriculture, among others. *Id.* ¶ 11.

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9. RAD Source's RS 420 Line of equipment operates within parameters prescribed by FDA under existing regulations to treat food products and is a safe alternative to gamma source irradiators and other processes used to treat marijuana. *Id.* ¶¶ 13-14.

10. Ionizing radiation has been used for more than a decade in Canada and the Netherlands specifically for the treatment of marijuana. *Id.* ¶ 12.

11. Food irradiation is endorsed by FDA, the World Health Organization (WHO), the Centers for Disease Control and Prevention (CDC), and the U.S. Department of Agriculture (USDA) to treat products for human consumption. *Id.* ¶ 15.

12. Specifically, irradiation is beneficial for prevention of foodborne illness, preservation, control of insects, delay of sprouting and ripening, and sterilization that may be present in untreated product for human consumption. *Id.* ¶ 16.

RS 420 Line of X-Ray Irradiators for Treatment of Marijuana Is a Safe and Preferred Method for Treating Marijuana.

13. The use of X-ray photons or emitters for ionizing radiation is the preferred method for the treatment of marijuana because radioactive isotopes (gamma sources) pose an environmental and security risk. *Id.* ¶ 17.

14. The RS 420 Line uses RAD Source's proprietary, patented QUASTAR® X-Ray technology. *Id.* ¶ 18

15. Within the United States, the RS 420 Line has been allowed to treat marijuana under California, Colorado, Illinois and Michigan's regulated marijuana markets. *Id.* ¶ 19.

Public Health and Safety Concerns Related to Untreated Marijuana

16. Given the multiple steps involved in harvesting, drying, processing, and packaging marijuana, it can be difficult to maintain perfectly sterile conditions throughout the entire marijuana production process. In order to ensure the safety of the product ultimately delivered to the consumer, growers utilize decontamination processes in the everyday processing of marijuana product and in converting quarantined product into safe, useable product. *Id.* ¶ 20.

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17. For example, RAD Source has numerous test results from multiple states, including Nevada, that show its use of X-ray treatment on marijuana has little to no impact on THC, terpenes, or moisture, and that there is no change to the core characteristics of the product after treatment. *Id.* ¶ 21.

18. Moreover, just like cultivating any other crop, marijuana is subject to a wide range of potential contaminants including yeast, mold, insects, and other pathogens. *Id.* ¶ 22.

19. The most concerning pathogen in the marijuana industry is *Aspergillus*. There have been documented cases of medicinal marijuana patients who have died from aspergillosis, a condition caused by inhaling *Aspergillus* spores. *Id.* ¶ 23.

20. The Department recently issued a public health and safety advisory warning concerning the presence of *Aspergillus* in Nevada marijuana, highlighting the importance of this issue and the significance of potential impact on the health and safety of Nevada citizens and consumers. *Id.* ¶ 24; **Exhibit E**, DOT Public Health and Safety Advisory 2019-02, attached to Hartman Decl.

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Voter Concern About Public Health and Safety When Passing the Ballot Initiative

21. Nevada voters have also demonstrated concern about public health and safety related to untreated marijuana.

22. During Nevada's 2016 General Election, the voters approved an initiative petition to legalize the recreational use of marijuana by persons 21 years of age or older. This initiative petition was codified as Chapter 453D of the Nevada Revised Statutes (the "Ballot Initiative").

23. In the Ballot Initiative, voters agreed that

> *In the interest of public health and public safety*, and in order to better focus state and local law enforcement resources on crimes involving violence and personal property, the People of the State of Nevada find and declare that the use of marijuana should be legal for persons 21 years of age or older, and its cultivation and sale should be regulated similar to other legal businesses.

NRS 453D.020(1) (emphasis added).

24. Therefore, public health and safety was a central concern of Nevada voters when they enacted the Ballot Initiative.

25. Further, Nevada voters agreed that

> The People of the State of Nevada proclaim that marijuana should be regulated in a manner similar to alcohol so that:
>
> ...
>
> (c) Cultivating, manufacturing, testing, transporting and selling marijuana will be strictly controlled through state licensing and regulation; [and]
>
> ...
>
> (g) Marijuana sold in the State will be tested and labeled.

NRS 453D.020(3).

26. Therefore, the safe treatment, and ultimately consumption, of marijuana was likewise an express and implied concern of the voters.

27. In the Ballot Initiative, the voters mandated that the Department establish regulations as follows:

> Not later than January 1, 2018, the Department shall adopt all regulations necessary or convenient to carry out the provisions of this chapter. *The regulations must not prohibit the operation of marijuana establishments, either expressly or through regulations that make their operation unreasonably impracticable.* The regulations shall include:
>
> ...
>
> (f) Requirements for the testing and labeling of marijuana and marijuana products sold by marijuana establishments.

NRS 453D.200 (emphasis added).

28. Thus, under the express language of the Ballot Initiative, the Department was forbidden from creating regulations that made the operation of recreational marijuana establishments unreasonably impracticable. This would include, among other things, improperly excluding certain treatment processes, such as the RS 420 line of equipment, that effectively treat marijuana, protecting both the public health and welfare, as well as promoting the economic health of the industry.

The RS 420 Line Was in Use for Two Years Prior to the Department's Ban

29. From March 2017 through March 2019, Nevada marijuana growers utilized the RS 420 Line in everyday processing of marijuana to reduce yeast, mold (e.g., *Aspergillus*), and other pathogens and in converting quarantined product into safe, useable marijuana product. Hartman Decl., ¶ 25.

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30. During this time, the Department was aware that growers were using RAD Source's technology to treat marijuana and did not raise concerns regarding its use. In fact, there have never been any concerns raised related to the use of the RS 420 Line and the product safely and effectively treated by the machines. *Id.* ¶ 26.

The Department Shuts Down the RS 420 Line and Provides a 6-point Checklist to Obtain Approval

31. Earlier this year, without any notice to RAD Source or any legitimate justification, the Department banned RAD Source customers from using the RS 420 Line of equipment. *Id.* ¶ 27.

32. RAD Source immediately and consistently engaged in good faith communications with the Department in an effort to resolve any concerns the Department may have regarding its technology. *Id.* ¶ 28.

33. On April 9, 2019, Dave Witkowski, DOT Inspector II, communicated to RAD Source a list of six criteria that the Department required in order to approve the use of irradiation instrumentation utilizing ionizing radiation to treat marijuana and marijuana products. *Id.* ¶ 29; **Exhibit A**, email from D. Witkowski to J. Mugan dated April 9, 2019, attached to Hartman Decl.

34. The following week, the Department acknowledged that RAD Source had addressed all but one of the six criteria to its satisfaction, specifically, certification from the U.S. Food and Drug Administration ("FDA") or a letter of exemption from FDA (the "FDA Requirement"). *Id.* ¶ 30; **Exhibit B**, email from D. Witkowski to J. Mugan dated April 16, 2019 and previous emails in string, attached to Hartman Decl.

The Single Remaining Item on the Checklist, the FDA Requirement, is Impossible to Obtain

35. Marijuana and anything made with marijuana, such as edible marijuana products, do not constitute "food" regulated by FDA. *Id.* ¶ 31.

36. Marijuana is a controlled substance under the Controlled Substances Act ("CSA") and its production, possession, and distribution are federally proscribed. 21 U.S.C. § 801 *et seq.*

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Therefore, it is not possible for RAD Source, or anyone else, to obtain FDA approval for devices used to process marijuana. Hartman Decl., ¶ 32.

37. In its effort to appease the Department, RAD Source reached out to FDA to inquire as to the possibility of obtaining some form of certification or letter of exemption per the Department's request and requirement for the same. *Id.* ¶ 33.

38. In response, a representative of FDA informed RAD Source that: (i) the request being made by the Department is impossible as marijuana products do not constitute food; and (ii) FDA, as a federal agency, will not review or issue any certification or letter of exemption on a marijuana product because it is not legally permitted under federal law. *Id.* ¶ 34; **Exhibit C**, email from Jeremiah Fasano, Consumer Safety Officer, FDA, dated April 22, 2019, attached to Hartman Decl.

39. RAD Source has gone to great lengths to resolve the FDA Requirement to the Department's satisfaction, including multiple discussions with the Department representatives and counsel, in person and over the phone, and providing documentation explaining (1) marijuana is not a "food" and therefore is not subject to FDA oversight, and (2) as marijuana is a federally controlled substance, it is impossible to satisfy the FDA Requirement. *Id.* ¶ 35.

40. However, the Department continues to ban the RS 420 Line based on the inapplicable, and impossible, FDA Requirement. *Id.* ¶ 36.

41. The FDA Requirement is not embodied, or in any way referenced, in any Nevada Revised Statute or Nevada Administrative Code provision. Instead, the Department appears to have created the FDA Requirement outside of the Department's standard process of enacting rules and regulations.

42. The Department does not require other marijuana treatment processes or equipment to meet the FDA Requirement. In short, the Department's ban affects only RAD Source, while competitors of RAD Source who have not had and cannot have their processes or machines approved by the FDA for use with marijuana, continue to operate. *Id.* ¶ 37.

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The Department Approves Similarly Situated Competitor Devices Including Irradiation Devices

43. Despite the Department refusing to approve the RS 420 Line without the FDA Requirement, the Department approved one of RAD Source's competitors, Ziel, which also treats marijuana with irradiation, without requiring Ziel or its customers to satisfy the FDA Requirement. *See id.* ¶ 38.

44. Ziel's technology uses a form of irradiation to treat marijuana. Ziel advertises on its website that "Ziel's food safety technology uses *RF photons* to energize (activate) molecules in the host commodity and its pests, inducing thermal effects that lead to disinfection (pasteurization), disinfestation, enzyme inactivation and drying effects." *The System,* Ziel, https://zielps.com/system/ (accessed November 1, 2019) (emphasis added); *see also* Hartman Decl., ¶ 39.

45. Ziel further advertises on its website that "Ziel's process uses *electromagnetic energy waves* to energize molecules in commodities and pests." *How It Works,* Ziel, https://zielps.com/how-it-works/ (accessed November 1, 2019) (emphasis added).

46. To be clear, "RF" refers to Radio Frequency (RF) Radiation, one of the several types of radiation that comprise the electromagnetic spectrum. While Ziel may not use the word "irradiation," its technology most certainly is a form of irradiation.

47. The technology utilized by RAD Source is X-ray irradiation, another form of radiation on the electromagnetic spectrum. See **Exhibit D**, RAD Source's August 23, 2019 letter to Jorge Pupo, DOT (attachments excluded), attached to Hartman Decl.

48. Neither RF radiation nor Ziel's device are approved by the FDA for use in treatment of marijuana, nor can they obtain any such approval. *See* Hartman Decl., ¶ 38.

49. The Department also allows, and therefore tacitly approves, other treatment processes and devices, including an ozone-based treatment process used by Willow, another competitor of RAD Source. *Id.* ¶ 41.

50. Neither ozone treatment nor Willow's device are approved by the FDA for use in treatment of marijuana, nor can they obtain any such approval. *Id.* ¶ 42.

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51. The Department's approval of one or more non-FDA approved treatment processes, but not another, is unequal treatment. *Id.* ¶ 40.

52. Given that the FDA Requirement is impossible to satisfy, the Department either did not impose or waived this requirement for Ziel, Willow, and its customers. Yet the Department still requires RAD Source and its customers to comply with the impossible FDA Requirement as a pre-requisite to obtaining approval. This unequal treatment of similarly situated competitors is unlawful. *Id.* ¶ 44.

53. Further, given voter concerns about public health and safety in the Ballot Initiative, and given the Department's recently issued public health and safety advisory warning concerning the presence of *Aspergillus* in Nevada marijuana, it is in the public interest to approve the RS 420 Line and return it to use. *Id.* ¶ 45.

54. This is especially true given that X-ray irradiation, as used by RAD Source, is a safe and preferred method for the treatment of marijuana. In fact, at no time has the Department ever questioned the safety of using X-ray irradiation to treat marijuana. *Id.* ¶ 46.

55. Rather, the Department has banned the RS 420 Line based on the inapplicable, and impossible, FDA Requirement. *Id.* ¶ 47.

RAD Source Sends Multiple Requests to the Department to Withdraw Its Unlawful FDA Requirement

56. Immediately after the Department banned the RS 420 Line, RAD Source sent the Department a letter on April 10, 2019, through its counsel at the time, that explained the inapplicability of the FDA Requirement. *Id.* ¶ 48; **Exhibit F**, April 10, 2019 Letter from Kolesar & Leatham to DOT, attached to Hartman Decl.

57. Over the next weeks and months, RAD Source worked extensively with the Department to resolve the issue regarding the inapplicable, and impossible, FDA Requirement. *Id.* ¶ 49.

58. Given the Department's unwillingness to withdraw the FDA Requirement, on August 23, 2019, RAD Source sent the Department a white paper with detailed exhibits and references. *Id.* ¶ 50; **Exhibit D** attached to Hartman Decl. This paper described how the RS 420

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Line worked, its history of use, and its recognition as safe and effective. *Id.* Further, RAD Source thoroughly explained the inapplicability, and impossibility, of the FDA Requirement. *Id.*

59. Despite this detailed explanation, the Department still refused to withdraw the FDA Requirement. So, in a final effort to resolve this issue outside of a legal action, RAD Source sent another letter, on November 1, 2019, to Steven Shevorski, head of complex litigation at Nevada's Office of Attorney General. *Id.* ¶ 51; **Exhibit G,** November 1, 2019 Letter from H1 Law Group to Steven Shevorski, Office of the Attorney General (attachments omitted), attached to Hartman Decl.

60. This final letter explained in detail that (1) the RS 420 Line was in use for two years prior to the Department's ban; (2) the FDA Requirement is inapplicable and impossible; (3) the Department has approved similar devices without requiring them to meet the FDA Requirement; and (4) the Department has acted arbitrarily and capriciously. Hartman Decl., ¶ 52.

61. Despite these many letters and detailed explanations, the Department has refused to resolve this matter and insists on the RS 420 Line meeting the inapplicable, and impossible, FDA Requirement. *Id.* ¶ 53.

RAD Source has Suffered, and Will Continue to Suffer, Significant Harm

62. Due to the Department's unlawful ban of the RS 420 Line, five (5) clients of RAD Source in Nevada have 11 machines that have been shut down. Collectively, these 5 clients paid more than $2 million for their 11 machines, and the Department's ban has rendered the machines effectively unusable. Understandably, RAD Source's clients are dissatisfied with this situation. *Id.* ¶ 54.

63. In addition, at the time of the Department's unlawful ban, RAD Source was in negotiations for the sale of additional RS 420 machines with prospective customers. At a minimum, RAD Source lost twelve (12) prospective machine sales. For just the costs of the units, and not factoring in additional revenues from add-on items and services or renewed warranties, this has resulted in $2,395,000.00 of lost sales. *Id.* ¶ 55.

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64. RAD Source customers historically have been highly satisfied with the effectiveness of the RS 420 products, and as a result have purchased multiple machines. The Department's unlawful ban has precluded all such sales. *Id.* ¶ 56.

65. In addition, RAD Source anticipates further lost sales from other industry participants that had expressed interest in and/or that are familiar with the RS 420 Line, but who have learned of the unlawful ban. RAD Source estimates $2 million to $4 million in lost potential sales from these prospective customers if the ban is not lifted. Further, this estimate is a minimum because the longer the ban is in place, the greater RAD Source's lost potential sales will be. *Id.* ¶ 57.

66. The Department also has allowed Ziel and Willow's similarly situated products but banned RAD Source's RS 420 Line. Because of this, RAD Source is losing, and has lost, significant market share as well as its competitive advantage for its superior and preferable products. *Id.* ¶ 58.

67. Moreover, the Department's ban has caused RAD Source to lose customer goodwill and business reputation. *Id.* ¶ 59.

68. Money damages are inadequate to compensate RAD Source's loss of market share, competitive advantage, goodwill, and reputation. *Id.* ¶ 60.

69. Further, the longer the ban remains in place, the greater the harm will be to RAD Source's sales, market share, competitive advantage, goodwill, and reputation. *Id.* ¶ 61.

70. The Department has informed RAD Source that it has no right to appeal its decisions and actions. *Id.* ¶ 62.

III. ARGUMENT

A. The Court Has Authority to Enter an Order Directing the Department to Show Cause Why a Writ of Certiorari, Mandamus, or Prohibition Shall Not be Issued.

For writs of certiorari, NRS § 34.030 states:

> The application shall be made on affidavit by the party beneficially interested, and the court or judge to whom the application is made may require a notice of the application to be given to the adverse party, *or may grant an order to show cause*

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why it should not be allowed, or may grant the writ without further notice. (emphasis added).

For writs of mandamus, NRS § 34.190 states:

1. The writ shall be either alternative or peremptory.

2. The alternative writ shall state generally the allegation against the party to whom it is directed, and command such party, immediately after the receipt of the writ, or at some other specified time, to do the act required to be performed, *or to show cause before the court,* at a specified time and place, *why the party has not done so.* (emphasis added).

For writs of prohibition, NRS § 34.340 states:

1. The writ must be either alternative or peremptory.

2. The alternative writ must state generally the allegation against the party to whom it is directed and command such party to desist or refrain from further proceedings in the action or matter specified therein, until the further order of the court from which it is issued, and *to show cause before such court*, at a specified time and place, *why such party should not be absolutely restrained from any further proceedings in such action or matter.*

(emphasis added).

Here, the Department has unlawfully (1) banned RAD Source's RS 420 Line of X-ray irradiators, even though x-ray irradiation is a safe and preferred method for treating marijuana; (2) required RAD Source to meet an impossible FDA Requirement before its RS 420 Line can be approved; (3) applied different standards to similarly situated competitors, e.g., by requiring RAD Source's irradiation products to meet the FDA Requirement, but not requiring Ziel's irradiation products to meet the FDA Requirement; and, (4) applied different standards to similarly situated competitors, e.g., by requiring RAD Source's treatment method to meet the FDA Requirement, but not requiring the Ziel or Willow methods to meet the FDA Requirement. Facts, *supra*, ¶¶ 1-70.

As it stands, RAD Source's products have been unlawfully banned from Nevada, while its competitors' similar products are allowed and held to far less stringent standards. Due to the Department's unlawful ban of the RS 420 Line, RAD Source estimates its current monetary damages at a minimum of $2 million and its future damages at $2 million to $ 4 million, at a minimum. *Id.* ¶¶ 62-65.

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Further, since the Department has allowed Ziel and Willow's similarly situated products but banned RAD Source's RS 420 Line, RAD Source is losing, and has lost, significant market share as well as its competitive advantage for its superior and preferable products. *Id.* ¶ 66. RAD Source has also suffered lost customer goodwill and business reputation. *Id.* ¶ 67. Moreover, the longer the Department's ban on RAD Source's products remains in place, the greater the loss to RAD

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Source's sales, market share, competitive advantage, goodwill, and reputation. *Id.* ¶ 68. Therefore, money damages are inadequate to remedy RAD Source's damages.

For these reasons, RAD Source is entitled to an Order to Show Cause Why a Writ of Certiorari, Mandamus, or Prohibition should not issue.

B. In the Alternative, a Preliminary Injunction Should Be Granted to RAD Source.

In the alternative, the Court should grant a preliminary injunction to RAD Source. Under Nevada law,

> Determining whether to grant or deny a preliminary injunction is within the district court's sound discretion. In exercising its discretion, the district court must determine whether the moving party has shown a likelihood of success on the merits and that the nonmoving party's conduct, should it continue, would cause irreparable harm, for which there is no adequate legal remedy.

Labor Com'r of State of Nevada v. Littlefield, 123 Nev. 35, 38–39, 153 P.3d 26, 28 (2007).

C. RAD Source Has Shown a Likelihood of Success on the Merits

RAD Source has shown a likelihood of success on the merits of its claims of (1) writ of certiorari; (2) writ of mandamus; (3) writ of prohibition; (4) declaratory judgment; (5) intentional interference with contractual relations; and (6) intentional interference with prospective economic advantage.

1. RAD Source Is Likely to Succeed on Its Writ of Certiorari Claim

For its first cause of action, RAD Source has shown a likelihood of success for a writ of certiorari. Under NRS § 34.020:

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> The writ [of certiorari] *shall be granted* in all cases when an inferior tribunal, board or officer, exercising judicial functions, has exceeded the jurisdiction of such tribunal, board or officer and there is no appeal, nor, in the judgment of the court, any plain, speedy and adequate remedy.

(emphasis added).

In this case, the Department has exceeded its authority. During Nevada's 2016 General Election, the voters approved an initiative petition to legalize the recreational use of marijuana by persons 21 years of age or older. This initiative petition was codified as Chapter 453D of the Nevada Revised Statutes (the "Ballot Initiative"). Under the express language of the Ballot Initiative, the Department was forbidden from creating regulations that made the operation of recreational marijuana establishments unreasonably impracticable. NRS 453D.020(1); NRS 453D.020(3); NRS 453D.200(f); *see* Facts, *supra*, ¶¶ 21-28.

However, the Department's actions related to RAD Source's products make the operation of recreational marijuana establishments unreasonably impracticable. It is undisputed that there are significant health and safety concerns with untreated marijuana. Facts, *supra*, ¶¶ 16-20. It is undisputed that the RS 420 Line safely and effectively decontaminates marijuana. *Id.* ¶¶ 6-17, 29. At no time in the parties' prior communications has the Department ever disputed the safety or effectiveness of the RS 420 Line in treating marijuana. *Id.* ¶ 54.

Moreover, it is undisputed that the RS 420 Line is used to safely and effectively treat marijuana in California, Colorado, Illinois and Michigan, as well as Canada and the Netherlands. *Id.* ¶¶ 10, 15. It is undisputed that the RS 420 Line was in use in Nevada for two years prior to the Department's unlawful ban. *Id.* ¶¶ 29-30.

Despite these undisputed facts, the Department banned the RS 420 Line of equipment, without any justification. Thus, the Department has exceeded the express language of the Ballot Initiative by making the operation of recreational marijuana establishments unreasonably impracticable. *See* NRS 453D.020(1); NRS 453D.020(3); NRS 453D.200(f).

The Department also exceeded its authority by creating impossible-to-meet standards. In order to lift the ban on the RS 420 Line, the Department required RAD Source to obtain certification from the U.S. Food and Drug Administration ("FDA") or a letter of exemption from

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FDA (the "FDA Requirement"). Facts, *supra*, ¶ 34. However, marijuana is not a "food" and therefore is not regulated by FDA. As such, RAD Source cannot obtain an FDA certification or letter of exemption for products treating marijuana. Further, FDA, as a federal agency, will not review or issue any certification or letter of exemption on a marijuana product because it is not legally permitted under federal law. *See* 21 U.S.C. § 801 *et seq.*; Exhibit C attached to Hartman Decl., email from Jeremiah Fasano, Consumer Safety Officer, FDA, dated April 22, 2019; Facts, *supra*, ¶¶ 35-42. Therefore, the FDA requirement is both inapplicable and impossible to meet. By insisting that RAD Source's products meet the FDA Requirement, the Department has made the operation of recreational marijuana establishments unreasonably impracticable, which exceeds its authority under the Ballot Initiative.

Finally, the Department has exceeded its authority by applying different standards to similarly situated competitors. Facts, *supra*, ¶¶ 43-55. In particular, the Department has approved Ziel's and Willow's products for use in treating marijuana without having them meet the impossible FDA Requirement, even though they use radio frequency radiation and ozone treatment, respectively. *Id.* The Department's unfair, unequal, and discriminatory treatment of RAD Source's products is unjustified and unreasonable. Therefore, the Department has exceeded its authority under the Ballot Initiative.

In addition, the Department has informed RAD Source that it has no right to appeal these decisions and actions. *Id.* ¶ 70. Therefore, RAD Source does not have any plain, speedy, and adequate remedy. Because the Department has exceeded its authority and RAD Source does not have a plain, speedy, or adequate remedy, RAD Source has shown a likelihood of success for a writ of certiorari. A preliminary injunction should be granted.

2. RAD Source Is Likely to Succeed on Its Writ of Mandamus Claim

For its second cause of action, RAD Source has shown a likelihood of success on its writ of mandamus claim. Under NRS § 34.160:

> The writ may be issued by the Supreme Court, the Court of Appeals, a district court or a judge of the district court, to compel the performance of an act which the law especially enjoins as a duty resulting from an office, trust or station; or to compel the admission of a party to the use and enjoyment of a right or office to which the

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party is entitled and from which the party is unlawfully precluded by such inferior tribunal, corporation, board or person.

In other words, "[a] writ of mandamus is available to compel the performance of an act that the law requires as a duty resulting from an office, trust, or station or to control an arbitrary or capricious exercise of discretion." *Nevada Yellow Cab Corp. v. Eighth Judicial Dist. Court in & for Cty. of Clark*, 132 Nev. 784, 787, 383 P.3d 246, 248 (2016) (quoting *Humphries v. Eighth Judicial Dist. Court*, 129 Nev. 788, 791, 312 P.3d 484, 486 (2013)). For a writ to issue, generally a party must not have "an adequate and speedy legal remedy." *Id.*

As described above, the Department is prohibited under the Ballot Initiative from creating regulations that make the operation of recreational marijuana establishments unreasonably impracticable. NRS 453D.020(1); NRS 453D.020(3); NRS 453D.200(f); Facts, *supra*, ¶¶ 21-28. The Department failed to meet this obligation when it (1) banned, without any justifiable reason, the RS 420 Line, which is a safe and preferred method for treating marijuana; (2) created impossible-to-meet standards for RAD Source, namely requiring FDA certification or an FDA letter of exemption in order to lift the ban on the RS 420 Line; and (3) applied different standards to similarly situated competitors, like RAD Source versus Ziel and Willow. *See* Facts, *supra*, ¶¶ 1-70.

To the extent the Department's actions were an exercise of discretion, the Department acted arbitrarily and capriciously. *Id.*

Finally, RAD Source was denied a right to appeal the Department's decisions and actions. Therefore, there is no plain, speedy, and adequate remedy for RAD Source. *Id.* ¶ 70. For these reasons, RAD Source has shown a likelihood of success on the merits of its writ of mandamus claim and a preliminary injunction should be granted.

3. RAD Source Is Likely to Succeed on Its Writ of Prohibition Claim

For its third cause of action, RAD Source has shown a likelihood of success on its writ of prohibition claim. Under NRS § 34.320:

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> The writ of prohibition is the counterpart of the writ of mandate. It arrests the proceedings of any tribunal, corporation, board or person exercising judicial functions, when such proceedings are without or in excess of the jurisdiction of such tribunal, corporation, board or person.

Under NRS § 34.330:

> The writ may be issued only by the Supreme Court, the Court of Appeals or a district court to an inferior tribunal, or to a corporation, board or person, in all cases where there is not a plain, speedy and adequate remedy in the ordinary course of law.

As explained above, the Department was without or in excess of its authority when it (1) banned, without any justifiable reason, the RS 420 Line, which is a safe and preferred method for treating marijuana; (2) created impossible-to-meet standards for RAD Source, namely the FDA Requirement; and (3) applied different standards to similarly situated competitors, like RAD Source versus Ziel and Willow. *See* Facts, *supra*, ¶¶ 1-70.

Further, the Department has informed RAD Source that it has no right to appeal these actions or decisions. Therefore, RAD Source does not have any plain, speedy, and adequate remedy for the Department's unlawful actions. *Id.* ¶ 70. As such, RAD Source has shown a likelihood of success on the merits of its writ of prohibition claim and a preliminary injunction should be granted.

4. RAD Source Is Likely to Succeed on Its Declaratory Judgment Claim

For its fourth cause of action, RAD Source has shown a likelihood of success on its declaratory judgment claim. Under NRS § 30.030:

> Courts of record within their respective jurisdictions shall have power to declare rights, status and other legal relations whether or not further relief is or could be claimed. No action or proceeding shall be open to objection on the ground that a declaratory judgment or decree is prayed for. The declaration may be either affirmative or negative in form and effect; and such declarations shall have the force and effect of a final judgment or decree.

As explained above, the Department acted unlawfully when it (1) banned, without any justifiable reason, the RS 420 Line, which is a safe and preferred method for treating marijuana; (2) created impossible-to-meet standards for RAD Source, namely the FDA Requirement; and (3) applied different standards to similarly situated competitors, like RAD Source versus Ziel and Willow. *See* Facts, *supra*, ¶¶ 1-70. For these reasons, RAD Source has shown a likelihood of

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success on the merits of its declaratory judgment claim and a preliminary injunction should be granted.

5. RAD Source Is Likely to Succeed on Its Claim for Intentional Interference with Contractual Relations

For its fifth cause of action, RAD Source has shown a likelihood of success on its claim for intentional interference with contractual relations. In an action for intentional interference with contractual relations, a plaintiff must establish:

(1) a valid and existing contract;

(2) the defendant's knowledge of the contract;

(3) intentional acts intended or designed to disrupt the contractual relationship;

(4) actual disruption of the contract; and

(5) resulting damage.

J.J. Indus., LLC v. Bennett, 119 Nev. 269, 274, 71 P.3d 1264, 1267 (2003).

> To prove knowledge, "the plaintiff must demonstrate that the defendant knew of the existing contract, or at the very least, establish facts from which the existence of the contract can reasonably be inferred." ...To prove intent, the plaintiff must show that the defendant acted with the specific motive or purpose of interfering with the contract.

Barraco v. Robinson, No. 72566-COA, 2019 WL 1932068, at *4 (Nev. App. Apr. 26, 2019) (quoting *J.J. Indus.*, 119 Nev. at 274, 71 P.3d at 1267).

First, valid and existing contracts existed between RAD Source and its Nevada customers who used the RS 420 Line for treating marijuana. Facts, *supra*, ¶¶ 62-63. Second, the Department knew of these contracts, or at least could have reasonably inferred the existence of these contracts, when it banned RAD Source's customers from using the RS 420 Line of equipment that they had purchased. *See id.* ¶¶ 30, 62.

Third, the Department took intentional acts intended or designed to disrupt RAD Source's contractual relationships, namely through banning the use of the RS 420 Line, creating the impossible-to-meet FDA Requirement for the RS 420 Line, and applying different standards to similarly situated competitors like RAD Source, Ziel, and Willow. *Id.* ¶¶ 31-55.

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Fourth, actual disruption of the contracts occurred because RAD Source's customers are no longer allowed to use their purchased RS 420 Line equipment in their treatment of marijuana. *Id.* ¶ 62.

Finally, RAD Source has suffered damages as a result of the Department's intentional and unlawful conduct. RAD Source estimates its total lost sales at a minimum of $2 million. *Id.* ¶ 62. RAD Source has also suffered non-monetary damages such as lost market share, competitive advantage, goodwill, and reputation. *Id.* ¶¶ 66-67. Again, the longer the ban remains in place, the greater the harm will be to RAD Source's market share, competitive advantage, goodwill, and reputation. *Id.* ¶ 69.

For these reasons, RAD Source has shown a likelihood of success on the merits of its claim for intentional interference with contractual relations. A preliminary injunction should be granted.

6. RAD Source Is Likely to Succeed on its Claim for Intentional Interference with Prospective Economic Advantage

For its sixth cause of action, RAD Source has shown a likelihood of success on its claim for intentional interference with prospective economic advantage. Under Nevada law:

> Liability for the tort of intentional interference with prospective economic advantage requires proof of the following elements: (1) a prospective contractual relationship between the plaintiff and a third party; (2) knowledge by the defendant of the prospective relationship; (3) intent to harm the plaintiff by preventing the relationship; (4) the absence of privilege or justification by the defendant; and (5) actual harm to the plaintiff as a result of the defendant's conduct.

Wichinsky v. Mosa, 109 Nev. 84, 87-88, 847 P.2d 727, 729-30 (1993).

Under the first element, RAD Source had prospective contractual relationships with potential customers in Nevada who treat marijuana. Facts, *supra*, ¶¶ 63-65. Second, the Department knew of these prospective relationships because it knew RAD Source had already sold, and sought to continue to sell, its RS 420 Line to customers in Nevada. *Id.* ¶¶ 30, 34, 38-39, 56-61. Third, the Department intended to harm RAD Source by preventing these relationships when it banned the RS 420 Line, created the impossible-to-meet FDA Requirement for the RS

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420 Line, and applied different standards to similarly situated competitors like RAD Source, Ziel, and Willow. *Id.* ¶¶ 31-61.

Fourth, as discussed above, the Department's actions are not justified. *Id.*, ¶¶ 1-70.

