Cannabis Compliance Board Regulatory Workshop
Meeting Minutes

The Cannabis Compliance Board (CCB) held a public meeting on January 19, 2021, beginning at 10:00 a.m. In compliance with the Governor's Emergency Directive #006, dated March 22, 2020, the Workshop was conducted by means of electronic communication.

Cannabis Compliance Board Members Present:

Michael Douglas, Chair
Jerrie Merritt
Dennis Neilander
Riana Durrett
Dr. Bryan Young

Tyler Klimas, Executive Director, called the meeting to order at 10:05am. Deputy Attorney General Asheesh Bhalla confirmed the workshop had been properly noticed.

I. Public Comment: Public comment was asked to be submitted online to be read into the record at the meeting. Any comments received from that point on or after will be read at the closing public comment period and/or posted online in their entirety.

Tiana Bohner, Public Information Officer for the Cannabis Compliance Board read public comments received.

Dr. Pejman Bady submitted public comment on behalf of Clark Natural Medicinal Solutions in support of the repeal of Regulation 12.065. The labeling requirement in 12.065 is unnecessary and creates an undue hardship on cultivators. Treating cannabis with ionizing radiation is safe and prevents mold and aspergillus from developing post-testing. Radiation has a spectrum from basic light bulbs to computed topography and therefore the language is not clear in its application. The warning language is not scientifically supported and misleading to consumers.

Chao-Hsiung Tung, Ph.D. of G3 Labs submitted public comment recommending deletion of 12.065. Nevada assigns all activities of radioactive material to purview of Department of Health and Human Services (DHHS) under NRS 459. NCCR 12.065 does not correlate with that regulatory authority. If 12.065 invokes the definition of "radiation" from NAC 459.068, it implies permission to use ionizing radiation, ignoring that some are impractical for treatment of cannabis. No regulatory specifications exist in DHHS for radiation/irradiation of cannabis. The designated low dose of radiation is effective to reduce or eliminated microorganisms and is considered safe. The "NOTICE" is misleading as it applies the FDA food labeling requirements to cannabis without a dose level threshold. FDA does not require individual ingredients in multi-ingredient foods be labeled.

Amanda Connor submitted public comment on behalf of Integral Cultivation, LLC and CCLV Manufacturing Center, LLC requesting that 12.065 be stricken from NCCR for the reasons set forth in the petition submitted by RAD Source Technologies.

Tim Fitzpatrick submitted public comment on behalf of WhiteCloud Botanicals, which had purchased the RADSource 420 system. WhiteCloud made that decision so their patients and adult-use clients would benefit from their product being clean and free of harmful yeast, mold, and bacteria. The addition of labels for no reason could be misleading to the public and should not be required.

Will Adler of Silver State Government Relations submitted public comment. He stated there was a need for more language around the post-harvest treatment of cannabis, the equipment used to do so, and the effects of the post treatment on cannabis. The equipment has a place in remediating cannabis of microbial outbreaks. It is reasonable to have all products which required secondary treatment to provide some notification to the consumer, even if not the current language in the NCCR. Equipment that is allowed to be used by cultivators should also be allowed to be used to treat other facilities products. This would broaden the availability to secondary treatment.

II. Deputy Director Michael Miles presented the proposed amendments to NCCR.

NCCR 5.120 is being updated to clarify that any person, without limitation, who wishes to own less that 5 percent of a cannabis establishment must apply for a registration card, absent a waiver pursuant to NCCR 5.125.

NCCR 5.130 is being updated to include titles of various executive positions that must obtain a cannabis executive agent registration card.

There were no questions from the Board Members regarding the changes to Regulation 5.

NCCR 6.025 is a rewrite of the time and effort billing regulation. The rewrite was done to clarify what the CCB was already billing the licensees for. The rewrite encompasses and clarifies what is currently being done. The only addition to the regulation is that the CCB will be billing licensees for travel expenses such as airfare and hotel, if and only if, travel is necessary for an investigation. An example would be flying to Canada to interview an executive of a company that is attempting to purchase a license. The CCB felt the regulation as drafted was outdated and in need of updating and clarifying language.

There were no questions from the Board Members regarding the changes to Regulation 6.

III. Member Young led the discussion of potential changes to Regulation 12.065 and included a presentation by RAD Source.

Member Young thanked the public for their comments and wished for more comments from consumers. Member Young asked to begin with the presentation by RAD Source, and asked Kara Cronkhite (Health Program Manager II for the CCB) to provide information on the current testing of cannabis products, including what is tested for, what kind of contaminants there are, and the labeling process.

