COOPER LEVENSON
ATTORNEYS AT LAW

3016 W. Charleston Blvd., Suite 195
Las Vegas, NV 89102
Phone (702) 366-1125
Toll Free (800) 529-3161

Fax (702) 366-1857
www.cooperlevenson.com

KIMBERLY MAXSON-RUSHTON, ESQ.
EMAIL: krushton@cooperlevenson.com

Direct Phone (702) 832-1900
Direct Fax (702) 832-1901

July 26, 2021

Hon. Michael Douglas, Chair
Nevada Cannabis Compliance Board
555 E. Washington Ave., Ste. 4200
Las Vegas, NV 89101

Dear Chair Douglas:

This letter is respectfully submitted in support of the proposed changes to Nevada Cannabis Compliance Regulations ("NCCR") 11.015 previously filed by RSR Analytical Laboratories ("RSR").

Please find attached hereto and identified as Exhibit 1 a copy of the current regulation (11.015). Also, attached is Exhibit 2, which contains a copy of the changes to NCCR 11.015 as proposed by CCB Staff. Lastly, attached hereto and identified as Exhibit 3 are regulation amendments proposed by RSR, which specifically address impartiality between an independent testing facility and other cannabis establishments (cultivation and production facilities).

RSR's proposed language, which derives from Nevada Gaming Commission ("NGC") Regulations 14.390, 14.395 and 14.420, seeks to accomplish the following: (a) identification and clarification of specific acts, which constitute a failure of a licensed cannabis establishment (cultivation/production and laboratory) to maintain independence from one another; and, (b) notice to the cannabis industry of actions, which if undertaken by a cannabis establishment otherwise constitutes an unsuitable method of operation.

Nevada defines a regulation as 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 an agency." Nevada Revised Statute ("NRS") 233B.038 (emphasis added). Although exempt from NRS 233B, the CCB maintains the obligation to ensure that the applicability and purpose of a regulation relates (in some way) to the governing statutes and that it be of general applicability. As drafted, Staff's proposed changes to NCCR 11.015 fail to meet either standard.

The statutory requirements specific to cannabis regulations are primarily contained in NRS 678A.450, 678B.650 and 678D.500. Nowhere in these statutes is the CCB authorized to regulate business practices to the extent sought in the proposed amendments to NCCR 11.015, nor does the law allow the CCB without justification to restrict the business practices of one group of cannabis establishments – independent testing laboratories. Moreover, lacking any information/evidence supporting Staff's requested changes the draft amendments are deemed to be arbitrary and capricious.

As held by the Nevada Supreme Court in *Felton v. Douglas County*, 134 Nev. Adv. Op. 6, 410 P.3d 991 (2018), a reviewing court "will not hesitate to declare a regulation invalid when the regulation violates the constitution, conflicts with existing statutory provisions or exceeds the statutory authority of the agency or is otherwise arbitrary and capricious." Citing, *Meridian Gold Co.,* 119 Nev. at 635, 81 P.3d at 519 (quoting, *State, Div. of Ins. v. State Farm Mut. Auto. Ins. Co.,* 116 Nev. 290, 293, 995 P.2d 482, 485 (2000)).

As drafted Staff's proposed language is overly broad and inaccurately infers that a laboratory's decision to refund or waive a testing fee is evidence of impartiality yet there's been no information / testimony presented by Staff supporting said assumption. Thus, the proposed amendment to NCCR 11.015 contained in Exhibit 2 fails to meet the necessary legal standards applicable to all regulations in Nevada.

On behalf of RSR we'd like to thank the Cannabis Compliance Board for your review and consideration of the proposed regulation amendments to NCCR 11.015 as contained in Exhibit 3. My clients and I will be present at the CCB Hearing currently scheduled for July 27, 2021, and welcome the opportunity to provide further information on the proposed regulation (11.015).

Sincerely yours,

Kimberly Maxson Rushton, Esq.

Enclosures

cc: T. Klimas, Ex. Director
R. Richardson, RSR
R. Rushton, RSR

RSR Analytical Laboratories

EXHIBIT 1

Current NCCR 11.015

11.015 Requirements for testing facility to handle, test or analyze cannabis.
1. A cannabis testing facility shall not handle, test or analyze cannabis unless:
(a) The cannabis testing facility has been issued a license;
(b) The cannabis testing facility is independent from all other persons involved in the cannabis industry in Nevada; and
(c) No person with a direct or indirect interest in the cannabis testing facility has a direct or indirect financial interest in:
(1) A cannabis sales facility;
(2) A cannabis product manufacturing facility;
(3) A cannabis cultivation facility;
(4) A cannabis distributor;
(5) A provider of health care who provides or has provided written documentation for the issuance of registry identification cards or letters of approval; or
(6) Any other entity that may benefit from the cultivation, manufacture, dispensing, sale, purchase or use of cannabis or cannabis products.
2. A cannabis testing facility is not required to use a cannabis distributor to collect or move samples for testing.

RSR Analytical Laboratories

EXHIBIT 2

Staff Proposed Changes to NCCR 11.015

11.015 Requirements for testing facility to handle, test or analyze cannabis. 1. A cannabis *independent testing laboratory*~~facility~~ shall not handle, test or analyze cannabis unless:

(a) The cannabis *independent testing laboratory*~~facility~~ has been issued a license;

(b) The cannabis *independent testing laboratory*~~facility~~ is independent from all other persons involved in the cannabis industry in Nevada; and

(c) No person with a direct or indirect interest in the cannabis *independent testing laboratory*~~facility~~ has a direct or indirect financial interest in:

(1) A cannabis sales facility;

(2) A cannabis product*ion* ~~manufacturing~~ facility;

(3) A cannabis cultivation facility;

(4) A cannabis distributor;

(5) A provider of health care who provides or has provided written documentation for the issuance of registry identification cards or letters of approval; or

(6) Any other entity that may benefit from the cultivation, manufacture, dispensing, sale, purchase or use of cannabis or cannabis products.