Finally, RAD Source has suffered actual harm from the Department's conduct. RAD Source estimates its lost negotiations at the time of the ban at around $2.3 million. *Id.* ¶ 63. RAD Source's also has lost on multiple machine purchases from these potential customers. *Id.* ¶ 64. Further, RAD Source estimates lost sales from other industry participants at $2 million to $4 million, which will continue to grow the longer the ban is in place. *Id.* ¶ 65.

RAD Source has also suffered non-monetary damages such as lost market share, competitive advantage, goodwill, and reputation. *Id.* ¶¶ 66-67. Again, the longer the ban remains in place, the greater the harm will be to RAD Source's market share, competitive advantage, goodwill, and reputation. *Id.* ¶ 69.

For these reasons, RAD Source has shown a likelihood of success on the merits of its claim for intentional interference with prospective economic advantage. A preliminary injunction should thus be granted.

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D. RAD Source Has Shown Irreparable Harm for Which There Is No Adequate Legal Remedy

A preliminary injunction should be granted because RAD Source will suffer irreparable harm if the Department's ban on the RS 420 Line continues. Due to the Department's unlawful ban of the RS 420 Line, RAD Source estimates (1) its lost contracts at $2 million; (2) its lost negotiations at around $2.3 million; and (3) its lost multiple machine purchases and lost sales from other industry participants at $2 million to $4 million. *Id.* ¶¶ 62-65. Further, the Department has allowed Ziel and Willow's products to be used in Nevada but banned RAD Source's products. Because of this, RAD Source is losing, and has lost, significant market share as well as its competitive advantage for its superior and preferable products. *Id.* ¶ 66. Moreover, the Department's ban has caused RAD Source to lose customer goodwill and business reputation. *Id.* ¶ 67.

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Money damages are inadequate to compensate RAD Source's loss of market share, competitive advantage, goodwill, and reputation. *Id.* ¶ 68. Further, the longer the ban remains in place, the greater the harm will be to RAD Source's market share, competitive advantage, goodwill, and reputation. *Id.* ¶ 69. Finally, RAD Source's money damages against the Department are statutorily capped at $100,000. NRS § 41.035; *Landeros v. Las Vegas Metro. Police Dep't*, No. 214CV1525JCMCWH, 2019 WL 1994456, at *4 (D. Nev. May 3, 2019) (holding that plaintiff's damages were reduced to statutory cap of $100,000). Thus, RAD Source is suffering irreparable harm, for which there is no adequate remedy. A preliminary injunction should be granted.

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E. The Balance of Hardships Heavily Weighs In RAD Source's Favor

"In considering preliminary injunctions, courts also weigh the potential hardships to the relative parties and others, and the public interest." *Univ. & Cmty. Coll. Sys. of Nevada v. Nevadans for Sound Gov't*, 120 Nev. 712, 721, 100 P.3d 179, 187 (2004).

In this case, the balance of hardships weighs heavily in RAD Source's favor. As a result of the ban, RAD Source has incurred, and continues to incur, substantial money damages. Further, RAD Source is losing, and has lost, significant market share, competitive advantage, customer goodwill, and business reputation. These losses are exacerbated by the fact that the Department has allowed Ziel and Willow's products in Nevada, which compete directly with RAD Source's RS 420 Line. Even more, all of RAD Source's monetary and non-monetary harm substantially increases the longer the Department's ban remains in place. Taken together, RAD Source stands to suffer an enormous amount of loss.

In contrast, the Department will suffer no harm by lifting its ban on the RS 420 Line. It is undisputed that the RS 420 Line safely and effectively decontaminates marijuana and has been approved for use by other States as well as other countries. It is undisputed that the RS 420 Line was used in Nevada for two years prior to the ban. It is undisputed that RAD Source's x-ray irradiation process is safe and preferable method for treating marijuana. At no time has the Department disputed the safety or effectiveness of the RS 420 Line. Facts, *supra*, ¶¶ 6-17, 29-30,

54. Rather, the Department wants the RS 420 Line, and only the RAD 420 Line, to meet the FDA Requirement, which is both inapplicable and impossible. *Id.* ¶¶ 35-55. No other product, process, or competitor is required by the Department to meet the FDA Requirement, which demonstrates that the FDA Requirement is entirely arbitrary and capricious and in no way necessary. *Id.* ¶¶ 43-55. In sum, there will be no harm to the State in allowing RAD Source to do what it did for years, what it is doing in other jurisdictions, and what its competitors are doing. Therefore, a preliminary injunction should be granted and the ban on the RS 420 Line should be lifted.

F. Public Policy Warrants a Preliminary Injunction

Public policy warrants a preliminary injunction. As discussed above, there are significant public health and safety concerns with untreated marijuana, including the potentially deadly *Aspergillus* spores. Facts, *supra*, ¶¶ 16-20. X-ray irradiation is a proven safe, effective, and preferable method for treating marijuana. *Id.* ¶¶ 6-17, 29-30, 54. Therefore, public health and safety would best be served if the ban was lifted from the RS 420 Line.

Additionally, lifting the ban would also serve the public policy against making the operation of recreational marijuana establishments unreasonably impracticable. NRS 453D.020(1); NRS 453D.020(3); NRS 453D.200(f). Moreover, lifting the ban would also promote the economic health of the marijuana treatment industry. Finally, public policy also mandates the equal treatment of market participants. The State cannot create an unfair environment where only some participants are allowed to compete. For all these reasons, public policy warrants a preliminary injunction.

G. The Bond Should Be Nominal

Because the RS 420 Line is undisputed as a safe, effective, and preferable method for treating marijuana, and because there will be no harm if an injunction is entered precluding the unlawful ban on the RAD 420 Line, the bond required for a preliminary injunction should be nominal. NRCP 65(c).

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IV. CONCLUSION

Based on the foregoing, RAD Source respectfully requests that this Court:

(1) Enter an order against the Department requiring it to show cause why a writ of certiorari, mandamus, or prohibition should not issue;

(2) Grant a preliminary injunction compelling the Department to (i) lift the ban on the RS 420 Line and approve of its use for the treatment of marijuana; (ii) cease and desist requiring the RS 420 Line to meet the impossible FDA Requirement; and (iii) apply the same standards to similarly situated competitors, like RAD Source, Ziel, and Willow; and

(3) Grant an order shortening time for hearing of this motion.

Dated this 13th day of December 2019.

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CERTIFICATE OF SERVICE

The undersigned, an employee of H1 Law Group, hereby certifies that on the 13th day of December 2019, she caused a courtesy copy of the foregoing to be hand delivered to Department 29, The Honorable David Jones.

Karen M. Morrow, an employee of H1 LAW GROUP

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EXHIBIT 1

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EIGHTH JUDICIAL DISTRICT COURT

CLARK COUNTY, NEVADA

RAD SOURCE TECHNOLOGIES, INC., a Florida Corporation, Plaintiff, vs. THE STATE OF NEVADA *ex rel.* DEPARTMENT OF TAXATION, MARIJUANA ENFORCEMENT DIVISION, Defendant.	Case No.: A-19-805074-W Dept. 29 **ORDER:** **(1) TO SHOW CAUSE WHY A WRIT OF CERTIORARI, MANDAMUS, AND/OR PROHIBITION SHOULD NOT ISSUE; AND** **(2) SHORTENING TIME FOR HEARING ON (1) MOTION FOR ORDER TO SHOW CAUSE WHY A WRIT OF CERTIORARI, MANDAMUS, AND/OR PROHIBITION SHOULD NOT ISSUE; (2) ALTERNATIVE MOTION FOR PRELIMINARY INJUNCTION**

TO: THE STATE OF NEVADA *ex rel.* DEPARTMENT OF TAXATION, MARIJUANA ENFORCEMENT DIVISION ("Defendant")

WHEREAS, the Court has reviewed Plaintiff RAD Source Technologies, Inc.'s (1) Motion for Order to Show Cause Why a Writ of Certiorari, Mandamus, and/or Prohibition Should Not Issue; (2) Alternative Motion for Preliminary Injunction; and (3) Application for Order Shortening Time (the "Motion"), and good cause having been shown for a hearing on

whether a writ of certiorari, mandamus, and/or prohibition should issue, or in the alternative whether a preliminary injunction should be entered,

NOW, THEREFORE, YOU, AND EACH OF YOU SERVED WITH A COPY OF THIS ORDER ARE HEREBY ORDERED to appear in Department 29 in the above entitled court at the hour of 9 AM .m., on the 15th day of January, 2020, and show cause, if you have any, why a writ of certiorari, mandamus, and/or prohibition should not issue, or in the alternative whether a preliminary injunction should be entered, as requested in the Motion.

IT IS FURTHER ORDERED that the Motion and this Order shall be served upon the Defendant and the hearing shall be based on these pleadings, papers and documents and those on file herein. Defendant shall have until December 26, 2019 to file an Opposition to the Motion, and Plaintiff shall have until January 3, 2020 to file a Reply.

DATED this _____day of December 2019.

DISTRICT COURT JUDGE

Prepared and Submitted By:

H1 LAW GROUP

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EXHIBIT 2

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DECLARATION OF WILLIAM HARTMAN IN SUPPORT OF RAD SOURCE TECHNOLOGIES, INC.'S (1) MOTION FOR ORDER TO SHOW CAUSE WHY A WRIT OF CERTIORARI, MANDAMUS, AND/OR PROHIBITION SHOULD NOT ISSUE; (2) ALTERNATIVE MOTION FOR PRELIMINARY INJUNCTION; AND (3) APPLICATION FOR ORDER SHORTENING TIME

I, William Hartman, being duly sworn, depose and state:

1. I am the President and Chief Executive Officer of RAD Source Technologies, Inc., a Florida Corporation ("RAD Source"), and have personal knowledge of the facts contained herein, except for those matters stated upon information and belief, and as to those matters, I believe them to be true, and if called upon to testify, could and would do so.

2. I make this Declaration in support of RAD Source's (1) Motion for Order to Show Cause Why a Writ of Certiorari, Mandamus, and/or Prohibition Should Not Issue; (2) Alternative Motion for Preliminary Injunction; and (3) Application for Order Shortening Time ("Motion").

3. RAD Source is and was at all relevant times hereto a foreign corporation, duly organized and existing under the laws of the State of Florida, and which has applied for and received authority to conduct business in the State of Nevada, and has its principal offices in Buford, Georgia.

RAD Source Is a World-Renowned Manufacturer of Irradiators

4. RAD Source was founded in 1997 with the purpose of creating safer irradiation methods than those used at the time, which involved radioactive gamma sources. For over 20 years, RAD has been the industry leader in manufacturing renewable, non-isotope, ionizing radiation products worldwide.

5. RAD Source's patented and proprietary QUASTAR® technology produces high output X-Ray radiation efficiently and reliably for a wide variety of irradiation applications including blood, cell and tissue, insects, biological research, and viral inactivation.

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6. RAD Source's equipment is utilized in these various applications throughout the United States and worldwide.

7. Currently, RAD Source's equipment resides in hundreds of major pharmaceutical labs, healthcare institutions, and renowned universities worldwide. RAD Source's impressive and extensive client list includes the American Red Cross, the Mayo Clinic, and the U.S. Food and Drug Administration's National Center for Toxicological Research, to name a few.

Irradiation Is a Safe, Widely-Utilized, and Well-Studied Process

8. Irradiation is the process by which an object is exposed to radiation, i.e. energy transmitted in waves or streams of particles. Types of electromagnetic radiation include visible light, radio frequency, microwaves, infrared light, ultraviolet light, X-rays and gamma rays.

9. RAD Source is the developer of the RS 420 Line of X-ray Irradiators.

10. The RS 420 Line is used for the safe and effective treatment of marijuana, as described herein.

11. Irradiation is a safe, widely utilized, and well-studied process that is used in marijuana decontamination, sterilization, blood transfusion, immunology and oncology research, and agriculture, among others.

12. Ionizing radiation has been used for more than a decade in Canada and the Netherlands specifically for the treatment of marijuana.

13. RAD Source's RS 420 Line of equipment and is a safe alternative to gamma source irradiators and other processes used to treat marijuana.

14. RAD Source's RS 420 Line of equipment also operates within parameters prescribed by FDA under existing regulations to treat food products.

15. Food irradiation is endorsed by FDA, the World Health Organization (WHO), the Centers for Disease Control and Prevention (CDC), and the U.S. Department of Agriculture (USDA) to treat products for human consumption.

16. Specifically, irradiation is beneficial for prevention of foodborne illness, preservation, control of insects, delay of sprouting and ripening, and sterilization that may be present in untreated product for human consumption.

RS 420 Line of X-Ray Irradiators for Treatment of Marijuana Is a Safe and Preferred Method for Treating Marijuana

17. The use of X-ray photons or emitters for ionizing radiation is the preferred method for the treatment of marijuana because radioactive isotopes (gamma sources) pose an environmental and security risk.

18. The RS 420 Line uses RAD Source's proprietary, patented QUASTAR® X-Ray technology.

19. Within the United States, the RS 420 Line has been allowed to treat marijuana under California, Colorado, Illinois and Michigan's regulated marijuana markets.

Public Health and Safety Concerns Related to Untreated Marijuana

20. Given the multiple steps involved in harvesting, drying, processing, and packaging marijuana, it can be difficult to maintain perfectly sterile conditions throughout the entire marijuana production process. In order to ensure the safety of the product ultimately delivered to the consumer, growers utilize decontamination processes in the everyday processing of marijuana product and in converting quarantined product into safe, useable product.

21. For example, RAD Source has numerous test results from multiple states, including Nevada, that show its use of X-ray treatment on marijuana has little to no impact on THC, terpenes, or moisture, and that there is no change to the core characteristics of the product after treatment.

22. Moreover, just like cultivating any other crop, marijuana is subject to a wide range of potential contaminants including yeast, mold, insects, and other pathogens.

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23. The most concerning pathogen in the marijuana industry is *Aspergillus*. There have been documented cases of medicinal marijuana patients who have died from aspergillosis, a condition caused by inhaling *Aspergillus* spores.

24. The Department recently issued a public health and safety advisory warning concerning the presence of *Aspergillus* in Nevada marijuana, highlighting the importance of this issue and the significance of potential impact on the health and safety of Nevada citizens and consumers. See **Exhibit E**, DOT Public Health and Safety Advisory 2019-02.

The RS 420 Line Was in Use for Two Years Prior to the Department's Ban

25. From March 2017 through March 2019, Nevada marijuana growers utilized Rad Source's RS 420 Line in everyday processing of marijuana to reduce yeast, mold (e.g., Aspergillus), and other pathogens and in converting quarantined product into safe, useable marijuana product.

26. During this time, the Department was aware that growers were using RAD Source's technology to treat marijuana and did not raise concerns regarding its use. In fact, there have never been any concerns raised related to the use of the RS 420 Line and the product safely and effectively treated by the machines.

The Department Shuts Down the RS 420 Line and Provides a 6-point Checklist to Obtain Approval

27. Earlier this year, without any notice to RAD Source or any legitimate justification, the Department banned RAD Source customers from using the RS 420 Line of equipment.

28. RAD Source immediately and consistently engaged in good faith communications with the Department in an effort to resolve any concerns the Department may have regarding its technology.

29. On April 9, 2019, Dave Witkowski, DOT Inspector II, communicated to RAD Source a list of six criteria that the Department required in order to approve the use of irradiation instrumentation utilizing ionizing radiation to treat marijuana and marijuana

products. *See* email from D. Witkowski to J. Mugan dated April 9, 2019, a true and correct copy of which is attached hereto as **Exhibit A**.

30. The following week, the Department acknowledged that RAD Source had addressed all but one of the six criteria to its satisfaction, specifically, certification from the U.S. Food and Drug Administration ("FDA") or a letter of exemption from FDA (the "FDA Requirement"). *See* email from D. Witkowski to J. Mugan dated April 16, 2019 and previous emails in string, true and correct copies of which are attached hereto as **Exhibit B**.

The Single Remaining Item on the Checklist, the FDA Requirement, is Impossible to Obtain

31. Marijuana and anything made with marijuana, such as edible marijuana products, do not constitute "food" regulated by FDA.

32. Marijuana is a controlled substance under the Controlled Substances Act ("CSA") and its production, possession, and distribution are federally proscribed. Therefore, it is not possible for RAD Source, nor any end user or any other party, to obtain FDA approval for devices used to process marijuana.

33. In its effort to appease the Department, RAD Source reached out to FDA to inquire as to the possibility of obtaining some form of certification or letter of exemption per the Department's request and requirement for the same.

34. In response, a representative of FDA informed RAD Source that: (i) the request being made by the Department is impossible as marijuana products do not constitute food; and (ii) FDA, as a federal agency, will not review or issue any certification or letter of exemption on a marijuana product because it is not legally permitted under federal law. *See* email from Jeremiah Fasano, Consumer Safety Officer, FDA, dated April 22, 2019, a true and correct copy of which is attached hereto as **Exhibit C**.

35. RAD Source has gone to great lengths to resolve the FDA Requirement to the Department's satisfaction, including multiple discussions with the Department representatives and counsel, in person and over the phone, and providing documentation explaining (1) marijuana is not a "food" and therefore is not subject to FDA oversight, and

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(2) as marijuana is a federally controlled substance, it is impossible to satisfy the FDA Requirement.

36. However, the Department continues to ban the RS 420 Line based on the inapplicable, and impossible, FDA Requirement.

37. The Department does not require other marijuana treatment processes or equipment to meet the FDA Requirement. In short, the Department approved competitors of RAD Source have not had their processes or machines approved by the FDA for use with marijuana.

The Department Approves Similarly Situated Competitor Devices Including Irradiation Devices

38. Upon information and belief, despite the Department refusing to approve the RS 420 Line without the FDA Requirement, the Department approved one of RAD Source's primary competitors without requiring it, or its customers, to satisfy the FDA Requirement.

39. Upon information and belief, this competitors' technology uses a form of irradiation (to generate heat, as opposed to RAD Source technology which does not require the creation of heat) to treat marijuana.

40. The Department's approval of one irradiation device and not another is unequal treatment and is arbitrary and capricious.

41. Upon information and belief, the Department also approved other treatment processes and devices, including an ozone-based treatment process used by another primary competitor of RAD Source.

42. Neither ozone treatment nor the competitor's device are approved by the FDA for use in treatment of marijuana.

43. The Department's approval of one or more non-FDA approved treatment processes, but not another, is unequal treatment, and is arbitrary and capricious.

44. Given that the FDA Requirement is impossible to satisfy, the Department must have waived this requirement for Rad Source's competitors and their customers. Yet

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the Department still requires RAD Source and its customers to comply with the impossible FDA Requirement as a pre-requisite to obtaining approval. This unequal treatment of similarly situated competitors is unlawful.

45. Further, given voter concerns about public health and safety in the Ballot Initiative, and given the Department's recently issued public health and safety advisory warning concerning the presence of *Aspergillus* in Nevada marijuana, it is in the public interest to approve the RS 420 Line and return it to use.

46. This is especially true given that X-ray irradiation, as used by RAD Source, is a safe and preferred method for the treatment of marijuana. In fact, at no time has the Department ever questioned the safety of using X-ray irradiation to treat marijuana.

47. Rather, the Department has banned the RS 420 Line based on the inapplicable, and impossible, FDA Requirement.

RAD Source Sends Multiple Requests to the Department to Withdraw Its Unlawful FDA Requirement

48. Immediately after the Department banned the RS 420 Line, RAD Source sent the Department a letter on April 10, 2019, through its counsel at the time, that explained the inapplicability of the FDA Requirement. *See* April 10, 2019 Letter from Kolesar & Leatham to DOT, a true and correct copy of which is attached hereto as **Exhibit F**.

49. Over the next weeks and months, RAD Source worked extensively with the Department to resolve the issue regarding the inapplicable, and impossible, FDA Requirement.

50. Given the Department's unwillingness to withdraw the FDA Requirement, on August 23, 2019, RAD Source sent the Department a white paper with detailed exhibits and references. See RAD Source's August 23, 2019 letter to Jorge Pupo, DOT, a true and correct copy of which is attached hereto as **Exhibit D** (attachments excluded). This paper described how the RS 420 Line works, its history of use, and its recognition as safe and effective. *Id.* at

2-8. Further, RAD Source thoroughly explained the inapplicability, and impossibility, of the FDA Requirement. *Id.* at 8-9.

51. Despite this detailed explanation, the Department still refused to withdraw the FDA Requirement. So, in a final effort to resolve this issue outside of a legal action, RAD Source sent another letter, on November 1, 2019, to Steven Shevorski, head of complex litigation at Nevada's Office of Attorney General. *See* November 1, 2019 Letter from H1 Law Group to Steven Shevorski, Office of the Attorney General, a true and correct copy of which, without attachments, is attached hereto as **Exhibit G**.

52. This final letter explained in detail that (1) the RS 420 Line was in use for two years prior to the Department's ban; (2) the FDA Requirement is inapplicable and impossible; (3) the Department has approved similar devices without requiring them to meet the FDA Requirement; and (4) the Department has acted arbitrarily and capriciously. *Id.* at 1-5.

53. Despite these many letters and detailed explanations, the Department has refused to resolve this matter and insists on the RS 420 Line meeting the inapplicable, and impossible, FDA Requirement.

RAD Source has Suffered, and Will Continue to Suffer, Significant Harm

54. Due to the Department's unlawful ban of the RS 420 Line, 5 clients of RAD Source in Nevada have 11 machines that have been shut down. Collectively, these 5 clients paid more than $2 million for their 11 machines, and the Department's ban has rendered the machines effectively unusable. Understandably, RAD Source's clients are dissatisfied with this situation.

55. In addition, at the time of the Department's unlawful ban, RAD Source was in negotiations for the sale of additional RS 420 machines with prospective customers. At a minimum, RAD Source lost 12 prospective machine sales. For just the costs of the units, and not factoring in additional revenues from add-on items and services or renewed warranties, this has resulted in $2,395,000.00 of lost sales.

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56. RAD Source customers historically have been happy with the effectiveness of the RS 420 products, and as a result have purchased multiple machines. The Department's unlawful ban has precluded all such sales.

57. In addition, RAD Source anticipates further lost sales from other industry participants that had expressed interest in and/or that are familiar with the RS 420 Line, but whom have learned of the unlawful ban. RAD Source estimates $2 million to $4 million in lost potential sales from these prospective customers if the ban is not lifted.

58. The Department also has allowed competitor's similarly situated products but banned RAD Source's RS 420 Line. Because of this, RAD Source is losing, and has lost, significant market share as well as its competitive advantage for its superior and preferable products.

59. Moreover, the Department's ban has caused RAD Source to lose customer goodwill and business reputation.

60. Money damages are inadequate to compensate RAD Source's loss of market share, competitive advantage, goodwill, and reputation.

61. Further, the longer the ban remains in place, the greater the harm will be to RAD Source's market share, competitive advantage, goodwill, and reputation.

62. The Department has informed RAD Source that it has no right to appeal its decisions and actions.

I declare under penalty of perjury under the law of the State of Nevada that the foregoing is true and correct.

Executed on December 10, 2019.

WILLIAM HARTMAN

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EXHIBIT A

Joseph J. Mugan

From: David Witkowski <dwitkowski@tax.state.nv.us>
Sent: Tuesday, April 09, 2019 8:55 AM
To: Joseph J. Mugan
Cc: Karalin Cronkhite
Subject: Irradiation instrumentation approval

Good morning Mr. Mugan,

The following criteria must be met prior to approving the use of any type of irradiation instrumentation utilizing ionizing radiation to treat marijuana and marijuana products:

1) That the instrumentation is registered/certified as required by the Department of Public and Behavioral Health - Radiation Control Program. (End User)
2) Certification from the Food and Drug Administration (FDA) or a letter of exemption. (End User)
3) If bags are used to contain the product, they must be on the approved list provided by the FDA.
4) If the manufacturer of the instrumentation make the claims that the instrumentation/technology reduces mold/mildew, bacteria and viruses, then the manufacturer should have an Environmental Protection Agency (EPA) establishment number.
5) Documentation that the instrument manufacturer has provided training to the purchaser/end users of the instrumentation.
6) Written Approval from the Marijuana Enforcement Division. (End User)

Please contact our office with any concerns or questions regarding this matter.

Thank you,
Dave

Dave Witkowski
Inspector II
Marijuana Enforcement Division
Nevada Department of Taxation
555 E. Washington Ave. Suite 4100
Las Vegas, NV 89101
Phone: 702.486.5405
Cell: 702.468.2685
dwitkowski@tax.state.nv.us

EXHIBIT B

From: David Witkowski [dwitkowski@tax.state.nv.us]
Sent: Tuesday, April 16, 2019 10:52 AM
To: Joseph J. Mugan
Cc: Karalin Cronkhite; Jordan D. Wolff; George Terry; Will Hartman
Subject: RE: Irradiation instrumentation approval

Good morning Joseph,

Thank you for your response.

For verification purposes, would it be possible to get any conformation from the FDA or your client regarding your comments highlighted in yellow below? Even an email confirming the conversation / information that was exchanged between your client and the FDA?

Thank you,
Dave

From: Joseph J. Mugan [mailto:jmugan@klnevada.com]
Sent: Saturday, April 13, 2019 12:08 PM
To: David Witkowski <dwitkowski@tax.state.nv.us>
Cc: Karalin Cronkhite <kcronkhite@tax.state.nv.us>; Jordan D. Wolff <jwolff@klnevada.com>; 'George Terry' <GTerry@radsource.com>; Will Hartman <whartman@radsource.com>
Subject: FW: Irradiation instrumentation approval

Dave:

As a follow up to our discussions yesterday and in a good faith effort to assist the Division in better understanding the use of the subject irradiation equipment, please find attached the following: (i) a brief summary prepared by the Company about itself, its equipment and the process; and (ii) an article titled "Evaluating the Effects of Gamma Irradiation for Decontamination of Medical Cannabis" for your reference.

As to the request relating to the Food and Drug Administration set forth below, we understand that such request as to some form of a certification or letter of exemption from the FDA is a requirement of an end-user but please note that my client has been diligently working in good faith to resolve this issue.

As discussed and in accordance with applicable law, marijuana and anything made with marijuana, such as marijuana brownies, do not constitute "food" by the Food and Drug Administration. Marijuana is a controlled substance and governed by The Controlled Substances Act ("CSA") and the DEA. Its production, possession, and distribution are federally proscribed by CSA. In fact, and in response to your request below notwithstanding the above, my client reached out directly to representatives of the FDA and an FDA consultant to discuss whether there was any possibility in obtaining some form of certification or letter of exemption, despite the fact that marijuana products do not constitute food. My client was specifically informed by the FDA that: (i) the request being made by the Division is inapplicable as such products do not constitute food; and (ii) the FDA, as a federal agency, will not review or issue any certification or letter of exemption on a marijuana product which is not legally permitted under federal law. Basically, the FDA informed my client that they, in essence, will not touch it.

Due to the foregoing, the guidance you cite regarding food processing and irradiation is inapplicable to a

Schedule I controlled substance and it is not possible for my client, nor any end user or any other party using similar equipment, to comply with the Division's request to obtain some form of certification or letter of exemption from the FDA for marijuana. We respectfully request that the Division remove this requirement as it is inapplicable and impossible to satisfy by any party.

Finally, my client is willing to travel to Las Vegas and meet with the Division early next week to discuss the foregoing in a good faith effort to resolve these issues in a timely fashion. It is more than my client's commercial issue, we believe it is a public health issue. Please let us know if the Division would like to have such a meeting and we can plan accordingly.

Thanks and we look forward to hearing from you.

Joe

Joseph J. Mugan, Esq.
Shareholder
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ATTORNEYS AT LAW

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This communication (including any attachments) is not intended or written to be used, and it cannot be used, for the purpose of avoiding tax penalties that may be imposed on the taxpayer.

This transmission is intended only for the use of the addressee and may contain information that is privileged, confidential and exempt from disclosure under applicable law. If you are not the intended recipient, any use of this communication is strictly prohibited. If you have received this communication in error, please notify us immediately.

From: David Witkowski [mailto:dwitkowski@tax.state.nv.us]
Sent: Thursday, April 11, 2019 8:04 AM
To: Joseph J. Mugan <jmugan@klnevada.com>
Cc: Karalin Cronkhite <kcronkhite@tax.state.nv.us>; Jordan D. Wolff <jwolff@klnevada.com>; George Terry

<GTerry@radsource.com>; 'Will Hartman' <whartman@radsource.com>
Subject: RE: Irradiation instrumentation approval

Good morning Mr. Mugan,

Thank you for your prompt response. As it appears that the instrument manufacturer is in good shape, item number 2 that you responded to is an end user requirement.

> Certification from the Food and Drug Administration (FDA) or a letter of exemption. (End User)

The Division's understanding, based on the two attached documents is that the establishment/firm/end user who is going to employ a process commercially, is required to get FDA approval.

1) "Understanding Food Irradiation: What Industry Needs to Know"; This is an FDA publication that states that using sources of radiation to treat food requires approval by FDA before the process can be employed commercially and that the interested party may submit a food additive petition to FDA that contains data demonstrating the safety of the proposed use. This document goes on to give direction on how obtain approval.
   https://www.fda.gov/food/ingredientspackaginglabeling/irradiatedfoodpackaging/ucm242021.htm

2) "CFR Title 21 Part 179 Irradiation in the Production, Processing and Handling of Foods"; Specifically, Section 179.25 (a) states that "Any firm that treats foods with ionizing radiation shall comply with the requirements of parts 110 and 117 of this chapter and other applicable regulations". The Section goes on to detail several other requirements that shall be followed by a firm performing food irradiation. Section 179.26 talks about the conditions a firm should be following when employing Ionizing radiation to food including limitations on dosing.
   https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=179&showFR=1

I have also attached links to CFR Title 21 parts 110 & 117 that are referenced in CFR Title 21 part 179 below.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=110&showFR=1

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=117&showFR=1

Please do not hesitate to contact me or the Division regarding this matter,
Thank you,
Dave
From: Joseph J. Mugan [mailto:jmugan@klnevada.com]
Sent: Wednesday, April 10, 2019 11:13 AM
To: David Witkowski <dwitkowski@tax.state.nv.us>
Cc: Karalin Cronkhite <kcronkhite@tax.state.nv.us>; Jordan D. Wolff <jwolff@klnevada.com>; George Terry <GTerry@radsource.com>; 'Will Hartman' <whartman@radsource.com>
Subject: RE: Irradiation instrumentation approval

Good morning Mr. Witkowski:

Attached, please find our response to the criteria listed in your correspondence below. In the event you have

any questions or comments, please do not hesitate to contact us. Thanks.

Joe

Joseph J. Mugan, Esq.
Shareholder
KOLESAR & LEATHAM
ATTORNEYS AT LAW

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Web: www.klnevada.com Bio: Attorney Bio
400 S. Rampart Blvd. | Suite 400 | Las Vegas | NV 89145

From: David Witkowski [mailto:dwitkowski@tax.state.nv.us]
Sent: Tuesday, April 09, 2019 8:55 AM
To: Joseph J. Mugan <jmugan@klnevada.com>
Cc: Karalin Cronkhite <kcronkhite@tax.state.nv.us>
Subject: Irradiation instrumentation approval

Good morning Mr. Mugan,

The following criteria must be met prior to approving the use of any type of irradiation instrumentation utilizing ionizing radiation to treat marijuana and marijuana products:

1) That the instrumentation is registered/certified as required by the Department of Public and Behavioral Health - Radiation Control Program. (End User)
2) Certification from the Food and Drug Administration (FDA) or a letter of exemption. (End User)
3) If bags are used to contain the product, they must be on the approved list provided by the FDA.
4) If the manufacturer of the instrumentation make the claims that the instrumentation/technology reduces mold/mildew, bacteria and viruses, then the manufacturer should have an Environmental Protection Agency (EPA) establishment number.
5) Documentation that the instrument manufacturer has provided training to the purchaser/end users of the instrumentation.
6) Written Approval from the Marijuana Enforcement Division. (End User)

Please contact our office with any concerns or questions regarding this matter.