Kimberly Maxson-Rushton appeared on behalf of RAD Source and introduced co-counsel Joel Schwarz. The following persons were present and available from RAD Source: Will Hartman (CEO), George Terry (Executive Vice President), Nathan Kroeger (Vice President of Sales), Jeff Duvall (Account Executive), and Justin Czerniawski (Head of Research and Development).

Ms. Rushton thanked the CCB for their consideration of RAD Source's petition to repeal NCCR 12.065. An introductory memorandum was submitted to the CCB that provided information regarding RAD Source, its instrumentality, and the safe utilization of ionizing radiation to decontaminate various products, including cannabis. Opinion letters in support and information from a study that confirmed the benefits and safety of RAD Source's decontamination process were also submitted. The scientific evidence demonstrates the value of the said processes and lack of necessity of requiring the noticing label such as that contained in NCCR 12.065.

Mr. Joel Schwarz stated that lengthy written materials and a PowerPoint presentation were provided and available, but he would highlight four main points from the presentation and answer any questions.

The first point was that ionizing radiation in general, and RAD Source's x-ray machines specifically, are a safe and effective means of decontaminating cannabis flower. Mr. Schwarz pointed out slides 15 through 19 of the presentation (or exhibit 7 in the written materials) showed a paper published in the Frontiers of Pharmacology which demonstrates the necessity of decontaminating cannabis flower, especially for medicinal use. One thing to address is how and when harvested product is tested and what that testing regimen is. There is the initial test done to ensure that there is no more than a maximum of colony forming units (CFUs), but there is not testing done later to determine if the product has grown more microbes. The conclusion of the paper was that ionizing radiation was the ideal means to decontaminate, and it was safe and effective. In 2020 a study was requested by Marijuana Enforcement Division using a RAD Source machine to test lots of harvested flower. The results were favorable, and that it was safe (safe meaning: not negatively effecting chemical components in the products; not creating new and potentially harmful compounds; and the product does not become radioactive).

The second point was that RAD Source has provided a great deal of material to show that although the use of RAD Source's technology was safe and effective for food, cannabis is not food. Cannabis is a drug. In slide 42 or exhibit 19, the FDA determined that irradiation regulations with regard to over-the-counter drugs was out of date and unnecessary. The FDA rescinded the labeling requirement for drugs that are sterilized using ionizing

radiation. The only labeling required on food that is treated with radiation, is food treated with a certain amount of radiation and only on final packaging.

The third main point was in regard to how Regulation 12.065 came to be adopted. A timeline was provided on slide 37. Mr. Schwarz alleged that the regulation was not properly adopted.

The fourth main point was addressed in RAD Source's materials and in public comment by Dr. Tung. Mr. Schwarz did not think that NCCR 12.065 accomplished what the goal of the CCB and RAD Source. Mr. Schwarz felt that the goal was that when consumers buy the end product, they can feel comfortable with the information provided in the packing and the knowledge that the product is as safe as it could be. There are inherent dangers in a product that is smoked. The notice that is required to be on a product that was treated with irradiation, implies that there is something unsafe with the product. The notice is a deterrent. There is no useful information provided and nowhere to look for information showing the benefits of ionizing radiation. There is no information about alternative treatment forms for decontamination. The label notice suggests something is wrong with the product.

Member Young asked Kara Cronkhite to provide comment on what is required in terms of testing, what are we testing for, the amount of decontamination that is seen, and what are the other cultivators doing in regard to decontamination if required.

Kara Cronkhite, Health Program Manager 2 for the Cannabis Compliance Board, provided information on the cannabis testing process, including lot size and how the lot is collected. The cannabis is tested for moisture, potency, terpenes, foreign matter, mycotoxins, heavy metals, pesticides, yeast and mold, Enterobacteriaceae, salmonella, e. coli, four species of aspergillus, and coliforms. A certificate of analysis (COA) is provided by the lab after testing, which shows the values for each category. On average, only about 15% of usable cannabis grown at cultivation does not pass. This shows that 85% of cannabis is grown with sanitary practices and is able to meet the testing requirements without remediation. The most common reason for failure is microbial contamination, and most common in that category is yeast and mold. Typically, the failed lot would be sent to a production facility for extraction as part of remediation.

