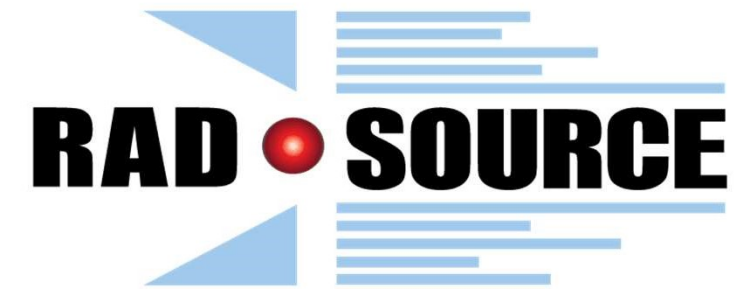
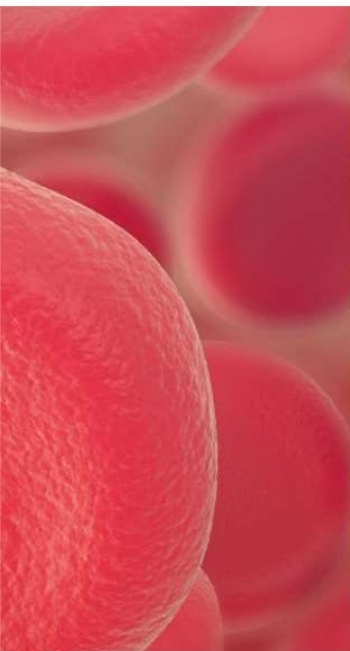


- ▶ Founded in 1997
- ▶ Industry leader in manufacturing renewable, non-isotope, ionizing radiation products
- ▶ Patented and proprietary QUASTAR technology





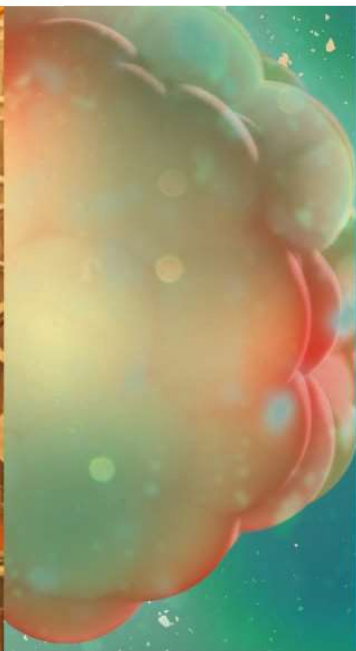
## MACHINES ARE USED IN A WIDE RANGE OF APPLICATIONS



**BLOOD  
IRRADIATION**



**SMALL ANIMAL  
RESEARCH**



**CELL RESEARCH**



**VIRAL  
INACTIVATION**

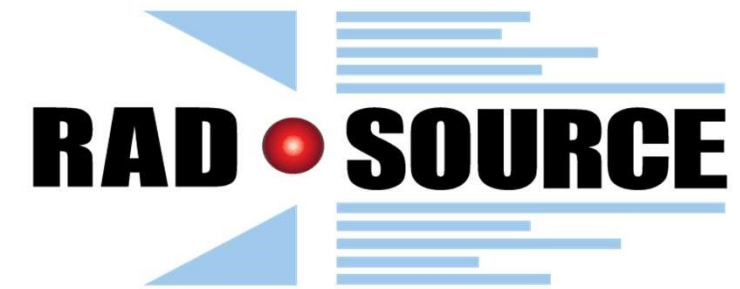


**CANNABIS  
DECONTAMINATION**



**STERILE INSECT  
TECHNOLOGY**





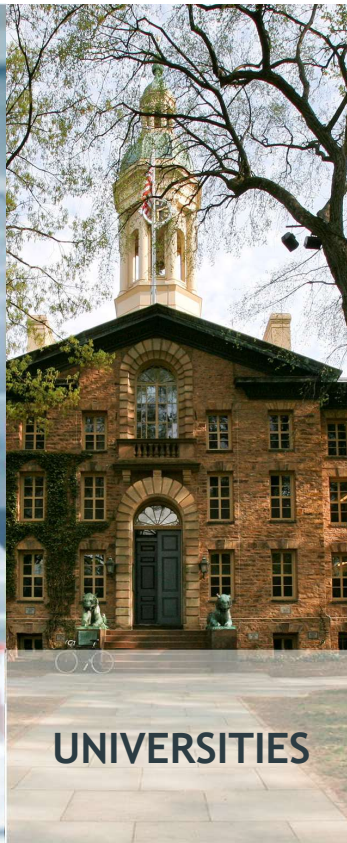
# MACHINES ARE USED IN A WIDE RANGE OF LOCATIONS



MAJOR  
HOSPITALS



PHARMACEUTICAL  
LABS



UNIVERSITIES



AMERICAN RED  
CROSS

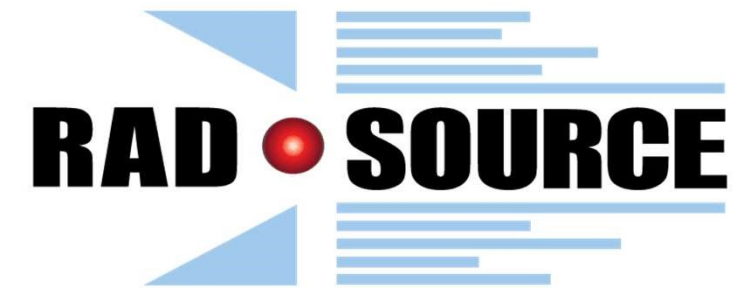


FDA NATIONAL  
CENTER FOR  
TOXICOLOGICAL  
RESEARCH



U.S.D.A.





# MACHINES ARE USED IN A WIDE RANGE OF LOCATIONS



## Methods



X-ray irradiator at Miami CPHST lab

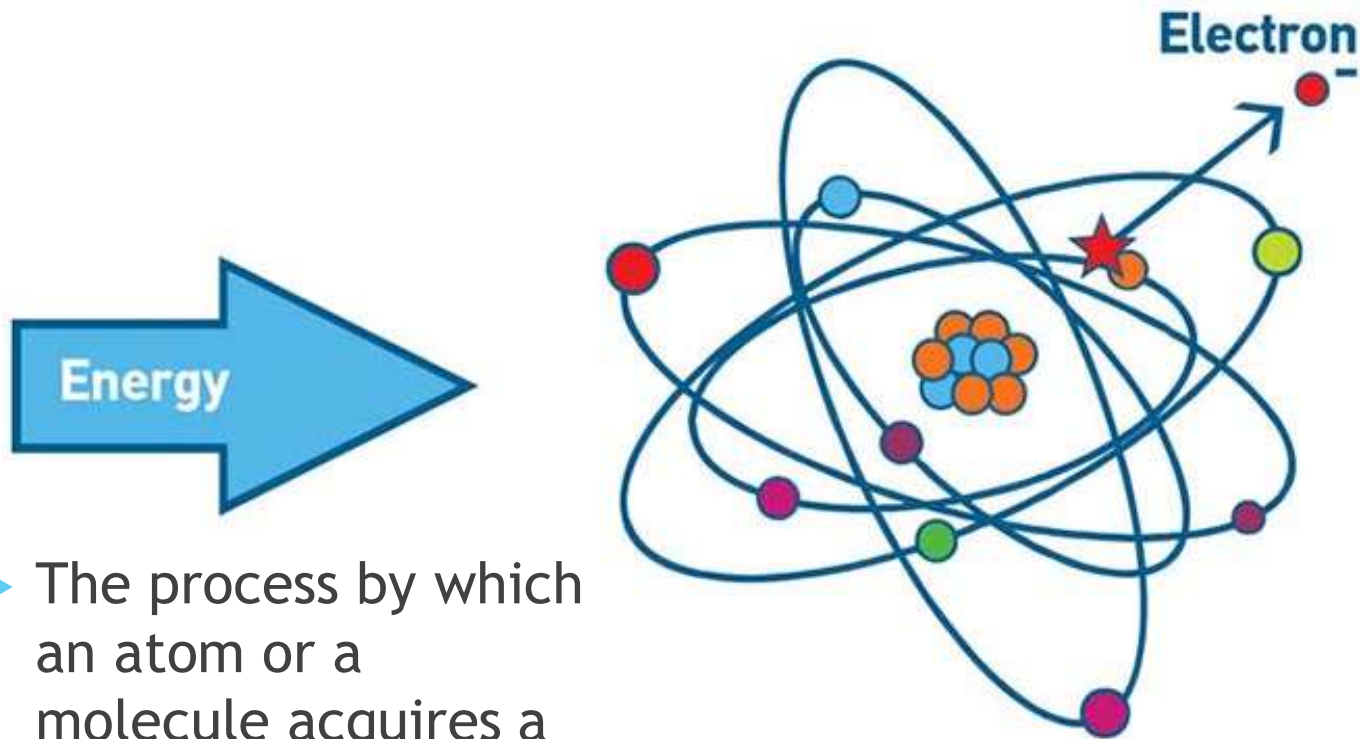


Lemon with arenas for individual mites



*Brevipalpus* mites on lemon

# WHAT IS IONIZATION?



- ▶ The process by which an atom or a molecule acquires a negative or positive charge by gaining or losing electrons