Thank you,
Dave

Dave Witkowski
Inspector II

Marijuana Enforcement Division
Nevada Department of Taxation
555 E. Washington Ave. Suite 4100
Las Vegas, NV 89101
Phone: 702.486.5405
Cell: 702.468.2685
dwitkowski@tax.state.nv.us

EXHIBIT C

From: Fasano, Jeremiah [Jeremiah.Fasano@fda.hhs.gov]
Sent: Monday, April 22, 2019 9:58 AM
To: George Terry
Subject: RE: Irradiation instrumentation approval

Mr. Terry-

This is in response to your inquiry about irradiation of cannabis. You conveyed to us that a state regulator has requested that you obtain a certification or a letter of exemption from the Food and Drug Administration (FDA) with respect to your use of irradiation to treat cannabis offered for sale in that state. Specifically, it is my understanding that you are requesting a certification or letter of exemption from FDA's Center for Food Safety and Applied Nutrition, Office of Food Additive Safety, with respect to your use of irradiation to treat cannabis that is used in human food products that are sold within the state. While you inquired about the irradiation of cannabis generally, here we discuss only the regulatory considerations relating to sources of irradiation applied to food as defined in the Federal Food, Drug and Cosmetic Act (FD&C Act).

Based on our phone call of Friday, April 12, 2019, it is my understanding that the food uses at issue are not permitted under the FD&C Act. I therefore do not recommend pursuit of a food additive approval for any currently unapproved uses of irradiation, because such an approval would not overcome the other legal barriers to your proposed food use of cannabis. For more information about FDA regulation of cannabis and cannabis-derived products, please see our Questions and Answers webpage.

You have likely already reviewed much of this material, but for completeness I am providing you with background information regarding FDA's regulation of irradiation. In the United States regulatory framework, sources of irradiation used to treat food are regulated as food additives. As such, the use of irradiation to treat food must be in conformity with a regulation under 21 CFR Part 179 or an exemption (for investigational use) in effect pursuant to section 409(j) of the Federal Food, Drug and Cosmetic Act. The current list of approved uses of irradiation to treat food can be found in 21 CFR 179.26(b).

Regards-
Jeremiah Fasano
Consumer Safety Officer

Center for Food Safety and Applied Nutrition
Office of Food Additive Safety
U.S. Food and Drug Administration
Tel: 240-402-1173
jeremiah.fasano@fda.hhs.gov

From: George Terry <GTerry@radsource.com>
Sent: Friday, April 12, 2019 11:23 AM
To: Fasano, Jeremiah <Jeremiah.Fasano@fda.hhs.gov>
Subject: FW: Irradiation instrumentation approval

Jeremiah,

Below is the request we received from the State. Since we are having email issues, for now can you just confirm receipt?
Thank you very much for your help with this!

From the State,

Thank you for your prompt response. As it appears that the instrument manufacturer is in good shape, item number 2 that you responded to is an end user requirement.

Certification from the Food and Drug Administration (FDA) or a letter of exemption. (End User)

The Division's understanding, based on the two attached documents is that the establishment/firm/end user who is going to employ a process commercially, is required to get FDA approval.

1) "Understanding Food Irradiation: What Industry Needs to Know"; This is an FDA publication that states that using sources of radiation to treat food requires approval by FDA before the process can be employed commercially and that the interested party may submit a food additive petition to FDA that contains data demonstrating the safety of the proposed use. This document goes on to give direction on how obtain approval.
https://www.fda.gov/food/ingredientspackaginglabeling/irradiatedfoodpackaging/ucm242021.htm

2) "CFR Title 21 Part 179 Irradiation in the Production, Processing and Handling of Foods"; Specifically, Section 179.25 (a) states that "Any firm that treats foods with ionizing radiation shall comply with the requirements of parts 110 and 117 of this chapter and other applicable regulations". The Section goes on to detail several other requirements that shall be followed by a firm performing food irradiation. Section 179.26 talks about the conditions a firm should be following when employing Ionizing radiation to food including limitations on dosing.
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=179&showFR=1

I have also attached links to CFR Title 21 parts 110 & 117 that are referenced in CFR Title 21 part 179 below.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=110&showFR=1

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=117&showFR=1

Please do not hesitate to contact me or the Division regarding this matter,
Thank you,

State signature

Thank you,

George Terry
EVP Sales & Marketing
gterry@radsource.com

RAD SOURCE TECHNOLOGIES, Inc.
"Leading the way in Non-nuclear irradiation"
4907 Golden Parkway
Ste 400
Buford, GA 30518
(954) 873-2085
www.radsource.com

EXHIBIT D

To: Jorge Pupo, Deputy Executive Director
Department of Taxation
Marijuana Enforcement Division
555 E. Washington Blvd., Ste. 4100
Las Vegas, NV 89101

Date: August 23, 2019

Re: Rad Source Technologies, Inc.
Request for Approval of RS 420 Line of X-Ray Irradiators in Treatment of Cannabis

RAD SOURCE

To: Jorge Pupo, Deputy Executive Director
Department of Taxation
Marijuana Enforcement Division
555 E. Washington Blvd., Ste. 4100
Las Vegas, NV 89101

Date: August 23, 2019

Re: Rad Source Technologies, Inc.
Request for Approval of RS 420 Line of X-Ray Irradiators in Treatment of Cannabis

Dear Mr. Pupo:

Rad Source Technologies, Inc. ("RAD Source") is the developer of the RS 420 line of X-ray Irradiators. Until recently, and for approximately the preceding two years, RAD Source customers in Nevada had been utilizing RAD Source equipment in the production of cannabis to reduce yeast, mold, and other pathogens.

By way of this letter, RAD Source hereby requests formal approval of its RS 420 equipment line for irradiation of cannabis in Nevada. To aid in your review, please refer to the enclosed documents:

1. RAD Source RS 420 White Paper;
2. Citations;
3. Appendices 1-3; and
4. RAD Source Standard Form SOPs.

We believe these materials provide excellent detail regarding the safety and effectiveness of the RAD 420 equipment line.

The RS 420 line has been approved for use in the treatment of cannabis in Colorado and Michigan. We trust that, after MED has the opportunity to review these materials, Nevada will likewise permit the continued use of the RS 420 line.

We urge MED to reinstitute use of the RS 420 line as soon as possible. Should you have any questions, please do not hesitate to contact William Hartman or George Terry at 678-765-7900.

William Hartman
Chief Executive Officer
whartman@radsource.com

George Terry
EVP of Sales and Marketing
gterry@radsource.com

RAD SOURCE TECHNOLOGIES, INC.

RS 420: White Paper – State of Nevada
Marijuana Enforcement Division (MED)

Introduction

Cannabis is increasingly becoming legal at the state level in the United States for medical and/or recreational use. Each state has to contend with the question of how to ensure the safety of a new product that is not covered under any existing federal safety guidelines. The purpose of this whitepaper is to address the efficacy and safety of x-ray irradiation, a form of ionizing radiation, in the treatment of cannabis.

RAD Source is proud to offer the RS 420 equipment line for the safe and effective irradiation of cannabis: the RS 420 X-Ray Irradiator, the RS 420•M X-Ray Irradiator, and the RS 420•XL X-Ray Irradiator. Within the United States, the RS 420 line has been approved for use in the treatment of cannabis in Colorado and Michigan. Until recent requests for additional information were made, the RS 420 line was operational at multiplate locations within the state of Nevada for approximately the prior two years.

By way of an overview, the RS 420 X-Ray Irradiator is a cabinet X-ray device that conforms to 21 CFR 1020.40 for optimal safe use. The units in the RS 420 line are equipped with either a single or dual X-ray Emitter. It rotates individual canisters around this X-ray Emitter for a specific period of time so that ionizing radiation (photons) is delivered to the contents of the canisters. The RS 420 line utilizes proprietary, patented technology. *See* Patents 7,346,147 7,515,686, and patents pending.

The RS 420•M X-Ray Irradiator and the RS 420•XL X-Ray Irradiator utilize the same technology (ionizing radiation) at smaller and larger capacities.

Please refer to the Specification Sheets, Operator's Manuals, and Standard Operating Procedures for information regarding the safety and function of each device in the attached appendices:

Appendix 1: *RS 420 X-Ray Irradiator*

1.1 Specification Sheet for RS 420 X-Ray Irradiator
1.2 Operator's Manual for RS 420 X-Ray Irradiator

Appendix 2: *RS 420•M X-Ray Irradiator*

2.1 Specification Sheet for RS 420•M X-Ray Irradiator
2.2 Operator's Manual for RS 420•M X-Ray Irradiator

Appendix 3: *RS 420•XL X-Ray Irradiator*

3.1 Specification Sheet for RS 420•XL X-Ray Irradiator
3.2 Operator's Manual for RS 420•XL X-Ray Irradiator

The Public Health and Safety Concerns

Just like cultivating any other crop, cannabis is subject to a wide range of potential contaminants including yeast, mold, insects, and other pathogens.[1] The most concerning pathogen in the cannabis industry is *Aspergillus*. While no state has reported an overdose from medicinal cannabis among those that have legalized its use, there have been documented cases of medicinal cannabis patients who have died from aspergillosis, a condition caused by inhaling *Aspergillus* spores.[2]

Given the multiple steps involved in harvesting, drying, processing, and packaging cannabis, it can be difficult to maintain perfectly sterile conditions throughout the entire cannabis production process.[3] In order to ensure the safety of the product ultimately delivered to the consumer, growers utilize decontamination processes in the everyday processing of cannabis product and in converting quarantined product into safe, useable cannabis product.[4]

How X-Ray Irradiation Works

1. What is Ionizing Radiation?

Irradiation is the process by which an object is exposed to radiation. Simply stated, radiation is energy transmitted in waves or a stream of particles. Think of radiation as energy that travels and spreads out as it goes, *i.e.*, the visible light that comes from a lamp in your house or the radio waves that come from a radio station (RF).

The other types of electromagnetic radiation that make up the electromagnetic spectrum are microwaves, infrared light, ultraviolet light, X-rays and gamma rays. See the figure below depicting the electromagnetic spectrum.[5]

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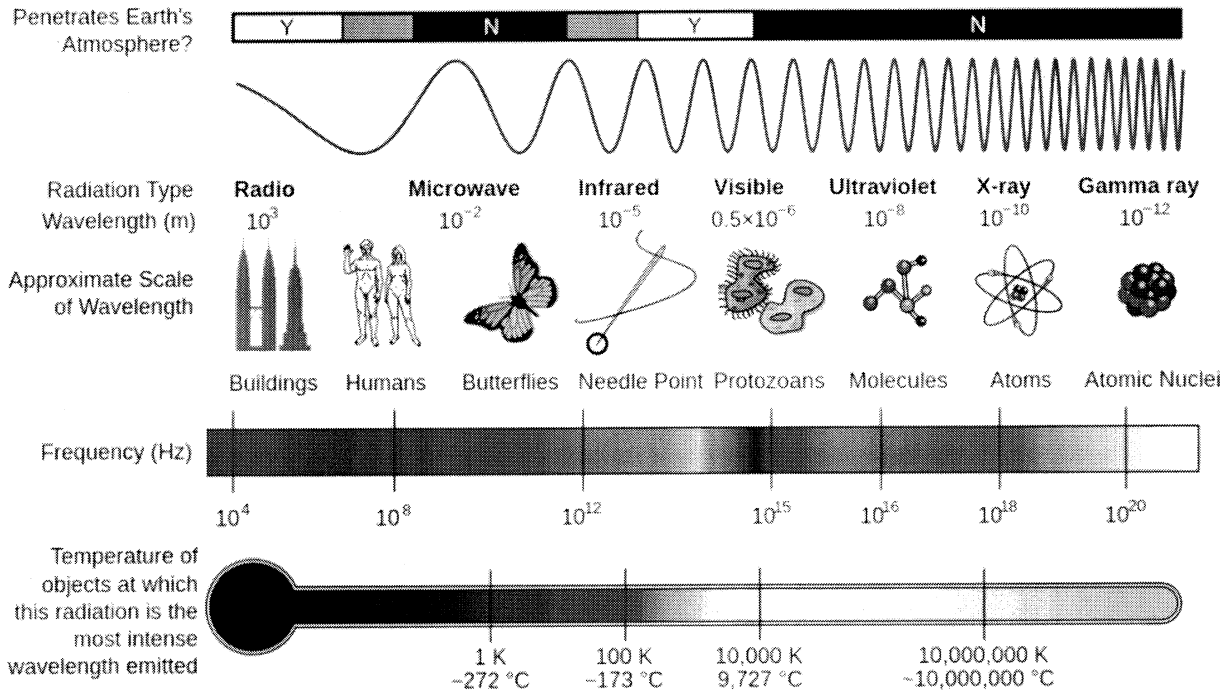
[1] Hazekamp, Arno, Evaluating the Effects of Gamma-Irradiation for Decontamination of Medical Cannabis, Frontiers in Pharmacology, 2016, 7: 108.
[2] Gargani, Yousef et al., Too Many Mouldy Joints – Marijuana and Chronic Pulmonary Aspergillosis, Mediterranean Journal of Hematology and Infectious Diseases, 2011, 3.
[3] *See* Hazekamp, *supra*.
[4] *Id.*
[5] Figure courtesy of http://www.sun.org/encyclopedia/electromagnetic-spectrum.



Ionization is the process by which an atom or a molecule acquires a negative or positive charge by gaining or losing electrons, often in conjunction with other chemical changes. Ionizing radiation can come from either natural radioactive isotopes (sometimes referred to as "gamma") or from a non-radioactive electronic X-ray tube (Emitter). Ionizing radiation produces photons which inactivate DNA in living pathogenic organisms (e.g., mold and bacteria).

Because of the penetrating properties of ionizing radiation and the ability to neutralize microorganisms, ionizing radiation is used to sterilize or reduce the microbial load of many different types of products such as medical devices, packaging, cosmetics, foods, and agricultural products.

2. *How Does Ionizing Radiation Treat Cannabis?*

Irradiation reduces or eliminates mold, related toxins, and other pathogens in cannabis.[6] Importantly, the therapeutic components of the product remain unaltered. Ionizing radiation has no humanly discernable effect on cannabinoids and terpenes.[7]

In layman's terms, the process can be described as follows: pathogens (such as mold, fungus, *Aspergillus*, etc.) are living organisms. Cells of living organisms normally grow and divide to form new cells. Radiation works by making small breaks in the DNA inside cells. Because

[6] *See* Hazekamp, *supra*.
[7] *Id.*

DNA is required for an organism to replicate, this damage either destroys the pathogen or renders it unable to reproduce.[8] As a result, the pathogen cannot pass on to the human during consumption and/or the pathogen cannot replicate in the human.

Other decontamination methods are not viable options, as they either affect the chemical content or texture of the product (*i.e.*, through the use of heat, steam, chemicals such as ozone, etc.) or do not penetrate the product deep enough to treat beyond the surface of the dense cannabis flowers.[9]

3. Why is X-Ray Irradiation the Preferred Method?

As depicted in the preceding chart, there are several types of ionizing radiation, ranging from radio waves to gamma rays.

The use of X-ray sources for ionizing radiation is the preferred method for the treatment of cannabis because radioactive isotopes (gamma sources) pose an environmental and security risk.[10] Unlike the "clean" process used with X-ray sources, gamma sources result in a harmful byproduct that requires particularized methods for storage and disposal, a burden and risk for the local jurisdiction, and carry stringent licensing requirements. In fact, the Department of Energy at Los Alamos specifically has a program in place designed to remove gamma sources and replace them with X-ray sources (which they deem as equivalent alternatives) as a means to reduce security risks associated with radioactive isotopes and terrorist activity.[11]

4. Is Ionizing Radiation Safe?

Yes. Irradiation is a safe, widely-utilized, and highly-studied process that is used for a variety of applications including sterilization, diagnostic imaging, blood transfusion, immunology and oncology research, and agriculture, among others.[12]

Ionizing radiation has been used for more than a decade in Canada and the Netherlands specifically for the treatment of marijuana. The RS 420 line has been approved for use in the treatment of cannabis in Colorado and Michigan.

Relevant to products treated for human consumption, food irradiation is endorsed by the FDA, the World Health Organization (WHO), the Centers for Disease Control and Prevention (CDC),

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[8] Radiation Therapy Basics, American Cancer Society (ACS), available at: https://www.cancer.org/treatment/treatments-and-side-effects/treatment-types/radiation/basics.html.
[9] *See* Hazekamp, *supra*.
[10] For additional information regarding the differences between X-ray and gamma sources, refer to Gamma vs. X-Ray Comparison, available on RAD Source's website at https://www.radsource.com/wp-content/uploads/2016/06/Gamma_vs_X-ray_Comparison_082415.pdf.
[11] See, https://osrp.lanl.gov/ .
[12] Uses of Radiation, United States Nuclear Regulatory Commission (NRC), available at: https://www.nrc.gov/about-nrc/radiation/around-us/uses-radiation.html.

and the U.S. Department of Agriculture (USDA).[13] Specifically, food irradiation is beneficial for prevention of foodborne illness, preservation, control of insects, delay of sprouting and ripening, and sterilization that may be present in untreated food product.[14]

RAD Source and Its Technology

RAD Source is the developer of the RS 420 line of X-ray Irradiators.

1. About RAD Source

RAD Source was founded in 1997 for the purpose of creating non-gamma irradiation alternatives.[15] Even prior to the more recent security issues associated with radioactive gamma sources, RAD Source was dedicated to solving environmental disposal and related practical issues associated with "hot" source equipment (Isotope based). RAD Source introduced its first products in 1999 and has become the leading provider of renewable, non-isotope, ionizing radiation replacements for self-shielded gamma irradiators worldwide.[16]

RAD Source's patented and proprietary QUASTAR® technology produces high output X-Ray radiation efficiently and reliably for a wide variety of irradiation applications including, but not limited to, blood, cell and tissue, insects, biological research, and viral inactivation.[17] RAD Source equipment is utilized for one application or another in close to all 50 states.[18] It is recognized by the U.S. government as a safe alternative to gamma source irradiators, where over the last 3 years, Rad Source has replaced radioactive isotope (gamma) based irradiators throughout the country and now is extending the program to other countries desiring replacement of gamma sources.

Currently, RAD Source equipment resides in more than 300 major pharmaceutical labs, healthcare institutions, and renowned universities around the world.[19] RAD Source boasts an

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[13] Food Irradiation: What You Need to Know, United States Food and Drug Administration (FDA), Food Facts, June 2016, available at: https://www.fda.gov/food/buy-store-serve-safe-food/food-irradiation-what-you-need-know.

[14] *Id; see also* MSU, X-ray Machines Help Kill Bacteria in Food, 2010 ("X-ray does can kill dangerous bacteria that make people sick, such as salmonella, E. coli, vibrio, shigella, and listeria. The process simply removes harmful bacteria and does not alter the food product in any other way."); Journal of Food Protection Vol. 69, No. 7, Effect of X-ray Irradiation on Reducing the Risk of Listeriosis in Ready-to-Eat Vacuum-Packaged Smoked Mullet, 2006, at p.1564 ("In summary, X-ray irradiation proved to be an effective treatment to control L. monocytogenes [listeria] on smoked mullet without adversely affecting sensory quality."); International Journal of Food Microbiology 130, Reduction of Vibrio Vulnificus in Pure Culture, Half Shell and Whole Shell by X-ray, 2009, at p. 135 (concluding x-ray irradiation is an effective treatment to control foodborne pathogenic microorganism vibrio on oysters).

[15] *See* RAD Source website available at: https://www.radsource.com/

[16] *Id.*

[17] 2019 Capabilities Statement, RAD Source.

[18] Figure depicting RAD Source presence throughout the United States.

[19] *See* RAD Source website, *supra.*

impressive and extensive client list including the American Red Cross, the Mayo Clinic, and the FDA – National Center for Toxicological Research, to name a few.[20]

2. The RS 420 Equipment Line Restricts the Radiation Dose That Can Be Delivered

Gray (Gy) is a measure of ionizing radiation dose in the International System of Units (SI).

A Dose is the accumulated amount of Gy to be delivered to the cannabis material by the RS 420.

As set forth in the accompanying Standard Operating Procedures, the RS 420 line cannot be set to a Dose exceeding 7000 Gy by any user. This is an internal safeguard in the control and operating system which cannot be overridden by operators. More importantly, the effective Dose for a typical cannabis operation is 1600 Gy to 1800 Gy, with the dose determined by the bioburden of the facility itself.

Further, all RAD Source equipment complies with safety standards contained in 21 CFR 1020.40 for Cabinet X-ray devices.

3. RAD Source's Technology Would Comply with FDA Regulations Without Need for a Certification or Exemption if Cannabis Was Federally Permissible

MED previously requested that RAD provide either (i) a certification, or (ii) a letter of exemption from the FDA in order to approve use of the RS 420 device in the Nevada cannabis industry. Respectfully, there are two problems with this position.

First, marijuana is a controlled substance. Its production, possession, and distribution are federally proscribed by the Controlled Substances Act. As such, the FDA will neither certify nor exempt any device used in processing marijuana or anything made with marijuana, such as "edibles" or other consumable cannabis products.[21]

Second, even if marijuana was a food subject to regulation by the FDA (which it is not), the RS 420 line would comply with the parameters to treat food products prescribed by the FDA under existing regulations – *without any need for certification or exemption.* The FDA regulates food irradiation based on the energy source used in the ionizing radiation process. *See* 21 CFR Part 179 – Irradiation in the Production, Processing and Handling of Food, Subpart B – Radiation and Radiation Sources. Where the energy source used is "X rays generated from machine sources using tantalum or gold as the target material," which is the case with the RS 420, ionizing radiation for treatment of foods may be performed when "using energies not to exceed 7.5 (MeV). 21 CFR 179.26(a)(4). The RS 420 commonly utilizes a photon energy of less than or equal to 160 (keV). This is well below the 7.5 (MeV) maximum under the FDA's regulations for

[20] *See* RAD Client List, updated 2018, available at: https://www.radsource.com/our-clients/.
[21] Email from Jeremiah Fasana (FDA) to George Terry (RAD Source) dated April 22, 2019; *see also* FDA Regulation of Cannabis and Cannabis-Derived Products: Questions and Answers, FDA, available at: https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-questions-and-answers.

food irradiation. Thus, if cannabis was federally permissible, the RS 420 would comply with the regulations that govern the irradiation of products for human consumption.

WHITE PAPER REFERENCES

TAB	DESCRIPTION
A.	**RAD Source Materials**
1.	2019 Capabilities Statement
2.	Client List
3.	RAD Source in the USA - 50 states chart
4.	Gamma v. X-ray Comparison
B.	**Radiation in general**
1.	NASA - The Electromagnetic Spectrum Introduction
2.	NRC - Uses of Radiation
3.	American Cancer Society – Radiation Therapy Basics
C.	**Scholarly Articles**
1.	Evaluating the Effects of Gamma-Irradiation for Decontamination of Medicinal Cannabis
2.	Effect of X-Ray Irradiation on Reducing the Risk of Listeriosis in Ready-to-Eat Vacuum-Packaged Smoked Mullet
3.	Reduction of Vibrio Vulnificus in Pure Culture, Half Shell and Whole Shell Oysters (Crassostrea virginica) by X-ray
4.	Too Many Mouldy Joints – Marijuana and Chronic Pulmonary Aspergillosis
5.	X-ray Machines Help Kill Bacteria in Food
D.	**FDA**
1.	Food Irradiation: What You Need to Know
2.	Understanding Food Irradiation: What Industry Needs to Know
3.	Email from Jeremiah Fasano (FDA) to George Terry (RAD Source) dated April 22, 2019 re: Irradiation instrumentation approval

EXHIBIT E

STATE OF NEVADA
DEPARTMENT OF TAXATION
Web Site: https://tax.nv.gov
1550 College Parkway, Suite 115
Carson City, Nevada 89706-7937
Phone: (775) 684-2000 Fax: (775) 684-2020

RENO OFFICE
4600 Kietzke Lane
Building L, Suite 235
Reno, Nevada 89502
Phone: (775) 687-9999
Fax: (775) 688-1303

STEVE SISOLAK
Governor
JAMES DEVOLLD
Chair, Nevada Tax Commission
MELANIE YOUNG
Executive Director

LAS VEGAS OFFICE
Grant Sawyer Office Building, Suite1300
555 E. Washington Avenue
Las Vegas, Nevada 89101
Phone: (702) 486-2300 Fax: (702) 486-2373

HENDERSON OFFICE
2550 Paseo Verde Parkway, Suite 180
Henderson, Nevada 89074
Phone: (702) 486-2300
Fax: (702) 486-3377

Public Health and Safety Advisory 2019-02

The Nevada Department of Taxation is hereby issuing Health and Safety Notice Advisory 2019-02 on September 16, 2019 advising consumers and patients to avoid consuming marijuana which is the subject of this notice.

The affected marijuana, listed below, failed secondary microbial testing conducted by an independent testing laboratory. The results indicated total yeast and mold on the affected marijuana existed at levels of 10,909; 32,001; 33,676; and 48,693 CFU/g. The amount permitted under NAC 453D.780 is <10,000 CFU/g. One lot also failed for aspergillus, coliforms, and bile tolerant gram-negative bacteria.

The Department is advising consumers who have purchased the affected marijuana to avoid consuming the products. Consumption of the affected marijuana should particularly be avoided by individuals with suppressed immune systems.

It is believed the affected marijuana was sold in the form of flower and pre-rolls between 7/10/19 and 8/28/19 by the following Retail Stores/Medical Dispensaries:

1. Acres Medical, LLC (license # 11058209030610809158)
2. D. H. Flamingo, Inc (license # 01359449685112111637)
3. Naturex II, LLC (license # 50748233769645953480)
4. Desert Aire Wellness, LLC (license # 25729455103203031356)

The affected marijuana was cultivated by D. H. Aldebaran Inc. (license # 04584977759671021505) and Las Vegas Natural Caregivers, LLC (license # 82798431024231095044) and harvested between 5/28/19 and 7/10/19.

The affected marijuana bears the following batch and lot numbers:

Gelato #41	Harvest date 7/10/2019	Batch # G41-07102019	Lot# 01
Northern Lights Blue Flower	Harvest date 6/5/2019	Batch # NLB-06052019	Lot# 01
Funky Malawi	Harvest date 7/10/2019	Batch # FM-07102019	Lot# 02
BWID flower	Harvest date 5/28/2019	Batch #BWID052819	Lot# L1

All marijuana and marijuana products properly sold by a licensed store or dispensary should have a product label on the packaging. The batch and lot number can be found on the label, typically near the top, directly below the facility information.

There are no known reports of illness. Health impacts from yeast and mold may exist. The Centers for Disease Control and Prevention does have general information on how mold can affect people. See https://www.cdc.gov/mold/faqs.htm#affect. Consumers with concerns about their personal health should contact their physician with related questions.

There is no reason to believe that the dispensaries or cultivators had any knowledge that the products exceeded allowable limits.

EXHIBIT F

KOLESAR & LEATHAM

ATTORNEYS AT LAW

400 SOUTH RAMPART BLVD., SUITE 400
LAS VEGAS, NEVADA 89145
702.362.7800

klnevada.com

April 10, 2019

Via Electronic Mailing (dwitkowski@tax.state.nv.us)

Marijuana Enforcement Division
Nevada Department of Taxation
Attn: Dave Witkowski, Inspector II
555 E. Washington Ave., Suite 4100
Las Vegas, NV 89101

RE: Rad Source Technologies, Inc. – Cannabis Irradiator

Dear Mr. Witkowski:

This firm represents Rad Source Technologies, Inc. (the "Company"), the developer of the RS 420 line of X-ray Irradiators (the "Device") used by its customers in the cannabis industry in Nevada. This is submitted in satisfaction of your list of criteria (the "Criteria") that the Marijuana Enforcement Division (the "Division") requires the Company and its customers to satisfy prior to the approval by the Division of the continued use of the Device in Nevada, a copy of such criteria attached hereto as Schedule "1" for reference purposes.

I. Registration/Certification of the Instrumentation by the Department of Public and Behavior Health – Radiation Control Program ("Department")

The Company is very familiar with this requirement since it affects most of their X-ray line and most states have this requirement for x-ray devices. In this regard, the Company instructs each end-user of its devices that they are required to register such Device with the applicable department for their state. The Company further provides the necessary information about the x-ray source, including serial number and specs, so the end-user can register directly with the State of Nevada.

II. Certification from the Food and Drug Administration ("FDA") or a Letter of Exemption

Please note that due to the structure and use of the Device, it is already permitted and approved under the applicable Code of Federal Regulations governing the ionizing radiation for the treatment of food, without any need for certification or exemption.

Specifically, 21 C.F.R. 179.26(a) provides, in pertinent part, that ionizing radiation for treatment of foods may be safely used under "[x] rays generated from machine sources using tantalum or gold as the target material and using energies not to exceed 7.5 (MeV)." Accordingly, no certificate or letter of exemption is required from the FDA as its approved use has been federally codified.

III. Use of Approved Bags by the FDA

In a good faith effort to assist in strictly complying with this requirement, the Company will advise each end-user of the Device in writing that the bags/containers to be used with the Device must comply with the approved packaging materials set forth under 21 C.F.R. 179.45.

IV. Environmental Protection Agency ("EPA") Establishment Number

Attached as Schedule "2", please find the written notification from the EPA, with Establishment Number 94601-GA-1.

V. Documentation of Training to the End-Users of the Device

Attached as Schedule "3", please find the Training Log with the description of the training on the Device utilized by the Company. At the time of installation of the Device and prior to its use by an end-user, the Company provides on-site training to all end-user employees by an experienced Device operator, with each employee required to sign in under the Training Log.

VI. Written Approval from the Division

We note that the Division has indicated this is a requirement that must be satisfied by the end-user. To that end and in order to satisfy this requirement, the Company has prepared a checklist based on your criteria that the end-user will submit to the Division to obtain the Division's written approval.

Specifically, the following is a checklist for an end-user to submit to the Division:

1. Registration/Certification of the Device by the Department;

2. Use of Approved Bags by the FDA under 21 CFR 179.45; and

3. Documentation of Training to the End-Users of the Device.

We respectfully request your written confirmation that the Company has satisfied the foregoing requirements so that the end-user can resume using the Device in their operations and to permit us to immediately inform them to submit the foregoing checklist items to obtain the written approval from the Division. This will also allow the Company to confidently incorporate these items in strict compliance for all future sales of the Device in Nevada.

In the event you have any questions or comments relating to the foregoing, or need anything further from the Company evidencing its strict compliance with the foregoing request, please let us know at your earliest convenience. We look forward to finalizing these issues in a timely manner and seeing that the customers are, again, successfully using the Device to product a safe product to cannabis consumers in Nevada.

Very truly yours,

KOLESAR & LEATHAM

Joseph J. Mugan, Esq.

JJM/lhw

Enclosures – as stated

cc: Ms. Karalin Cronkhite – Marijuana Enforcement Division (via e-mail)
George Terry – Rad Source Technologies, Inc. (via e-mail)
Will Hartman – Rad Source Technologies, Inc. (via e-mail)
Jordan D. Wolff, Esq. – Kolesar & Leatham (via e-mail)

Schedule "1"

Joseph J. Mugan

From: David Witkowski <dwitkowski@tax.state.nv.us>
Sent: Tuesday, April 09, 2019 8:55 AM
To: Joseph J. Mugan
Cc: Karalin Cronkhite
Subject: Irradiation instrumentation approval

Good morning Mr. Mugan,

The following criteria must be met prior to approving the use of any type of irradiation instrumentation utilizing ionizing radiation to treat marijuana and marijuana products:

1) That the instrumentation is registered/certified as required by the Department of Public and Behavioral Health - Radiation Control Program. (End User)
2) Certification from the Food and Drug Administration (FDA) or a letter of exemption. (End User)
3) If bags are used to contain the product, they must be on the approved list provided by the FDA.
4) If the manufacturer of the instrumentation make the claims that the instrumentation/technology reduces mold/mildew, bacteria and viruses, then the manufacturer should have an Environmental Protection Agency (EPA) establishment number.
5) Documentation that the instrument manufacturer has provided training to the purchaser/end users of the instrumentation.
6) Written Approval from the Marijuana Enforcement Division. (End User)

Please contact our office with any concerns or questions regarding this matter.

