MEETING MINUTES
INDEPENDENT LABORATORY ADVISORY COMMITTEE

The Independent Laboratory Advisory Committee held a public meeting on August 5, 2019, beginning at 2:00 p.m. at the following locations:

VIDEO-CONFERENCE SITE:
Department of Taxation
1550 College Parkway, Large Conference Room
Carson City, Nevada

VIDEO-CONFERENCE SITE:
Department of Taxation
2550 Paseo Verde Parkway, Suite 180
Henderson, Nevada

1. Call to order; determination of quorum

ILAC Chairperson Brenda Shalloo called the meeting to order at 2:10pm.
Present: Brenda Shalloo, Craig Kovl, Cindy Orser, Nikhil Kumar, Ed Alexander, Nick Malmquist
Teleconference: Darryl Johnson
Absent: Duke Fu, Andre Rhodes

2. Public Comment (No action may be taken on this item of the agenda.)

No public comment was taken.

3. Approval of June 10, 2019 meeting minutes

Shalloo asked if any errors, corrections, or additional comments were needed for the minutes. There was none. Shalloo made motion to approve minutes. Alexander seconded. Approved.

4. New ILAC Members

Shalloo asked new member Nikhil Kumar to introduce himself. Kumar is the senior microbiologist at Canalysis Laboratories. His background is in genomics which is why he is attracted to this industry. He is happy to be a part of the committee.

Shalloo welcomed Kumar and stated they needed a microbiologist on the committee. The other new member Andre Rhodes was not present at the meeting. Shalloo asked if anyone had heard from him. Alexander stated he had been in contact with Rhodes who was looking forward to participating.

5. Revision to ILAC Bylaws

Kara Cronkhite from the Department presented the revision to the Bylaws. Throughout the document the word "Department" was replaced with "Agency" in anticipation of the Cannabis Compliance Board. In Article II, the "Administrator" is designated as the "Deputy Director". In Article II and Article III, "all" was added before "marijuana products" to cover concerns that products may be missed in the list. "Determine" was replaced with "recommend" because the committee makes recommendations.

Shalloo asked for discussion relating to changes. Orser asked if the idea was to move ILAC from under the Department of Taxation to the proposed governor's task group and was there an effective date? Alexander responded that discussion regarding the governor's task force will be addressed later in the agenda. The Cannabis Control Board will be in existence July 2020. There will be some time before the shift in who ILAC reports to.

Shalloo asked in regards to Article II, there is a reference to the policy manual. Shalloo does not have any information regarding this and will speak to Ky Plaskon. Malmquist commented that at the last meeting, someone stated that the policy manual was a compilation of all the rulings and was something that should be maintained.

Malmquist added in Article III A, section 2 there is still a reference to "determine" instead of "recommend". Shalloo will email the Department regarding that additional correction to be made.
Shallo made motion to approve Bylaws as presented. Unanimous approval.

6. List of items the Division would like ILAC to discuss.

Malmquist made contact with the Department and presented three general areas that they would like ILAC to address. First was reporting of residual solvents, particularly ethanol. Second was standardizing if possible plate-based microbial assays and method for reporting replicates. Third was standardizing foreign matter pass/fail, particularly with regards to powdery mildew contamination.

Orser asked for clarification on the third item. Malmquist explained that there is no existing accepted molecular assay for powdery mildew within the guidelines. In practice, laboratories are identifying the presence or absence of powdery mildew by identifying it as foreign matter. Some laboratories will fail a lot if they see any amount of powdery mildew. Others will identify it as matter other than marijuana and if above 5% limit it will fail. This suggests that the topic should be addressed.

Shalloo commented that both of those microbiology issues were to be addressed by Duke Fu. In addition, some of those tasks were to be given to Kumar to work on. Kovl is presenting on residual solvents. Alexander asked for clarification from the Department if powdery mildew is foreign matter or a microbial contamination. The Department will provide clarification at a later time.

Shallo made motion to close discussion. Alexander seconded. Unanimous.

7. Pesticides in concentrates

Orser stated that the task may no longer be relevant since the State issued their list. These were listed in Orsers' handout as well. Orser, Rene Adler, and Glenn Miller put together recommendations for pesticide levels. Orser questioned who came up with the pesticide action levels for Nevada and what was the rationale behind it. Some of the numbers went up and some went down. For example, Imidacloprid levels increased five-fold. Product that would have failed, will now pass under the new limits. Commented there is a lack of harmonization between the states. Nevada had been the leader on cannabis testing. There is opportunity now to lead in standardization amongst states across all of the testing. Orser included in the recommendations from Digipath Labs, the acceptable daily intake, and the acute reference dose.

Alexander thanked Orser for putting this together. He agreed that four years ago Nevada was leading the industry with national push for regulations and now Nevada seems to be following California. He would like to see open discussion and data on current crops in Nevada, what is the overall pass/fail with the new limits. Are the limits on the date the plant is planted or the date it is harvested? Is material that failed before the new limits, able to be retested and pass with the new limits? Department of Agriculture was not aware that anyone was using the information they put out on the limits.

Shalloo added that she has had several customers ask her at what point do the new limits come in? Asked if the State can put out a ListServ to clarify that. Shalloo asked Orser to provide explanation on why she thought additional pesticides Chlorpyrifos and Cyprodinil should be added to the list. Orser stated Chlorpyrifos as been found to be one of the most toxic neurotoxins targeting the nervous system. This chemical has been found in 87% of newborn cord blood tested and there is no reason why anyone should be using it. At 0.1 ppm, it will be the maximum daily intake for that chemical. It would be easy to add to the list of pesticides that are not permitted. It should be grouped with the list including Abamectin, Cypermethrin, Daminozide, and Paclobutrazol. Shalloo asked where Chloropyrifos is used. Rene Adler answered that it is a commonly used insecticide and usually used in combination with Fludioxinil. They are approved for use in other crops. Orser added that for any crop that has not gone through the standardized pesticide trial evaluation, it is 10 parts per billion across the board for pesticide.