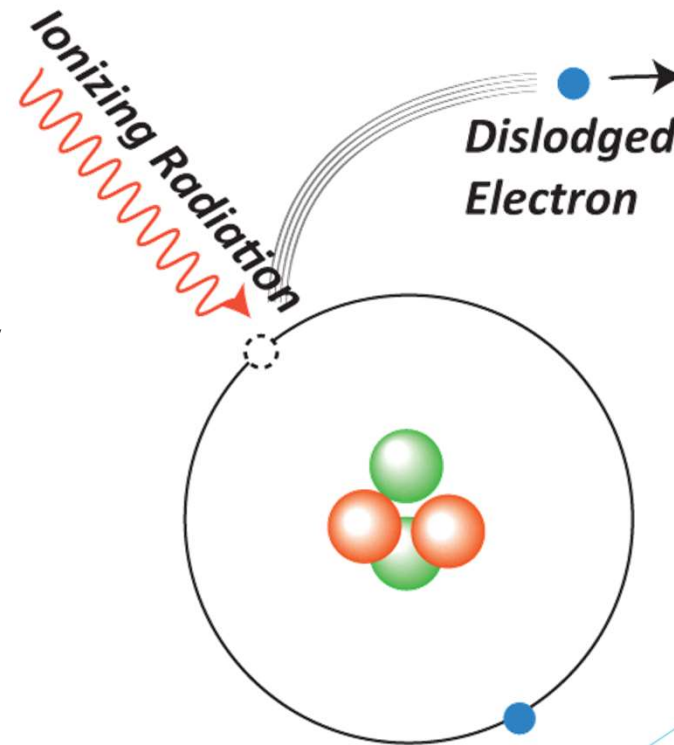
# IONIZATION DESTROYS PATHOGENS



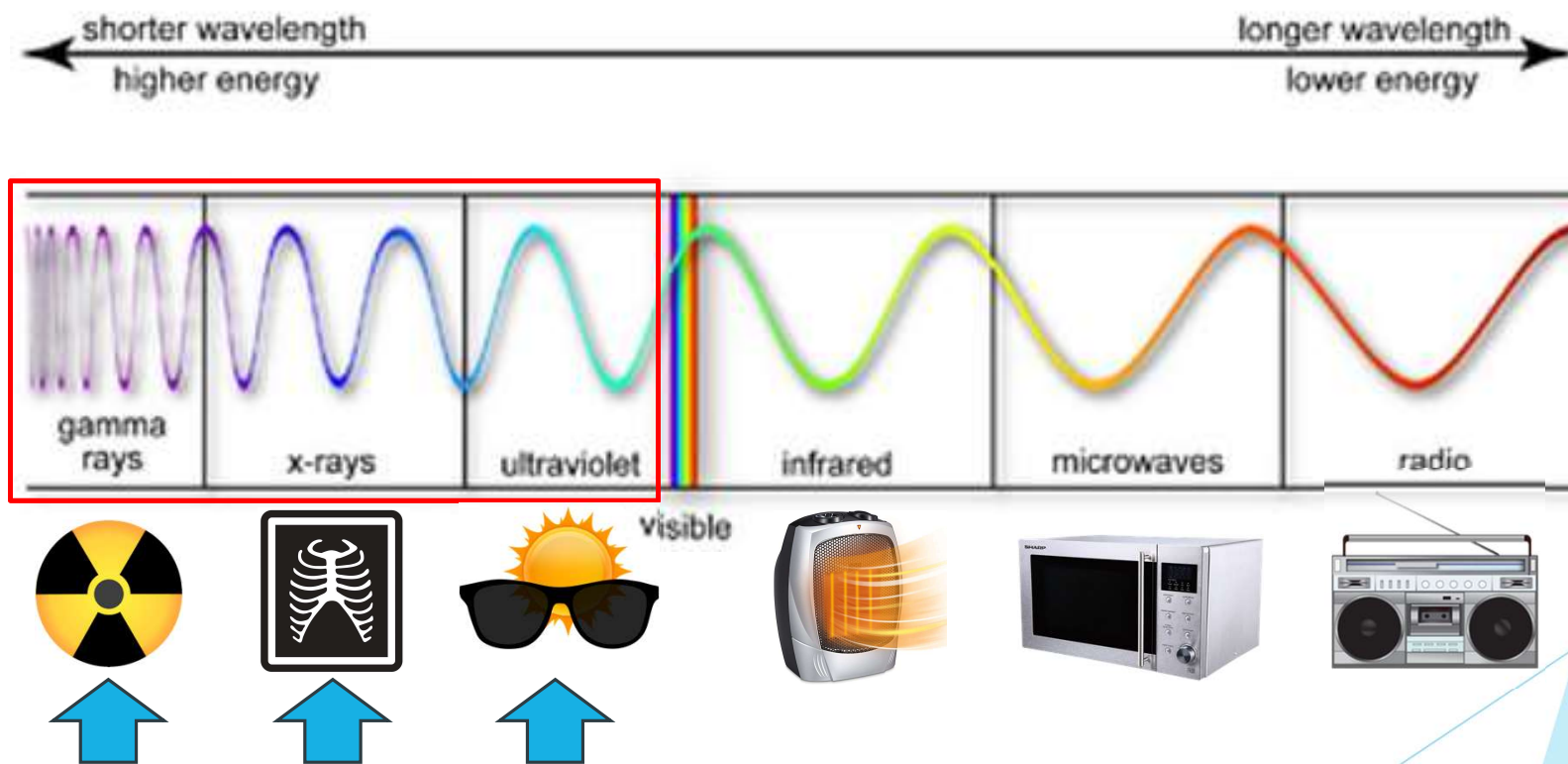


# WHAT IS IONIZING RADIATION?

- ▶ Any type of particle or electromagnetic wave that carries enough energy to ionize (i.e., remove electrons) from an atom



# IONIZING VS. NON-IONIZING RADIATION



3 TYPES OF ELECTROMAGNETIC WAVES  
CAN IONIZE ATOMS

# X-RAYS AND IONIZING RADIATION

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 ( $\text{He}^2$ ), protons, electrons, positrons (anti-electrons), X-rays and gamma

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

The use of irradiation for the processing of food has been in the works for nearly 100 years, evolving and improving alongside development of new technologies<sup>1</sup>. Organizations such as the International Atomic Energy Agency (IAEA), the World Health

X- and gamma rays are merely high-energy forms of light, with energies of  $\sim 1$  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:

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

vation of the target material or contamination by radioisotopes. With these two details in mind, X-ray irradiation is an

X-ray irradiators, such as those manufactured and sold by Rad Source Technologies, and gamma sources, like  $^{137}\text{Cs}$ , reside, the photons can only interact with the electrons of atoms, and not the nuclei. Consequently, the material being irradiated will not become radioactive,

(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

[illegible]

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.

between the two is the origin of the light. X-rays are produced by the acceleration of charge, such as synchrotron and

2017-11-14 14:14:14

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”<sup>1</sup>.