2. *A cannabis independent testing laboratory shall implement business practices which are structured and managed so as to safeguard impartiality in testing including:*

(a) A testing laboratory may not offer a different fee schedule or waive payment in the event of failing or otherwise undesirable test results; and

(b) Refunds, rebates or any other return of payment in the form of alternate compensation is not permitted for the reason of failing or otherwise undesirable test results.

3. A cannabis *independent testing laboratory*~~facility~~ is not required to use a cannabis distributor to collect or move samples for testing.

RSR Analytical Laboratories

EXHIBIT 3

RSR's Proposed Changes to NCCR 11.015

Proposed Changes to NCCR 11.015(2) –(6)

Submitted on behalf of RSR Analytical Laboratory

(2) To be considered independent from a cultivator, producer and/or dispensary, an independent testing laboratory, including its employees, management, directors, owners:

(a) Must not have a financial or other interest, direct or otherwise, in a cannabis establishment doing business in Nevada;

(b) Must not participate, consult, or otherwise be involved in the cultivation or production of cannabis; and

(c) Must not have any other interest in or involvement with a cannabis cultivator, producer and/or dispensary that could cause the independent testing laboratory to act in a manner that is not impartial.

(3) An independent testing laboratory is not required to use a cannabis distributor to collect or transfer samples for testing.

(4) The restrictions denoted in subsection 2 are not intended to limit an independent testing laboratory, or the above listed individuals, from providing consulting services to a cultivation establishment, production establishment and/or dispensary, provided that such services do not directly or indirectly indicate, suggest, or imply how to cultivate or produce cannabis.

(5) If a registered independent testing laboratory hires a person who was previously employed by, or performed any work for, a cultivator, producer and/or dispensary within one year prior to the person's date of employment with the independent testing laboratory, the independent testing laboratory shall not permit that person to perform any tests for which the person had any involvement with, whatsoever, while the person was employed by the cultivator, producer and/or dispensary for a period of one year from the person's date of employment with the independent testing laboratory.

(6) A cultivator, producer or dispensary shall not:

(a) Attempt, directly or indirectly, to improperly influence an independent testing laboratory, or any of its employees, management, or owners, regarding any sample currently being tested by the laboratory

(b) Engage in any transaction with an independent testing laboratory it is utilizing, has utilized, or intends to utilize to test cannabis, which would require the independent testing laboratory to participate, consult, or otherwise be involved in the cultivation or production of cannabis. This restriction is not intended to limit a cultivator, producer or dispensary from engaging an independent testing laboratory to provide consulting or research and development services, provided that such services do not directly or indirectly indicate, suggest, or imply how to cultivate or produce cannabis.

COOPER LEVENSON
ATTORNEYS AT LAW

3016 W. Charleston Blvd., Suite 195
Las Vegas, NV 89102
Phone (702) 366-1125
Toll Free (800) 529-3161
Fax (702) 366-1857
www.cooperlevenson.com

Direct Phone (702) 832-1900
Direct Fax (702) 832-1901

KIMBERLY MAXSON-RUSHTON
EMAIL: krushton@cooperlevenson.com

FILE NO.

June 25, 2021

Hon. Michael Douglas, Chair
Nevada Cannabis Compliance Board
555 Washington Ave, 4200
Las Vegas, NV 89101

Re: Nevada Cannabis Compliance Regulation 11.015

Dear Chairman and CCB Members:

Please find enclosed herein proposed changes to Nevada Cannabis Compliance Regulation ("NCCR") 11.015 respectfully submitted on behalf of RSR Analytical Laboratories ("RSR").

RSR's proposed changes are in response to the draft language, pertaining to NCCR 11.015, recently considered by the CCB during the June 15, 2021 Regulatory Workshop. The proposed language is intended to strengthen the regulatory requirements relative to impartiality and further the CCB's mandate that testing labs be independent from other cannabis establishments. The proposed changes also seek to ensure that members of the cannabis industry clearly understand how the CCB construes the term "impartiality."

In brief, the language proposed by RSR specifically sets forth acts which, if committed, would constitute a lack of impartiality by an independent testing laboratory. The language also prohibits a cultivator, producer and/or dispensary from certain acts that could impact the impartiality of a testing lab in Nevada; said language is proposed in response to CCB Member Durrett's concern relative to "lab shopping." RSR's suggested language also preserves a labs ability to provide consulting as well as research and development services for clients. As evidenced by the article attached hereto, authored by RSR's Microbial Scientist, Anthony Repay, research and development within the cannabis industry is necessary and imperative to ensuring the safety of cannabis products sold in Nevada.

Correspondingly, RSR respectfully requests that the draft language currently being proposed (NCCR 11.015(2)) be removed for the following reasons: To date, no evidence has been presented by any party nor Staff demonstrating how the business practice of refunding a service fee or cost constitutes impartiality; and, the draft language in NCCR 11.015(2)(a) and (b) is ambiguous and in part redundant. Thus, RSR submits the enclosed proposed language in a good faith effort to clarify what

acts, within the cannabis industry, constitute "impartiality" and to alleviate any concern relative to "lab shopping."

Lastly, on behalf of RSR, my clients and I would like to thank the CCB for its consideration of these proposed changes to NCCR 11.015. Without question a robust regulatory scheme aids both the Board and the cannabis industry in navigating Nevada's cannabis laws. RSR welcomes the opportunity to provide further input and assistance to the CCB relative to regulatory revisions, which serve to strengthen Nevada's cannabis laws.