Thank you,
Dave

Dave Witkowski
Inspector II
Marijuana Enforcement Division
Nevada Department of Taxation
555 E. Washington Ave. Suite 4100
Las Vegas, NV 89101
Phone: 702.486.5405
Cell: 702.468.2685
dwitkowski@tax.state.nv.us

Schedule "2"

Joseph J. Mugan

Subject: FW: Form 3540-8 Accepted for Establishment RAD SOURCE TECHNOLOGIES

From: helpdesk@epacdx.net [mailto:helpdesk@epacdx.net]
Sent: Wednesday, April 3, 2019 10:41 AM
To: Rodney Wilson
Subject: Form 3540-8 Accepted for Establishment RAD SOURCE TECHNOLOGIES

April 03, 2019

Re: Establishment Number: 94601-GA-1
EPA Region: 04

RAD SOURCE TECHNOLOGIES, INC
Attn: Rodney Wilson
4907 GOLDEN PARKWAY, SUITE 400

BUFORD, GA 30518 USA

This email serves as notification of registration of the pesticide-producing establishment for which you applied, pursuant to Section 7 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The Form 3540-8 for establishment RAD SOURCE TECHNOLOGIES has been accepted. The new Establishment Number is: 94601-GA-1. This establishment registration will remain in effect, provided pesticide reports on production and sales or distribution amounts are submitted annually as required.

Part 167 of the Code of Federal Regulations (40 CFR) requires your company to submit an initial report for Pesticide-Producing Establishments, EPA Form 3540-16, within 30 days of receipt of this email. EPA Form 3540-16, Pesticide Report for Pesticide-Producing Establishments, and instruction for completing the form can be found at
http://www2.epa.gov/compliance/pesticide-establishment-registration-and-reporting.
Please note that the report asks for production amounts for year **2018**. **If you are a foreign (non-U.S.) establishment, please mail the completed report(s) to the EPA Washington, D.C. office or submit reports on our electronic reporting system: https://cdx.epa.gov. . Failure to submit your Initial report(s) within 30 days may subject your establishment(s) to an administrative civil penalty.**

After the initial report, future reports must be submitted on a yearly basis. Production reports for establishments registered to produce pesticides and pesticidal devices are due by March 1st as long as the establishment is active, regardless of whether or not production has occured (regulations pursuant to Section 7 of FIFRA).

Parts of the 40 CFR which apply to pesticide establishments are: (1) *Part 167-Registration of Pesticide and Active Ingredient Producing Establishments, Submission of Pesticide Reports* and (2) *Part 169-Books and Records of Pesticide Production and Distribution.*

Changes in name, address, or ownership of the company or any establishments are to be reported to this office within thirty (30) days of the change. If your company decides to cease production of all pesticides and

pesticidal-devices, you may request termination of the establishment(s). Requests for termination of establishments can be sent to this office, or completed on our electronic reporting system at https://cdx.epa.gov.

The container of each pesticide product which is released for shipment must bear the EPA Establishment Number assigned to the establishment in which it was produced. This number, which is to be preceded by "EPA Est.", may appear in any suitable location on the label or immediate container. It must also appear on the outside container or wrapper of the package if the EPA Establishment Number on the immediate container cannot be clearly read.

Schedule "3"

Training Log

RAD SOURCE

Description of Training:	

Name	Signature	Date

EXHIBIT G

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November 1, 2019

Via email only

Steven G. Shevorski
Head of Complex Litigation
Office of the Attorney General
555 E. Washington Ave., Suite 3900
Las Vegas, NV 89101
SShevorski@ag.nv.gov

RE: RAD Source Technologies, Inc. adv. State of Nevada, Department of Taxation, Marijuana Enforcement Division ("DOT") – Request for Immediate Approval of RS 420 Line of X-Ray Irradiators in Treatment of Cannabis

Dear Mr. Shevorski:

This letter follows my letter to you dated October 2, 2019 regarding our client RAD Source Technologies, Inc.'s demand that the DOT immediately take steps to approve the use of RAD Source's RS 420 Line of X-Ray Irradiators for treatment of cannabis in Nevada, and our follow-up conversations regarding this matter.

Based on our conversations, it appears that the DOT is laboring under a misapprehension as to the material facts. The purpose of this letter is to clarify any misunderstandings and reiterate RAD Source's demand for approval of its equipment in the treatment of cannabis in Nevada.

The RS 420 Line Was in Use for Two Years Prior to the DOT's Ban

By way of background, from March 2017 through March 2019, Nevada cannabis growers utilized the RS 420 Line in everyday processing of cannabis to reduce yeast, mold (e.g., aspergillus), and other pathogens and in converting quarantined product into safe, useable cannabis product. The DOT was aware that growers were using RAD Source's technology to treat cannabis during this time period and did not raise concerns regarding its use.

The DOT Shuts Down the RS 420 Line and Provides a 6-point Checklist to Obtain Approval

Earlier this year, without any notice to RAD Source or legitimate justification, the DOT banned RAD Source customers from using the RS 420 Line of equipment. RAD Source engaged in good faith communications with the DOT to resolve any concerns the DOT may have regarding its technology.

On April 9, 2019, Dave Witkowski, Inspector II, communicated to RAD Source a list of six criteria that the DOT required in order to approve the use of irradiation instrumentation utilizing ionizing radiation to treat marijuana and marijuana products. *See* **Exhibit A**, email from D. Witkowski to J. Mugan dated April 9, 2019. The following week, the DOT acknowledged that RAD Source had addressed all but one of the six criteria to its satisfaction, i.e., certification from the Food and Drug Administration (FDA) or a letter of exemption (the "FDA Requirement"). *See* **Exhibit B**, email from D. Witkowski to J. Mugan dated April 16, 2019 and previous emails in string.

The Single Remaining Item on the Checklist, i.e., the FDA Requirement, Is Impossible to Obtain

As we have previously discussed and RAD Source has stated *ad nauseum* in its communications with the DOT, marijuana and anything made with marijuana, such as edible cannabis products, do not constitute "food" regulated by the FDA. To be clear, marijuana is a controlled substance governed by The Controlled Substances Act ("CSA") and the Drug Enforcement Agency ("DEA"). Its production, possession, and distribution are federally proscribed by CSA. Therefore, is not possible for our client, nor any end user or any other party using similar equipment to obtain FDA approval for devices used in processing marijuana.[1]

In effort to appease the DOT, RAD Source reached out to the FDA to inquire as to the possibility of obtaining some form of certification or letter of exemption per the DOT's request and requirement for same. In response, a representative of the FDA informed RAD Source that: (i) the request being made by the DOT is inapplicable as marijuana products do not constitute food;

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[1] Even if marijuana was a food subject to regulation by the FDA (which it is not), the RS 420 line would comply with the parameters to treat food products prescribed by the FDA under existing regulations – without any need for certification or exemption. The FDA regulates food irradiation based on the energy source used in the ionizing radiation process. *See* 21 CFR Part 179 – Irradiation in the Production, Processing and Handling of Food, Subpart B – Radiation and Radiation Sources. Where the energy source used is "X rays generated from machine sources using tantalum or gold as the target material," which is the case with the RS 420, ionizing radiation for treatment of foods may be performed when "using energies not to exceed 7.5 (MeV). 21 CFR 179.26(a)(4). The RS 420 commonly utilizes a photon energy of less than or equal to 160 (keV). This is well below the 7.5 (MeV) maximum under the FDA's regulations for food irradiation. Thus, if cannabis was federally permissible, the RS 420 would comply with the regulations that govern the irradiation of products for human consumption.

and (ii) the FDA, as a federal agency, will not review or issue any certification or letter of exemption on a marijuana product which is not legally permitted under federal law. *See* **Exhibit C**, email from Jeremiah Fasano, Consumer Safety Officer, FDA, dated April 22, 2019.

RAD Source has gone to great lengths to resolve the FDA Requirement to the DOT's satisfaction, including multiple discussions with DOT representatives and counsel, in person and over the phone, and providing documentation explaining the impossibility of satisfying the FDA Requirement. RAD Source contends that the DOT's continuation the ban in light of the foregoing is plainly actionable as arbitrary and capricious conduct.

The DOT Approves Devices of Similarly Situated Competitors

RAD Source has become aware that two of its competitors, Ziel and Willow, recently received DOT approval for the use of their technology in the treatment of cannabis. This despite the clear fact that neither companies' process is approved by the FDA for use in the treatment of marijuana or marijuana products. Willow utilizes an ozone-based technology and Ziel utilizes an irradiation-based technology.

During our most recent conversation, you represented that the DOT has not approved any irradiation-based technology for the treatment of cannabis. That is false. Ziel, like RAD Source, uses a form of irradiation to treat cannabis. From Ziel's website:

> *Ziel's food safety technology uses RF photons to energize (activate) molecules in the host commodity and its pests, inducing thermal effects that lead to disinfection (pasteurization), disinfestation, enzyme inactivation and drying effects*

https://zielps.com/system/ (emphasis added).

Also from Ziel's website:

> *Ziel's process uses electromagnetic energy waves to energize molecules in commodities and pests.*

https://zielps.com/how-it-works/ (emphasis added).

To be clear, "RF" refers to Radio Frequency (RF) Radiation, one of the several types of radiation that comprises the electromagnetic spectrum. While Ziel may not use the word "irradiation" to describe its technological process, it most certainly is a form of irradiation.

The technology utilized by RAD Source is X-ray irradiation, another form of radiation on the electromagnetic spectrum. *See* **Exhibit D**, RAD Source's August 23, 2019 letter to Jorge Pupo, DOT, requesting formal approval and accompanying materials.

In sum, the DOT has approved at least two other cannabis treatment devices or processes not approved by the FDA for use with marijuana or marijuana products, while refusing to approve RAD Source's device. RAD Source believes that in addition to these two examples, there may be other devises and processes the DOT has permitted without FDA approval. This is unequal treatment, plain and simple.

Waiver of the FDA Requirement for Competitors

Given its impossibility, the DOT clearly must have waived the FDA Requirement for Ziel and Willow, and any other similarly situated entities. Or it never required satisfaction of this requirement from these manufacturers in the first place. The fact that the DOT is still requiring RAD Source to comply with the impossible FDA Requirement as a pre-requisite to obtain approval amounts to unequal treatment of similarly situated competitors.

The DOT Has Acted Arbitrarily and Capriciously

An agency abuses its discretion and is subject to judicial reversal where it takes an action that is arbitrary and capricious and not related to the public welfare. *See County of Clark v. Atlantic Seafoods*, 96 Nev. 608, 615 P.2d 233 (1980); *see also Henderson v. Henderson Auto*, 77 Nev. 118, 359 P.2d 743 (1961).

Here, the DOT's refusal to approve the RS 420 Line is arbitrary and capricious because it is not based on substantial evidence, but instead, on a mistaken belief that FDA approval is available for any cannabis-related technology. Moreover, the DOT is engaging in unequal treatment of similarly situated manufacturers of cannabis treatment equipment by approving Ziel and Willow, and not RAD Source. Lastly, upon information and belief, the DOT waived the FDA Requirement for Ziel and Willow, and refuses to do so for RAD Source.

Approval of the RS 420 Line Serves Public Health and Safety

While fair and equal treatment of the players in the cannabis industry should be sufficient cause in and of itself for the DOT to approve the RS 420 Line, RAD Source wishes to convey that its technology serves the public health and safety of Nevada cannabis consumers.

As explained more fully in the materials accompanying RAD Source's August 23, 2019 letter to the DOT requesting formal approval, cannabis (like any other crop) is subject to a wide range of potential contaminants including yeast, mold, insects, and other pathogens. *See* Exhibit D.

As you may be aware, the most concerning pathogen in the cannabis industry is Aspergillus.[2] In light of the DOT's recently issued public health and safety advisory warning concerning the presence of Aspergillus in Nevada cannabis, it is in the public interest to approve the RS 420 Line and return it to use. *See* **Exhibit E**, DOT Public Health and Safety Advisory 2019-02.

Irradiation reduces or eliminates mold (including Aspergillus), related toxins, and other pathogens in cannabis, leaving the therapeutic components of the product unaltered. X-ray irradiation, as used by RAD Source, is the preferred method for the treatment of cannabis.

Final Demand Prior to Litigation

Our office, our client, and our client's customers have made multiple direct appeals to the DOT to resolve this issue. These efforts have been rejected or ignored, while the DOT has moved forward to permit and allow the use of other irradiation devices sold by other similarly situated manufacturers.

We hereby make one final demand for the DOT to approve the RS 420 Line for the treatment of cannabis in Nevada. If we are unable to secure approval of these machines, we have been directed to immediately move forward with litigation on this issue.

We look forward to your response and hope for an immediate resolution to this issue.

Sincerely,

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Enclosures (as noted)

[2] While no state has reported an overdose from medicinal cannabis among those that have legalized its use, there have been documented cases of medicinal cannabis patients who have died from aspergillosis, a condition caused by inhaling Aspergillus spores. *See* Exhibit D.

EXHIBIT 16

REPL
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EIGHTH JUDICIAL DISTRICT COURT

CLARK COUNTY, NEVADA

RAD SOURCE TECHNOLOGIES, INC., a Florida Corporation, Plaintiff, vs. THE STATE OF NEVADA *ex rel.* DEPARTMENT OF TAXATION, MARIJUANA ENFORCEMENT DIVISION, Defendant.	Case No.: A-19-805074-W Dept. 29 **RAD SOURCE TECHNOLOGIES, INC.'S REPLY IN SUPPORT OF: (1) MOTION FOR ORDER TO SHOW CAUSE WHY A WRIT OF CERTIORARI, MANDAMUS, AND/OR PROHIBITION SHOULD NOT ISSUE; (2) ALTERNATIVE MOTION FOR PRELIMINARY INJUNCTION; AND (3) APPLICATION FOR ORDER SHORTENING TIME** **Date of Hearing:** January 15, 2020 **Time of Hearing:** 9:00 a.m.

RAD Source Technologies, Inc. ("RAD Source"),[1] by and through counsel, files this Reply in support of its (1) Motion for Order to Show Cause Why a Writ of Certiorari, Mandamus, and/or Prohibition Should Not Issue, (2) Alternative Motion for Preliminary Injunction; and (3) Application for Order Shortening Time (the "Motion").

[1] In its opposition brief, Defendant incorrectly identifies RAD Source as "RAD Solutions Technology, Inc. (RAD Tech)." *See id.* at 2:3.

This Reply is based upon the following Memorandum of Points and Authorities and supporting exhibits, including the Declaration of George Terry (the "Terry Decl.") attached hereto as **Exhibit 1** and the exhibits thereto, the Declaration of Justin Czerniawski, PhD (the "Czerniawski Decl.") attached hereto as **Exhibit 2** and the exhibits thereto**;** the Supplemental Declaration of Will Hartman (the "Hartman Supp. Decl.") attached hereto as **Exhibit 3**; and the Declaration of Joseph Mugan attached hereto as **Exhibit 4**; the papers and pleadings already on file herein, including the Motion and exhibits thereto, incorporated by reference as if fully set forth herein; and any argument of counsel or witness testimony the Court may permit at the hearing of this matter.

MEMORANDUM OF POINTS AND AUTHORITIES

I. INTRODUCTION

In its show cause order, this Court found that RAD Source had demonstrated good cause for writ relief and *ordered* the Department to show cause why the requested relief should not issue. The Department has failed to do so. The Department has not presented *any* evidence, nor any *tenable* legal arguments. To the contrary, the Department's response underscores why the requested relief is necessary.

Several key facts are made clear via the original application, the Department's response, and the present reply:

- RAD Source's X-ray irradiation technology is a safe and effective method for treating marijuana;
- The RAD Source technology was safely used in Nevada for over two years without incident;
- The RAD Source technology has the undeniable potential to benefit the health and safety of Nevada marijuana consumers;
- The Department has banned the RAD Source technology without reason or rationale;
- The Department's ban has no basis in science;
- The Department has not imposed bans on the processes used by RAD Source's competitors; and
- The Department is unable to identify the basis for its decision-making process (if any) related to the ban.

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RAD Source, first on its own, then through regulatory counsel, and finally through litigation counsel, attempted to engage with multiple people within the Department to address and resolve the Department's purported concerns. RAD Source provided ample information to the Department regarding the safety and efficacy of its technology, and addressed each and every issue initially raised by the Department. The Department, in return, refused to respond, and then actively rebuffed all attempts to communicate further. RAD Source was ultimately left with no option but to file an action and seek relief from the Court.

The Department's acts and omissions are in violation of its statutory duties. In short, the Department's acts and omissions are arbitrary and capricious. Having previously demanded that RAD Source (but not its competitors) obtain an impossibility, i.e., FDA approval for use of its technology on marijuana, the Department now conjures up new and additional, yet equally absurd, reasons to "support" its ban on RAD Source.

Writ relief is both proper and necessary. At minimum, RAD Source has demonstrated a likelihood of success on the merits of its claims, and a preliminary injunction is *immediately* warranted in the event the Court wishes to take additional time to consider the requested writ relief.

II. CLARIFICATION AND STATEMENT OF ADDITIONAL RELEVANT FACTS

The Department does not dispute any of the following facts established in the Motion and contained within documents provided to the Department in April 2019:

- RAD Source's RS 420 Line use its patented and proprietary X-ray irradiation technology.
- This technology is used safely and effectively throughout the medical field, including for treating blood, bone, and tissue, in biological research, and for viral inactivation.
- X-ray irradiation technology is accepted by the American Red Cross, the Mayo Clinic, and the U.S. Food and Drug Administration's National Center for Toxicological Research, as well as by medical facilities and universities throughout the United States and the world.
- Irradiation is recognized as a safe and effective method to treat food for human consumption by FDA, the World Health Organization (WHO), the Centers for Disease Control and Prevention (CDC), and the U.S. Department of Agriculture (USDA).

- Ionizing radiation has been used for more than a decade in Canada and the Netherlands to treat marijuana.
- RAD Source's RS 420 Line has been allowed to treat marijuana under California, Colorado, Illinois, and Michigan's regulated marijuana markets.
- The RS 420 Line was used in Nevada for over two years without any safety or health issue.

Nevertheless, the Department questions whether this patented, widely-used technology is safe for marijuana decontamination based upon non-scientific, irrelevant, and uncredentialed sources.

RAD Source's X-Ray Technology Is a Safe and Effective Method for Decontaminating Marijuana

In its Opposition, the Department questions whether RAD Source's RS 420 machines are safe for users and whether irradiation of marijuana is safe for consumers.

As set forth in the Terry Declaration, the Department has never requested information regarding the safety of the RS 420 machines to users. *See* Ex. 1 at ¶ 6. Had such information been requested, it would have been provided. The RS 420 machines conform to federal safety and operational guidelines, and are surveyed for safety on two occasions before being put into use. *See id.* at ¶¶ 7-15 and Ex. 1-B. In short, the RS 420 machines are safe for use and the Department's speculation to the contrary is completely unfounded.

Moreover, as set forth in the Czerniawski Declaration, the Department's conjecture regarding the safety of irradiated cannabis has no scientific basis and reflects fundamental misunderstandings, *inter alia*: (1) regarding the difference between ionizing radiation and radioactivity; (2) how ionizing radiation is used effectively and safely for decontamination of cannabis; and (3) how other cannabis decontamination and remediation processes, which have been allowed by the Department to remain in use, actually work and the potential risks and shortfalls of such methods. *See* Ex. 2 at ¶¶ 4-6; 10-21 and Exs. 2-A, 2-B; *see also* Ex. 1-E at 7 ("Irradiation (gamma, e beam, X ray) at typical energies for radiation processing WILL NOT cause any of the irradiated products to become radioactive or leave any radioactive residue.").

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RAD Source Made Every Reasonable Effort to Resolve this Conflict before Commencing Litigation, But the Department Refused to Engage in Good Faith

In its Opposition, the Department contends "Here, RAD Tech employs hyperbole and gotcha legal tactics as a substitute for good faith negotiation." The evidence before the Court, all of which has come from RAD Source, demonstrates precisely the opposite.

As already established in the Hartman Declaration submitted with the Motion, and as further detailed in the Terry Declaration, Hartman Supplemental Declaration, and Mugan Declaration filed herewith, RAD Source tried, first on its own, then with attorney Joseph Mugan, and finally with litigation counsel, to find a resolution short of litigation. *See* Ex. 1 at ¶¶ 17-26, Ex. 3 at ¶¶ 4-7, Ex. 4 at ¶¶ 4-10; *see also* Hartman Decl., already on file, at ¶¶ 27-53. Despite its efforts, RAD Source was repeatedly rebuffed or outright ignored by the Department, and the Department would have allowed its "moratorium" (i.e., ban) to continue indefinitely had RAD Source not brought this action.

RAD Source's Competitors Have Been Treated Differently

The Department does not dispute that RAD Source's competitors, most notably Ziel and Willow, have been treated differently than RAD Source. Specifically, the Department does not dispute that Ziel and Willow were not required to obtain FDA approval, or meet some comparable threshold, for their decontamination methods. Furthermore, the Department has not provided any evidence demonstrating that it understands how the competitors' treatments work, let alone that they are safe and effective. *See* Ex. 2 at ¶¶ 11-13.

III. ARGUMENT

The Court found that RAD Source showed good cause for writ relief and ordered the Department to show cause why writ relief should not issue. The Department has failed to meet this directive.

The Department has not presented any evidence or set forth any tenable legal arguments. To the contrary, the Department's arguments underscore why the requested relief is necessary.

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A. A Writ of Mandamus Should Issue

In its opposition brief, the Department has wholly failed to present any salient evidence or arguments refuting writ relief in this case.

"Mandamus is appropriate to prevent improper action by [an agency], as well as to compel [it] to perform an act which is [its] duty under the law." *Lundberg v. Koontz*, 82 Nev. 360, 363, 418 P.2d 808, 809 (1966). For example, "mandamus will lie to enforce ministerial acts or duties and to require the exercise of discretion." *Gragson v. Toco*, 90 Nev. 131, 133, 520 P.2d 616, 617 (1974). In addition, mandamus is appropriate to "control the discretion" of an agency when it "is exercised arbitrarily or through mere caprice." *Id.*

1. The Department's acts violated its duties under the law

In its opposition brief, the Department argues it had no legal duty to "authorize or otherwise facilitate the use of marijuana processing equipment." Opp. Br., at 6. This is incorrect. NRS 453D.200(f), entitled in part "***Duties of Department*** relating to regulation and licensing of marijuana establishments," provides in pertinent part:

> Not later than January 1, 2018, the Department shall adopt all regulations necessary or convenient to carry out the provisions of this chapter. *The regulations* ***must not*** *prohibit the operation of marijuana establishments, either expressly or through regulations that make their operation unreasonably impracticable*. The regulations shall include:
>
> * * *
>
> (f) Requirements for the testing and labeling of marijuana and marijuana products sold by marijuana establishments including a numerical indication of potency based on the ratio of THC to the weight of a product intended for oral consumption….

Id. (emphasis added).

Thus, the Department does have an express statutory duty to not make the operation of recreational marijuana establishments unreasonably impracticable. Through the "moratorium" on RAD Source's machines, the Department violated this duty. It made the operation of marijuana establishments unreasonably impracticable by, among other things, improperly excluding certain treatment processes, such as the RS 420 line of equipment, that safely and effectively treat marijuana, protecting both the public health and welfare, as well as promoting the economic health of the industry. It further violated this duty, and took "improper action," by setting

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unreasonable and impossible standards for RAD Source's technology, while not holding RAD Source's similarly situated competitors to these same standards. *See Lundberg*, 82 Nev. at 363, 418 P.2d at 809. Because the Department violated its statutory duty, a writ of mandamus should issue.

2. The Department's acts were arbitrary and capricious

Similarly, a writ of mandamus should be granted against the Department's actions, because to the extent there were discretionary actions by the Department (discussed further below) they were at best arbitrary and capricious. *See Gragson v. Toco*, 90 Nev. at 133, 520 P.2d at 617.

a. The Department's determination that the RS 420 Line is unsafe is arbitrary and capricious

The Department speculates the RS 420 Line might be unsafe based on spurious and non-scientific grounds.

Alta-Dena Dairy v. San Diego Cty., 271 Cal. App. 2d 66, 70-71, 76 Cal. Rptr. 510, 513-14 (Ct. App. 1969) is particularly instructive to the present case. In both this case and *Alta-Dena Dairy*, a state agency raised scientifically-unfounded concerns about the safety of a product for human consumption—in *Alta-Dena Dairy*, the production of raw milk, and in this case, X-ray irradiators that treat marijuana. In both cases, the state agency prohibited the allegedly unsafe product until such time as it could be "proven safe." Just like *Alta-Dena Dairy*, RAD Source has shown, in both its pre-litigation communications to the Department and in the filings in this case, that its X-ray irradiators are safe and effective.

Like the Director of Public Health in *Alta-Dena Dairy* who failed to raise legitimate, well-grounded safety concerns, the Department in this case has no scientific or credible backing for its alleged safety concerns. In its opposition brief, the Department raises the <u>*possibility*</u> that RAD Source's irradiators "involve a potential for trace amounts of radiation to be absorbed through the stomach or lungs into a living human being." Opp. Br., at 4. Notably, the Department provides no scientific or technical support for this statement, and as set forth above this conjecture is based upon a fundamental misunderstanding of ionizing radiation as compared to radioactivity. Thus,

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the Department's alleged safety concern is absolutely unfounded and non-scientific.

The Department next claims that X-ray irradiation "may cause irreparable damage to delicate lung tissue." Opp. Br., at 8. To support this assertion, the Department cites an EPA website that states radiation in tobacco "may play a part" in causing cancer. *Id.* at 8 n.2. But what is the potential radiation at issue in tobacco? Radon[2]—a radioactive gas that results from the natural decay of uranium and radium found in nearly all rocks and soils[3]; and radium[4]—a naturally occurring radioactive metal formed by the decay of uranium and thorium in the environment.[5] Importantly, ***RAD Source's X-ray irradiators do not use, and have never used, either radon or radium.*** This crucial distinction seems entirely lost on the Department. To be clear, there is ***zero*** evidence that X-ray irradiation to marijuana causes cancer or damages lung tissue. Thus, the Department's spurious claim of unsafety is both unfounded and irrational.[6]

Finally, the Department cites Kristina Etter, an online contributing author who is uncredentialed and has no scientific expertise,[7] for the proposition that "opponents of irradiation question the safety and quality of consumables treated with radiation." Opp. Br., at 10.[8] Exactly what, one may ask, is the specific safety and quality concerns raised by Ms. Etter? Simply, that some consumers feel irradiation alters cannabis "flavor and effect." *Id.* Such consumer opinion, which is neither scientific nor well-grounded, merely repeated as hearsay in an online article, is

[2] EPA, *Radioactivity in Tobacco*, https://www.epa.gov/radtown/radioactivity-tobacco (accessed January 3, 2020), attached as **Exhibit 5**, cited in the Opp. Br. at 8 n.2.

[3] EPA, *Radionuclide Basics: Radon*, https://www.epa.gov/radiation/radionuclide-basics-radon (accessed January 3, 2020), attached as **Exhibit 6.**

[4] *Supra* footnote 2.

[5] EPA, *Radionuclide Basics: Radium*, https://www.epa.gov/radiation/radionuclide-basics-radium (accessed January 3, 2020), attached as **Exhibit 7.**

[6] The Department further cites an article about the negative health effects of vaping. Opp. Br., at 8 n.3. Notably, the article cited by the Department does not pertain, in ***any*** way, to X-ray irradiation.

[7] Daily Marijuana Observer, *Kristina Etter*, https://mjobserver.com/author/kristinaetter/ (accessed January 3, 2020) (noting that Ms. Etter spent "20 years in Corporate IT" before becoming an online contributing author on cannabis issues), attached as **Exhibit 8.**

[8] Citing Kristina Etter, Daily Marijuana Observer, *Weighing the Pros and Cons of Irradiated Cannabis*, https://mjobserver.com/plants/weighing-the-pros-and-cons-of-irradiated-cannabis (December 5, 2018), attached as **Exhibit 9**.

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wholly insufficient grounds for the Department to claim that X-ray irradiation is unsafe. To be clear, research — provided to the Department in April 2019 — contradicts the non-scientific conjecture of the Department supported by the musings of a blogger. As such, the Department's alleged safety concerns are entirely unsupported and non-scientific.[9]

In *Alta-Dena Dairy*, the Director of Public Health's reports, documents, and regulations failed to show that the minimal presence of the complained of bacteria rendered raw milk unsafe for human consumption. 271 Cal. App. 2d at 72–73, 76 Cal. Rptr. at 515. Similarly, in this case, the Department has wholly failed to provide scientific, well-grounded backing that X-ray irradiation renders marijuana unsafe for human consumption. Like the ban on Alta-Dena Dairy's raw milk was an abuse of discretion, the Department's ban of the RS 420 Line in this case is an abuse of discretion, and arbitrary and capricious. Therefore, a writ of mandamus should be issued.

b. The Department's revolving position on FDA approval is arbitrary and capricious

The Department's position on FDA approval for RAD Source's RS 420 Line is ever-changing and impossible to meet. First, on April 9, 2019, David Witkowski, an inspector with the Marijuana Enforcement Division of Nevada's Department of Taxation, told RAD Source that its irradiators must obtain "[c]ertification from the Food and Drug Administration (FDA) or a letter of exemption" in order to lift the ban. Hartman Decl., already on file, at Ex. A.

On April 10, 2019, RAD Source's regulatory counsel emailed a letter to Mr. Witkowski stating that the RS 420 Line uses levels of irradiation already acknowledged by FDA as acceptable, and thus no certificate or letter of exemption was required. *Id.* at Ex. F.

Yet, on April 11, 2019, Mr. Witkowski again repeated that the Department required RAD Source's irradiators to "get FDA approval" because he believed "using sources of radiation to treat food requires approval by FDA." *Id.* at Ex. B.

[9] The Department also raises a vague concern that allowing X-ray irradiation may disincentivize cultivators from minimizing the presence of mold and insects on their plants. Opp. Br., at 10. Yet again, the Department provides no scientific backing for this hypothesis. In addition, presumably, both ozone and radio frequency treatment, of which the Department has approved, would also be a cause of this hypothetical concern. Yet the Department provides no justification for why it singled out RAD Source's X-ray irradiators and specifically banned these products.

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Over the next few days, RAD Source's regulatory counsel discussed with Mr. Witkowski that FDA approval was both inapplicable and impossible to obtain. *Id.* at Ex. B, Ex. F. Yet, on April 16, 2019, Mr. Witkowski again stated "would it be possible to get any conformation [sic] from the FDA or your client regarding your comments…?" *Id.* at Ex. B.

Over the next several months RAD Source attempted to meet with the Department to lift the ban, to no avail. *See* Ex. 1 at ¶¶ 17-26, Ex. 3 at ¶¶ 4-7, Ex. 4 at ¶¶ 4-10; *see also* Hartman Decl., already on file, at ¶¶ 27-53. So, on August 23, 2019, both RAD Source's chief executive officer and executive vice president of sales and marketing submitted a detailed paper to Jorge Pupo, Executive Director of the Department of Taxation. Hartman Decl., already on file, at Ex. D. In that paper, RAD Source explained that marijuana was a controlled substance under federal regulations, FDA did not treat marijuana as a "food" subject to its regulations, and, regardless, RAD Source's irradiators operated within the irradiation levels already accepted by FDA. *Id.* at Ex. D, RAD_000008-09. As part of its exhibits, RAD Source sent to Mr. Pupo the response it received from FDA declining to issue a certification or letter of exemption. *Id.* at Ex. C; *id.* at Ex. D, RAD_000010.

The Department still refused to lift the ban, so on November 1, 2019, RAD Source's litigation counsel sent a final letter to Steven Shevorski, Head of Complex Litigation at the Office of the Attorney General. *Id.* at Ex. G. This letter explained that the FDA Requirement was both inapplicable and impossible to obtain. *Id.* at Ex. G, p. 2-3. Despite this final explanation, the Department still refused to lift the ban.

Notably, at no time during the last eight months did the Department notify RAD Source that FDA approval was no longer required to lift the ban. Also, at no point did the Department notify RAD Source that approvals from entities other than FDA were acceptable to lift the ban.

Despite all this, the Department now contends that it no longer requires FDA approval for RAD Source's X-ray irradiators. *See* Opp. Br., at 5, 7, 9 (claiming that the FDA requirement was simply a "casual email from a Department employee" or an "imprecisely drafted email by a non-lawyer compliance investigator"). Yet, in the very same brief, the Department states that "[e]vidence of FDA approval, or some comparable approval, is important…." *Id.* at 10; *see also*

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id. at 8 (stating the Department requires RAD Source to show that "its equipment has been independently evaluated" or that "its X ray equipment has been evaluated and approved by the FDA, or an agency with comparable expertise"). The Department insists (wrongly) that RAD Source can complete FDA's petition process for food additives to obtain FDA approval of its X-ray irradiators to treat marijuana. Opp. Br., at 11-12.