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  $10^{13}$  to  $10^{15}$  MeV, there are X-ray irradiators, such as those manufactured and sold by Rad Source Technologies, and gamma sources, like  $^{60}\text{Co}$ , 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"<sup>4</sup>. Due to these details, many organizations around the globe including the United States Nuclear Regulatory

Sincerely,  
Aaron Jezghani, PhD



# X-RAYS AND IONIZING RADIATION



## 1. RAD Tech Equipment provides a safe and effective method of destroying pathogens:

- 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.
- 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*

- 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.
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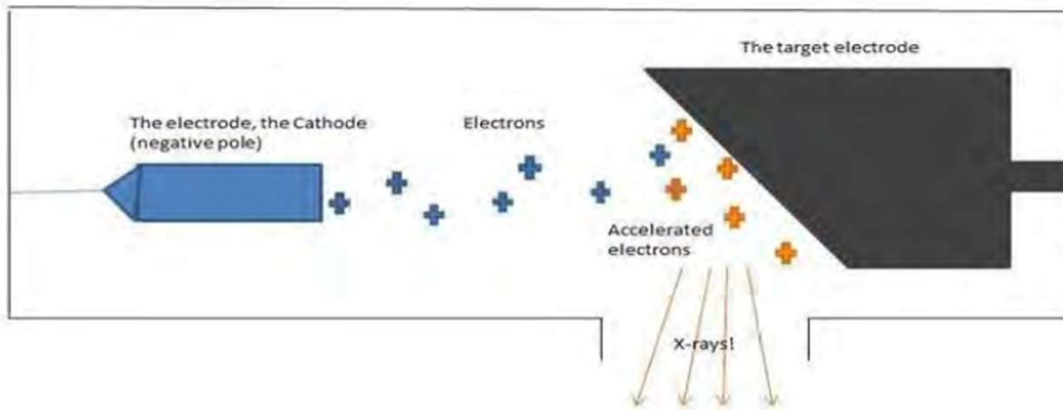
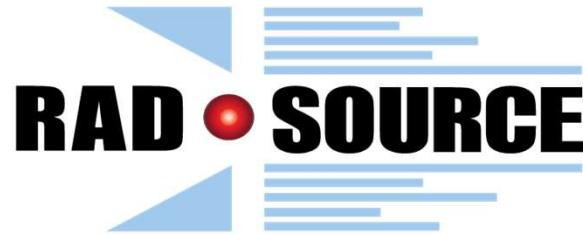
Prepared and submitted by:

A handwritten signature in black ink, reading "Roger Kern".

Roger Kern, Ph.D.  
President and Co-founder  
Agate Biosciences, LLC

# X-RAYS AND IONIZING RADIATION

- ▶ RAD Source machines use an x-ray emitter as the source of ionizing radiation



# X-RAYS ARE APPROVED RADIATION SOURCE FOR THE U.S.D.A.



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



United States Department of Agriculture

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.