As always, thank you for your consideration of this matter.

Respectfully Submitted,

Kimberly Maxson-Rushton, Esq.

Enclosures

cc: R. Rushton, RSR
R. Richardson, RSR
T. Klimas, Ex. Director

Proposed Changes to NCCR 11.015

(Subsections (2)-(6)

Submitted on behalf of RSR Analytical Laboratories

(2) To be considered independent from a cultivator, producer and/or dispensary, an independent testing laboratory, including its employees, management, directors, owners:

(a) Must not have a financial or other interest, direct or otherwise, in a cannabis establishment doing business in Nevada;

(b) Must not participate, consult, or otherwise be involved in the cultivation or production of cannabis; and

(c) Must not have any other interest in or involvement with a cannabis cultivator, producer and/or dispensary that could cause the independent testing laboratory to act in a manner that is not impartial.

(3) An independent testing laboratory is not required to use a cannabis distributor to collect or transfer samples for testing.

(4) The restrictions denoted in subsection 2 are not intended to limit an independent testing laboratory, or the above listed individuals, from providing consulting services to a cultivation establishment, production establishment and/or dispensary, provided that such services do not directly or indirectly indicate, suggest, or imply how to cultivate or produce cannabis.

(5) If a registered independent testing laboratory hires a person who was previously employed by, or performed any work for, a cultivator, producer and/or dispensary within one year prior to the person's date of employment with the independent testing laboratory, the independent testing laboratory shall not permit that person to perform any tests for which the person had any involvement with, whatsoever, while the person was employed by the cultivator, producer and/or dispensary for a period of one year from the person's date of employment with the independent testing laboratory.

(6) A cultivator, producer or dispensary shall not:

(a) Attempt, directly or indirectly, to improperly influence an independent testing laboratory, or any of its employees, management, or owners, regarding any sample currently being tested by the laboratory

(b) Engage in any transaction with an independent testing laboratory it is utilizing, has utilized, or intends to utilize to test cannabis, which would require the independent testing laboratory to participate, consult, or otherwise be involved in the cultivation or production of cannabis. This restriction is not intended to limit a cultivator, producer or dispensary from engaging an independent testing laboratory to provide consulting or research and development services, provided that such services do not directly or indirectly indicate, suggest, or imply how to cultivate or produce cannabis.

Temperature Comparison of 3M Rapid Yeast and Mold Petrifilm Utilizing Manufacturer's Suggested Temperatures on Dried Cannabis Flower (Cannabis spp.)

April 16, 2021

Anthony J. Repay

Cannabis Science and Technology, April 2021, Volume 4, Issue 3
Pages: 32-34

In this study, dried cannabis flower found to have yeast and mold during compliance screening were randomly chosen to be plated at two different incubation temperatures to compare total amount of yeast and mold growth.

When using 3M rapid yeast and mold petrifilm for the analysis of dried cannabis flower (Cannabis spp.), the manufacturer suggests two different incubation temperature ranges, 25 °C ± 1 °C or 28 °C ± 1 °C. In this study, dried cannabis flower found to have yeast and mold during compliance screening were randomly chosen to be plated at both temperatures to compare total amount of yeast and mold growth. These plates were incubated between 60–72 h in accordance with manufacturer guidelines for microbial testing. Overall, it was found that all plates that exhibited growth showed higher colony forming unit (CFU) counts at 25 °C and some observed to be statistically significant in their difference in favor of 25 °C. I urge all cannabis microbiologists and state compliance boards to require 3M rapid yeast and mold petrifilm, when testing dried cannabis flower, to be incubated at 25 °C to ensure accuracy in testing and safety of the consumers.

There is such a diversity of microorganisms on dried cannabis flower (*Cannabis spp.*) that it has led us to selectively test for the ones harmful to humans. These guidelines are a pass–fail system that are regulated on a state-to-state basis, and can be set up as either a colony forming unit (CFU) threshold or through presence and absence testing (1). One area of concern for cannabis has been yeast and mold contamination of the flower through the growing and drying process. Several different types of yeast and mold have been found to find a suitable environment in cannabis production conditions through a speciation process (2). Cultivators have also now started adding different microorganisms, including fungi, to help facilitate the growth of their product in a way to be more natural in their growing situations (3). The problem stems from that some of the microorganisms, in large enough quantities, can lead to human harm if not properly tested for (1).

The overall purpose of this study is to compare CFU counts at two different manufacturer recommended temperatures to determine the optimum temperature for measuring yeast and mold on dried cannabis flower. Dried cannabis flower is defined as the crude flowering part of the cannabis plant (4). This is generally the main part of the cannabis plant that is tested. The manufacturer of petrifilm, 3M, recommends two different temperatures for the incubation period of their rapid yeast and mold product Cat: 6475/7477. These temperatures are 28 °C ±1 °C or 25 °C ± 1 °C. After reaching out to 3M their response stated that there were two different ranges because some yeast and mold organisms are better recovered at 25 °C while others grew better at 28 °C. Following this inquiry, the question was asked is there a difference between 28 °C ±1 °C or 25°C ± 1 °C for incubation temperature? Secondly, if there is a difference in temperature, which of the two temperatures would be the optimal temperature for dried cannabis flower?