Member Young asked how many cultivators are using a post-harvest decontamination of any sort. Ms. Cronkhite estimated that 10% of cultivators may use post-harvest decontamination. Mr. Schwarz pointed out that a passing test does not mean that there are not contaminants, but that the contaminants are below 10,000 CFUs. RAD Source can get the product contaminant level to too few to detect, so it decreases the likelihood of something growing at a later date. Mr. Schwarz stated that testing is typically done immediately post-harvest, which would be the cleanest the product would be. It is not tested again at a later date and there is no limitation in the regulations on shelf life. Contaminants could grow on the product for weeks and it would not be retested.

Member Young clarified that the RAD Source machine does not sterilize the product, and there could be contaminant growth on product treated by the RAD Source method. Mr. Schwarz agreed that was correct, but it is less likely than product that has not been treated. Member Young commented that 85% of what is tested is safe. Mr. Schwarz thought that more than 10% of cultivators used some form of post-harvest decontamination, whether it was RAD Source, Ziel, or Willow.

Member Young asked for comment about the paper in exhibit 7, where the study was done with gamma rays, but RAD Source's machines use x-ray, and was its RAD Source's statement that irradiation in general has been shown to be effective. Mr. Schwarz agreed it was a different source, but it is an ionizing radiation. Member Young if there was information specific to the RAD Source device? George Terry from RAD Source stated that they have thousands of tests that show the decontamination of the flower post-harvest once it runs thru the irradiator. The Flower One paper is the only one that exists on x-ray and cannabis. G3 Labs has also done some work on it. X-rays are a larger and higher wavelength. Dr. Justin Czerniawski explained the difference between gamma rays and x-rays. There is a difference in the method of photon production, one being a radioactive isotope with a gamma source, whereas the x-ray is more like a high-powered lightbulb that can be turned on and off. RAD Source has had a lot of success in the blood industry with gamma ray machines being replaced by x-ray machines as a safe and effective option.

Member Young asked about the Flower One study and decontamination in regard to decreasing microbials. Dr. Czerniawksi responded that a decontaminating dose was delivered, and it did not affect the flower, did not produce any radiolytic species and does change the profile of the cannabis plant. Mr. Terry added that the Flower

One study was on x-ray and the other study was on gamma rays because x-ray technology was not available at that time. The lower power of the x-ray is more of an absorbed dose and is more effective at a lower power.

Member Young asked Mr. Schwarz to comment on his claim that cannabis was not food, considering that there are edibles and aspects that are ingested. Is it reasonable to think that it is a food like product? Mr. Schwarz responded that RAD Source machines have been used at the USDA in research of food products as an effective decontamination. In addition, the labeling requirements in regard to food only pertains to the end final product, if that is the product that is treated with ionizing radiation. Mr. Schwarz added that this discussion was in regard to labeling, and the CCB does not have any other regulations that were carried over from food. The only regulation carried over was in regard to ionizing radiation. As 12.065 is currently written, radiation is not defined, and does not describe the processes involved.

Member Young asked about labeling information provided in exhibits 8-13, do those products require special labeling or the Radura symbol. Mr. Schwarz responded that if it is not an end product, then they are not required. Mr. Terry responded that according to the FDA, cannabis is a controlled substance and not under their purview. However, if cannabis was considered a food additive, then per the FDA, if the cannabis was irradiated and then added to a brownie, it would not require a label. If cannabis is a drug, such as aspirin, labeling is not required.

Member Young asked again if the FDA requires the symbol on shellfish, lemons, or peaches, for example. Mr. Terry thought that labeling was required was meat, fish, poultry, and produce.

Member Young asked for examples of OTC drugs treated by RAD Source technology that do not require labeling. Mr. Terry responded that typically, OTC drugs are treated with gamma rays. X-ray technology is newer and is not yet in use with OTC drugs. Dr. Czerniawksi commented that studies presented were done with ionizing radiation on the gamma level, but the fundamentals of the technology are consistent between the two. Some of the studies will need to be redone with x-ray machines, because the absorbed dose is much higher than with the gamma wavelengths. Mr. Terry clarified that RAD Source did not claim to sterilize product, but that the detection levels are at a level that is too low for the lab's equipment to detect.

Member Young asked for examples of products that are using x-ray technology that do not require special labeling. Dr. Czerniawski stated blood and insects. Nathan Kroeger added that there are no customers that use their machines that are required to label their product. Member Young asked specifically if there are any foods or food like products treated with the x-ray technology are required to have special labeling. Mr. Kroeger stated that if the final package was irradiated then they would be required to, but they did not have any customers that were doing that.