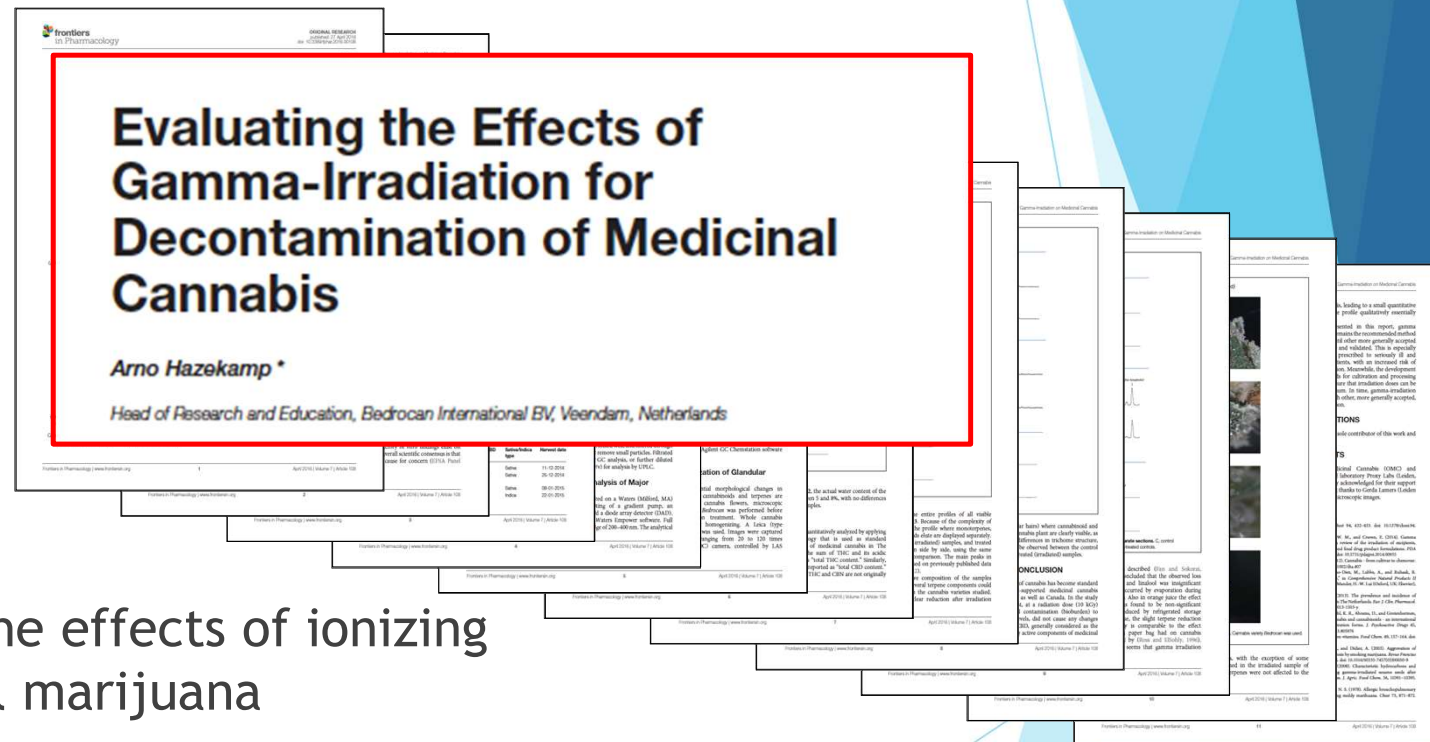


# IONIZING RADIATION ON PRODUCTS FOR HUMAN CONSUMPTION





# IONIZING RADIATION IS A SAFE AND EFFECTIVE METHOD FOR DECONTAMINATION

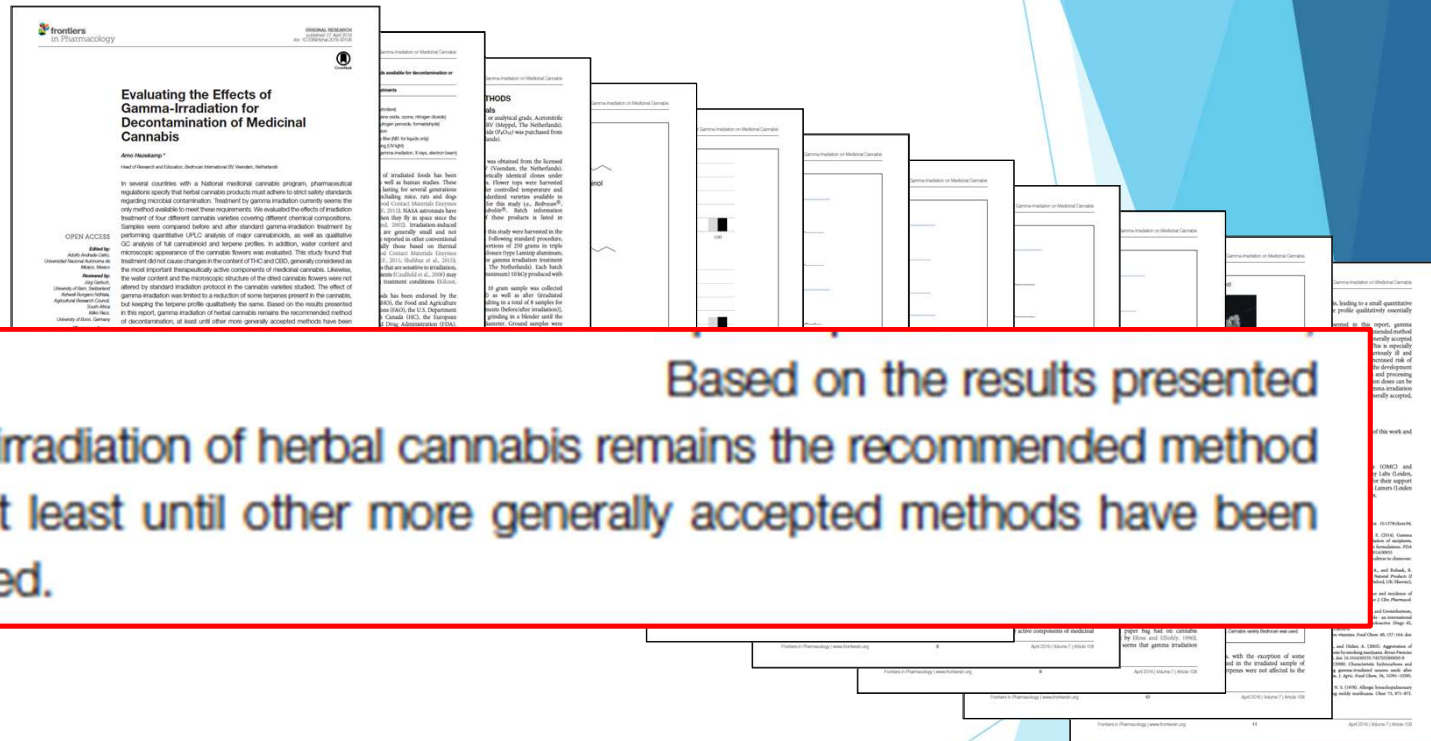


- ▶ Published study of the effects of ionizing radiation on medical marijuana
- ▶ Concludes ionizing radiation is a safe and effective method for decontamination

# IONIZING RADIATION IS A SAFE AND EFFECTIVE METHOD FOR DECONTAMINATION



frontiers  
in Pharmacology





# IONIZING RADIATION IS A SAFE AND EFFECTIVE METHOD FOR DECONTAMINATION

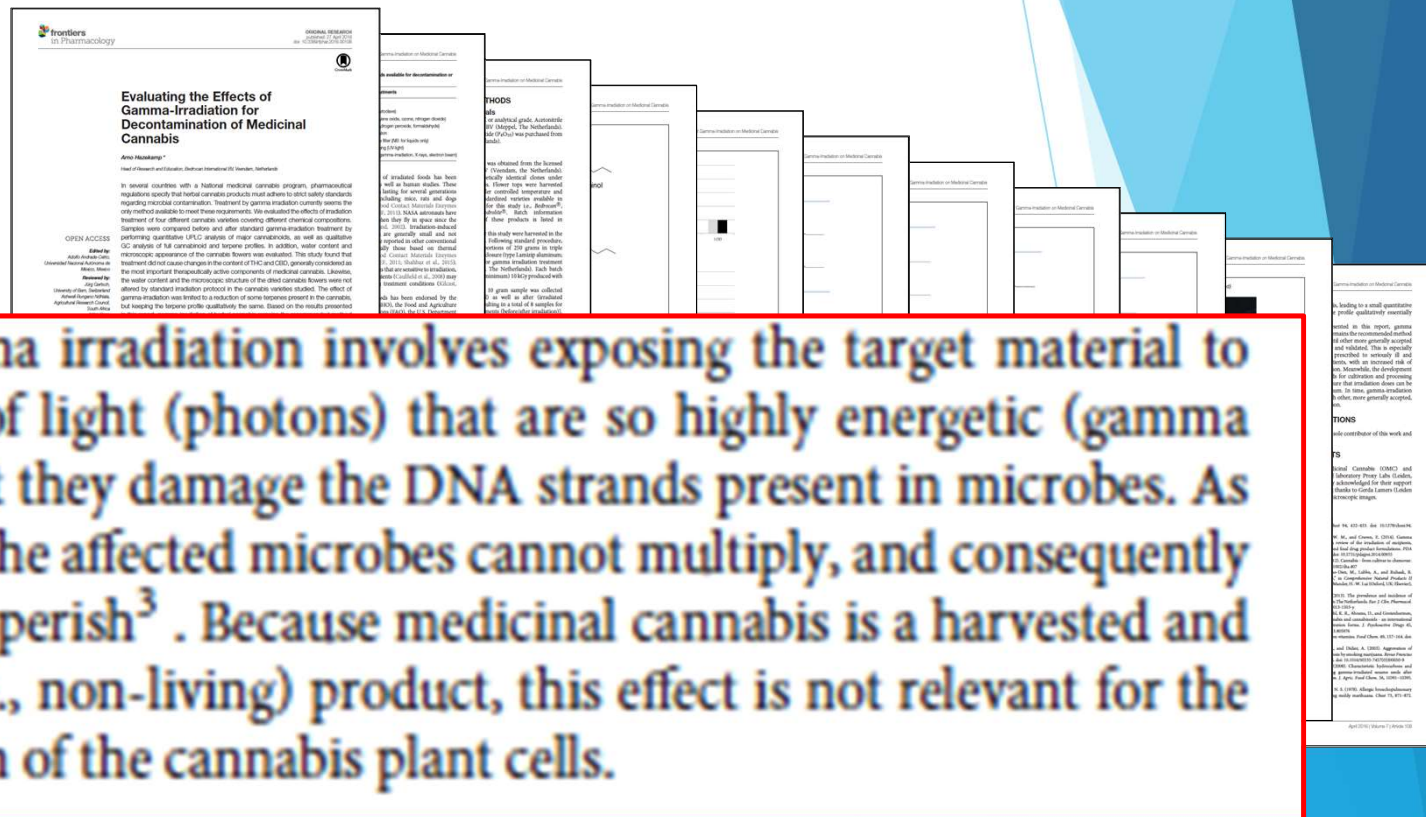


Decontamination of medicinal (herbal) cannabis is a necessity, as it has yet not been possible to grow cannabis plants under sufficiently sterile conditions to keep contamination levels below the required safety limits. Even if this were feasible, the multiple steps involved in harvesting, drying, processing 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<sup>1,2</sup>.