Experimental

Five client samples that were found to have a total yeast and mold count under full panel compliance testing were chosen at random to be used in this temperature comparison. These samples were crushed to form a homogeneous cannabis mix in a sterile bag and transferred to the weighing area. Next, 1 g from each sample was weighed out aseptically into a sterile filtered bag to which 99 mL of sterile butterfield's diluent was added. Following that, 1 mL of this solution was transferred to petrifilm and pressed. This process was repeated 50 times on to 3M rapid yeast and mold petrifilm for each of the five samples. This was done in accordance with the instructions given by the manufacturer and Association of Official Agricultural Chemists (AOAC) recommendations (2,4,5). Petrifilm is a simple, ready to use plate system with specialized antibiotics to facilitate the growth of only yeast and mold on the plate in a rapid manner (5). These 50 replicates were then equally divided randomly to either be incubated at 28 °C ±1 °C or 25 °C ±1 °C. Following the state of Nevada and 3M guidelines for incubation, these plates were incubated between 60–72 h along with a blank and a laboratory control spike (LCS). This LCS was made from a pure culture of *Candida albicans* (NCPF 3179/ATCC10231) to confirm fungi growth can occur under present conditions. The blank was plated to confirm that no cross-over contamination occurred throughout the process. Due to client confidentiality, the names of the clients will be hidden and will be given a four-digit number to associate the sample with. These numbers are as follows: 5205, 5124, 5251, 5308, and 5166.

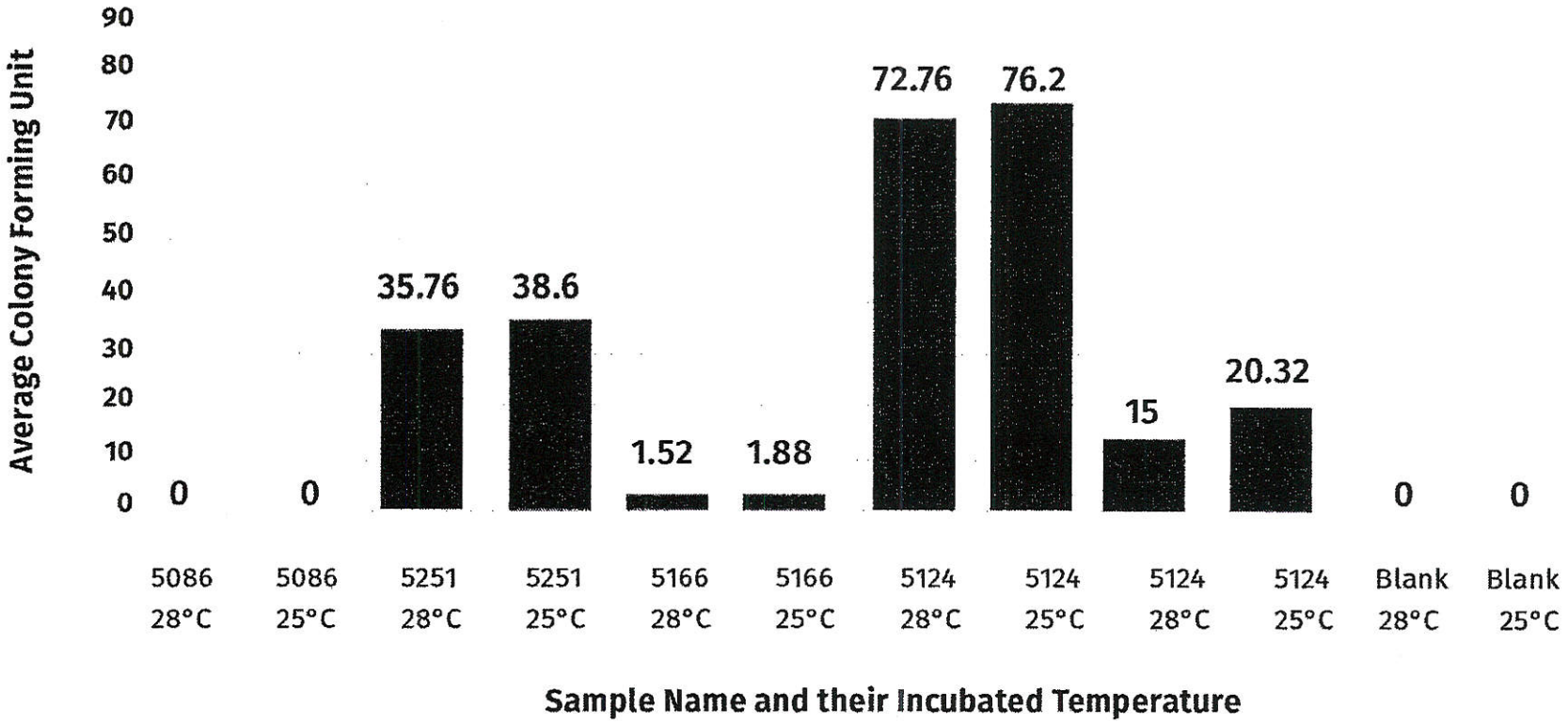
Results

CFU Count Comparison

Table I: Two-sided T-Test (df=48) of sample means. This analysis was done utilizing r statistical software.

CC No.	28 °C Mean	25 °C Mean	Difference in Means	Confidence Interval	T - Statistics	P- Value
5251	35.76	38.60	-2.84	(-4.973, -0.707)	-2.678	0.010
5166	1.52	1.88	-0.36	(-1.022, 0.302)	-1.095	0.279
5205	72.76	76.20	-3.44	(-15.658, 8.778)	-0.568	0.573
5124	15.00	20.32	-5.32	(-7.196, -3.444)	-5.707	0.000

Figure I: Averages of given samples at their respective temperature of incubation. CFU is an abbreviation for "colony forming unit." The LCS's for both temperatures came back as too numerous to count (TNTC).