At this point, the Department's position regarding FDA approval is shifting and outright contradictory. Is FDA approval required or not? If approval is required from another entity, then who? Simply put, after over *eight months* of lengthy communications with RAD Source, the Department refuses to answer these basic questions. The Department has completely failed to set a concrete and reachable standard for RAD Source. This is the very height of arbitrary and capriciousness.

Importantly, RAD Source *cannot obtain FDA approval for its RS 420 Line even through FDA's food additive process.* Hartman Decl., already on file, at Ex. C. Specifically, Jeremiah Fasano, a Consumer Safety Officer for FDA, stated: "it is my understanding that the food uses at issue [i.e. for marijuana] are not permitted under the FD&C Act [Federal Food, Drug and Cosmetic Act]. *I therefore do not recommend pursuit of a food additive approval for any currently unapproved uses of irradiation, because such an approval would not overcome other legal barriers to your proposed food use of cannabis.*" *Id.* (emphasis added).

As stated to the Department multiple times, it is legally impossible for RAD Source to obtain FDA approval for its X-ray irradiators to treat cannabis. Marijuana is a controlled substance under the Controlled Substances Act ("CSA") and its production, possession, and distribution are federally prohibited. 21 U.S.C. § 801 *et seq*. Moreover, FDA has explicitly told RAD Source its irradiators cannot overcome these legal obstacles. *See* Hartman Decl., already on file, at Ex. C.

Although RAD Source cannot obtain FDA approval, it is undisputed that RAD Source's RS 420 Line of irradiators meets current FDA regulations for treating food products with irradiation. According to the FDA:

Ionizing radiation for treatment of foods *may be safely used* under the following

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> conditions…(a)(4) X rays generated from machine sources using tantalum or gold as the target material and using energies not to exceed 7.5 (MeV) [million electron volts]."

See 21 C.F.R. § 179.26(a)(4) (emphasis added). It is undisputed that the RS 420 Line of X-ray irradiators uses tantalum or gold and energies below 7.5 MeV.

In sum, RAD Source's X-ray irradiators meet FDA irradiation requirements, but cannot receive "FDA approval" because they are used to treat marijuana, a federally controlled substance. There is no reason for the Department to require the extra, impossible, step of FDA approval when the underlying FDA regulations are undisputedly met. For these reasons, requiring RAD Source to obtain FDA approval, or some "comparable approval," whatever that means, is arbitrary and capricious. A writ of mandamus should thus issue.

c. The Department's unequal and unfair treatment of RAD Source is arbitrary and capricious

The Department does not deny that it has treated RAD Source differently than its competitors. For example, the Department does not deny that Ziel and Willow, who use radio frequency photons and ozone chemicals to treat marijuana, respectively, are not required to obtain FDA approval, or some comparable approval, for their devices.

The Department questions whether "X-rays are qualitatively no different than radio waves in terms of their potential to generate radioactive particles." Opp., Br., at 4. Once again, this statement demonstrates a complete lack of understanding of the science behind not only ionizing radiation, but also behind all of the other treatment methods allowed by the Department.

Quite simply, there is no reason to require RAD Source's X-ray irradiators to obtain FDA approval—which could only apply to food—and not Ziel or Willow's methods. This unequal and unfair treatment is arbitrary and capricious. *Cox v. Louisiana Dep't of Agric. & Forestry*, 636 So. 2d 950, 956 (La. Ct. App.), *writ denied*, 94-1597 (La. 9/30/94), 642 So. 2d 875, *and writ denied*, 94-1612 (La. 9/30/94), 642 So. 2d 875 ("The Department may not arbitrarily assess a penalty against one violator and not against others in the same or similar circumstances simply because that violator questions the agency's actions and subsequently seeks relief through the courts."). Therefore, a writ of mandamus should issue.

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d. The Department's irrational fear of RAD Source's motives is arbitrary and capricious

RAD Source participates in the lawful business in Nevada of manufacturing and selling products for treating marijuana for human consumption. *See* NRS 453D.020(1), 453D.020(3), 453D.200(f) (treatment and sale of marijuana is a lawful business in Nevada). Yet, the Department attempts to creates a bogeyman out of RAD Source. The Department's theorizes conspiratorially that RAD Source may have "strategically selected regional marijuana markets in which to sell its equipment." Opp. Br., at 9. The Department takes its conspiracy even further: it suspects "RAD [Source's] business objectives" were to take advantage of the "relatively unregulated" regional marijuana markets as opposed to first submitting its products to "the federally-regulated market for food and conventional medicine." Opp. Br., at 9.

The Department offers no emails, communications, data, or other documents to support these outlandish assertions. Moreover, the Department ignores that RAD Source's RS 420 Line was sold and used in Nevada for two years prior to the Department's abrupt ban without any safety or health issue.

The Department ignores that RAD Source's competitors also cannot supply FDA approval for their devices, or that these competitors too have opted to sell their products in the "relatively unregulated" Nevada marijuana market. If prior approval in some "federally-regulated market for food and conventional medicine" was so important to the Department, why does it require it of *only* RAD Source and not its competitors? Simply put, the Department's own conduct shows that its targeting of RAD Source is highly disingenuous.

3. RAD Source Has No Plain, Speedy, and Adequate Remedy at Law

The Department does not dispute that RAD Source was denied a right to appeal its decisions and actions. The Department does not dispute that there is no plain, speedy, and adequate remedy for RAD Source. *See Nevada Yellow Cab Corp. v. Eighth Judicial Dist. Court in & for Cty. of Clark*, 132 Nev. 784, 787, 383 P.3d 246, 248 (2016). Therefore, a writ of mandamus should issue.

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4. The Department Has Engaged in Impermissible Ad Hoc Rulemaking.

In its opposition brief, the Department asserts, for the first time, that it has not banned marijuana facilities from using X-ray irradiation technology, but merely imposed a "moratorium" on such technology until some unknowable future time. Opp. Br., at 3. However, this indefinite moratorium (i.e., ban) was imposed by the Department without the proper procedures: that is, without any notice to interested stakeholders or any opportunity to be heard as required by the Nevada Administrative Procedures Act (the "Nevada APA"). As such the Department's moratorium on all X-ray irradiation constitutes ad hoc rulemaking in violation of the Nevada APA.

"When an agency engages in conduct that constitutes the making of a regulation, it must adhere to the notice and hearing requirements set forth under NRS 233B.060 and 233B.061."[10] *S. Nevada Operating Engineers Contract Compliance Tr. v. Johnson*, 121 Nev. 523, 528, 119 P.3d 720, 724 (2005).

An agency engages in prohibited ad hoc rulemaking when it promulgates standards of

[10] NRS 233B.060(1) provides: "Except as otherwise provided in subsection 2 and in NRS 233B.061, before adopting, amending or repealing any permanent or temporary regulation, the agency must give at least 30 days' notice of its intended action, unless a shorter period of notice is specifically permitted by statute." NRS 233B.061 states that:

> 1. All interested persons must be afforded a reasonable opportunity to submit data, views or arguments upon a proposed regulation, orally or in writing.
>
> 2. Before holding the public hearing required pursuant to subsection 3, an agency shall conduct at least one workshop to solicit comments from interested persons on one or more general topics to be addressed in a proposed regulation. Not less than 15 days before the workshop, the agency shall provide notice of the time and place set for the workshop:
>
> (a) In writing to each person who has requested to be placed on a mailing list; and
>
> (b) In any other manner reasonably calculated to provide such notice to the general public and any business that may be affected by a proposed regulation which addresses the general topics to be considered at the workshop.
>
> 3. With respect to substantive regulations, the agency shall set a time and place for an oral public hearing, but if no one appears who will be directly affected by the proposed regulation and requests an oral hearing, the agency may proceed immediately to act upon any written submissions. The agency shall consider fully all written and oral submissions respecting the proposed regulation.
>
> 4. The agency shall keep, retain and make available for public inspection written minutes of each public hearing held pursuant to subsection 3 in the manner provided in subsections 1 and 2 of NRS 241.035.
>
> 5. The agency may record each public hearing held pursuant to subsection 3 and make those recordings available for public inspection in the manner provided in subsection 4 of NRS 241.035.

general applicability that effect policy without complying with the Nevada APA. *See Las Vegas Transit Sys., Inc. v. Las Vegas Strip Trolley*, 105 Nev. 575, 780 P.2d 1145 (1989); NRS 233B.038 (describing "regulation" as a "standard" of "general applicability" which "effectuates policy").[11]

Even when an agency's decision is directed to a single entity, it can still be of general applicability and subject to the Nevada APA. *Public Service Comm'n v. Southwest Gas Corp.*, 99 Nev. 268, 662 P.2d 624 (1983); *see also Coury v. Whittlesea-Bell Luxury Limousine*, 102 Nev. 302, 306, 721 P.2d 375, 378 (1986) (holding that when an order of an agency involves a "major policy concern" and is "of significance" to other operators in an industry, the requirements of the

[11] Specifically, the statute provides:

NRS 233B.038 "Regulation" defined.

1. "Regulation" means:
   (a) An agency rule, standard, directive or statement of general applicability which effectuates or interprets law or policy, or describes the organization, procedure or practice requirements of any agency;
   (b) A proposed regulation;
   (c) The amendment or repeal of a prior regulation; and
   (d) The general application by an agency of a written policy, interpretation, process or procedure to determine whether a person is in compliance with a federal or state statute or regulation in order to assess a fine, monetary penalty or monetary interest.
2. The term does not include:
   (a) A statement concerning only the internal management of an agency and not affecting private rights or procedures available to the public;
   (b) A declaratory ruling;
   (c) An intraagency memorandum;
   (d) A manual of internal policies and procedures or audit procedures of an agency which is used solely to train or provide guidance to employees of the agency and which is not used as authority in a contested case to determine whether a person is in compliance with a federal or state statute or regulation;
   (e) An agency decision or finding in a contested case;
   (f) An advisory opinion issued by an agency that is not of general applicability;
   (g) A published opinion of the Attorney General;
   (h) An interpretation of an agency that has statutory authority to issue interpretations;
   (i) Letters of approval, concurrence or disapproval issued in relation to a permit for a specific project or activity;
   (j) A contract or agreement into which an agency has entered;
   (k) The provisions of a federal law, regulation or guideline;
   (l) An emergency action taken by an agency that is necessary to protect public health and safety;
   (m) The application by an agency of a policy, interpretation, process or procedure to a person who has sufficient prior actual notice of the policy, interpretation, process or procedure to determine whether the person is in compliance with a federal or state statute or regulation in order to assess a fine, monetary penalty or monetary interest;
   (n) A regulation concerning the use of public roads or facilities which is indicated to the public by means of signs, signals and other traffic-control devices that conform with the manual and specifications for a uniform system of official traffic-control devices adopted pursuant to NRS 484A.430;
   (o) The classification of wildlife or the designation of seasons for hunting, fishing or trapping by regulation of the Board of Wildlife Commissioners pursuant to the provisions of title 45 of NRS; or
   (p) A technical bulletin prepared pursuant to NRS 360.133.

(Added to NRS by 1977, 1383; A 1999, 2406; 2013, 159)

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Nevada APA governing regulation promulgation must be followed).

Courts have noted that an agency moratorium, which by its terms has general application, is a legislative act. *See La Conner Associates LLC v. Berg*, 73 Fed. Appx. 994, 2003 WL 22097997, at *2-*3 (affording legislative immunity to town council adopting zoning moratorium because the same constituted a "legislative act").

In this case, the Department engaged in ad hoc rulemaking and violated the Nevada APA. Under the Department's own admission, it has issued a moratorium on all X-ray irradiation equipment used to treat marijuana. Opp. Br., at 3. Even though the Department's ban specifically involved RAD Source's technology, the moratorium is of general applicability to all X-ray irradiation equipment. *See id*. The Department's moratorium is also part of a general policy to stop marijuana facilities from using any X-ray irradiation equipment until the Department is satisfied with such technology (which, as discussed above, involves arbitrary and capricious terms). Like the Commission's rate design order in *Southwest Gas*, the Department's moratorium in this case should have been "done by the rule making process." 99 Nev. at 273; 662 P.2d at 627. Just as the Nevada Supreme Court upheld the rate design order being set aside in *Southwest Gas*, this Court should set aside the Department's moratorium and grant a writ of mandamus.

B. Other Forms of Writ Relief Are Also Warranted

The Department disputes whether writs of certiorari and writs of prohibition apply to this case. Opp. Br., at 5 n.1. Such writ relief is appropriate in this case.

Under NRS § 34.020(2), a writ of certiorari,

> ***shall be granted*** in all cases when an inferior tribunal, board or officer, exercising judicial functions, has exceeded the jurisdiction of such tribunal, board or officer and there is no appeal, nor, in the judgment of the court, any plain, speedy and adequate remedy."

(emphasis added). In Nevada, "an extraordinary writ, such as certiorari, is the proper vehicle for seeking judicial review of the merits of the agency's actions to determine whether the agency acted arbitrarily or capriciously." *Washington v. Clark Cty. Liquor & Gaming Licensing Bd.*, 100 Nev. 425, 428, 683 P.2d 31, 33–34 (1984).

In this case, the Department has acted arbitrarily and capriciously, as explained above in

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Part III.A.2, and thus exceeded its authority, by (1) deciding, upon non-scientific and unfounded grounds, that X-ray irradiation is unsafe; (2) requiring the RS 420 Line to obtain FDA approval and shifting positions on this issue; (3) treating RAD Source differently than its similarly situated competitors; and (4) basing the ban on an irrational fear of speculative bad faith motivations.

The Department does not dispute that RAD Source had no right to appeal these decisions and actions, and thus had no plain, speedy, or adequate remedy at law. *See* NRS § 34.020. Therefore, a writ of certiorari should issue against the Department.

Under NRS § 34.320, a writ of prohibition:

> arrests the proceedings of any tribunal, corporation, board or person exercising judicial functions, when such proceedings are without or in excess of the jurisdiction of such tribunal, corporation, board or person.

In *Van Heukelom v. Nevada State Bd. of Chiropractic Examiners*, 67 Nev. 649, 655-56, 224 P.2d 313, 316 (1950), a writ of prohibition was an available remedy when a state licensing board took, weighed, and considered evidence, and then, "in the exercise of its judgment and discretion, not only [made] findings of fact but conclusions of law."

Here, the Department allegedly took, weighed, and considered evidence regarding RAD Source's RS 420 Line of X-ray irradiators and banned these irradiators for arbitrary and capricious reasons, as explained above in Part III.A.2. This exceeded its authority. NRS § 34.320.

It is undisputed that RAD Source had no right to appeal the Department's decisions and actions, and thus had no plain, speedy, or adequate remedy at law. NRS § 34.330. Therefore, a writ of prohibition should issue against the Department.

C. At a Minimum, a Preliminary Injunction Should Be Granted to RAD Source

At a minimum, a preliminary injunction should be granted to RAD Source. RAD Source is likely to succeed on the merits of its claims, is suffering irreparable harm, and public policy favors an injunction. *Labor Com'r of State of Nevada v. Littlefield*, 123 Nev. 35, 38-39, 153 P.3d 26, 28 (2007).

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1. RAD Source Has Shown a Likelihood of Success on the Merits of its Mandamus, Certiorari, and Prohibition Claims

For its mandamus claim, as explained above in Part III.A.1, the Department made the operation of marijuana establishments unreasonably impracticable, in violation of its statutory duties. As explained above in Part III.A.2, the Department acted arbitrarily and capriciously.

For its certiorari and prohibition claims, for the same reasons listed immediately above, RAD Source has shown that the Department exceeded its authority. Further, it is undisputed that RAD Source had no right to appeal the Department's decisions and actions, and thus had no plain, speedy, or adequate remedy at law. Therefore, RAD Source is likely to succeed on the merits of its certiorari and prohibition claims and a preliminary injunction should be granted.

2. RAD Source Is Likely to Succeed on Its Declaratory Judgment Claim

RAD Source is likely to succeed on its declaratory judgment claim. The Department's sole dispute to this claim is that the Department did not act in excess of its statutory authority. Opp. Br., at 6. However, as shown above in Part III.A, the Department has indeed acted not only in excess of its statutory authority, but also in violation of its duties and arbitrarily and capriciously. The Department has infringed on RAD Source's rights to lawfully carry on its business, treated RAD Source unfairly and unequally, and denied RAD Source due process.

For these reasons, RAD Source has shown a likelihood of success on the merits of its declaratory judgment claim and a preliminary injunction should be granted.

3. RAD Source Is Likely to Succeed on Its Tort Claims

RAD Source is likely to succeed on its tort claims as the core elements of the claims have not been contested by the Department. Further, the Department is not entitled to discretionary act immunity.

a. RAD Source has met the elements for its tort claims

RAD Source is likely to succeed on its claim for intentional interference with contractual relations. The Department does not dispute (1) valid contracts existed between RAD Source and customers, (2) the Department's knowledge of those contracts, (3) intentional acts by the Department intended or designed to disrupt those contractual relationships, (4) actual disruption

of the contracts, or (5) resulting damages to RAD Source. *See J.J. Indus., LLC v. Bennett*, 119 Nev. 269, 274, 71 P.3d 1264, 1267 (2003). Rather, the Department merely disputes that it did not act in excess of its statutory authority. Opp. Br., at 6. However, as explained above in Part III.A, this is patently false. The Department acted in excess of its authority, in violation of its duties, and arbitrary and capriciously, therefore a preliminary injunction should be granted.

Likewise, RAD Source has shown a likelihood of success on its claim for intentional interference with prospective economic advantage. Again, the Department does not dispute that (1) prospective contractual relationships existed between RAD Source and potential customers; (2) the Department's knowledge of these prospective relationships; (3) the Department's intention to harm RAD Source by preventing these relationships; or (4) the actual harm suffered by RAD Source. *See Wichinsky v. Mosa*, 109 Nev. 84, 87-88, 847 P.2d 727, 729-30 (1993). Rather, as before, the Department merely disputes that it did not act in excess of its statutory authority. Opp. Br., at 6. This has been disproven by RAD Source as explained above. *Supra*, Part III.A. Therefore, a preliminary injunction should be granted.

b. Discretionary act immunity does not apply to this situation

The Department argues it is immune from RAD Source's tort claims under discretionary act immunity. Opp. Br., at 6-7. However, discretionary act immunity does not apply to this case.

An agency's decision is entitled to discretionary immunity under NRS 41.032 only if the decision: "(1) involves an element of individual judgment or choice and (2) is based on considerations of social, economic, or political policy." *Estate of Sauceda v. City of N. Las Vegas*, 380 F. Supp. 3d 1068, 1086 (D. Nev. 2019) (internal citations omitted). "A 'discretionary act' requires personal deliberation, decision, and judgment." *Herrera v. Las Vegas Metro. Police Dep't*, 298 F. Supp. 2d 1043, 1054 (D. Nev. 2004). As a general rule, state officials have a duty to exercise ordinary care in performing their duties. *Butler ex rel. Biller v. Bayer*, 123 Nev. 450, 464, 168 P.3d 1055, 1065 (2007).

In this case, there is no evidence of a discretionary act. The Department has provided no evidence of who supposedly engaged in the discretionary act, let alone evidence of that person's decision-making process. The Department is in sole possession of such evidence and has wholly

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failed to support its immunity claim. The Department all but admits in its opposition brief that no decision-making process was used to arrive at its arbitrary and capricious ban of the RS 420 Line. *See* Opp. Br., at 5 n.1.

Further, even if there was a discretionary act, there is no evidence that such act was undertaken in good faith. "Decisions made in bad faith…are not protected under the immunity statute even if they arise out of a discretionary function." *Jones v. Las Vegas Metro. Police Dep't*, 873 F.3d 1123, 1133 (9th Cir. 2017). In this case the Department acted in bad faith. After the RS 420 Line was used for two years in Nevada with no issue, the Department banned it suddenly and with no justification. Despite every effort made by RAD Source for *over eight months* to satisfy the Department, it has refused to lift this ban. Now, the Department reveals its decision was based on non-scientific and highly inaccurate suspicions of unsafety, unjustified disparate treatment of RAD Source versus its competitors, and unsubstantiated dislike—even potential vilification—of RAD Source's motives. Such conduct should not be tolerated by this Court. The Department acted in bad faith, and there is no discretionary act immunity in this case.

Finally, intentional torts are *never* protected by discretionary act immunity. *Sauceda*, 380 F. Supp. 3d at 1086 ("NRS 41.032 does not shield government actors from liability for intentional torts."). Both of RAD Source's tort claims are intentional, i.e. intentional interference with contractual relations and intentional interference with protective economic advantage. Therefore, the Department has no immunity in this case. A preliminary injunction should be granted.

D. RAD Source Has Shown Irreparable Harm for Which There Is No Adequate Legal Remedy

The Department does not dispute that RAD Source has suffered irreparable harm. Additionally, the Department's claims for immunity further evidence irreparable harm to RAD Source in this case. *Nalco Co. v. U.S. E.P.A.*, 786 F. Supp. 2d 177, 188 (D.D.C. 2011) ("Where a plaintiff cannot recover damages from the defendant due to the defendant's sovereign immunity ... any loss of income suffered by plaintiff is irreparable *per se*.") (internal quotations omitted) (emphasis in original). A preliminary injunction should therefore be granted.

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E. The Balance of Hardships Heavily Weighs in RAD Source's Favor

The Department does not discuss, and therefore concedes, that RAD Source has suffered, and will continue to suffer, significant hardships resulting from the ban. These include lost sales, customers, potential customers, market share, business reputation, and goodwill. The Department does not dispute that RAD Source's hardships are exacerbated by the Department's allowance of Ziel and Willow in the marketplace while holding them to less stringent standards.

The Department does not discuss, and therefore concedes, that the State will suffer little to no harm in allowing RAD Source to do what it did for years, what it is doing in other jurisdictions, and what its competitors are doing. While, for the first time, the Department raises safety concerns generally in its opposition brief, these concerns are not based on scientific grounds or credible sources. Therefore, the balance of hardships heavily weighs in RAD Source's favor and a preliminary injunction should be granted.

F. Public Policy Warrants a Preliminary Injunction

The Department does not dispute the public policies favoring a preliminary injunction, namely allowing a safe and effective treatment for marijuana, not making the operation of recreational marijuana establishments unreasonably impracticable, promoting the economic health of the marijuana treatment industry, and treating lawful businesses equally. The Department does not dispute the health risks of untreated or improperly treated marijuana. *See* Hartman Decl., already on file, at Ex. E.

The Department simply raises its concerns about the safety of X-ray irradiators, which, as shown above, is a position not based upon scientific grounds or credible sources. To be clear, there are no safety issues with the use of X-ray irradiation to treat marijuana.

Even more, the public is actually suffering great harm by the Department's ban. On December 27, 2019, the Department had to shut down a marijuana testing lab and announced that contaminated product had been sold.[12] If protecting public safety is the Department's goal, it is

[12] Carolyn Williams, 8NewsNow.com, *Check Your Marijuana: Dispensary Speaks Out After Las Vegas Testing Facility Closes Immediately Due to Failed Microbial Tests*, https://www.8newsnow.com/news/local-news/check-your-

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not being served by the Department arbitrarily banning a safe and effective treatment method, such as the RS 420 Line of X-ray irradiators. For these reasons, public policy warrants a preliminary injunction.

G. The Bond Should Be Nominal

The Department does not discuss, and therefore concedes, that the bond for a preliminary injunction should be nominal.

IV. CONCLUSION

Based on the foregoing, RAD Source respectfully requests that this Court enter a writ of mandamus, certiorari, or prohibition against the Department, or grant a preliminary injunction, compelling the Department to (1) lift the ban on the RS 420 Line and approve of its use for treating marijuana; (2) cease and desist requiring the RS 420 Line to get FDA approval or some other "comparable approval"; and (3) apply the same standards to similarly situated competitors like RAD Source as compared to, e.g., Ziel and Willow.

Dated this 3rd day of January 2020.

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marijuana-las-vegas-testing-facility-closed-immediately-batches-failed-secondary-microbial-testing/ (December 30, 2019), attached as **Exhibit 10.**

CERTIFICATE OF SERVICE

The undersigned, an employee of H1 Law Group, hereby certifies that on the 3rd day of January 2020, she caused a copy of the foregoing to be transmitted by electronic service in accordance with Administrative Order 14.2, to all interested parties, through the Court's **Odyssey E-File & Serve** system.

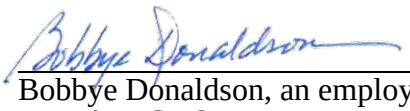

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EXHIBIT 1

DECLARATION OF GEORGE TERRY IN SUPPORT OF RAD SOURCE TECHNOLOGIES, INC.'S REPLY IN SUPPORT OF (1) MOTION FOR ORDER TO SHOW CAUSE WHY A WRIT OF CERTIORARI, MANDAMUS, AND/OR PROHIBITION SHOULD NOT ISSUE; (2) ALTERNATIVE MOTION FOR PRELIMINARY INJUNCTION; AND (3) APPLICATION FOR ORDER SHORTENING TIME

I, George Terry, state that:

1. I am the Executive Vice President of Sales and Marketing of Plaintiff RAD Source Technologies, Inc. ("RAD Source"), and have personal knowledge of the facts contained herein, except for those matters stated upon information and belief, and as to those matters, I believe them to be true, and if called upon to testify, could and would do so.

2. I make this Declaration in support of RAD Source's reply in support of its *(1) Motion for Order to Show Cause Why a Writ of Certiorari, Mandamus, and/or Prohibition Should Not Issue; (2) Alternative Motion for Preliminary Injunction; and (3) Application for Order Shortening Time* ("Motion").

3. I have reviewed the opposition (the "Opposition") to the Motion filed by Defendant the State of Nevada, Department of Taxation Marijuana Enforcement Division (the "Department").

4. In the Opposition, the Department suggests, without any supporting evidence and despite being provided with information about RAD Source, its equipment, and the safety and efficacy of X-ray irradiation in April 2019, that the RS 420 line of X-ray irradiation machines sold by RAD Source to marijuana producers in Nevada might not be safe for users of the machines.

5. As set forth in the Motion and the supporting exhibits thereto, and further discussed below, since the Department's ban on the RS 420 machines went into effect in March 2019, RAD Source has made extensive efforts to provide any information requested by the Department and to demonstrate the safety of the RS 420 machines.

6. ***The Department has never requested information regarding user safety***. Had such information been requested, it would have been provided. RAD Source has over

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200 RS Units in use in the US for varying applications including over 30 units at the American Red Cross for use in Blood Irradiation.

7. The RS 420 machines are cabinet X-ray machines, which are built and operate within specifications set forth in 21 CFR 1020.40, the federal safety standards for cabinet x-ray devices. The RS 420 machines come in three sizes, and pictures of the three different models are attached hereto as **Exhibit 1-A**.[1]

8. To conform with the federal regulations, the RS 420 machines must contain several safety interlocks which prevent the machines from being opened while in operation. Even if the machines are somehow opened while in operation, which would require a tremendous amount of force beyond the strength of a single person, the required safety mechanisms of the machines would force an immediate shutdown, and the machines cannot return to operation until reset. *See* 21 CFR 1020.40(c)(4), (6).

9. RAD Source files reports with the FDA Center for Devices and Radiological Health setting forth the design and operational specifications of each machine, and after each filing receives an accession number for each machine. Thus, the FDA does not "approve" any X-ray machine for any purpose. Instead, it issues accession numbers for devices conforming with the specifications set forth in 21 CFR 1020.40.

10. In addition, the federal regulations mandate that the radiation emitted from the RS 420 machines may not exceed .5 millireoentgen (mR) per hour at any point five centimeters outside the external surface of the machines. *See id.* At 1020.40(c)(1).

11. RAD Source has voluntary imposed even more stringent standards for its machines, requiring that the machines test at below .4 mR/hr then tightening further to below .2 mR/hr, or .002 millisieverts/hr.[2]

[1] While RAD Source would be willing to bring a unit into Court to show the Court what a unit looks like and how it works, the smallest unit weighs over 1,300 pounds, so it likely is not feasible for such a demonstration in the courtroom.

[2] There are 2 units of measurement for assessing exposure of ionizing radiation. The roentgen (R), and the Sievert (Sv). 1 millisievert = 100 milliroentgen .

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12. For all RS 420 machines sold by RAD Source, both to customers in and outside Nevada, there are two rounds of surveys performed to ensure that the machines operate below RAD Source's self-imposed emission limits. First, the machines are surveyed before they are shipped as a part of the quality process. They are surveyed again on site once delivered and installed and before purchasers are trained or allowed to use the machines.

13. By way of example, attached hereto as **Exhibit 1-B** are the pre-shipping and installation surveys for RS machine serial number 4012, which was a machine shipped to Nevada before the Department's ban went into effect, and which was set up for use in the hope that the ban would be lifted, but which remains inoparable. These surveys show that the machines were well below emission limits and thus do not place any user at biological risk.

14. RAD Source has both pre-shipping and installation surveys for all machines sold to Nevada customers, and all machines have passed each inspection.

15. Once RS 420 machines are shipped and go into use, they are recommended to be surveyed annually. This can be done more frequently by the customer if the customer purchases a survey meter, or annually as a part of a service plan by RAD Source.

16. In sum, the RS 420 machines are safe for use and the Department's speculation to the contrary is completely unfounded.

17. In the Opposition to the Motion, the Department also suggests that RAD Source somehow did not engage with the Department in good faith after the Department abruptly and unexpectedly imposed its "moratorium" (i.e., ban) on the RS 420 machines in March 2019, and that RAD Source was simply setting up "straw man" issues for litigation.

18. These contentions are demonstrably inaccurate, and in fact the converse is true. RAD Source made every reasonable effort to avoid the current litigation, and it was the Department that failed and/or refused to engage in good faith.

19. In March and April 2019, RAD Source on its own and then quickly through counsel Joseph Mugan sent numerous communications to Department employees and provided materials regarding the efficacy of ionizing radiation as a decontamination method

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and the safety of cannabis and other materials treated with ionizing radiation to humans. When these efforts stalled as a result of non-communication by the Department, RAD Source retained litigation counsel who again tried to resolve the issues without the need for litigation. Through its own counsel, the Department again refused to engage, forcing RAD Source to commence litigation.

20. I was personally involved with several attempts to discuss the ban on the RS 420 machines with the Department.

21. On March 28, 2019, I sent an invitation to Department employee David Witkowski to discuss the ban. In his response, Mr. Witkowski declined the invitation and suggested he would "try to reach out to [me] so that we can set up a time to discuss any issues pertaining to this matter." See March 28, 2019 email, a true and correct copy of which is attached hereto as **Exhibit 1-C**.

22. On April 13, 2019, RAD Source's regulatory counsel sent an email to Mr. Witkowski, copying several other Department employees at the direction of Mr. Witkowski, stating in pertinent part:

> Finally, my client is willing to travel to Las Vegas and meet with the Division early next week to discuss the foregoing in a good faith effort to resolve these issues in a timely fashion. It is more than my client's commercial issue, we believe it is a public health issue. Please let us know if the Division would like to have such a meeting and we can plan accordingly.

See April 13, 2019 email, a true and correct copy of which is attached hereto as **Exhibit 1-D**. There was no response to this email.

23. On April 17, 2019, Will Hartman was in Las Vegas and after multiple communications from RAD Source's counsel, Mr. Hartman was able to meet with Mr. Witkowski. Based upon that meeting, RAD Source expected a resolution of what it understood to be the final issue for the Department - its insistence on a response from the FDA – within days. Instead, after late April, there was no communication from the Department for several months.

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24. On September 10, 2019, I was in Las Vegas again and so I attempted to meet with the Department to discuss the continued RS 420 ban. I went to the Department's office and first asked to speak with supervisor Kara Cronkhite. I was told that Ms. Cronkhite was at her desk and was asked to wait in the waiting area. Five minutes later, the assistant for Marc Chmiel, another Department employee, came out and informed me that Ms. Cronkhite had gone to lunch. I asked to speak to Mr. Chmiel instead, and was told he was "off." I then asked to speak with Mr. Witkowski,and was told that he too was "off." I therefore told the assistant that I would wait for Ms. Cronkhite to return from lunch, and the assistant suggested I leave and come back instead. I left, and as I was leaving I called and left a message for Ms. Cronkhite asking her to call me back so that we could meet that afternoon. She never responded.