# IONIZING RADIATION IS A SAFE AND EFFECTIVE METHOD FOR DECONTAMINATION



frontiers  
in Pharmacology

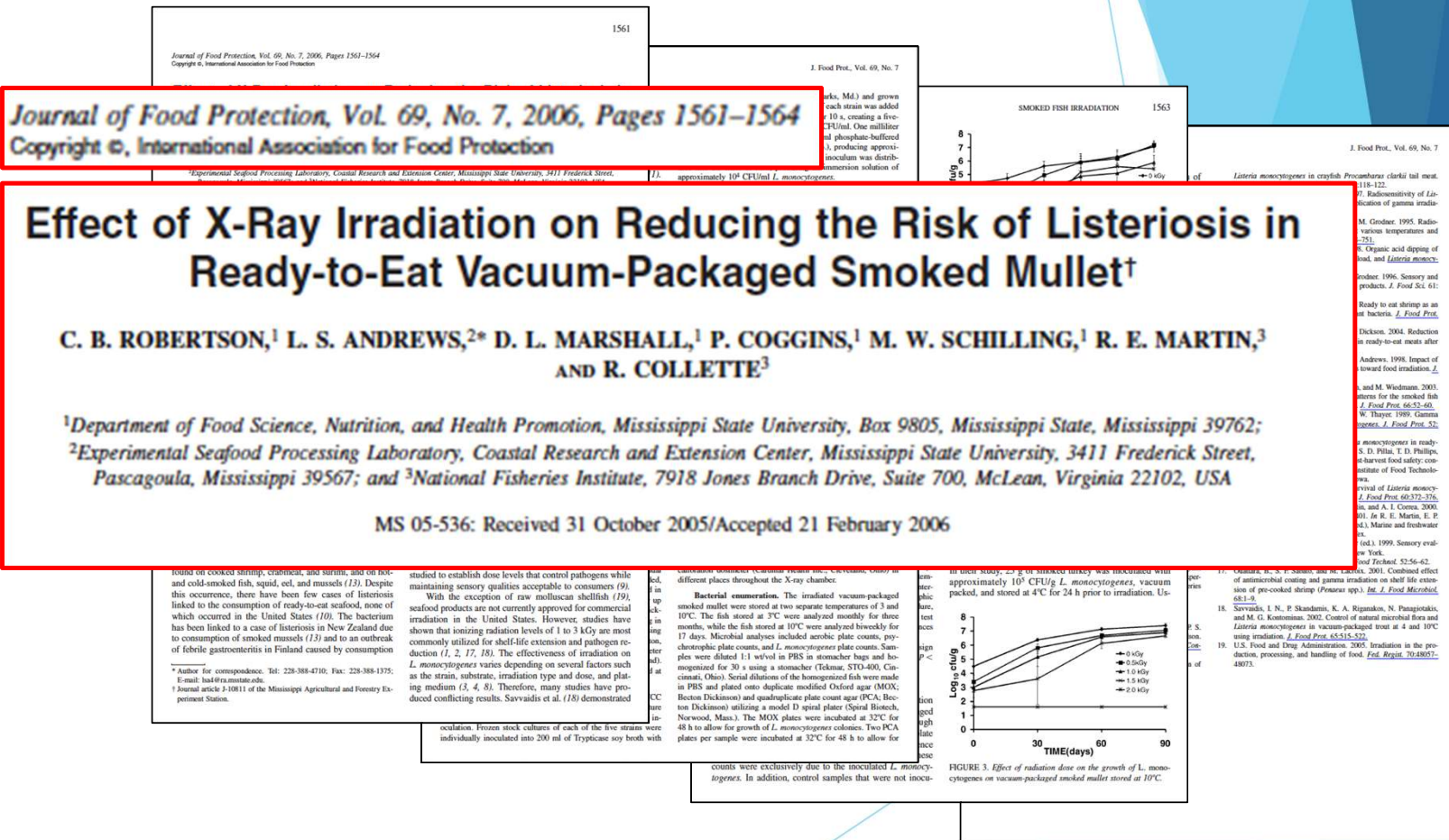


# IONIZING RADIATION IS A SAFE AND EFFECTIVE METHOD FOR DECONTAMINATION

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.



# IONIZING RADIATION IS A SAFE AND EFFECTIVE METHOD FOR DECONTAMINATION





# IONIZING RADIATION IS A SAFE AND EFFECTIVE METHOD FOR DECONTAMINATION



International Journal of Food Microbiology 130 (2009) 135–139

Contents lists available at ScienceDirect

International Journal of Food Microbiology

journal homepage: [www.elsevier.com/locate/ijfoodmicro](http://www.elsevier.com/locate/ijfoodmicro)

135–139

Industrial cabinet X-ray irradiator. The total net are 80 cm by 78.7 cm by 76.2 cm. The chamber are 914 cm by 600 cm by 63.5 cm. It requires 200-watt AC, three-phase, 50/60 Hz, rating range of the X-ray tube varies from 25 to mA. The X-ray generating tube consists of a

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Contents lists available at ScienceDirect

International Journal of Food Microbiology

journal homepage: [www.elsevier.com/locate/ijfoodmicro](http://www.elsevier.com/locate/ijfoodmicro)

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

Barakat S.M. Mahmoud<sup>\*</sup>

Experimental Seafood Processing Laboratory, Coastal Research & Extension Center, Mississippi State University, 3411 Frederic St., Pascagoula, MS 39567, United States

<sup>\*</sup> Tel.: +281 763 77834304.  
E-mail address: [s.m.mahmoud@mississippi.edu](mailto:s.m.mahmoud@mississippi.edu).  
0168-1655/\$ – see front matter © 2009 Elsevier B.V. All rights reserved.  
doi:10.1016/j.ijfoodmicro.2009.01.023

aging (Parker et al., 1994), UV treatments (Tampin and Capers, 1992), electrolyzed water (Iken and Shi, 2005) and high-pressure treatments

detection. All plates were incubated at 37 °C for 24 h. Colonies that are round (2–3 mm diameter) and considered positive for *V. vulnificus*. Results were ring numbers of APW tubes that were positive for *V. vulnificus*, using an MPN table.

examined dose, two half shell and two whole shell from the exposure chamber. Whole and half

log MPN ml<sup>-1</sup> (Table 1).

Dose (kGy)	Whole shell	Half shell
1.5	2.5	2.5
2.5	0.0	0.0
3.0	0.0	0.0

event  $p < 0.05$ .

<sup>☆</sup> <http://www.elsevier.com/locate/ijfoodmicro>

A. 1992. Resistance of *Vibrio vulnificus* to heat in Gulf Coast oysters, exposed to seawater, distributed with UV light. *Journal of Food Microbiology* 58, 108–110.

B. 1994. Varied clinical presentations of *Vibrio vulnificus* infections: a case series from the literature. *Southern Medical Journal* 87, 100–102.

C. 1995. *Vibrio vulnificus* in the Chesapeake Bay. *Applied and Environmental Microbiology* 61, 100–102.

D. 2004. A review of the market structure of the Louisiana oyster industry. The Journal of Food Distribution Research 34, 100–102.

# IONIZING RADIATION IS A SAFE AND EFFECTIVE METHOD FOR DECONTAMINATION

MISSISSIPPI STATE  
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5/7/2010

X-ray machines help kill bacteria in foo...

5/7/2010

X-ray machines help kill bacteria in foo...

## X-ray machines help kill bacteria in food

By Karen Templeton  
MSU Ag Communications

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."

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."

[msucares.com/news/.../100415.html](http://msucares.com/news/.../100415.html)



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)

-30-

dated: April 15, 2010  
Contact: Dr. Barakat Mahmoud, (228) 762-7783 x304  
Locations may [download image](#) at 200 ppi

**MISSISSIPPI STATE  
UNIVERSITY**  
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[msucares.com/news/.../100415.html](http://msucares.com/news/.../100415.html)

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# DECONTAMINATING CANNABIS



STEVE SISOLAK  
Governor  
JAMES DEVOLLD  
Chair, Nevada Tax Commission  
MELANIE YOUNG  
Executive Director

## 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

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Grant Sawyer Office Building, Suite 1300  
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Phone: (775) 687-9999  
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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.**

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.html#affect>. Consumers with concerns about their personal health should contact their physician with related questions.

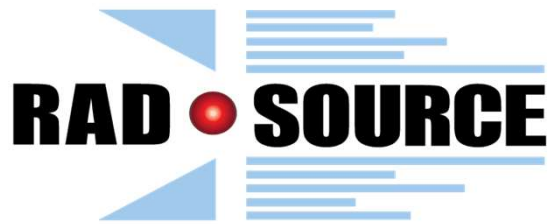
# DECONTAMINATING CANNABIS

- ▶ RAD Source machines reduce pathogen levels to “too few to detect”