Samples 5124 and 5251 CFU counts were found to be significantly different at the 95% confidence interval (Table I). Samples 5308, 5166, and 5202 were found to be nonsignificant even though the average CFU count was higher at the lower temperature (Figure 1). To determine whether a significant difference between samples existed, a two-sample t-test with df=48 was conducted, with alpha set at the 0.05 level. In all four samples that experienced growth, all difference of means were negative again showing that high counts were observed at the lower temperature recommendation. Sample 5308 showed no growth at the dilution. From this data we can deduce that the lower incubation temperature is likely more ideal for yeast and molds commonly found on dried cannabis.

Conclusion

When testing dried cannabis flower for total yeast and mold, utilizing 3M yeast and mold rapid petrifilm, 25 °C offers statistically higher counts in comparison to 28 °C. Sample 5251 and 5124 showed significant difference between temperatures at the 95% confidence interval (Table I). All samples that showed growth yielded higher counts at the lower temperature (Figure 1). Along with higher counts, colonies are easier to enumerate because of the increase in morphological diversity observed on the plates. These morphological differences mainly pertain to the shade of color of the colonies found on the plate. The remaining sample that showed no growth was determined to be plated at a dilution too high to see the true CFU count. Secondly, samples were in refrigerated storage prior to research and development for more than 30 days due to state guidelines of sample disposal. This could have also played into the lack of growth for sample 5308.

This preliminary research has areas of possible expansion in many ways. For one a selective agar, such as Dichloran Rose-Bengal Chloramphenicol agar (DRBC), could be used to compare the counts of different temperatures to a single count. Secondly, temperatures outside of manufacturers specifications could be implemented because of the complex matrix of the dried cannabis flower. This matrix specifically on 3M rapid yeast and mold petrifilm can lead to misidentification to the untrained eye due to the cannabis matrix causing a blue color to appear, but these small matrix interferences do not match the morphology of other yeast and mold (6). With continuing innovations in temperature, media, and measurement of contaminate we can hope to minimize the effect of matrix interference in the sample measurement. Ultimately, the goal is to not only supply cultivations and manufacturers of cannabis with honest and accurate results so that they can better remediate their product, but to also not allow harmful product to reach the marketplace. In late 2020, the AOAC developed a task force to evaluate yeast and mold determination in cannabis, but as microbiologists in this new industry we are responsible for validating these methods to protect the consumers of the marketplace (7). Based on these preliminary results we have identified 25 °C to achieve the most reliable growth for rapid yeast and mold petri. I urge governing bodies of cannabis and method developers to require that laboratories that utilize the 3M rapid yeast and mold petrifilm to incubate at 25 °C or to research how these temperatures may affect growth in different states. This will maximize the potential for CFU growth for samples and limit the possible health concern of allowing contaminated product to enter the marketplace.

Acknowledgements

I would personally like to thank RSR Analytical Laboratories for help fund this research, Tao Zhong for aid in sample preparation, and Wyatt J. Tarter for statistical analysis.

References

1. R. Upton, L. Craker, M. ElSohly, A. Romm, E. Russo, and M. Sexton, *Cannabis Inflorescence: Cannabis spp.: Standards of Identity, Analysis, and Quality Control* (American Herbal Pharmacopoeia, Scotts Valley, California, 2014).
2. A.K. Gautam, M. Kant, and Y. Thakur, *Archives of Phytopathology and Plant Protection* **46**(6), 627–635 (2013).
3. Z.K. Punja, D. Collyer, C. Scott, S. Lung, J. Holmes, and D. Sutton, *Frontiers in Plant Science* **10,** doi:10.3389/fpls.2019.01120 (2019).
4. 3M Petrifilm Rapid Yeast and Mold Count Plate Interpretation Guide. 3M, https://multimedia.3m.com/mws/media/902046O/3m-petrifilm-rapid-ym-countplate-interpretation-guide.pdf. Accessed 2 February 2021.
5. P. Bird, J. Flannery, E. Crowley, J. Agin, D. Goins, and R. Jechorek, *Journal of AOAC INTERNATIONAL* **98**(3), 767–783 (2015).

6. N. Stolze, C. Bader, C. Henning, J. Mastin, A.E. Holmes, and A.L. Sutlief, *Journal of Microbiological Methods* **164,** 105681 doi:10.1016/j.mimet.2019.105681 (2019).
7. AOAC international Activates accelerated program to evaluate test kits that measure yeast and mold in cannabis. (2020, December 07). Retrieved March 13, 2021, from https://www.aoac.org/news/aoac-international-activates-accelerated-program-to-evaluate-test-kits-that-measure-yeast-and-mold-in-cannabis.

About the Author

ANTHONY J. REPAY, M.S., is the Director of Microbiology at RSR Analytical Laboratories. Direct correspondence to: repayanthony@gmail.com

July 26, 2021

Hon. Michael Douglas, Chairman
Nevada Cannabis Compliance Board

Dear Hon. Douglas,

As industry leaders in cannabis and pathogen genomics, we have spent decades working with quantitative polymerase chain reaction (qPCR) and culture-based methods for the detection of microorganisms. We are experts in the field with over 40 patents related to PCR and DNA sequencing based methods for detecting microorganisms. Kevin McKernan, Chief Scientific Officer at Medicinal Genomics Corp. (MGC) managed the Research and Development team for the Human Genome Project at the Whitehead Institute of MIT. He has over 41,097 citations related to his work in this field. Our scientists recommend the microbial testing specifications that will ensure that cannabis manufactured products are safe for patients. Due to our concerns for public health, we feel that the Dispensary Licensing Section of the Office of Medical Cannabis Control and Regulation should considering modifying your present required microbial testing to reflect ongoing efforts at the AOAC, USP, CDC and FDA, which are consistent with our findings at MGC.