25. I returned to the Department's office that afternoon and was met by Department inspector Chris Jacobsen. Mr. Jacobsen advised that Ms. Cronkhite was at her desk but she would not speak with me. When I attempted to discuss the issues regarding the still-ongoing ban with Mr. Jacobsen, he stated that the matter "was above his pay grade."

26. To date, the Department has never provided RAD Source with:

- Any data or information indicating that the RS 420 machines do not work for the decontamination or remediation of cannabis;
- Any customer complaints regarding the efficacy of the RS 420 machines;
- Any data or information indicating that the RS 420 machines are not safe for operators; or
- Any data or information indicating that the RS 420 machines rendered treated marijuana unsafe for human consumption.

27. In its Opposition, the Department argues that the FDA approval requirement is a straw man argument concocted by RAD Source. In actuality, in every meeting and communication with the Department, it was the Department that was fixated upon "FDA approval or exemption." As already set forth in the Motion and explained more fully above: (1) the FDA does not approve any X-ray machines, even those used to treat food; and (2) as was repeatedly explained to the Department, the FDA will never approve or exempt any device or method for the treatment of cannabis while it remains federally illegal.

28. Lastly, as RAD Source repeatedly attempted to explain to the Department, centralized irradiation facilities are used to safely and effectively irradiate food products. This process occurs on a large scale and requires equipment far larger than that currently produced by RAD Source, but RAD Source is in the process of developing larger machines for the centralized irradiation of food products. In addition, the USDA has been using RAD Source equipment in Florida since 2013 for phytosanitary treatment of fruits and vegetables. *See* USDA report, and true and correct copy of which is attached hereto as **Exhibit 1-E**.

I declare under penalty of perjury under the law of the State of Nevada that the foregoing is true and correct.

Executed on January 3, 2020.

GEORGE TERRY

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EXHIBIT 1-A

PASS

The ***ONLY RESULT*** you will see on your **BIO-TEST** with the RS 420 IRRADIATOR from Rad Source!

QUASTAR®

The RS 420 Cannabis Irradiator is an on-site X-ray Remediation System (bioburden reduction), that features proprietary QUASTAR® X-ray technology

PROVEN TREATMENT FOR:

- Total aerobic plate count (cfu/g)
- Total yeast and mold (cfu/g)
- Entero (cfu/g)
- Coliform (cfu/g)
- Powdery Mildew
- Aspergillus

FEATURES:

- Five - 7" Diameter canisters
- Processing volume: ~5 lbs of product per cycle
- Cabinet X-ray device - 21 CFR 1020.40
- Mounted on casters
- Single QUASTAR® X-ray Emitter

"PHOTONIC DECONTAMINATION" Technology

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MKT 016-Rev 5-06/19

THE RS 420 X-RAY IRRADIATOR

Higher yield,
INCREASED PROFIT!

TECHNICAL SPECIFICATIONS*:

- Unit dimensions: 46" W x 36" D x 74" H (116.84 x 91.44 x 187.96 cm)
- Weight: 2,450 lbs (1111 kgs)
- Electrical requirements: Single phase, 50/60 Hz, 208 / 240 VAC, 40 A (L1, L2/N, GND)
- Built per ISO 9001 Quality Standards

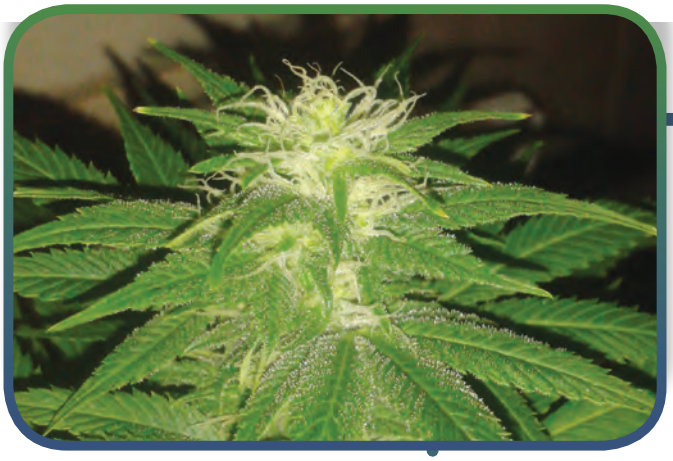
**Technical specifications are subject to change, please contact your Rad Source representative for the most current information.*

COOLING SPECIFICATIONS: REQUIRES EXTERNAL WATER CHILLER TO BE SUPPLIED BY CUSTOMER

- 5 GPM/40 PSI
- Requires minimum of 14,000 BTU's per hour
- Inlet/Outlet connections 3/4" NPT
- Water temp maintained between 65 and 85 degrees F
- Additional requirements will be provided

ADDITIONAL SPECIFICATIONS:

- Single chamber design
- Reliable uptime
- Company established in 1997
- Mounted on casters
- Safe, Self-shielded
- Turn-key installation
- System has no radioactive source
- Single QUASTAR® X-ray Emitter
- Warranty: The lesser of 12 months or 2400 hours of operation, parts, labor, and travel (US and Canada only)



Contact us *TODAY!*

RAD SOURCE

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MKT 016-Rev 5-06/19

Reduce Product LOSS

THE RS 420•M X-RAY IRRADIATOR

QUASTAR®

PROVEN TREATMENT FOR:

- Total aerobic plate count (cfu/g)
- Total yeast and mold (cfu/g)
- Entero (cfu/g)
- Coliform (cfu/g)
- Powdery Mildew
- Aspergillus

FEATURES AND BENEFITS:

- Processing Volume: ~2 lbs of product per cycle
- Single QUASTAR® X-ray Emitter
- Reliable uptime
- Safe, self-shielded unit with no radioactive source
- Secure-System is Password Protected
- Turn-key installation
- User friendly: Simple, easy-to-read touch pad

"PHOTONIC DECONTAMINATION Technology"

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Patents: See www.radsource.com/patent
MKT-029-Rev 3- 03/19

THE RS 420•M X-RAY IRRADIATOR

Increased production,
DECREASED LOSS!

TECHNICAL SPECIFICATIONS*:

- Unit Dimensions: 30" W x 36" D x 64" H
- Weight: 1350 lbs (612.35 kg)
- Electrical requirements: Single phase, 50/60 Hz, 240 VAC, 40A (L1, L2/N, GND)
- Built per ISO 9001 Quality Standards
- Remote access: Set programs, add/remove users, retrieve processing data, receive email notifications

**Technical specifications are subject to change, please contact your Rad Source representative for the most current information.*

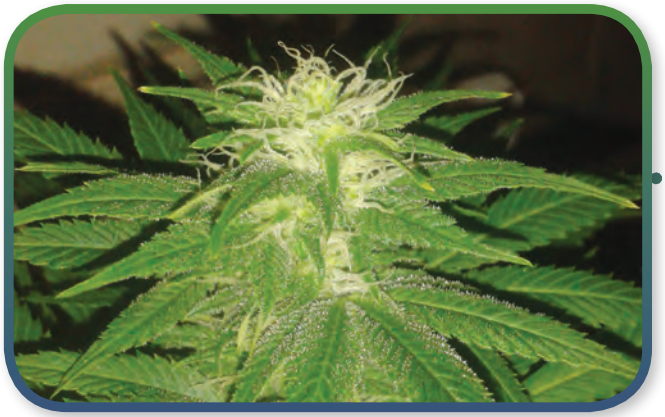
ADDITIONAL SPECIFICATIONS:

- Features single chamber design
- Easy to calibrate with NIST Certified Ion Chambers
- Company established in 1997
- Mounted on casters
- Safe, self-shielded
- Turn-key installation
- Warranty: The lesser of 12 months or 2400 hours of operation, parts, labor and travel (US and Canada only)

COOLING SPECIFICATIONS:

Water Chiller minimum (provided by end user):

- 5 GPM/40 PSI
- Requires minimum of 14,000 BTU's per hour
- Inlet/outlet connections 3/4" NPT
- Water Temp-maintained between 65 and 85 degrees F
- Additional requirements will be provided



Contact us *TODAY!*

System has no radioactive source.
Manufactured as a Cabinet X-ray device.

RAD SOURCE

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Patents: See www.radsource.com/patent
MKT-029-Rev 3- 03/19

Got MOLD?

THE RS 420•XL X-RAY IRRADIATOR

QUASTAR®

MOLD REMEDIATION

Perfect for LP's who choose to
control the process!

THE RS 420•XL MITIGATES:

- Total aerobic plate count (cfu/g)
- Total yeast and mold (cfu/g)
- Entero (cfu/g)
- Coliform (cfu/g)
- Powdery Mildew
- Aspergillus

FEATURES AND BENEFITS:

- Processing volume: ~25 to 40 lbs of product per cycle (based on density)
- Single chamber design with integrated multi-canister carousel
- Dual QUASTAR® X-ray Emitters
- Company established in 1997
- Mounted on casters
- Lab proven technology
- Turn-key installation
- Dual safety interlocks
- Manufactured as a cabinet X-ray device - 21 CFR 1020.40

"On-site treatment"

"PHOTONIC DECONTAMINATION" Technology

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MKT-022-Rev 7-04/19

THE RS 420•XL X-RAY IRRADIATOR

Increase your profit and production,
START SAVING TODAY!

TECHNICAL SPECIFICATIONS*:

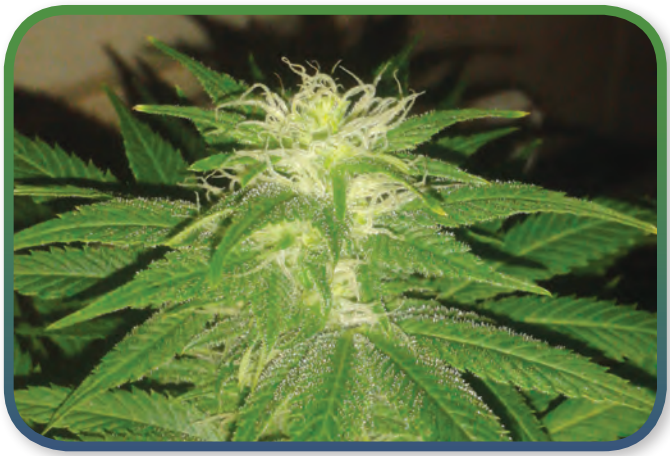
- Unit dimensions: 72" x 47" x 77" (182.88 cm x 119.38 cm x 195.58 cm)
- Weight: 6,300 lbs. (2858 kg)
- Electrical requirements: 1 Phase, 208/240 VAC, 60A (L1, L2/N, GND)
- Built per ISO 9001 Quality standards
- Warranty: The lesser of 12 months or 2400 hours of operation, parts, labor, and travel (US and Canada only)
- Remote access: Set programs, add/remove users, retrieve processing data, receive email notifications

**Technical specifications are subject to change, please contact your Rad Source representative for the most current information.*

COOLING SPECIFICATIONS:

Water Chiller minimum (provided by end user):

- 5 GPM/40 PSI
- 30,000 BTU's per hour
- Inlet/Outlet Connections 3/4" NPT
- Water Temp-maintained between 65 and 85 degrees F
- Additional requirements will be provided



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RAD SOURCE

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Patents: See www.radsource.com/patent
MKT-022-Rev 7-04/19

EXHIBIT 1-B

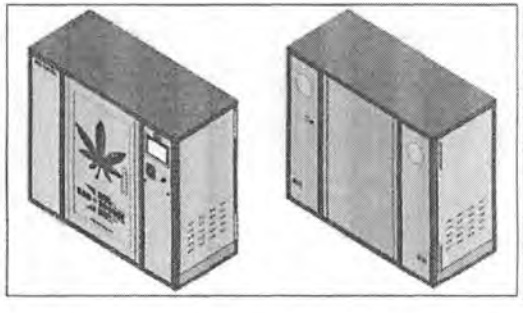
Radiation Survey - Data

RAD SOURCE

GM Survey Meter (if used)	
GM	
Settings	
Manufacturer	
Model	
Serial	
Cal. Due Date	

ICH Survey Meter (if used)	
Ion-Chamber	*RSM-002*
Settings	*0-500 µR/h*
Manufacturer	*Fluke*
Model	*451P*
Serial	*6339*
Cal. Due Date	*2/20/2019*

Survey Information	
Max kV	*160*
Max mA	*25*
Model	*RS 420-XL*
SN	*4012*
By	*Aaron Jezghani*
Date	*03/04/2019*



Procedure	The unabridged procedure is provided in P-039.
1	Sweep Front (top to bottom) and mark high readings, repeat process for Sides, Back, and Top.
2	Record high readings on the markers placed in step-1.
3	Terminate Cycle when readings are complete.
4	Transfer readings recorded on the markers to the following table.
5	IF 3400, Multiply highest reading by 1.3 and record the calculation in the following table to determine output for Conditioning (155kV,15mA).
6	If all readings (& calculation) are below 400 µR/h, issue "PASS", Else call Rad Source Technologies for Corrective Action Plan.

Survey Findings: µR/h maximum for each surface

Maximum (Cycle Mode)				Maximum (Condition Mode)			
Left Top	*15*	Front Top	*18*	Left Top	*15*	Front Top	*18*
Left Upper	*17*	Door Top	*350*	Left Upper	*17*	Door Top	*350*
Left Lower	*22*	Door Bottom	*187*	Left Lower	*22*	Door Bottom	*187*
		Front Lower	*20*			Front Lower	*20*
Back Top	*17*	Right Top	*13*	Back Top	*17*	Right Top	*13*
Back Upper	*24*	Right Upper	*18*	Back Upper	*24*	Right Upper	*18*
Back Lower	*18*	Right Lower	*23*	Back Lower	*18*	Right Lower	*23*

Pass/Fail

Not for use in China

If Maximum < 400 µR/h, Survey PASSES.
If Maximum > 400 µR/h, Survey FAILS.

Survey Complete

< 400 µR/h — Survey Passed

Operator Notes:

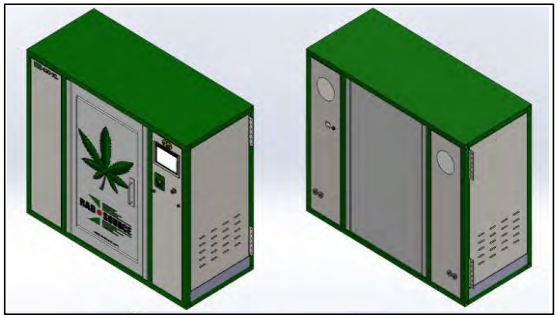
Notes:	*Using the GM or Ion Chamber to identify hot spots. There are no hot spots at any of the cabinet surfaces. Peak readings are "spurious-like" due to low values. Special attention given to front door and rear access panel. Irradiation Cycle Lamps confirmed to properly flash during survey. If any fail for over 400 µR/h, contact quality.*

Radiation Survey - Data

GM Survey Meter (if used)	
GM	*RSM-013*
Settings	*0-500 µR/h*
Manufacturer	*Thermo Scientific*
Model	*RadEye*
Serial	*32179*
Cal. Due Date	*6/26/2019*

ICH Survey Meter (if used)	
Ion-Chamber	
Settings	
Manufacturer	
Model	
Serial	
Cal. Due Date	

Survey Information	
Max kV	*160*
Max mA	*25*
Model	*RS 420·XL*
SN	*4012*
By	*BrandonGrissom*
Date	*3-27-19*



Procedure	The unabridged procedure is provided in P-039.
1	Sweep Front (top to bottom) and mark high readings, repeat process for Sides, Back, and Top.
2	Record high readings on the markers placed in step-1.
3	Terminate Cycle when readings are complete.
4	Transfer readings recorded on the markers to the following table.
5	IF 3400, Multiply highest reading by 1.6 and record the calculation in the following table to determine output for Conditioning (155kV,15mA).
6	If all readings (& calculation) are below 400 µR/h, issue "PASS", Else call Rad Source Technologies for Corrective Action Plan.

Survey Findings: µR/h maximum for each surface

Maximum (Cycle Mode)				Maximum (Condition Mode)			
Left Top	*11*	Front Top	*15*	Left Top	*11*	Front Top	*15*
Left Upper	*13*	Door Top	*238*	Left Upper	*13*	Door Top	*238*
Left Lower	*12*	Door Bottom	*225*	Left Lower	*12*	Door Bottom	*225*
		Front Lower	*33*			Front Lower	*33*
Back Top	*13*	Right Top	*12*	Back Top	*13*	Right Top	*12*
Back Upper	*13*	Right Upper	*13*	Back Upper	*13*	Right Upper	*13*
Back Lower	*12*	Right Lower	*12*	Back Lower	*12*	Right Lower	*12*

Pass/Fail

Not for use in China

If Maximum < 400 µR/h, Survey PASSES.
If Maximum > 400 µR/h, Survey FAILS.

Survey Complete

< 400 µR/h **Survey Passed**

Operator Notes:

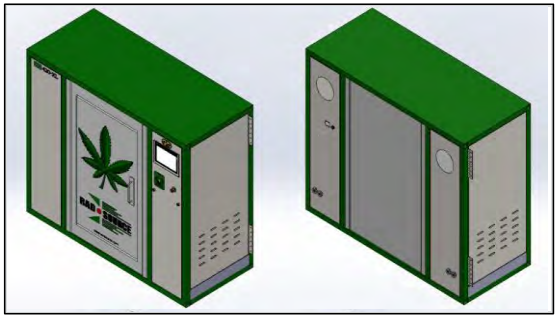
Notes:	*Using the GM or Ion Chamber to identify hot spots. There are no hot spots at any of the cabinet surfaces. Peak readings are "spurious-like" due to low values. Special attention given to front door and rear access panel. Irradiation Cycle Lamps confirmed to properly flash during survey. If any fail for over 400 µR/h, contact quality.*

Radiation Survey - Data

GM Survey Meter (if used)	
GM	*RSM-013*
Settings	*0-500 µR/h*
Manufacturer	*Thermo Scientific*
Model	*RadEye*
Serial	*32179*
Cal. Due Date	*6/26/2019*

ICH Survey Meter (if used)	
Ion-Chamber	
Settings	
Manufacturer	
Model	
Serial	
Cal. Due Date	

Survey Information	
Max kV	*160*
Max mA	*25*
Model	*RS 420·XL*
SN	*4012*
By	*BrandonGrissom*
Date	*3-27-19*



Procedure	The unabridged procedure is provided in P-039.
1	Sweep Front (top to bottom) and mark high readings, repeat process for Sides, Back, and Top.
2	Record high readings on the markers placed in step-1.
3	Terminate Cycle when readings are complete.
4	Transfer readings recorded on the markers to the following table.
5	IF 3400, Multiply highest reading by 1.6 and record the calculation in the following table to determine output for Conditioning (155kV,15mA).
6	If all readings (& calculation) are below 4 µSv/h, issue "PASS", Else call Rad Source Technologies for Corrective Action Plan.

Survey Findings: µSv/h maximum for each surface

Maximum (Cycle Mode)				Maximum (Condition Mode)			
Left Top	***0.11***	Front Top	***0.15***	Left Top	*0.11*	Front Top	*0.15*
Left Upper	***0.13***	Door Top	***2.38***	Left Upper	*0.13*	Door Top	*2.38*
Left Lower	***0.12***	Door Bottom	***2.25***	Left Lower	*0.12*	Door Bottom	*2.25*
		Front Lower	***0.33***			Front Lower	*0.33*
Back Top	***0.13***	Right Top	***0.12***	Back Top	*0.13*	Right Top	*0.12*
Back Upper	***0.13***	Right Upper	***0.13***	Back Upper	*0.13*	Right Upper	*0.13*
Back Lower	***0.12***	Right Lower	***0.12***	Back Lower	*0.12*	Right Lower	*0.12*

Pass/Fail

Not for use in China

If Maximum < 4 µSv/h, Survey PASSES.
If Maximum > 4 µSv/h, Survey FAILS.

Survey Complete

< 4 µSv/h **Survey Passed**

Operator Notes:

Notes:	*Using the GM or Ion Chamber to identify hot spots. There are no hot spots at any of the cabinet surfaces. Peak readings are "spurious-like" due to low values. Special attention given to front door and rear access panel. Irradiation Cycle Lamps confirmed to properly flash during survey. If any fail for over 4 µSv/h, contact quality.*

EXHIBIT 1-C

From: David Witkowski [dwitkowski@tax.state.nv.us]
Sent: Thursday, March 28, 2019 9:19 AM
To: George Terry
Subject: Declined: Speak with Rad Source
When: Thursday, March 28, 2019 2:30 PM-3:00 PM.
Where: A conference number will be provided

Good morning Mr. Terry,

Unfortunately, I have to decline the meeting invite as I am scheduled to be out on inspections all day today. I will try to reach out to you so that we can set up a time to discuss any issues pertaining to this matter. Thank you, Dave

EXHIBIT 1-D

information that was exchanged between your client and the FDA?

Thank you,
Dave

From: Joseph J. Mugan [mailto:jmugan@klnevada.com]
Sent: Saturday, April 13, 2019 12:08 PM
To: David Witkowski <dwitkowski@tax.state.nv.us>
Cc: Karalin Cronkhite <kcronkhite@tax.state.nv.us>; Jordan D. Wolff <jwolff@klnevada.com>; 'George Terry' <GTerry@radsource.com>; Will Hartman <whartman@radsource.com>
Subject: FW: Irradiation instrumentation approval

Dave:

As a follow up to our discussions yesterday and in a good faith effort to assist the Division in better understanding the use of the subject irradiation equipment, please find attached the following: (i) a brief summary prepared by the Company about itself, its equipment and the process; and (ii) an article titled “Evaluating the Effects of Gamma Irradiation for Decontamination of Medical Cannabis” for your reference.

As to the request relating to the Food and Drug Administration set forth below, we understand that such request as to some form of a certification or letter of exemption from the FDA is a requirement of an end-user but please note that my client has been diligently working in good faith to resolve this issue.

As discussed and in accordance with applicable law, marijuana and anything made with marijuana, such as marijuana brownies, do not constitute “food” by the Food and Drug Administration. Marijuana is a controlled substance and governed by The Controlled Substances Act (“CSA”) and the DEA. Its production, possession, and distribution are federally proscribed by CSA. In fact, and in response to your request below notwithstanding the above, my client reached out directly to representatives of the FDA and an FDA consultant to discuss whether there was any possibility in obtaining some form of certification or letter of exemption, despite the fact that marijuana products do not constitute food. My client was specifically informed by the FDA that: (i) the request being made by the Division is inapplicable as such products do not constitute food; and (ii) the FDA, as a federal agency, will not review or issue any certification or letter of exemption on a marijuana product which is not legally permitted under federal law. Basically, the FDA informed my client that they, in essence, will not touch it.

Due to the foregoing, the guidance you cite regarding food processing and irradiation is inapplicable to a Schedule I controlled substance and it is not possible for my client, nor any end user or any other party using similar equipment, to comply with the Division’s request to obtain some form of certification or letter of exemption from the FDA for marijuana. We respectfully request that the Division remove this requirement as it is inapplicable and impossible to satisfy by any party.

Finally, my client is willing to travel to Las Vegas and meet with the Division early next week to discuss the foregoing in a good faith effort to resolve these issues in a timely fashion. It is more than my client’s commercial issue, we believe it is a public health issue. Please let us know if the Division would like to have such a meeting and we can plan accordingly.

Thanks and we look forward to hearing from you.

Joe

EXHIBIT 1-E

USDA
United States Department of Agriculture

Phytosanitary Irradiation: Technology and Efficacy

Andrea Beam

Supervisory Biological Scientist
CPHST Miami Lab

Science and Technology
Plant Protection and Quarantine
Animal and Plant Health Inspection Services
United States Department of Agriculture

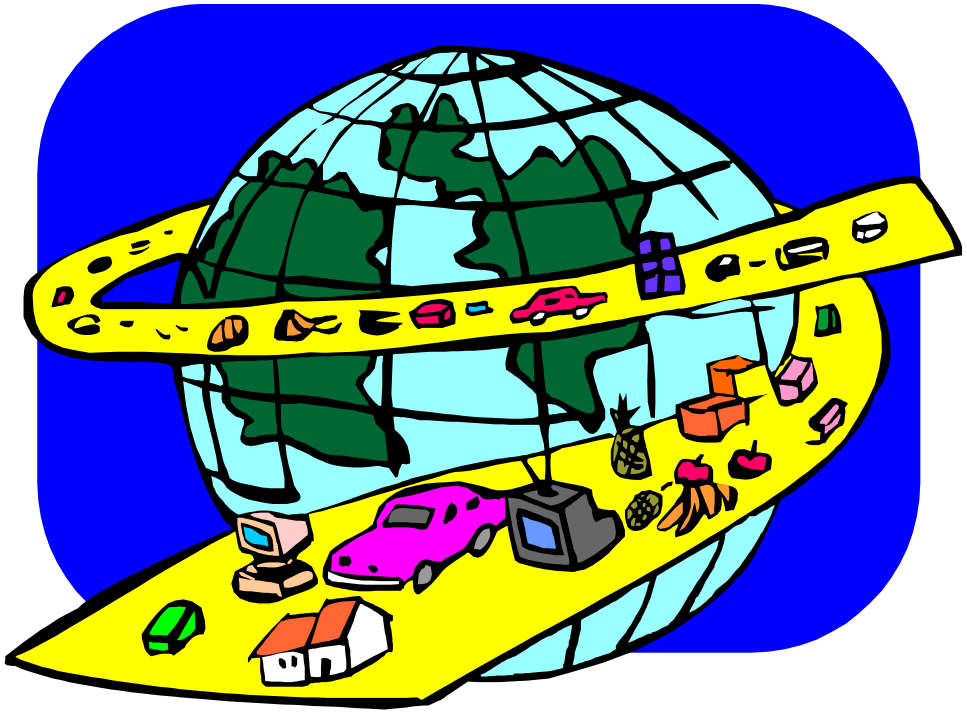
Outline

- Irradiation Technology
- Insect Efficacy
- Phytosanitary Irradiation History
- Mite Generic Dose Development

Background

Global trade of commodities

- New products for US consumers
- New export markets for US producers
- Exotic pests



PPQ Mission

Plant Protection and Quarantine (PPQ)
Animal and Plant Health Inspection Services
United States Department of Agriculture

APHIS

Safeguard U.S. agriculture and natural resources against the entry, establishment, and spread of economically and environmentally significant pests, and facilitate the safe trade of agricultural products.

Definitions & Concepts

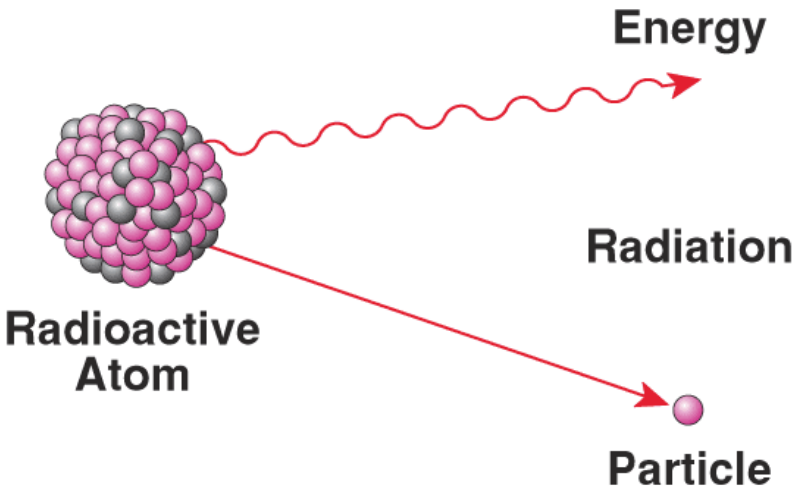
Phytosanitary Treatment- Regulatory measure intended to prevent the introduction or spread of quarantine pests by killing or sterilizing pests with high efficacy

Examples of Treatments:
Irradiation
Heat (44-48 °C)
Cold (0-2 °C)
Fumigation

Definitions & Concepts

Irradiation- The exposure of a substance to ionizing energy (radiation) for the purpose of achieving some desired technical benefit

- Food and agricultural products
  - phytosanitary treatment, shelf life extension, sprout inhibition, pathogen reduction
- Sterilization of medical products
- Materials modification
  - semiconducters, gemstone coloration, polymers



Irradiation (gamma, e-beam, X-ray) at typical energies for radiation processing WILL NOT cause any of the irradiated products to become radioactive or leave any radioactive residue.