Member Young asked Executive Director Klimas what brought the created of regulation 12.065. Mr. Klimas responded that it was part of the regular process of promulgating the NCCRs and Ms. Rushton had indicated that changing "Warning" to "Notice" was acceptable.

Member Young stated that the safety to the consumer was paramount and asked if the label indicates that the product is unsafe. Dr. Czerniawski responded there is a lack of consumer education and they do not know how to interpret the label and think that it is unsafe. Mr. Terry responded that the FDA has been fighting this, that people think the products that are irradiated are unsafe.

Member Young asked the CCB staff if there have been comments from the consumer wanting to know about post-harvest treatments. Director Klimas responded that public comment was received from consumers who wanted to have the labeling. Director Klimas added that the job of the CCB is to protect the public health and safety of Nevadans. The approach on 12.065 was to know that to acknowledge that there are some things that we don't know.

Chair Douglas stated that it is clear that 12.065 can't stand as it is presently written. The question is if should be amended or repealed. Chair Douglas asked Member Durrett to comment as she had just attended a vaping summit. One of the matters addressed was public safety and making the public aware. The public would like to be aware of concerns, so how can that be accomplished.

Member Durrett responded that it was reported that there needed to be warnings and notifications on labeling. However, Member Durrett felt that cannabis products had a lot of labeling, but that it could be streamlined and

focused on the most important warnings. In regard to this instance, if the CCB errs on the side of caution and give consumers information on what they are consuming, is there a way to let the consumer know that a product was treated post-harvest for decontamination in a more general way. Dr. Czerniawski recommended putting the CFU level at testing and the testing date on the packaging, as that is the hazard to the consumer.

Mr. Schwarz added that the regulations 12.030, 12.035, 12.040 have samples of what is considered an appropriate label, which includes the testing date. Adding the CFU count to the label would be informative to the consumer. There are a number of decontamination products used, but there does not seem to be any publicly available information about them, and it may not be able to be put on a label.

Member Young commented that the CFU is a very scientific term and adding it to the label could be confusing for most consumers. Member Young agreed that it sounds like the public wants to be informed on how their product is treated, which is not an unreasonable request.

Ms. Rushton recommended repealing 12.065 and amending one of the existing labeling statutes to add the CFU requirement, and thereafter define what that means. Mr. Terry commented that signaling out one part of the process is something to be looked at. Also, every decontamination technique has its own merits, and why would a consumer be concerned with which method is used.

Ms. Cronkhite pointed out that the CFU is included in the COA and is available to the consumer upon request, as well as available is the soil amendment report and method of extraction. This could be asked by anyone at the dispensary.

Mr. Schwarz thanked everyone for their work and effort at the workshop. Mr. Terry added that they are able to provide any additional information that is needed as they work for the public health and safety.

IV. Tiana Bohner read additional public comment received after the start of the workshop.

John Sande submitted public comment on behalf of NuLeaf in support of amending 12.065 to remove the notice requirements that cannabis treated with radiation when the only radiation the cannabis has been exposed to is non-ionizing radiation, consistent with the FDA. Non-ionizing radiation is safe, and individuals are commonly exposed to it throughout the day. Because exposure to non-ionizing radiation is safe, they believe the current notice requirement is misleading to consumers.

Carina Robinson submitted public comment against the removal of the Radura symbol from packaging. Ms. Robinson does not want to allow lesser restrictions on this human consumable product. Patients and adult users with compromised immune systems must be informed before consumption. Ms. Robinson did not want to lower the standards to pass more contaminated and failed materials. Nevada must make the cultivation staff disclose their methods.

Evan Marder, Director of Cultivation at Fleur Cannabis submitted public comment. Mr. Marder stated that if a cultivator is using radiation to destroy mold on their cannabis, it is essential to list post-harvest mold remediation techniques on all cannabis packaging; the consumer should be made aware of cannabis treated in this manner. Mr. Marder is an organic cultivator and has a 98.27% passing rate without any mold remediation process. It is possible to pass the stringent testing requirements without using a mold remediation process. It is unfair to cultivators that produce clean cannabis to have others not have to disclose those practices. Consumers have a right to know how their products are being produced and treated.

Chair Douglas stated the workshop was helpful and thanked Member Young for his work. This is an issue of public safety. The question is whether to amend or strike the regulation.

V. Meeting adjourned at 11:43am.