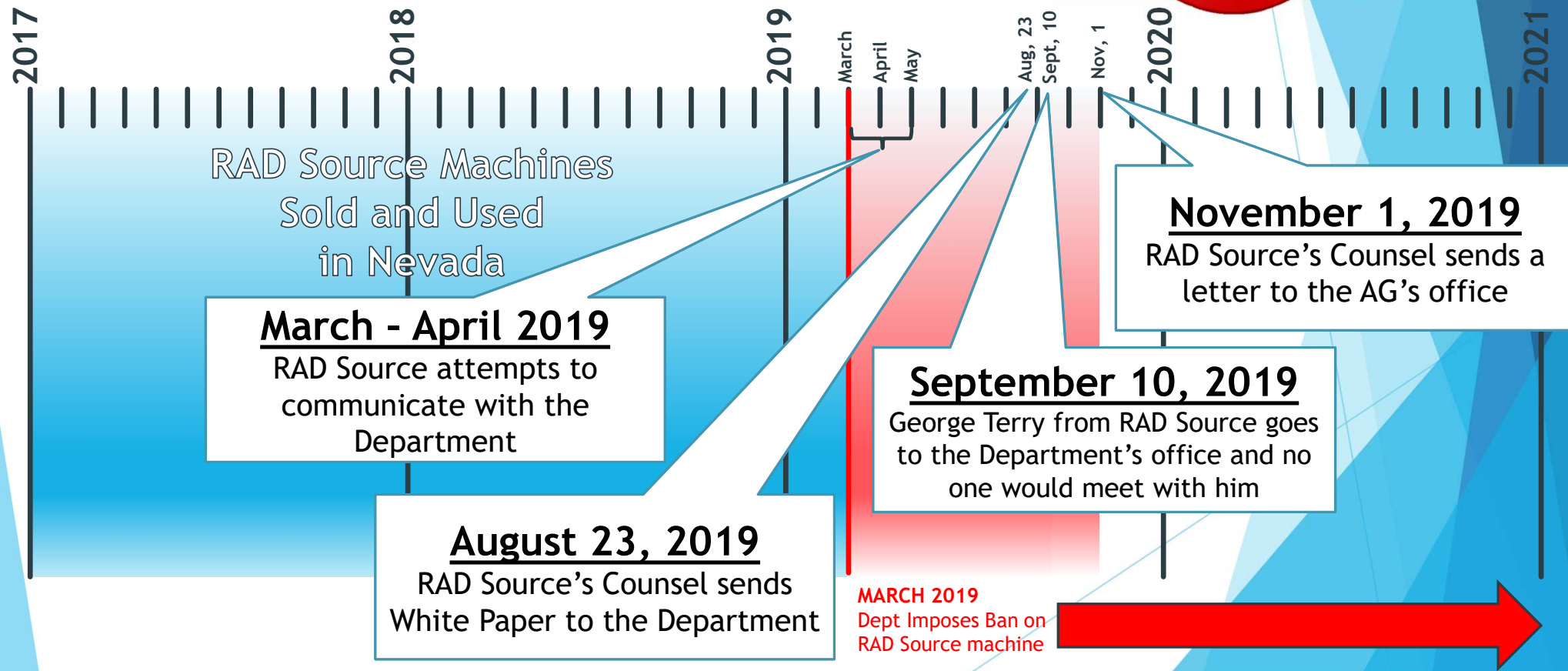
# DECONTAMINATING CANNABIS



- ▶ Nevada Department of Taxation, Marijuana Enforcement Division approved a study by FlowerOne using a RAD Source machine
- ▶ CCB has that study results in its files

# BAN ON RAD SOURCE MACHINES

# **RAD SOURCE**



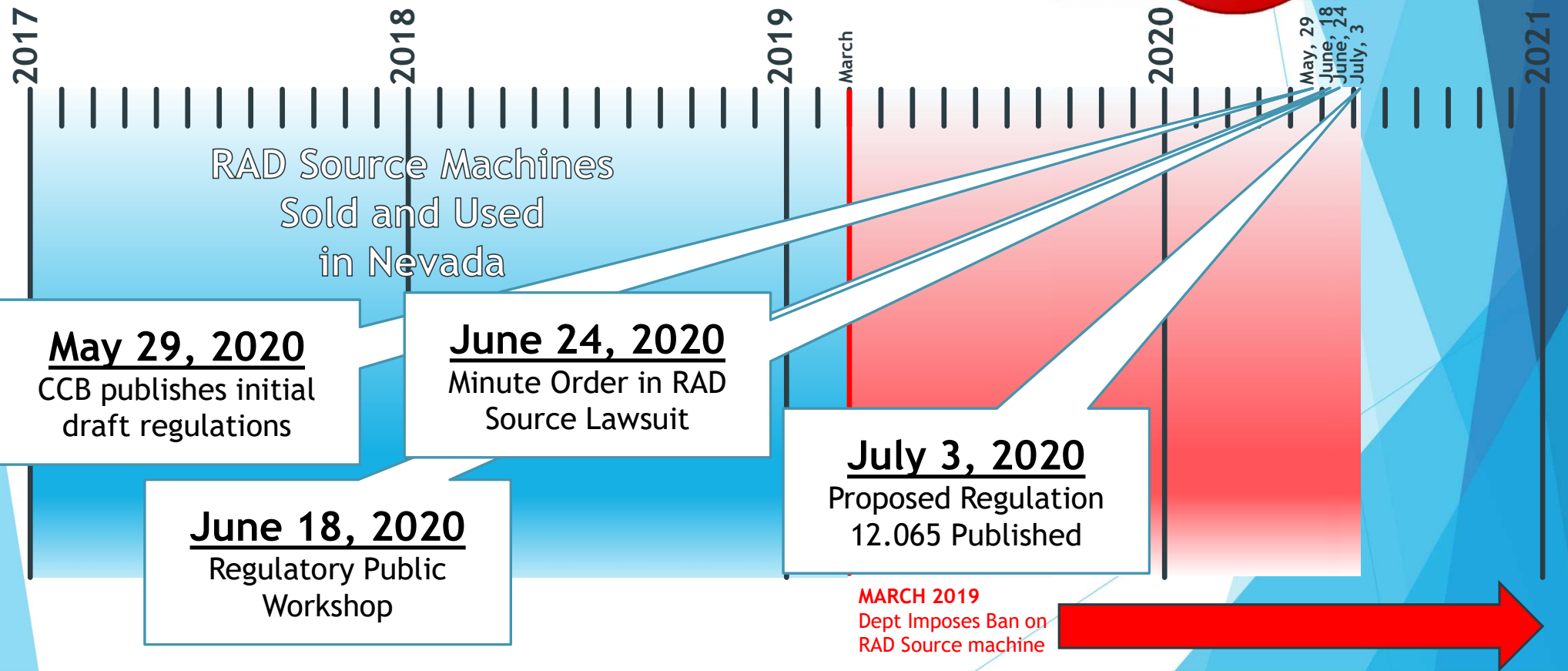
# BY NOVEMBER 2019:



- ▶ The Department's ban had been in place 8 months
- ▶ No communications from the Department in 6 months
- ▶ Department had never provided a scientific basis for the ban, but had insisted on FDA approval which was impossible
- ▶ RAD Source existing NV customers couldn't use their machines, and RAD Source couldn't sell any new machines
- ▶ As a last resort, RAD Source must file a lawsuit

# BAN ON RAD SOURCE MACHINES

# **RAD SOURCE**





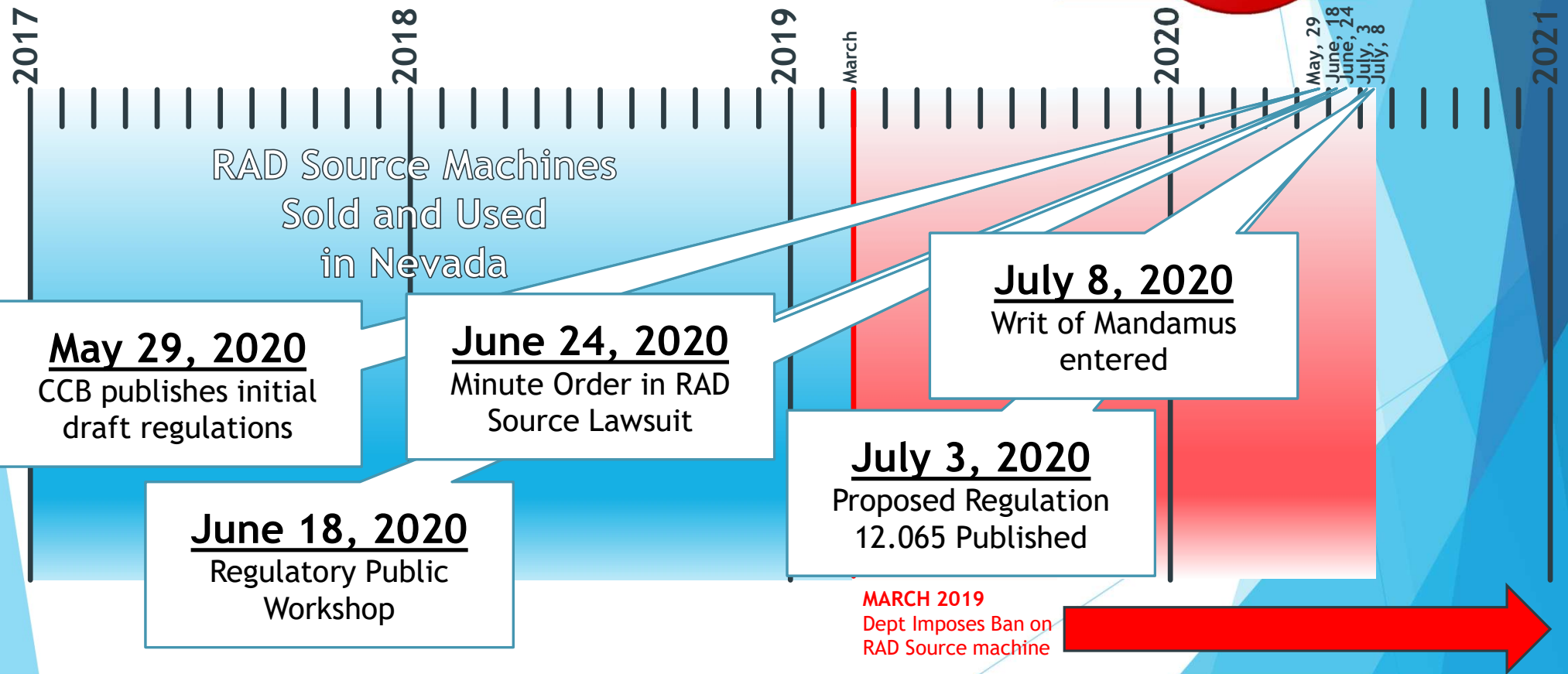
## PROPOSED REGULATION 12.065 - CANNABIS TREATED WITH RADIATION