Definitions & Concepts

Dose vs Absorbed Dose- Dose refers to the amount of ionizing radiation delivered; Absorbed dose refers to the quantity of radiating energy (in *Gray*) absorbed per unit of mass of a specified target

Gray (Gy)- a unit of absorbed dose where 1 Gy is equivalent to the absorption of 1 joule per kilogram of the specified material (1 Gy = 1 J/kg)

Typical Absorbed Dose Requirements

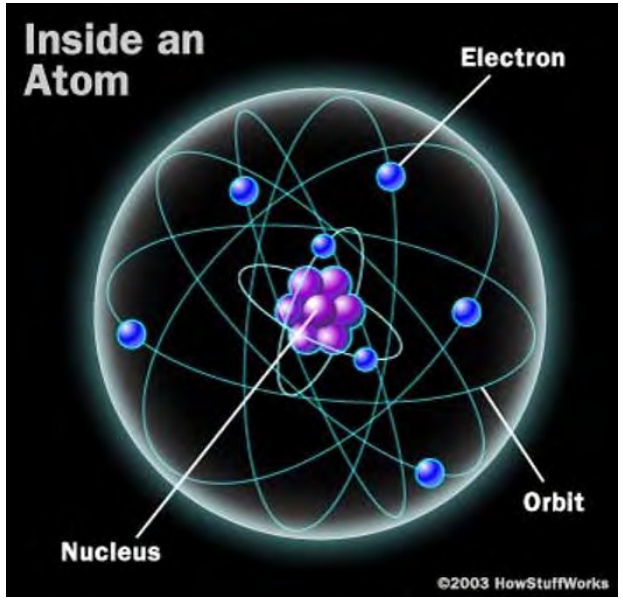
Purpose	Dose (Gray)
Inhibit Sprouting	50
Phytosanitary Irradiation	60-400
Pathogen Reduction (Meat and Poultry)	1,500
Spice Sanitation	6,500
Medical Device Sterilization	25,000
Food Sterilization (NASA)	46,000

Approved Irradiation Sources

Gamma: Cobalt 60 or Cesium 137 emits photons during decay

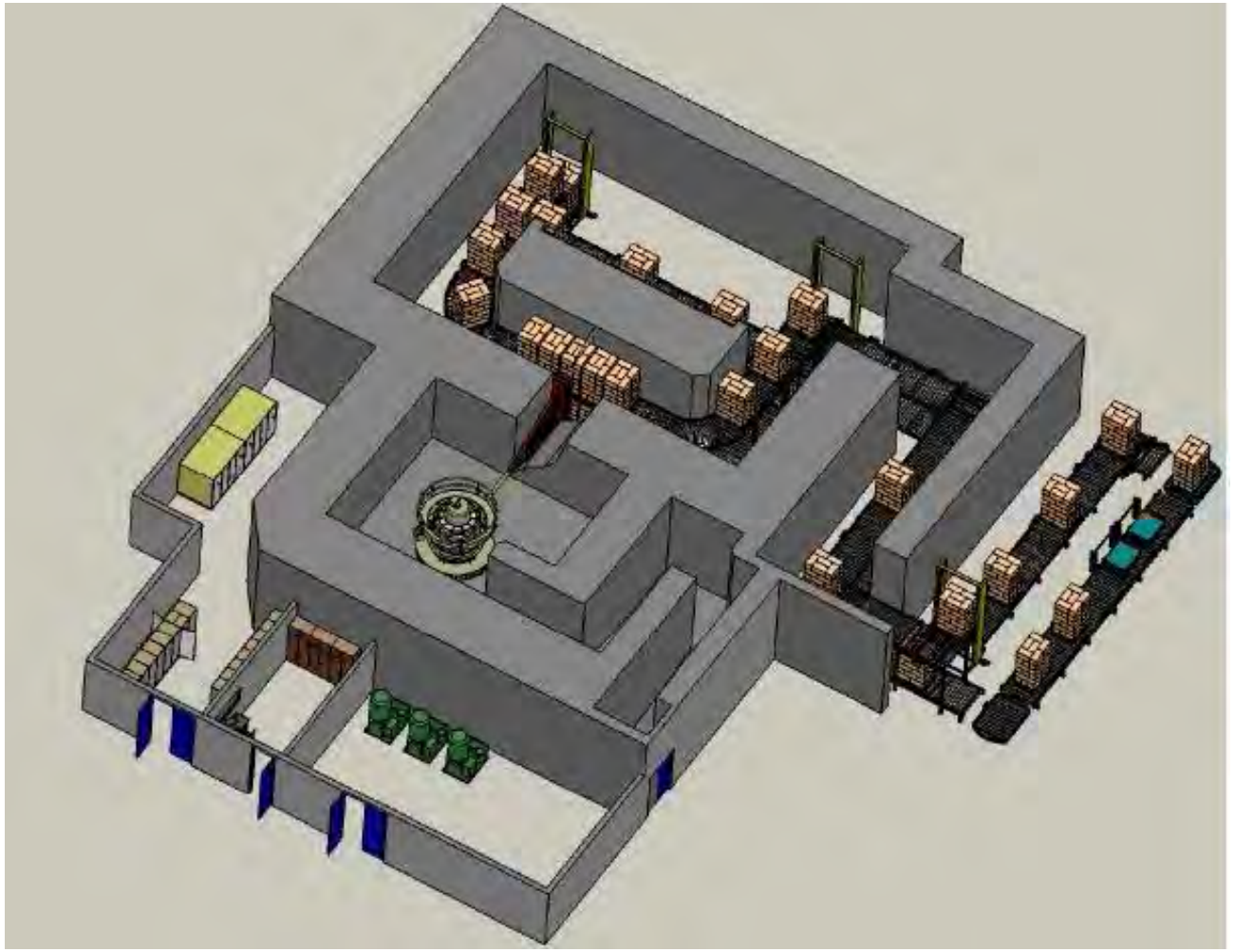
E-beam: High energy electrons propelled (particle beam) from an electron gun

X-ray: High energy electrons are converted to X-rays (photons)



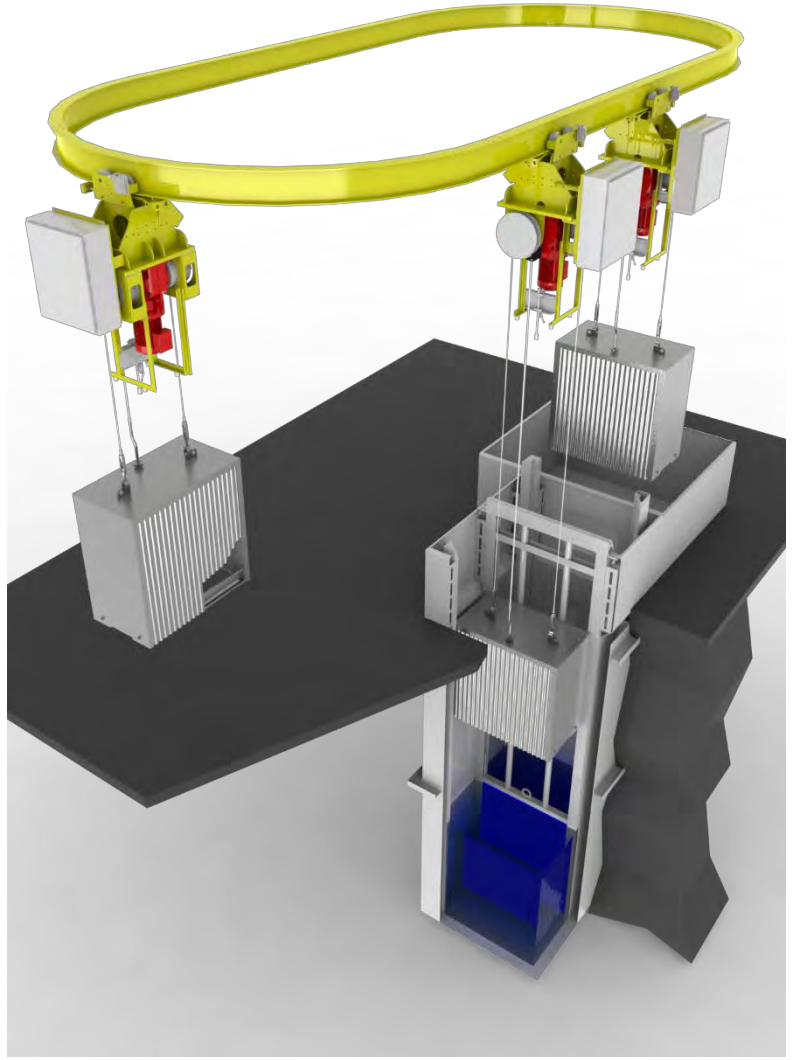
Components of Irradiation Facilities

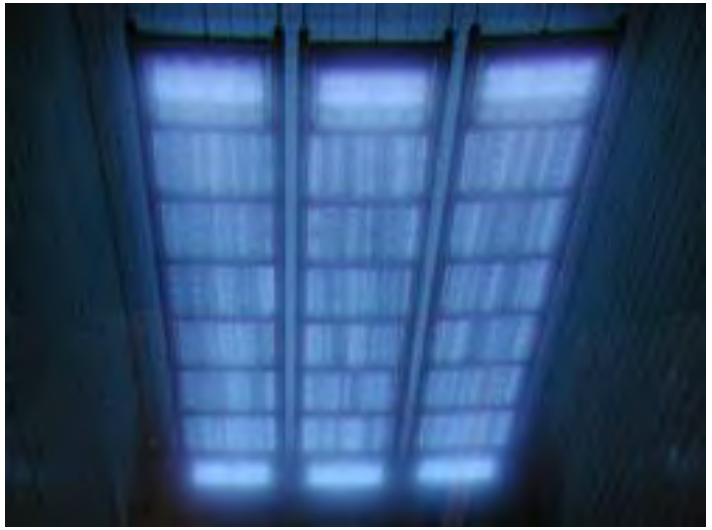
- Radiation source
  (gamma, x-ray, e-beam)
- Biological shield
- Product transport system
- Control and safety equipment



X-Ray Facility Image Credit: IAEA

Gamma Irradiator (Cobalt 60)

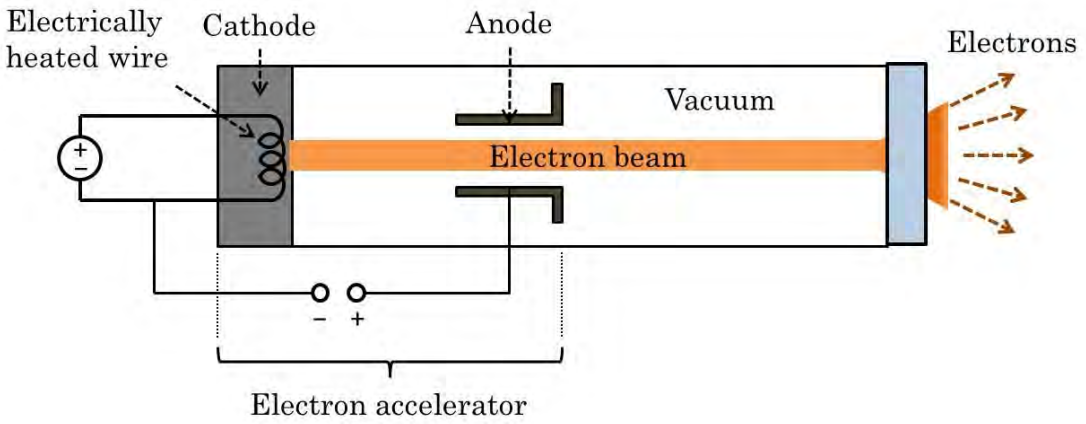




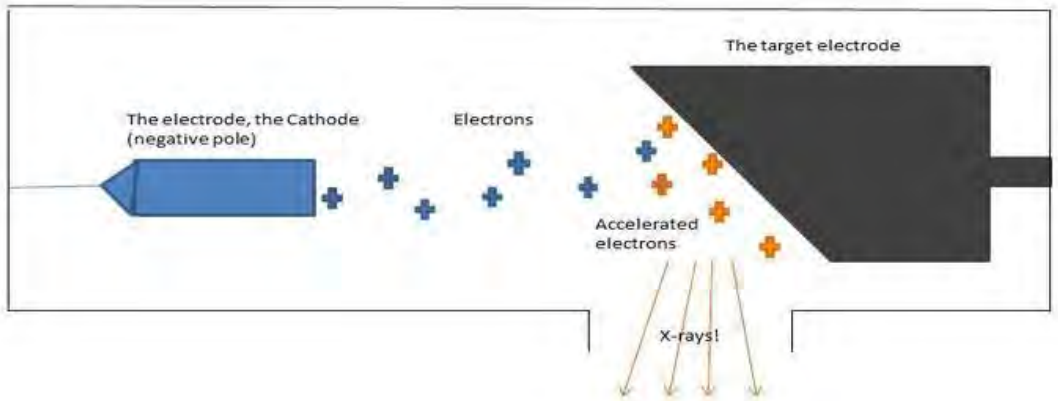
Cherenkov radiation

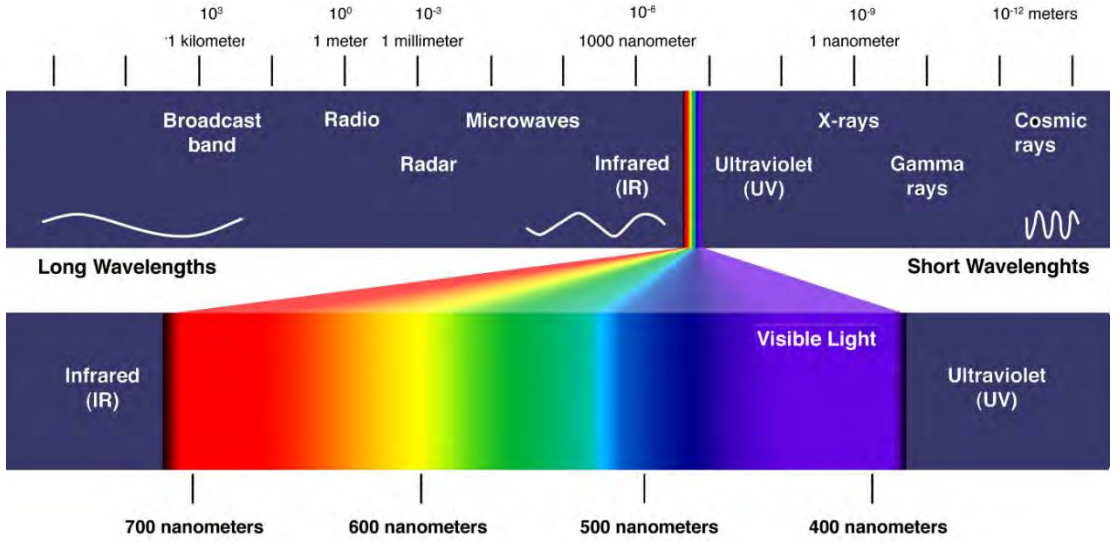
E-beam Irradiator

Image Credit: IAEA



X-Ray Irradiator

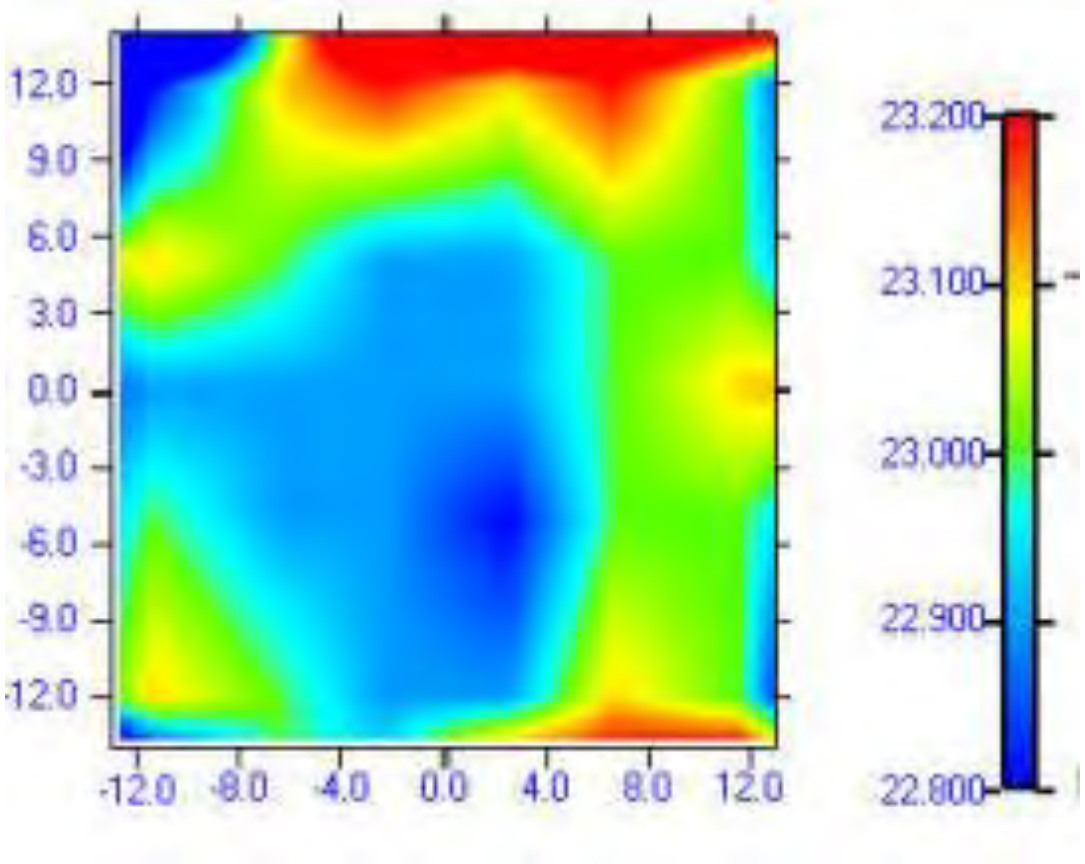




Definitions & Concepts

Dose Distribution- The spatial variation of absorbed dose throughout the process load, the dose having the extreme values *D*max and *D*min.

Note: FDA limits fresh fruit and vegetable treatments to 1000 Gy



From www.teasystems.com/WhitePapers/WeirPW_DoseUniformity.htm

Insect Efficacy

The objective of using irradiation as a phytosanitary measure is to prevent the introduction and spread of plant pests

This can be realized by achieving certain responses in the target pest(s) such as:

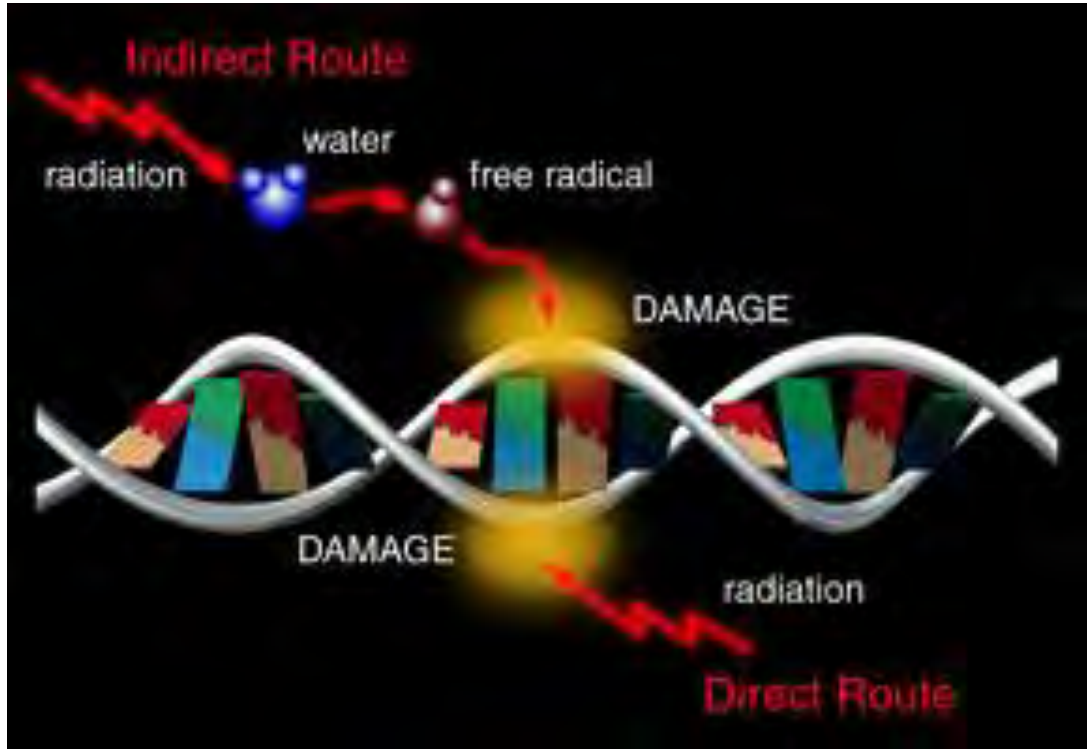
- mortality
- preventing development
- sterility
- inactivation

Mortality is usually not the target response for APHIS irradiation treatments and live insects may remain after treatment

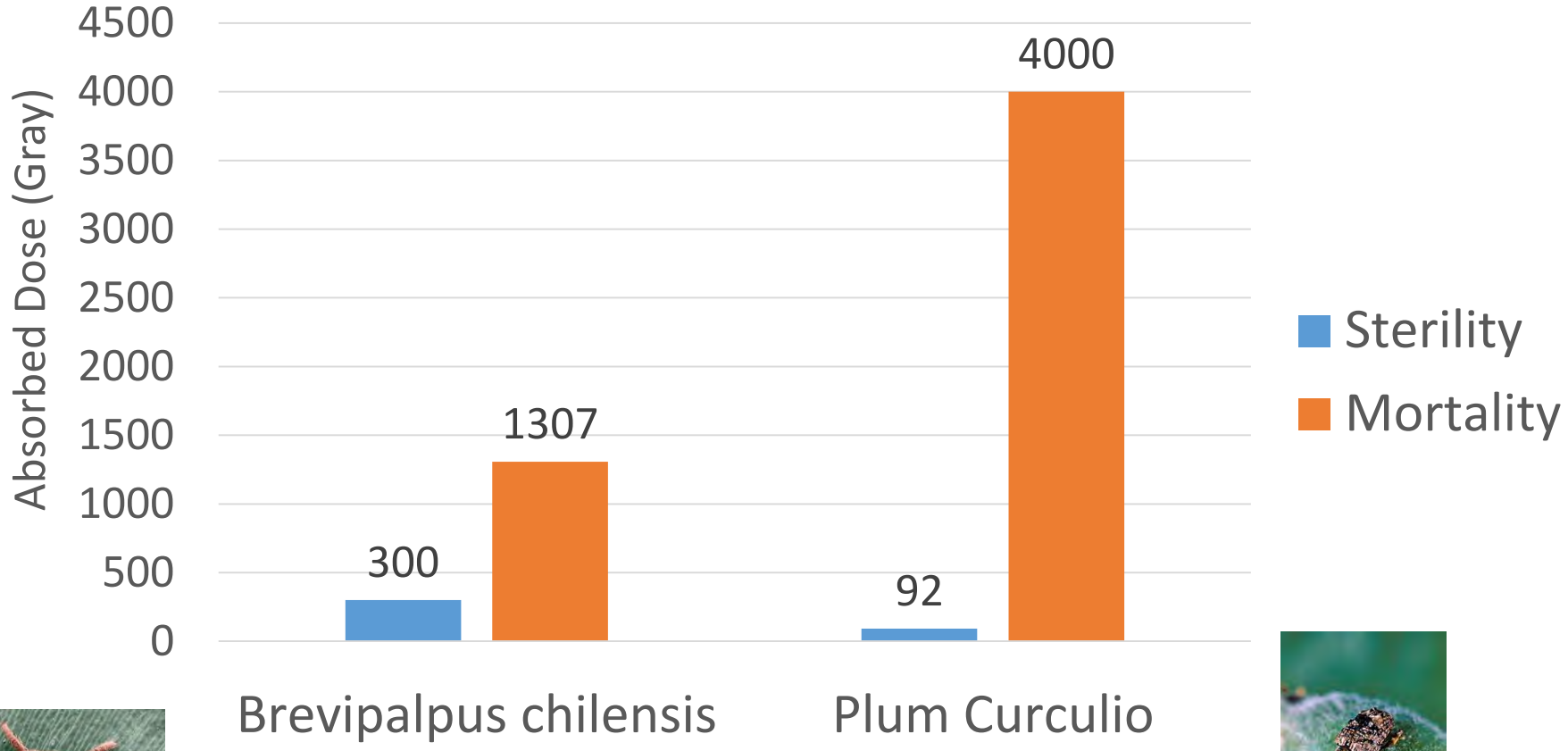
Insect Efficacy

Effects of ionizing radiation on insect pests:

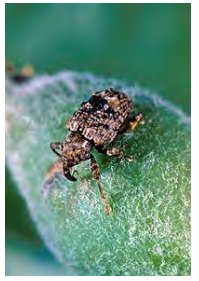
- Free radicals cause tissue damage
- Broken chemical bonds
- DNA damage can be fatal or prevent reproduction



Absorbed Doses Required for Sterility vs. Mortality



From Castro et al., 2004 and Hallman, 2003.



Phytosanitary Irradiation History

- 1986. US FDA approves irradiation of fruits and vegetables for insect disinfestation
- 1989. Approval of Hawaii papaya
- 1995. Hawaii produce exported with special permit
- 1996. USDA APHIS approves phytosanitary irradiation against fruit flies on any commodity

Phytosanitary Irradiation History

2002. Irradiation approved for all admissible fruits and vegetables from all countries to US

2004. Australian mangos to New Zealand

2006. USDA APHIS approves generic doses

2007. Thai mango to United States

2011. First Upon Arrival Irradiation Treatment

2015. First US exports of irradiated fruit

Generic vs. Specific Treatment

Generic

- Treatment covers multiple pests and commodities
- Subset of insects from group are tested

Specific

- Treatment applies to a single pest
- Often commodity-specific
- Single pest tested

APHIS Approved Irradiation Treatments

Pest	Dose (Gy)
All fruit flies of the family Tephritidae	150
All insects except adults and pupae of the order Lepidoptera	400
Eggs and larvae of the family Tortricidae	290

Pest	Dose (Gy)
Rhagoletis pomonella	60
Anastrepha ludens, Anastrepha obliqua, Anastrepha suspensa	70
Conotrachelus nenuphar	92
Anastrepha serpentina, Bactrocera jarvisi, Bactrocera tryoni, Ceratitis capitata, Copitarsia declora	100
Aspidiotus destructor, Cylas formicarius, Euscepes postfasciatus, Omphisa anastomosalis, Pseudaulacaspis pentagona, Bactrocera cucurbitae, Bactrocera dorsalis	150
Sternochetus frigidus	165
Cydia pomonella, Grapholita molesta, Epiphyas postvittana	200
Cryptophlebia ombrodelta, Cryptophlebia illepida	250
Brevipalpus chilensis, Sternochetus mangiferae	300

Generic Treatments in Use

Trading Partners	Commodity	Dose
Mexico to US	Citrus, manzano pepper, mango	150 Gy
India & Pakistan to US	Mango	400 Gy
Mexico to US	Guava	400 Gy
Vietnam to US	Dragonfruit	400 Gy
Australia to New Zealand	Mango, papaya	250 Gy
Australia to New Zealand	Lychee	350 Gy

Hallman, G., 2012. Generic phytosanitary irradiation treatments. Radiation Physics and Chemistry. 81:861–866.

USDA
United States Department of Agriculture

Dose Development - Mites

- Mites
  - Quarantine pests for many fresh commodities
  - Vectors for plant diseases
- Limited phytosanitary treatment options
  - Not covered by generic 400 Gy insect dose
- Australia and New Zealand
  - 400 Gy for Tetranychidae
  - 500 Gy for all other mites

Joseph Berger, Bugwood.org

USDA United States Department of Agriculture

Dose Development - Mites

Objective

- Determine irradiation dose that prevents reproduction of *Brevipalpus yothersi*
  - Endpoint = prevent F1 egg hatch

- Contribute to the body of literature required to establish a generic dose for mites

Brevipalpus yothersi

USDA United States Department of Agriculture

Methods

X-ray irradiator at Miami CPHST lab

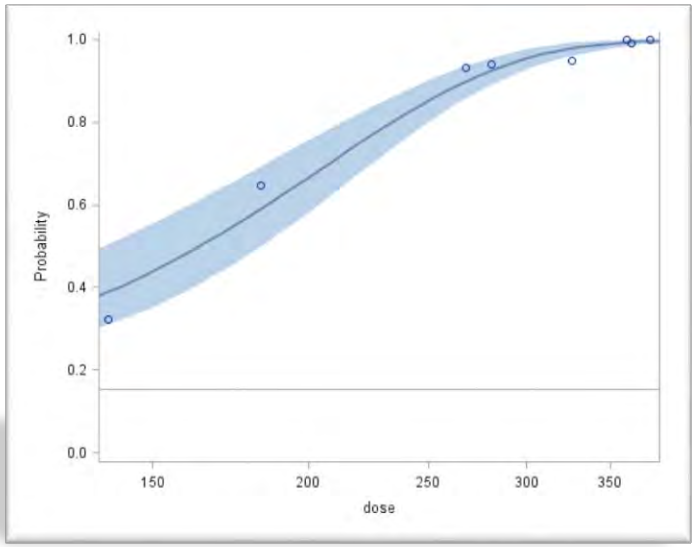
Lemon with arenas for individual mites

Brevipalpus mites on lemon

USDA
United States Department of Agriculture

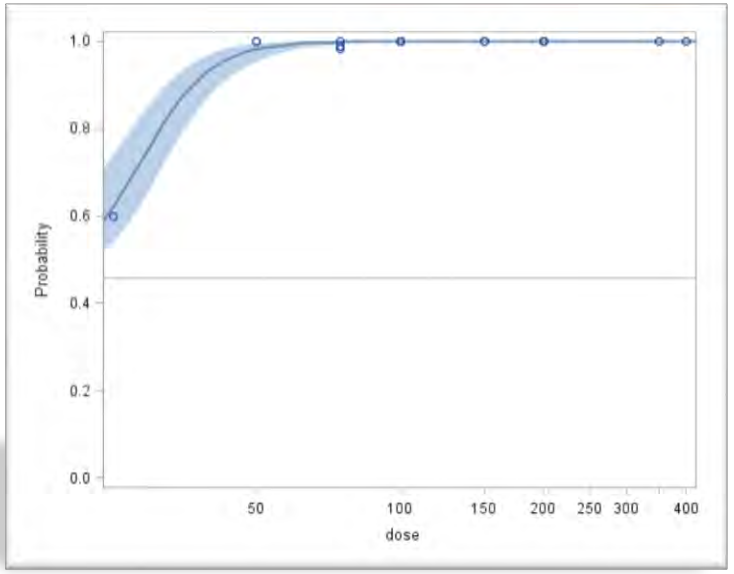
Preliminary Results

Adult (n=577)



Egg (n=1921)

insectimages.org



Life Stage	SD-99	SD-99.9	Model
Adult	352 (327-387)	406 (371-461)	Gompertz
Egg	61 (51-82)	90 (70-140)	Logistic

Concluding Thoughts

Benefits of PI

- Effective for many types of pests
- Minimal impact on commodity quality
- May be applied at diverse points post-harvest

Question for you:

What commodities could be added to the US irradiation program?

Questions?

Andrea.l.beam@aphis.usda.gov
(305) 278-4888

EXHIBIT 17

A-19-805074-W

DISTRICT COURT
CLARK COUNTY, NEVADA

Writ of Mandamus	**COURT MINUTES**	**June 24, 2020**

A-19-805074-W Rad Source Technologies Inc, Plaintiff(s)
vs.
State of Nevada Dept of Taxation Marijuana Enforcement Division, Defendant(s)

June 24, 2020 **3:00 AM** **Minute Order**

HEARD BY: Jones, David M **COURTROOM:** Chambers

COURT CLERK: Michaela Tapia

JOURNAL ENTRIES

- This Court heard Plaintiff Rad Source's motion regarding a writ of mandamus on January 15, 2020. After considering the pleadings, supplement documents, and counsels' oral arguments, this Court hereby GRANTS Plaintiff's writ of mandamus.

Plaintiff to prepare the order.

CLERK'S NOTE: This Minute Order was electronically served to all registered parties for Odyssey File & Serve. /mt

EXHIBIT 18

ORDG
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eric@h1lawgroup.com
Joel Z. Schwarz, NV Bar 9181
joel@h1lawgroup.com
Moorea L. Katz, NV Bar No. 12007
moorea@h1lawgroup.com
701 N. Green Valley Parkway, Suite 200
Henderson NV 89074
Phone 702-608-3720
Fax 702-608-3759

Attorneys for Plaintiff RAD Source Technologies, Inc.

EIGHTH JUDICIAL DISTRICT COURT

CLARK COUNTY, NEVADA

RAD SOURCE TECHNOLOGIES, INC., a Florida Corporation,

Plaintiff,

vs.

THE STATE OF NEVADA *ex rel.* DEPARTMENT OF TAXATION, MARIJUANA ENFORCEMENT DIVISION,

Defendant.

Case No.: A-19-805074-W
Dept. 29

ORDER GRANTING RAD SOURCE TECHNOLOGIES, INC.'S PETITION FOR WRIT OF MANDAMUS

This matter came before the Court for hearing on January 15, 2020 and January 22, 2020 on Plaintiff RAD Source Technologies, Inc. ("RAD Source")'s *(1) Motion for Order to Show Cause Why a Writ of Certiorari, Mandamus, and/or Prohibition Should Not Issue; (2) Alternative Motion for Preliminary Injunction; and (3) Application for Order Shortening Time* (the "Motion"). Having fully reviewed the Motion as well as the exhibits and declarations attached thereto; the opposition filed by the Defendant The State of Nevada *ex rel.* Department of Taxation, Marijuana Enforcement Division (the "Department") and the exhibits thereto; the reply in support of the Motion filed by RAD Source the exhibits and declarations attached thereto; all evidence and argument presented at the January 15, 2020 and January 22, 2020 hearings; RAD Source's *Response to February 4, 2020 Minute Order* filed February 20, 2020 and the exhibits thereto; and

RAD Source's *Amended Complaint and Petition for Writ of Certiorari, Mandamus, Prohibition, Declaratory Judgment, Intentional Interference with Contractual Relations, and Intention Interference with Prospective Economic Advantage* filed December 12, 2019, and good cause appearing, the Court makes the following Findings of Fact and Conclusions of Law and enters an Order granting RAD Source's Petition for a Writ of Mandamus:

FINDINGS OF FACT

1. RAD Source is a private company that was founded in 1997 and which develops and manufactures renewable, non-isotope, ionizing radiation products worldwide.

2. RAD Source's patented and proprietary QUASTAR® technology produces high output X-ray radiation efficiently and reliably for a wide variety of irradiation applications including blood, cell and tissue, insects, biological research, and viral inactivation.

3. RAD Source's equipment is utilized in these various applications throughout the United States and worldwide.

4. Currently, RAD Source's equipment resides in hundreds of major pharmaceutical labs, healthcare institutions, and renowned universities worldwide. RAD Source's client list includes the American Red Cross, the Mayo Clinic, and the U.S. Food and Drug Administration's National Center for Toxicological Research.

5. Irradiation is the process by which an object is exposed to radiation, i.e., energy transmitted in waves or streams of particles. Types of electromagnetic radiation include visible light, radio frequency, microwaves, infrared light, ultraviolet light, X-rays, and gamma rays.

6. Ionizing radiation is a term describing the effect of removing electrons from an atom. FDA and USDA regulations allowing the use of ionizing radiation for pathogen reduction, antimicrobial decontamination, and phytosanitary treatment do not distinguish between gamma or x-ray produced ionizing radiation. In short, it is widely understood and accepted that gamma and x-ray irradiation are functional equivalents.

7. Ionizing radiation is a safe, widely utilized, and well-studied process that is used in marijuana decontamination, sterilization, blood transfusion, immunology and oncology research, and agriculture, among others.

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Henderson, Nevada 89074
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8. X-ray irradiation technology is accepted by the American Red Cross, the Mayo Clinic, and the U.S. Food and Drug Administration's National Center for Toxicological Research, as well as by medical facilities and universities throughout the United States and the world.