The presence of microorganisms is common in natural products, such as cannabis flowers. One must be able to differentiate between harmless microbes ubiquitous in nature and those that are human pathogens that have contaminated the cannabis plant and/or manufactured products. Examples of species specific human pathogens that have been detected in cannabis are Shiga toxin producing *E. coli* (STEC), *Salmonella* spp. (all species are pathogenic), *Aspergillus flavus, A. fumigatus*, *A*. *niger*, and *A*. *terreus*. Total microbial count tests ("indicator tests"), such as Total Aerobic Microbial Count (TAMC) and Total Yeast and Mold Count (TYMC), **do not** test directly for the presence of species specific human pathogens. The American Herbal Pharmacopoeia's *Cannabis* Inflorescence *Cannabis* spp. monograph [1] states that total count tests with their corresponding action levels, such as TAMC and TYMC, **must never** be used to pass or fail a cannabis sample. The total count result **does not** provide any information on the presence of any pathogenic microorganisms in the cannabis sample, which may cause harm to patients.

Current required tests for microbial contamination in states that have adult-use cannabis programs vary among the states. Many states require a combination of some of the following tests: TAMC, TYMC, total coliforms, total bile-tolerant Gram-negative bacteria, and total *E. coli* or total pathogenic *E. coli* with various maximum allowable limits for each test and each

cannabis product type. All microbial tests have maximum allowable limits as colony forming units (cfu/g), which is the number of colonies that grow on the surface of an agar medium plate. Lastly, other states, such as California, require species specific tests for Shiga toxin producing *E. coli* (STEC), *Salmonella* spp., *Aspergillus fumigatus*, *A. flavus*, *A. niger*, and *A. terreus* with a maximum allowable limit of zero (0) cfu/g of product.

Section 11.050 of the Nevada Cannabis Compliance Regulations (NCCR) has a table, which describes the different product type(s) and the required quality assurance microbial tests with their corresponding action levels. Product set 1 ("sable cannabis, infused pre-rolls and crude collected resins") and product set 2 ("wet cannabis") have the same required microbial tests and corresponding action levels. These tests include:

(a) Total yeast and mold
(b) Total Enterobacteriaceae
(c) *Salmonella*
(d) Pathogenic *E. coli*
(e) *Aspergillus fumigatus*
(f) *Aspergillus flavus*
(g) *Aspergillus terreus*
(h) Aspergillus niger
(i) Total coliforms

To reiterate a statement from above, the 3 "Total" tests listed above **do not** provide any direct information on the presence of any pathogenic microorganisms in the cannabis sample, which may cause harm to patients.

Therefore, Medicinal Genomics **recommends** that the Cannabis Compliance Board modify the regulations for required microbial testing for adult-use cannabis and cannabis products to include only specific pathogen species tests. These six tests are:

1. *Salmonella* species
2. Shiga-toxin producing *Escherichia coli* (STEC)
3. *Aspergillus flavus*
4. *Aspergillus fumigatus*
5. *Aspergillus niger*
6. *Aspergillus terreus*

Since these microorganisms are harmful to humans and the Cannabis Compliance Board wants to ensure safe products for patient and consumer consumption, the action levels for all six tests should be "None detected/gram". The states of California, New York, Arizona, Alaska, and Missouri have either required the species specific human pathogen tests listed above or have

drafted regulations to replace Total Count tests with the species specific pathogenic tests noted above.

In the other Product sets where they are listed, Medicinal Genomics also recommends the Total yeast and mold, Total Enterobacteriaceae. Total coliforms, and Total aerobic count should be removed and Shiga-toxin producing *Escherichia coli* (STEC) should be substituted for Pathogenic *E. coli*.

Medicinal Genomics also recommends that the the required microbial testing for adult-use and medical cannabis and cannabis product rules should include a statement concerning allowable methods to read:

1. A validated method using guidelines for food and environmental testing put forth by the USP, FDA, and AOAC Appendix J and cannabis as a sample type; or

2. (i) Another approved AOAC, FDA, or USP validated method using cannabis as a sample type."

NOTE: "Another approved AOAC, FDA, or USP validated method using cannabis as a sample type" may include molecular methods, such as qPCR."

The reasons for this recommendation are outlined below.

Currently there are limited AOAC, FDA, or USP approved species specific pathogen testing methods for cannabis. Medicinal Genomics released the first version of our SenSATIVAx® (DNA extraction) and PathoSEEK® (qPCR assay) Manufacturer Validation Document in 2017. These method validations use cannabis as the sample type. At that time, there were no official guidelines published by any regulatory body describing how to validate a method for detecting microbes in the presence of a cannabis matrix. Due to this lack of available guidelines in the cannabis industry, our scientific team referenced guidelines for food and environmental testing put forth by the USP, FDA, and AOAC Appendix J. We continually add data to this document as we release new assays or make improvements to current assays. We are currently on version 31 of this document[2]. In addition, MGC's methods are currently going through additional validation according to AOAC's Standard Method Performance Requirements (SMPRs). AOAC has released 3 SMPRs for species specific testing for the species specific pathogens listed above (see #1-3 below).

1. Detection of *Aspergillus* in Cannabis and Cannabis Products https://www.aoac.org/wp-content/uploads/2019/10/SMPR-2019_001.pdf
2. Detection of *Salmonella* species in Cannabis and Cannabis Products https://www.aoac.org/wp-content/uploads/2020/07/SMPR-2020_002.pdf
3. Detection of Shiga toxin-producing *Escherihia coli* in Cannabis and Cannabis Products https://www.aoac.org/wp-content/uploads/2021/02/SMPR-2020_012.pdf

Medicinal Genomics is a member of **AOAC's Cannabis Analytical Science Program (CASP) Microbial Contaminants Working Group**. The goal and objectives of this working group are to

- Develop Standard Method Performance Requirements (SMPR) for cannabis and hemp
- Extend a Call for Methods for each of the completed SMPRs
- Empanel an Expert Review Panel to review candidate methods
- Deliver consensus-based validated Performance Test Methods (PTMs) & Final Action Official Methods for the cannabis industry

NOTE: Medicinal Genomics will have a single AOAC Certified qPCR PTM for the detection of the 4 *Aspergillus* species by August 2021 and a single AOAC Certified qPCR PTM for the detection of *Salmonella* spp. & STEC by September 2021.