- ▶ “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.”

# BAN ON RAD SOURCE MACHINES

# **RAD SOURCE**



# Writ of Mandamus: July 8, 2020 Order

## CONCLUSIONS OF LAW

1  
2 1. "A writ of mandamus is available to compel the performance of an act that the  
3 law requires as a duty resulting from an office, trust, or station or to control an arbitrary or  
4 capricious exercise of discretion." *Nevada Yellow Cab Corp. v. Eighth Judicial Dist. Court*  
5 *in & for Cty. of Clark*, 132 Nev. 784, 787, 383 P.3d 246, 248 (2016) (quoting *Humphries v.*  
6 *Eighth Judicial Dist. Court*, 129 Nev. 788, 791, 312 P.3d 484, 486 (2013)). For a writ to  
7 issue, generally a party must not have "an adequate and speedy legal remedy." *Id.*

8 2. The Department is prohibited under Nevada law from creating regulations that  
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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.

10 meet, namely requiring a 15% certification of an 15% level of exemption in order to be an  
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17 ban on the RS 420 Line.

18 5. To the extent the Department's actions were an exercise of discretion, the  
19 Department has acted arbitrarily and capriciously by banning RAD Source's RS 420 Line,  
20 which is a safe and effective method for treating marijuana.

21 6. To the extent the Department's actions were an exercise of discretion, the  
22 Department has acted arbitrarily and capriciously by requiring RAD source to meet  
23 impossible and inapplicable requirement of obtaining FDA certification or FDA letter of  
24 exemption before approving the RS 420 Line for treating marijuana.

25 7. To the extent the Department's actions were an exercise of discretion, the  
26 Department has acted arbitrarily and capriciously by applying different standards to similarly  
27 situated competitors.  
28



# Writ of Mandamus: July 8, 2020 Order

## CONCLUSIONS OF LAW

1  
2 1. "A writ of mandamus is available to compel the performance of an act that the  
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5 *in & for Cty. of Clark*, 132 Nev. 784, 787, 383 P.3d 246, 248 (2016) (quoting *Humphries v.*  
6 *Eighth Judicial Dist. Court*, 129 Nev. 788, 791, 312 P.3d 484, 486 (2013)). For a writ to  
7 issue, generally a party must not have "an adequate and speedy legal remedy." *Id.*

8 2. The Department is prohibited under Nevada law from creating regulations that  
9 make the operation of recreational marijuana establishments unreasonably impracticable.

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.

21 6. To the extent the Department's actions were an exercise of discretion, the  
22 Department has acted arbitrarily and capriciously by requiring RAD source to meet  
23 impossible and inapplicable requirement of obtaining FDA certification or FDA letter of  
24 exemption before approving the RS 420 Line for treating marijuana.

25 7. To the extent the Department's actions were an exercise of discretion, the  
26 Department has acted arbitrarily and capriciously by applying different standards to similarly  
27 situated competitors.

# Writ of Mandamus: July 8, 2020 Order

H1 LAW GROUP  
1111 Valley Parkway, Suite 200  
Reno, Nevada 89504  
702-608-3759  
Fax: 702-608-3759

1

**CONCLUSIONS OF LAW**

21. "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.*

22. 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).

23. 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.

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.

21. 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.

22. 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.

6

# Writ of Mandamus: July 8, 2020 Order

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701 N. Green Valley Parkway, Suite 200  
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Tel: 702-608-3720 Fax: 702-608-3759

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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

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Department has acted arbitrarily and capriciously by applying different standards to similarly situated competitors.

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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.

# Writ of Mandamus: July 8, 2020 Order

1 8. Additionally, when an agency engages in conduct that constitutes the making  
2 of a regulation, it must adhere to the notice and hearing requirements set forth under NRS  
3 233B.060 and 233B.061. *S. Nevada Operating Engineers Contract Compliance Tr. v.*  
4 *Johnson*, 121 Nev. 523, 528, 119 P.3d 720, 724 (2005).  
5 9. An agency engages in prohibited ad hoc rulemaking when it promulgates  
6 standards of general applicability that effect policy without complying with the Nevada APA.

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.

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



# Writ of Mandamus: July 8, 2020 Order

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23 FDA Requirement.

24 DATED this 7th day of July 2020.

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27 DISTRICT COURT JUDGE  
28 DEPARTMENT 29