9. Ionizing radiation is recognized as a safe and effective method to treat food for human consumption by FDA, the World Health Organization (WHO), the Centers for Disease Control and Prevention (CDC), and the U.S. Department of Agriculture (USDA).

10. Irradiation is beneficial for prevention of foodborne illness, preservation, control of insects, delay of sprouting and ripening, and sterilization.

11. Ionizing radiation, and in particular X-rays, will not cause any of the irradiated products to become radioactive or leave any radioactive residue.

12. RAD Source is the developer of the RS 420 Line of X-ray Irradiators, which are used for the safe and effective treatment of marijuana.

13. Title 21, Chapter I, Subchapter B, Part 179 of the Code of Federal Regulations ("C.F.R.") specifically uses the term, and permits, "ionizing radiation" for food treatment. The regulation further sets forth the operational parameters for X-ray equipment that is approved for use on food. RAD Source's RS 420 machines are fully compliant with these parameters.

14. Within the United States, the RS 420 Line has been used to treat marijuana in many state-regulated marijuana markets outside Nevada.

15. The RS 420 machines conform to federal safety and operational guidelines for cabinet X-ray devices, and are surveyed for emission safety on two occasions before being put into use.

Public Health and Safety Concerns Related to Untreated Marijuana

16. Given the multiple steps involved in harvesting, drying, processing, and packaging marijuana, it can be difficult to maintain perfectly sterile conditions throughout the entire marijuana production process. In order to ensure the safety of the product ultimately

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delivered to the consumer, growers utilize decontamination processes in the everyday processing of marijuana product and in converting quarantined product into safe, useable product.

17. Moreover, just like cultivating any other crop, marijuana is subject to a wide range of potential contaminants including yeast, mold, insects, and other pathogens.

18. The most concerning pathogen in the marijuana industry is Aspergillus. There have been documented cases of medicinal marijuana patients who have died from aspergillosis, a condition caused by inhaling Aspergillus spores. The Department recently issued a public health and safety advisory warning concerning the presence of Aspergillus in Nevada marijuana, highlighting the importance of this issue and the significance of potential impact on the health and safety of Nevada citizens and consumers.

The RS 420 Line Was in Use in Nevada for Two Years Before the Department Imposed a "Moratorium" on the Use of the Machines

19. From March 2017 through March 2019, Nevada marijuana growers utilized the RS 420 Line in everyday processing of marijuana to reduce yeast, mold (e.g., Aspergillus), and other pathogens and in converting quarantined product into safe, useable marijuana product.

20. In March 2019, without any prior notice to RAD Source, the Department informed RAD Source customers they were not allowed to continue using the RS 420 Line of equipment.

21. RAD Source immediately and consistently engaged in communications with the Department to try to resolve any concerns the Department may have regarding its technology.

22. On April 9, 2019, Dave Witkowski, DOT Inspector II, communicated to RAD Source a list of six criteria that the Department required in order to approve the use of irradiation instrumentation utilizing ionizing radiation to treat marijuana and marijuana products.

23. The following week, the Department acknowledged that RAD Source had addressed all but one of the six criteria to its satisfaction. The single remaining item the Department required was certification from the U.S. Food and Drug Administration ("FDA") or a letter of exemption from FDA (the "FDA Requirement").

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The Single Remaining Item on the Checklist, the FDA Requirement, Is Impossible to Obtain

24. Marijuana and anything made from marijuana, such as edible marijuana products, do not constitute "food" regulated by FDA.

25. Marijuana is a controlled substance under the Controlled Substances Act ("CSA") and its production, possession, and distribution are federally proscribed. 21 U.S.C. § 801 *et seq.* Therefore, it is not possible for RAD Source, nor any end user or any other party, to obtain FDA approval for devices used to process marijuana.

26. In its effort to appease the Department, RAD Source reached out to FDA to inquire as to the possibility of obtaining some form of certification or letter of exemption per the Department's request and requirement for the same. In response, a representative of FDA informed RAD Source that: (i) the request being made by the Department is impossible as marijuana products do not constitute food; and (ii) FDA, as a federal agency, will not review or issue any certification or letter of exemption on a marijuana product because it is not legally permitted under federal law.

27. RAD Source had multiple discussions with Department representatives and counsel, in person and over the phone, and providing documentation explaining (1) marijuana is not a "food" and therefore is not subject to FDA oversight, and (2) as marijuana is a federally controlled substance, it is impossible to satisfy the FDA Requirement.

28. However, the Department continued to prohibit the use of the RS 420 Line based on the FDA Requirement.

29. The FDA Requirement is not embodied, or in any way referenced, in any Nevada Revised Statute or Nevada Administrative Code provision. Instead, the Department appears to have created the FDA Requirement outside of the Department's standard process of enacting rules and regulations and outside of the procedures required under Nevada's Administrative Procedures Act, as codified in NRS Chapter 233B.

30. The Department has not required other marijuana treatment processes or equipment to meet the FDA Requirement.

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CONCLUSIONS OF LAW

1. "A writ of mandamus is available to compel the performance of an act that the law requires as a duty resulting from an office, trust, or station or to control an arbitrary or capricious exercise of discretion." *Nevada Yellow Cab Corp. v. Eighth Judicial Dist. Court in & for Cty. of Clark*, 132 Nev. 784, 787, 383 P.3d 246, 248 (2016) (quoting *Humphries v. Eighth Judicial Dist. Court*, 129 Nev. 788, 791, 312 P.3d 484, 486 (2013)). For a writ to issue, generally a party must not have "an adequate and speedy legal remedy." *Id.*

2. The Department is prohibited under Nevada law from creating regulations that make the operation of recreational marijuana establishments unreasonably impracticable. NRS 453D.020(1); NRS 453D.020(3); NRS 453D.200(f).

3. The Department violated NRS 453D.200(f) and failed to perform acts which the law compels it to perform by prohibiting the use of the RS 420 Line without any justification, hearing, or notice.

4. Additionally, the Department violated NRS 453D.200(f) and failed to perform acts which the law compels it to perform by creating impossible standards for RAD Source to meet, namely requiring FDA certification or an FDA letter of exemption in order to lift the ban on the RS 420 Line.

5. To the extent the Department's actions were an exercise of discretion, the Department has acted arbitrarily and capriciously by banning RAD Source's RS 420 Line, which is a safe and effective method for treating marijuana.

6. To the extent the Department's actions were an exercise of discretion, the Department has acted arbitrarily and capriciously by requiring RAD source to meet impossible and inapplicable requirement of obtaining FDA certification or FDA letter of exemption before approving the RS 420 Line for treating marijuana.

7. To the extent the Department's actions were an exercise of discretion, the Department has acted arbitrarily and capriciously by applying different standards to similarly situated competitors.

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8. Additionally, when an agency engages in conduct that constitutes the making of a regulation, it must adhere to the notice and hearing requirements set forth under NRS 233B.060 and 233B.061. *S. Nevada Operating Engineers Contract Compliance Tr. v. Johnson*, 121 Nev. 523, 528, 119 P.3d 720, 724 (2005).

9. An agency engages in prohibited ad hoc rulemaking when it promulgates standards of general applicability that effect policy without complying with the Nevada APA. *See Las Vegas Transit Sys., Inc. v. Las Vegas Strip Trolley*, 105 Nev. 575, 780 P.2d 1145 (1989); NRS 233B.038.

10. The Department's self-defined "moratorium" on ionizing radiation technology is in violation of Nevada's Administrative Procedures Act because the moratorium was enacted in violation of NRS Chapter 233B.

11. RAD Source was denied a right to appeal the Department's decisions and actions. Therefore, there is no plain, speedy, and adequate remedy in the ordinary course of law to correct the Department's failure to perform the acts required by law or to correct the Department's arbitrary and capricious use of discretion.

12. If any of the Conclusions of Law are properly findings of fact, they shall be treated as thought appropriately identified and designated.

ORDER

IT IS HEREBY ADJUDGED ORDERED AND DECREED that Plaintiffs' Petition for Writ of Mandamus is GRANTED. The Department of Taxation is hereby ordered to (1) immediately lift the prohibition on the RS 420 Line and allow the RS 420 machines to return to operation, and (2) cease and desist from requiring the RS 420 Line to meet the impossible FDA Requirement.

DATED this 7th day of July 2020.

DISTRICT COURT JUDGE
DEPARTMENT 29

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Prepared and submitted by:

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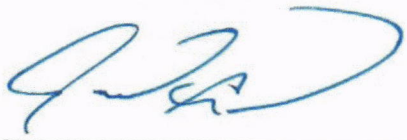

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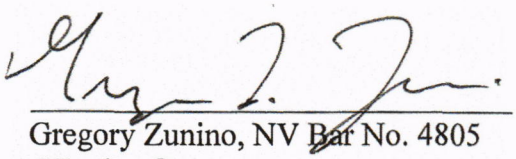

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EXHIBIT 19

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FILE NO.

December 2, 2020

Hon. Michael Douglas, Chair
Nevada Cannabis Compliance Board
555 E. Washington Avenue, Ste. 4500
Las Vegas, NV 89155

Re: Petition to Request Repeal or Amendment of Nevada CCB Regulation 12.065

Dear Chair Douglas:

On behalf of RAD Source Technologies, Inc., please allow this correspondence to serve as a Petition requesting to repeal or, alternatively, amend Nevada Cannabis Compliance Board (CCB) Regulation 12.065 (also referred to as "Labeling Requirement"). This Petition is respectfully submitted pursuant to CCB Regulation 4.145.

A. Petitioner's name, business address and telephone number

Petitioner is RAD Source Technologies, Inc. (RAD Source), and its contact information is as follows:

RAD Source Technologies, Inc.
4907 Golden Parkway, Suite 400
Buford, GA 30518
954.873.2085

B. Basis of request to repeal or amend CCB Regulation 12.065

RAD Source requests that the subject regulation be repealed as it fails to articulate an agency rule, standard, directive or statement of general applicability which effectuates or interprets law or policy, or describes the organization, procedure or practice requirements of any agency. *See*, Nevada Revised Statute (NRS) 233B.038(1)(a). Instead, CCB Reg. 12.065 can be construed as being applicable *only* to cannabis decontaminated, post-harvest, using RAD Source's equipment, even though there are multiple forms of electromagnetic radiation used in and/or that come into contact with cannabis products throughout the entirety of the growth and production process. Sunlight, UV, overhead lights, grow lights, X-ray and radio frequency technologies are *all* forms of electromagnetic energy which expose cannabis to

radiation. However, the current regulation appears to target only post-harvest decontamination using ionizing radiation.

Furthermore, the regulatory warning is neither supported by scientific evidence nor was it promulgated by legislation. *See*, Senate Bill 533, 2019 Nevada Legislative Session. In fact, none of the statutory directives contained in NRS 678A.450, 678B.650 or 678C.490 speak to labeling standards or warning notices akin to that required in CCB Regulation 12.065; instead they evidence the Legislature's directives to the CCB to develop regulations pertaining to licensing, regulatory compliance, advertising, racial and gender equality and economic stability within the cannabis industry. Clearly, CCB Regulation 12.065 in no way furthers these legislative directives. However, as the CCB is aware, the Legislature did in fact promulgate specific labeling requirements for cannabis products, thereby evidencing a clear intent to identify exactly what information should be included on labels. *See*, NRS 678D.420. As the statutory language in NRS 678D.420 is clear and unambiguous RAD respectfully submits that CCB Regulation 12.065 neither effectuates nor interprets any law.

There are a limited number of methods used in the cannabis industry to decontaminate harvested flower. The use of ionizing radiation, in the form of X-rays, is one of those methods. The CCB has data clearly demonstrating that RAD Source's machines are a safe and effective method of preventing the development of mold, powdery mildew and *Aspergillus which can produce dangerous mycotoxins*. The Labeling Requirement contained in CCB Reg. 12.065 does nothing to make cannabis products any safer for consumers. It does, however suggest to the public that there may be something unsafe about the product they are purchasing, when the exact opposite is true. Without question, deterring consumers from purchasing safe products is counterproductive.

Equally concerning is the CCB mandated use of the Radura symbol on cannabis labels. As outlined in the attached U.S. Food and Drug Administration (FDA) Notice, the FDA has no concerns about over-the counter drugs sterilized with ionizing radiation, and therefore it does not require any labeling. Recognizing that cannabis is a drug, not food, in repealing the Labeling Requirement the CCB would be acting consistent with the FDA. The labeling mandates currently proposed by the CCB for cannabis are the current requirements from the FDA regulating the notice of use of ionizing radiation on eggs, beef, poultry and shellfish, none of which are cannabis.

C. Specific regulation in question:

> **12.065 Cannabis treated with radiation.** If any cannabis or cannabis product has been treated with radiation at any time, any and all packaging of the irradiated cannabis or cannabis product must include labeling that contains the following statement: "NOTICE: This product contains ingredients that have been treated with irradiation" in bold lettering, along with the Radura symbol as used by the U.S. Food and Drug Administration.

D. Requested amendment to or detailed statement as to why regulation should be repealed:

In support of the request to repeal CCB Reg. 12.065 RAD respectfully refers the CCB to the attached FDA Notice announcing the repeal of a regulation pertaining to irradiation of products used in over the counter (OTC) drugs. *See, 21 CFR Part 310* (Dec. 2019). As determined by the FDA, the technology for decontamination by irradiation is well known therefore, product labeling requirements are no longer necessary. More specific to the subject regulation is the FDA's determination that the repeal of the labeling requirement *would not diminish public health protections*.

Additionally, the CCB is in possession of scientific studies, data, and other reports and information, which clearly show that the use of ionizing radiation, and specifically the use of x-ray irradiation by a RAD Source machine, is a safe and effective method for decontamination of cannabis flower. This information includes the results of a safety study, *requested by CCB Staff from one of RAD Source's Nevada customers using RAD Source's equipment*, which conclusively demonstrates the safe use for decontamination of cannabis thereby demonstrating that CCB Reg. 12.065 is entirely unnecessary.
As evidenced by the findings stated in the FDA notice confirming that decontamination of a drug by irradiation poses no threat to the health and safety of the public, coupled with the plethora of scientific evidence previously submitted to the CCB on this specific subject, RAD Source respectfully requests that the CCB repeal Regulation 12.065. Alternatively, RAD Source requests that the CCB open a regulatory workshop for the purposes of amending the regulation. *NRS* 678A.460(1)(d).

<u>Alternative CCB Regulation 12.065 language</u>:

In the event the CCB disagrees that Regulation 12.065 should be repealed, RAD Source respectfully submits the following proposed language as an alternative to the currently adopted regulation:

> Each retail package of flower, which has been treated in any manner to reduce pathogens to a level below those set forth in NCCB Regulation 11.050 shall be labeled as follows:
> "***For your safety***, ***post-harvest treatment of this product has been used to reduce pathogens potentially harmful to human health***."
> (1) Treatments to reduce pathogen levels in cannabis include the use of:
> (a) chemicals, reactive oxygen
> (b) gas(es), ozone
> (c) photons, or electromagnetic waves
> (d) any other process steps taken during the cultivation process to bring the cannabis into compliance with the regulated pathogen level(s).

E. Statement identifying persons or groups who may be affected by the repeal of CCB Regulation 12.065 and the manner in which they will be affected:

Following multiple discussions with various members of Nevada's cannabis industry RAD Source submits that most, if not all, cultivators will be *positively impacted* by the repeal of CCB Regulation 12.065. Almost all cultivators use some form of post-harvest decontamination to treat cannabis in an effort to prevent mold or Aspergillus from developing post testing and while available to consumers. Thus, the regulation imposes a requirement which serves no purpose, is unnecessarily costly, requires additional space on each label and could deter consumers from using their product.

Similarly, dispensary operators will benefit from the repeal of CCB Reg. 12.065 as it creates an additional level of product review – verification of whether cannabis was treated by irradiation and if so, whether the label contains the proper NOTICE language. Furthermore, the regulatory NOTICE could create consumer concern that decontamination by radiation is unsafe - which is not accurate - and/or that certain cannabis strains are potentially dangerous when in reality the use of x-ray irradiation by a RAD Source machine is a safe and effective method for decontamination of cannabis flower. As such, Regulation 12.065 as currently written is counterproductive.

F. Conclusion

For the reasons set forth herein and in concert with the FDA's position relative to irradiation, RAD respectfully requests that the CCB repeal Reg. 12.065, as confirmation of the fact that the post-harvest treatment of cannabis with irradiation is not dangerous to the health of the consuming public.

Very truly yours,

/s/Kimberly Maxson-Rushton

Kimberly Maxson-Rushton, Esq.

cc: T. Klimas, Executive Director
W. Hartman, RAD
G. Terry, RAD
J. Schwarz, Esq.
E. Hone, Esq.
M. Briggs, SDAG

regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that only affects air traffic procedures and air navigation, it is certified that this rule, when promulgated, does not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

The FAA has determined that this action qualifies for categorical exclusion under the National Environmental Policy Act in accordance with FAA Order 1050.1F, "Environmental Impacts: Policies and Procedures," paragraph 5–6.5a. This airspace action is not expected to cause any potentially significant environmental impacts, and no extraordinary circumstances exist that warrant preparation of an environmental assessment.

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.11D, Airspace Designations and Reporting Points, dated August 8, 2019, effective September 15, 2019, is amended as follows:

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.

* * * * *

ANE MA E5 Pittsfield, MA [Amended]

Pittsfield Municipal Airport, MA
(Lat. 42°25'39" N, long. 73°17'27" W)

That airspace extending upward from 700 feet above the surface within a 9.6-mile radius of the Pittsfield Municipal Airport, and within 6-miles each side of the 064° bearing of the airport, extending from the 9.6-mile radius to 18-miles northeast of the airport.

Issued in College Park, Georgia, on December 4, 2019.

Ryan Almasy,

Manager, Operations Support Group, Eastern Service Center, Air Traffic Organization.

[FR Doc. 2019–26857 Filed 12–13–19; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 310

[Docket No. FDA–2017–N–6924]

RIN 0910–AH47

Regulation Requiring an Approved New Drug Application for Drugs Sterilized by Irradiation

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is issuing a final rule repealing a regulation that requires an FDA-approved new drug application (NDA) or abbreviated new drug application (ANDA) for any drug product that is sterilized by irradiation (the irradiation regulation). Repealing the irradiation regulation will mean that over-the-counter (OTC) drug products that are generally recognized as safe and effective, are not misbranded, and comply with all applicable regulatory requirements can be marketed legally without an NDA or ANDA, even if they are sterilized by irradiation. FDA is taking this action because the irradiation regulation is out of date and unnecessary.

DATES: This rule is effective January 15, 2020.

ADDRESSES: For access to the docket to read background documents or comments received, go to *https://www.regulations.gov* and insert the docket number found in brackets in the heading of this final rule into the "Search" box and follow the prompts, and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Sudha Shukla, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 5234, Silver Spring, MD 20993–0002, 301–796–3345.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Executive Summary

In this final rule, FDA repeals the irradiation regulation, which provided that any drug sterilized by irradiation was a new drug. OTC drugs marketed pursuant to the OTC Drug Review that are generally recognized as safe and effective, are not misbranded, and comply with all applicable regulatory requirements now can be marketed legally without an FDA-approved NDA or ANDA, even if the drugs are sterilized by irradiation. As the Agency explained in the proposed rule published in the **Federal Register** of September 12, 2018 (83 FR 46121), FDA is taking this action because the Agency no longer concludes that drugs sterilized by irradiation are necessarily new drugs. The technology of controlled nuclear radiation for sterilization of drugs is now well understood. In addition, drugs that are marketed pursuant to the OTC Drug Review must be manufactured in compliance with current good manufacturing practices (CGMPs). Appropriate and effective sterilization of drugs, including by irradiation, is adequately addressed by the CGMP requirements. Repealing the irradiation regulation eliminates a requirement that is no longer necessary and will not diminish public health protections.

The estimated one-time costs of this rule range from $25 to $32. Avoiding the unnecessary preparation and review of a premarket drug application will generate an estimated one-time cost savings that range from about $0.40 million to $2.16 million. Over 10 years with a 7 percent discount rate, the annualized net cost savings range from $0.05 million to $0.29 million, with a primary estimate of $0.06 million; with a 3 percent discount rate, the annualized net cost savings range from $0.05 million to $0.25 million, with a primary estimate of $0.05 million. Over an infinite horizon, we assume that one sponsor will benefit from this deregulatory action every 10 years; the present value of the net cost savings over the infinite horizon range from $0.76 million to $4.11 million with a 7

percent discount rate and from $1.52 million to $8.21 million with a 3 percent discount rate.

II. Background

On February 24, 2017, E.O. 13777, "Enforcing the Regulatory Reform Agenda" (*https://www.gpo.gov/fdsys/pkg/FR-2017-03-01/pdf/2017-04107.pdf*) was issued (82 FR 12285). One of the provisions in the E.O. requires Agencies to evaluate existing regulations and make recommendations to the Agency head regarding their repeal, replacement, or modification, consistent with applicable law. As part of this initiative, FDA is repealing the irradiation regulation as specified in this rule.

In the November 29, 1955, issue of the **Federal Register**, FDA issued a statement of interpretation relating to the sterilization of drugs by irradiation (20 FR 8747 at 8748).[1] In the statement, FDA explained that there was an interest in the utilization of newly developed sources of radiation for the sterilization of drugs. The Agency went on to state that it was necessary in the interest of protecting the public health to establish by adequate investigations that the irradiation treatment does not cause the drug to become unsafe or otherwise unsuitable for use. For this reason, all drug products sterilized by irradiation would be regarded as new drugs within the meaning of section 201(p) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 321(p)), which would mean that an effective new drug application would be required for such products.

In 1996, FDA proposed to revise the statement and consolidate it with similar provisions into a single list of drugs that have been determined by previous rulemaking procedures to be new drugs within the meaning of section 201(p) of the FD&C Act (61 FR 29502 at 29503 to 29504 (June 11, 1996)). The Agency proposed to remove from the regulatory text any existing background information describing the Agency's basis for its determination of new drug status.

In 1997, FDA finalized these provisions, now located in § 310.502 (21 CFR 310.502), entitled "Certain drugs accorded new drug status through rulemaking procedures" (62 FR 12083 at 12084 (March 14, 1997)). Section 310.502(a) sets forth a list of drugs that have been determined by rulemaking procedures to be "new drugs" within the meaning of section 201(p) of the FD&C Act. Included on the list was "[s]terilization of drugs by irradiation" (§ 310.502(a)(11)). Because this regulation reflected an FDA determination that the drugs on the list are "new drugs," an NDA or ANDA had to be submitted and approved by FDA before those drugs could be marketed legally.

When the paragraph now reflected in § 310.502(a)(11) was published in 1955, the technology of controlled nuclear radiation for sterilization of drugs was not well understood. In addition, neither the OTC drug monograph system nor the CGMP requirements existed. The authorizing legislation that the CGMP regulations implement, section 501(a)(2)(B) of the FD&C Act (21 U.S.C. 351(a)(2)(B)), was enacted in 1962 ("Drug Amendments of 1962," October 10, 1962, Public Law 87–781, Title I, sec. 101), and the first CGMP regulations followed in 1963 ("Part 133—Drugs; Current Good Manufacturing Practice in Manufacture, Processing, Packing, or Holding," 28 FR 6385 (June 20, 1963) available at: *https://www.loc.gov/item/fr028120/*). The regulations creating procedures for establishing OTC drug monographs were issued in 1972 (37 FR 9464 (May 11, 1972)) available at: *https://www.loc.gov/item/fr037092/*).

Today, as the proposed rule explained (83 FR 46121 at 46123 to 46124), the technology of controlled nuclear radiation for sterilization of drugs is well understood, and all drug products marketed under the OTC Drug Review are subject to the requirement set forth in 21 CFR 330.1(a) that they be manufactured in compliance with current good manufacturing practices, as established by parts 210 and 211 (21 CFR parts 210 and 211). The CGMP requirements in parts 210 and 211 encompass sterilization, including by irradiation. As a result, as discussed in the proposed rule (83 FR 46121 at 46124), § 310.502(a)(11) can be repealed and manufacturers will still be obligated to ensure that, if they use radiation: (1) The drug products that they purport to be sterile are in fact sterile and (2) their use of radiation does not have a detrimental effect on their drug products' identity, strength, quality, purity, or stability.

III. Legal Authority

We are issuing this final rule under the drugs and general administrative provisions of the FD&C Act (sections 201, 301, 501, 502, 503, 505, 510, 701, 702, and 704 (21 U.S.C. 321, 331, 351, 352, 353, 355, 360, 371, 372, and 374)) and under section 361 of the Public Health Service Act (PHS Act) (42 U.S.C. 264). The FD&C Act gives us the authority to issue and enforce regulations designed to help ensure that drug products are safe, effective, and manufactured according to current good manufacturing practices, while section 361 of the PHS Act gives us the authority to issue and enforce regulations designed to prevent the introduction, transmission, or spread of communicable diseases.

IV. Comments on the Proposed Rule

We received five comment letters on the proposed rule by the close of the comment period, all from individuals. Each of the five comment letters contained general remarks supporting the proposed rule.

V. Effective Date

This final rule is effective January 15, 2020.

VI. Economic Analysis of Impacts

We have examined the impacts of the final rule under E.O. 12866, E.O. 13563, E.O. 13771, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). E.O.s 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). E.O. 13771 requires that the costs associated with significant new regulations "shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations." We believe that this final rule is not a significant regulatory action as defined by E.O. 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because few entities will be affected and the net effect will be cost savings to affected firms, we certify that the final rule will not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before issuing "any rule that includes any Federal mandate that may result in the expenditure by

[1] Available at: *https://www.loc.gov/item/fr020231/*. A month later, this provision was included in § 3.45 in the republication of chapter 21 of the Code of Federal Regulations (CFR) in the **Federal Register**. See 20 FR 9525 at 9554 (December 20, 1955), available at: *http://cdn.loc.gov/service/ll/fedreg/fr020/fr020246/fr020246.pdf*. In 1975, FDA republished and recodified the rule in 21 CFR 200.30. See 40 FR 13996 at 13997 (March 27, 1975), available at: *https://www.loc.gov/item/fr040060/*.

State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is $154 million, using the most current (2018) Implicit Price Deflator for the Gross Domestic Product. This final rule would not result in an expenditure in any year that meets or exceeds this amount.

Table 1 summarizes our estimate of the annualized costs and benefits of the final rule.

TABLE 1—SUMMARY OF BENEFITS, COSTS, AND DISTRIBUTIONAL EFFECTS OF THE RULE

[$ million]

Category	Primary estimate	Low estimate	High estimate	Units			Notes
				Year dollars	Discount rate (%)	Period covered (years)	
Benefits:							
Annualized Monetized $millions/year	$0.06	$0.05	$0.29	2018	7	10	Benefits are cost savings.
	0.05	0.05	0.25	2018	3	10	Benefits are cost savings.
Annualized Quantified				2018	7	10	
				2018	3	10	
Qualitative							
Costs:							
Annualized Monetized $millions/year	0.00	0.00	0.00	2018	7	10	Less than $100.
	0.00	0.00	0.00	2018	3	10	Less than $100.
Annualized Quantified				2018	7	10	
				2018	3	10	
Qualitative							
Transfers:							
Federal Annualized Monetized $millions/year	0.16	0.16	0.16	2018	7	10	User Fee.
	0.14	0.14	0.14	2018	3	10	User Fee.
	From:			To:			
Other Annualized Monetized $millions/year				2018	7	10	
				2018	3	10	
	From:			To:			

Effects:
State, Local, or Tribal Government: None.
Small Business: None.
Wages: None.
Growth: None.

In line with Executive Order 13771, in table 2 we estimate present and annualized values of costs and cost savings over an infinite time horizon. With a 7 percent discount rate, the estimated annualized net cost-savings equal $0.06 million in 2016 dollars over an infinite horizon. Based on these cost savings, this final rule would be considered a deregulatory action under E.O. 13771.

TABLE 2—EXECUTIVE ORDER 13771 SUMMARY

[In $ millions 2016 dollars, over an infinite horizon]

	Primary (7%)	Lower bound (7%)	Upper bound (7%)	Primary (3%)	Lower bound (3%)	Upper bound (3%)
Present Value of Costs	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00
Present Value of Cost Savings	0.88	0.75	4.01	1.75	1.50	8.01
Present Value of Net Costs	(0.88)	(0.75)	(4.01)	(1.75)	(1.50)	(8.01)
Annualized Costs	0.00	0.00	0.00	0.00	0.00	0.00
Annualized Cost Savings	0.06	0.05	0.28	0.05	0.05	0.24
Annualized Net Costs	(0.06)	(0.05)	(0.28)	(0.05)	(0.05)	(0.24)

Note: Net costs are calculated as costs minus cost savings. Values in parentheses denote net negative costs (*i.e.*, cost-savings).

We have developed a comprehensive Economic Analysis of Impacts that assesses the impacts of the final rule. The full analysis of economic impacts is available in the docket for this final rule (Ref. 1) and at: *https://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm.*

VII. Analysis of Environmental Impact

We have determined under 21 CFR 25.30(h) and 25.31(a) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VIII. Paperwork Reduction Act of 1995

This final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget

under the Paperwork Reduction Act of 1995 is not required.

IX. Federalism

We have analyzed this final rule in accordance with the principles set forth in E.O. 13132. We have determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, we conclude that the rule does not contain policies that have federalism implications as defined in the E.O. and, consequently, a federalism summary impact statement is not required.

X. Consultation and Coordination With Indian Tribal Governments

We have analyzed this rule in accordance with the principles set forth in E.O. 13175. We have determined that the rule does not contain policies that have substantial direct effects on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. Accordingly, we conclude that the rule does not contain policies that have tribal implications as defined in the E.O. and, consequently, a tribal summary impact statement is not required.

XI. Reference

The following reference is on display in the Dockets Management Staff (see **ADDRESSES**), and is available for viewing by interested persons between 9 a.m. and 4 p.m. Monday through Friday; it is also available electronically at *https://www.regulations.gov*. FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. FDA Final Regulatory Impact Analysis, "Regulation Requiring an Approved New Drug Application for Drugs Sterilized by Irradiation," available at *https://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm*.

List of Subjects in 21 CFR Part 310

Administrative practice and procedure, Drugs, Labeling, Medical devices, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 310 is amended as follows:

PART 310—NEW DRUGS

■ 1. The authority citation for part 310 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 360b–360f, 360j, 360hh–360ss, 361(a), 371, 374, 375, 379e, 379k–1; 42 U.S.C. 216, 241, 242(a), 262.

■ 2. In § 310.502, revise paragraph (a) introductory text and remove and reserve paragraph (a)(11) to read as follows:

§ 310.502 Certain drugs accorded new drug status through rulemaking procedures.

(a) The drugs listed in this paragraph (a) have been determined by rulemaking procedures to be new drugs within the meaning of section 201(p) of the Federal Food, Drug, and Cosmetic Act. An approved new drug application under section 505 of the Federal Food, Drug, and Cosmetic Act and part 314 of this chapter is required for marketing the following drugs:

* * * * *

Dated: December 9, 2019.

Brett P. Giroir,

Acting Commissioner of Food and Drugs.

[FR Doc. 2019–27046 Filed 12–13–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 807, 812, and 814

[Docket No. FDA–2018–N–0628]

RIN 0910–AH48

Medical Device Submissions: Amending Premarket Regulations That Require Multiple Copies and Specify Paper Copies To Be Required in Electronic Format

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is issuing a final rule amending requirements for medical device premarket submissions to remove paper and multiple copies and replace them with requirements for a single submission in electronic format. This action would reduce the number of copies in electronic format required, thus improving and making more efficient the FDA's premarket submission program for medical devices.

DATES: This rule is effective January 15, 2020.

ADDRESSES: For access to the docket to read background documents or comments received, go to *https://www.regulations.gov* and insert the docket number found in brackets in the heading of this final rule into the "Search" box and follow the prompts, and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Diane Garcia, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G609, Silver Spring, MD 20993, 301–796–6559, email: *Diane.Garcia@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Executive Summary

A. Purpose of the Final Rule

FDA is issuing this final rule to amend regulations on medical device premarket submissions to remove requirements for paper and multiple copies and replace them with requirements for a single submission in electronic format to improve the FDA's medical device premarket submission program and create a more efficient submission program. Because a medical device premarket submission in electronic format is easily reproducible, the requirement for multiple copies, whether in electronic format or paper form, is no longer necessary. FDA believes it is beneficial to the public to limit any burden and expense to