The primary advantage of using qPCR detection assays are that they are designed to identify unique specific DNA sequences either shared by an entire "group" of bacteria, such as all *Salmonella* species or a specific genus and species, such as STEC or the 4 different pathogenic *Aspergillus* species. If the unique sequences are present, then the qPCR test will detect it. Therefore, a qPCR test is very specific, very sensitive, and possesses a rapid turnaround time (6 hours) *vs.* plating methods that are less specific, less sensitive, and has a very slow turnaround time of days for colonies to form on a plate.

Furthermore, there are additional major disadvantages of using plating methods to detect species specific bacterial and fungal pathogens.

- The cannabinoids, which represent 10-20% of the cannabis flower by weight, have been shown to have antibiotic activity. Antibiotics inhibit the growth of bacteria in plating methods. *Salmonella* and STEC bacteria are very sensitive to antibiotics, which may lead to a false negative result.
- Plating methods cannot detect endophytes, which are fungi that live a part or all of their life cycle inside a plant. Examples of endophytes are the species specific *Aspergillus* pathogens and Fusarium. Methods to break open the plant cells to access these fungal endophytes for plating methods also lyses these fungal cells (killing these cells in the process). Therefore, these fungal endophytes will not be able to form colonies in a plating method.
- Selective media for fungal plating methods, such as Dichloran Rose-Bengal Chloramphenicol (DRBC) reduces fungal growth; especially *Aspergillus* by 5-fold. This may lead to a false negative result for this pathogen. Moreover, DRBC medium is typically used to reduce bacteria; it comes at the cost of missing 5 fold more yeast and molds than PDA + Chloramphenicol or molecular methods. Please see study results from the AOAC emergency validation. [3]

Respectfully,

Sherman Hom

Director of Regulatory Affairs
Medicinal Genomics
sherman.hom@medicinal.genomics.com

References

1. American Herbal Pharmacopoeia's *Cannabis* Inflorescence *Cannabis* spp. Monograph https://herbal-ahp.org/online-ordering-cannabis-inflorescence-qc-monograph/
2. MGC Validation Document https://1280717.app.netsuite.com/core/media/media.nl?id=5910362&c=1280717&h=6e4d1cce15d1eae41733&_xt=.pdf&fcts=20191014094610&whence=
3. AOAC TYM Study: Whole genome sequencing of colonies derived from cannabis flowers & the impact of media selection on benchmarking total yeast & mold detection tools: https://help.medicinalgenomics.com/hubfs/White%20Papers/WGS_of_colonies_derived_from_cannabis_flowers_5-14-21.sbmt.pdf

From: Sctt Matthews <420villenevada@gmail.com>
Sent: Monday, July 26, 2021 10:00 PM
To: CCB Meetings
Subject: CCB Public Comment

Hello,

I have two questions with comments.

1. Why haven't there been applications for cannabis businesses for at least two years?

I understand that many licenses were purchased by large corporations prior to 2019.

Trying to open a small cannabis business in Nevada with the cost to purchase a license for millions is not cost effective.

After investing in properties, building, attorneys and consulting firms to no prevail we are still without an application.

2. Why are these large corporations allowed to violate NRS codes?

For example, in Jackpot, NV.
NRS Code 678B.250 states that the distance from a public school must be 1,000 ft. from the front door of the cannabis business to the property line of the school.

The proposed cannabis dispensary in Jackpot is 600ft or less.

The code also states 300 ft from other public buildings such as a post office.

The proposed cannabis dispensary sits less than 120ft.. and less than 50 ft from the front door of the nearest residence.

The building for the cannabis dispensary is also sitting on a non-cannabis zoned parcel.

The question at hand is, why do the little guys have to follow all of the rules and receive nothing and the large corporations can bypass local and state-based rules and still open and operate?

Laid out in the NRS codes it states that a license must be in use within one year of getting a license. Most licenses given out in 2018 have yet to be in use but can be found being sold for millions of dollars. I understand Covid-19 but that also didn't happen until 2020.

Thanks for your time
420VILLE NEVADA LLC
Scott Matthews
420villenevada@gmail.com

From: Teresa Damien <jjhispanic22@gmail.com>
Sent: Monday, July 26, 2021 11:48 PM
To: CCB Meetings
Subject: Jackpot needs your help!

I as a resident of blue sky trailer park find it a palling that a dispensary would go right in front of our homes where our children play where we drive to and from work basically it's setting up shop in our backyard. We were never notified or asked her opinion either by the owner of the trailer park or by the county. Blue sky trailer park is predominantly Hispanic as am I. I believe it is set up in that location because they do not have to care what we think because we are the lowly Hispanics of the community. The owner of the trailer park does not even live in Jackpot I have lived in Jackpot for 41 years and have raised my family and my children here and while I'm not opposed to the dispensary I am a post at looking out my front door and it being right there.

Thank you
Proud Jackpot Resident

FENNEMORE.