# BAN ON RAD SOURCE MACHINES

# **RAD SOURCE**



RAD Source Machines  
Sold and Used  
in Nevada

**May 29, 2020**

CCB publishes initial  
draft regulations

**June 24, 2020**

Minute Order in RAD  
Source Lawsuit

**June 18, 2020**

Regulatory Public  
Workshop

**July 8, 2020**

Writ of Mandamus  
entered

**July 3, 2020**

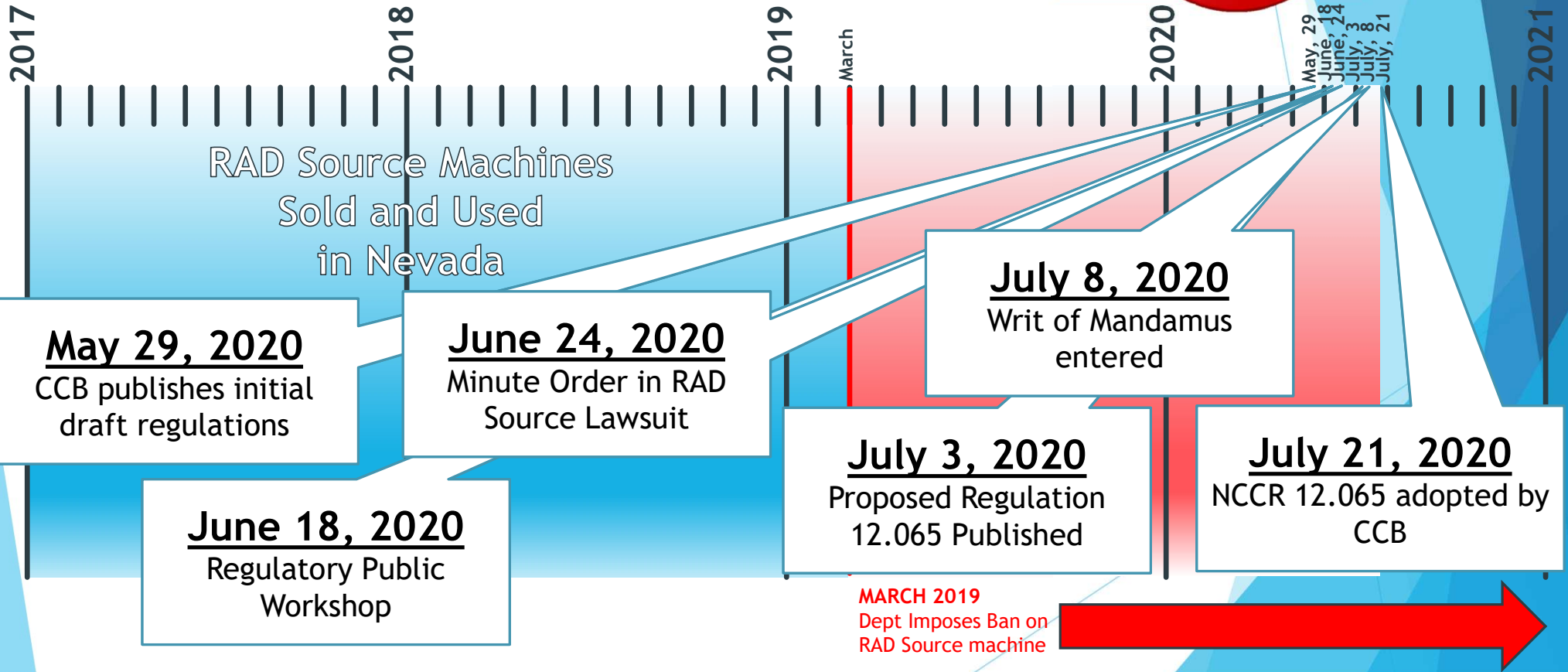
Proposed Regulation  
12.065 Published

**July 21, 2020**

NCCR 12.065 adopted by  
CCB

**MARCH 2019**

Dept Imposes Ban on  
RAD Source machine



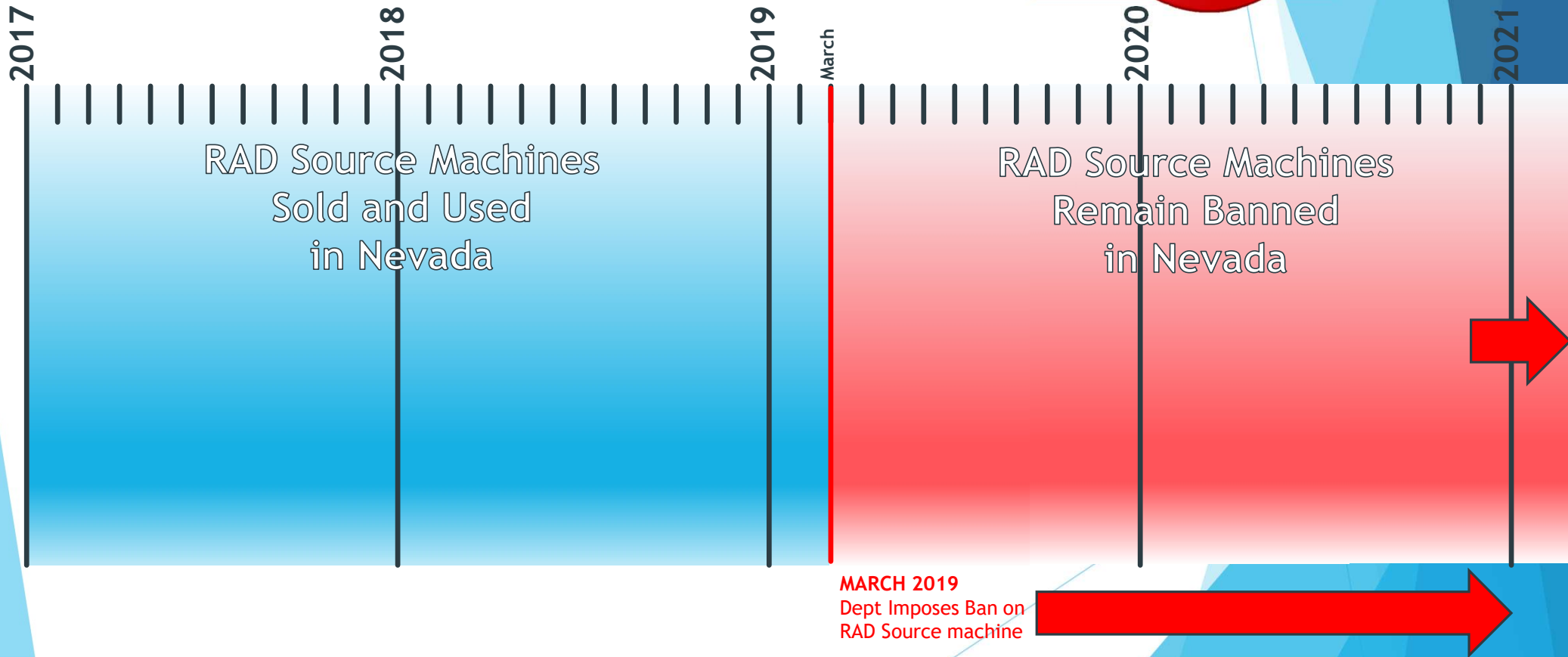
## ADOPTED REGULATION 12.065 - CANNABIS TREATED WITH RADIATION



- ▶ “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: “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.”

# BAN ON RAD SOURCE MACHINES

**RAD SOURCE**





# PROBLEMS WITH NCCR 12.065

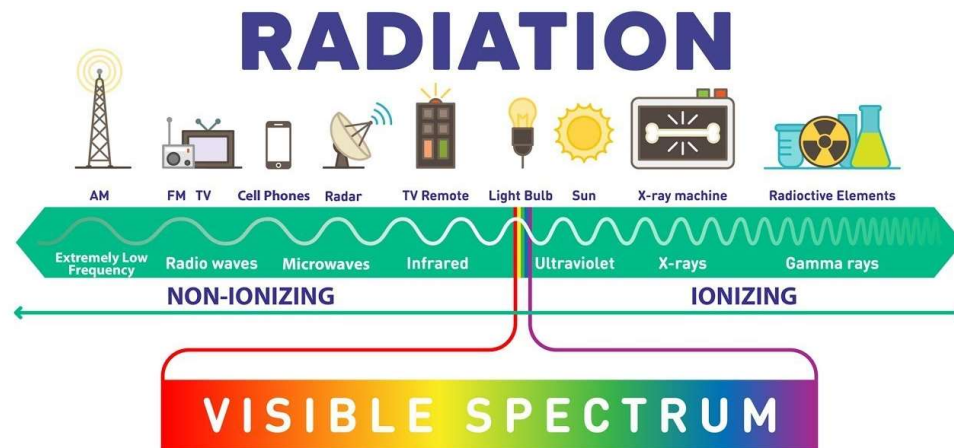


- ▶ NCCR violates NRS 678A.460(1)(a), (b):  
Was promulgated with less than 30 days' notice
- ▶ Not promulgated by any legislation

# PROBLEMS WITH NCCR 12.065



- ▶ The regulation uses the term “radiation,” which is never defined
- ▶ As written, it could apply to any number of common practices whereby cannabis is exposed to radiation



# PROBLEMS WITH NCCR 12.065



- ▶ If only intended to apply to ionizing radiation (i.e., RAD Source), then not a regulation of general applicability
- ▶ Not supported by any scientific evidence or data

# PROBLEMS WITH NCCR 12.065



Federal Register / Vol. 35, No. 12, June 12, 2020

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.



- ▶ FDA recognizes ionizing radiation of over the counter drugs to be safe and effective, and therefore does not require any labeling



# PROBLEMS WITH NCCR 12.065



- ▶ A labeling requirement is counterproductive
  - ▶ Suggests to the uninformed consumer that there is some danger, when in fact the opposite is true
  - ▶ Disincentivizes consumers from purchasing the safest available products

# WHAT TO DO NOW?



- ▶ CCB and RAD Source have a common goal: public health and safety
- ▶ Scaring consumers away from safe products does not accomplish that goal

# WHAT TO DO NOW?



- ▶ At a minimum, repeal NCCR 12.065
  - ▶ No scientific basis
  - ▶ Counterproductive
  - ▶ Did not follow proper procedures for adoption