Katherine L. Hoffman
Director
khoffman@fennemorelaw.com

7800 Rancharrah Parkway,
Reno, Nevada 89511
PH (775) 788-2245 | FX (775) 788-2246
fennemorelaw.com

July 26, 2021

ELECTRONIC MAIL

NEVADA CANNABIS COMPLIANCE BOARD
555 E. Washington Avenue, Suite 4100
Las Vegas, Nevada 89101
Electronic Mail: CCBmeetings@ccb.nv.gov

Re: **NOTICE OF INTENT TO AMEND REGULATION 11.075**;
Comments of Ziel Equipment, Sales & Services, Inc.

Dear Board Members:

We represent Ziel Equipment, Sales & Services, Inc. ("**Ziel**" or the "**Company**"). The purpose of this letter is to provide the Company's comments on the proposed amendments to Regulation 11.075 being considered for adoption at the July 27, 2021 meeting of the Nevada Cannabis Compliance Board ("**CCB**").

IDENTITY AND INTEREST OF THE COMMENTER

Ziel is a leading developer of Radio Frequency ("**RF**") equipment for the reduction of microbial pathogens. The food and cannabis industries across North America, Europe, South America, and Australia utilize RF technology to safely remediate products intended for human consumption or ingestion. Ziel's devices utilize non-ionizing radiation to pasteurize products like almonds, cashews, macadamias, sesame and chia. This technology has been adapted for the cannabis industry to successfully remediate bacterial and fungal pathogens. These devices help Nevada cannabis licensees ensure that they are providing a safe product that meets the highest safety and quality standards. Moreover, Ziel's technology allows licensees to satisfy these standards through a method that is compatible with the requirements for organic certification.

COMMENTS

The amendments under consideration provide that a lot or production run of cannabis that fails a residual solvents, pH, water activity, homogeneity, or microbial screening test may be "remediated." Ziel appreciates and supports the Board's proposal to recognize that remediation of cannabis is a safe and effective method to address certain issues flagged through screening tests. Adopting a regulation which allows licensees to treat cannabis with remediation technology supports and promotes the CCB's objective to ensure the safety of the cannabis sold to Nevada consumers. Additional regulatory and process changes, however, are necessary to

better and more efficiently integrate remediation into the cannabis cultivation and production processes.

1. Allow Licensees to Treat Cannabis without Delay

As currently written, the proposed amendments provide that licensees with failed product must obtain "approval of the appropriate Board Agent" before proceeding with remediation. This approval requirement creates additional and unnecessary work for agents and hinders the prompt remediation of cannabis. Such delay can result in worsening microbial conditions. Instead, if the CCB believes that Board Agents should be aware of remediation activities, the regulation could provide that licensees may remediate product "upon notice to the appropriate Board Agent . . .." Importantly, if a licensee elects to remediate, there will need to be a process in place to integrate the 10 gram retest sample back into the lot prior to remediation.[1]

2. Clarify the Process for Subsequent Testing After Remediation

The proposed amendments to Regulation 11.075(4) provide that licensees may not request a "retest" if the failed product has undergone remediation treatment following the initial testing. Ziel believes that this provision is meant to reflect the CCB's intention that the subsequent testing of remediated product is not a "retest" that counts towards any cap on the number of allowed retests. This intention, however, could be better reflected in Regulation 11.075. For example, Regulation 11.075(1) should state: "After processing, the remediated lot extract must pass all required quality assurance tests; such subsequent testing is not a retest subject to the requirements of Subsection 4 through Subsection 10. If the subsequent test provides passing results, the certificate of analysis for the subsequent test will be recorded."

3. Implement Changes to Metrc that Facilitate Remediation by All Licensees

Cannabis remediation is a crucial option that helps cultivation and production licensees ensure the safety of their products. Accordingly, the state's cannabis industry, and cannabis consumers, would benefit from a cultivation and treatment process that facilitates broader access to remediation technology. For some smaller cannabis licensees, it may not be efficient to invest in in-house remediation equipment. Instead, those licensees should be able to access the remediation services of other licensees who possess the appropriate equipment and expertise. This "tolling service" model of treatment is widely used in the food and agricultural industries.[2]

---

[1] Prior to the initial test, the testing lab pulls two 10-gram samples from the lot, one sample for the initial test and one sample for use in any retest.

[2] *See, e.g.*, Kevin T. Higgins, FOOD PROCESSING, *Tollers Expand Service Breadth To Meet Food Companies' Needs* (March 1, 2017) *available at* https://www.foodprocessing.com/articles/2017/toller-services-expand.

Companies without remediation equipment can secure treatment of their products, and companies with excess capacity in their treatment equipment can offer remediation services.

Metrc functionality must be adapted and improved, however, to allow failed cannabis to move from the original cultivator to another cultivation or production licensee for purposes of remediation. Metrc's current configuration does not directly allow licensees to transfer cannabis for the purpose of remediation and then have the treated cannabis returned for continued processing in the normal course. In connection with this improved functionality, the CCB should require that licensees offering tolling services comply with Standard Operating Procedures ("SOPs") that have been approved by a Board Agent. These SOPs should address how the remediating licensee will safeguard and store the cannabis during the intake, treatment, subsequent testing, and return process.

Ziel strongly supports the CCB's goal of ensuring safe and clean cannabis products and remediation is an important tool in achieving this objective. While the amendments proposed today are an important step forward in making this tool accessible to Nevada licensees, more must still be done. Licensees should be able to utilize remediation technology without pre-authorization by a Board Agent, and it's important that licensees understand the process for subsequent testing and obtaining certificates of analysis. Additionally, Metrc's functionality must be updated to incorporate and facilitate the remediation process, whether that remediation is done by the cultivating licensee or another licensee with remediation expertise. We appreciate the CCB's consideration of these issues and we look forward to working with CCB Staff to address these issues. Please advise if you have any questions or require additional information.

Sincerely,

FENNEMORE CRAIG, P.C.

/s/ *Katherine Hoffman*
Katherine L. Hoffman