Shalloo moved to close the discussion based on the fact that the State had come out with the limits, except to ask the State for clarification on when the new limits are applied (date of planting or date of harvest for example).

Alexander asked Orser where the acceptable daily intake was derived from. If there is an acceptable daily intake established for products and ILAC is establishing levels of exposure that are 0.01% of an acceptable daily intake allowance, is this too restrictive? Maybe the ADI column is the measurement that limits should be set at? Difficult for him to say that product would fail for Pyrethrin when it has less than half percent of total acceptable daily intake. Orser commented that the formulas used to calculate the acceptable daily intake and the acute reference dose are from Europe, where they are more concerned with pesticide exposure than the United States. They are also for ingestion and based on the size of child (60 pounds) so they are being conservative. These figures do not take into account inhalation – we do not know much about inhalation of pesticides. Orser clarified that the figures Alexander was looking at were those proposed by Digipath, which are different that the figures on the list put out by the Department.

Alexander stated that another way that they could look at it would be to figure out what the acceptable daily intake amount should be and then work the math backward from that to determine the acceptable exposure. May be more consistent to look at the acceptable daily intake.

Shalloo stated that if the State has already determined their numbers, then there didn't need to be more discussion on this topic. Alexander would like the State to show ILAC where they got the numbers. Shalloo clarified that the numbers were issued by the Department of Agriculture and not the Department of Taxation. Alexander responded that the Department of Agriculture should explain where their determinations because acceptable daily limits has never been discussed by ILAC. These figures have a potential negative impact on consumers and businesses.

Orser and Malmquist had reached out the Department of Agriculture and did not receive a response. Alexander commented that he reached out to Department of Agriculture and they stated they did not know where the figures came from. Steve Gilbert will contact the Department of Agriculture. Alexander stated that a lab owner was in contact with the Department of Agriculture and they were unaware that the information on the list would potentially have an impact in the industry because they did not know what those pesticides were being used.

Shalloo stated that they will contact Department of Agriculture and see if they will attend the next meeting.

Shalloo made motion to close discussion. Orser seconded. Discussion closed.

8. Microbiology testing standards

Shalloo stated this topic was to be presented by Duke Fu, who was not present at the meeting. Shalloo will contact Fu to see where he is at with this working group and then assign some of those tasks to Nikhil Kumar.

Members commented that some of the topics assigned to Fu were related to the tasks the Department wanted ILAC to look into.

Shalloo moved to close discussion. Alexander seconded. Discussion closed.

9. Governor's Advisory Panel.

Alexander had conversation with Department of Taxation and advisory panel have ended. As of December 31, 2019, there will be a beginning to the path forward with the Cannabis Control Board. But the Board will not be working on cannabis potentially until July 2020. Regarding potential inclusion of ILAC, the response was that is one of the things they will be looking at in July 2020. Alexander feels that a lot of things ILAC is working on now may become null and void when the Cannabis Control Board is established. Would like Department of Taxation to push for ILAC inclusion with the Board, however there is not indication at this time that that will take place. There may be more information at the end of the year.

Shalloo asked if there was anything further ILAC can do. Alexander responded that before the Board actually meets, he would like to see a to do list of things that the Cannabis Control Board will address. Industry is concerned with lounges and might take precedence over issues that are important to ILAC. It would be beneficial to meet with at least one member of the Board to go over the first twelve months of agenda items. He felt that potential Board members may be listening to those in industry who's objectives may not align with ILAC. He would like the Department of Taxation to assist starting the dialogue with the Governor's office.

Steve Gilbert stated the Department can explain the use of ILAC over the years to the Governor's office. ILAC is in the regulations so those would have to change in order for it to discontinue. The work of ILAC should continue as it has been.

Shalloo asked if the working group should be kept open and Alexander responded that he would like to keep it open. Alexander will work with Steve Gilbert.

Shalloo made motion to close discussion. Alexander seconded. Discussion closed.

10. Residual solvent testing

Kovl was tasked with leading discussion on whether ILAC should recommend adding solvents to the testing list. His main priority at the meeting was to align the ILAC member's thinking and to establish where and how to inform the decision making. Some cannabis products are manufactured with solvents. Some levels of the solvents can remain in the product. Samples can also be contaminated from other sources. Testing for the solvents are required to ensure consumer safety. The primary authority on manufacturing consumable products with solvents is the USP. Chapter 467 addresses these issues and offers general guidance on how to approach residual solvents likely to be found in products. USP 467 creates a framework on how to approach establishing which solvents to test for and their limits based on risk from exposure. The primary approach is stated as the testing of drug substances, excipients and drug products for residual solvents should be performed when production or purification processes are known to result in the presence of such residual solvents. It is only necessary to test for residual solvents that are used or produced in the manufacture or purification of drug substances, excipients, or products. The production of solvent based cannabis products in Nevada is limited to butane, heptane, and propane. Additional solvents may be used at the approval of the Division. Interpretation of the USP 467 suggests that the testing list is limited to analytes that are used in the production process. Nevada currently requires testing for these approved solvents. There is a mechanism in place to review production processes, establish which solvents are being used, and require a testing limit. The current system follows USP but on a case by case basis, rather than a broad mandate. Because USP 467 deals with solvents likely to be found in our product and we have a protocol in place to expand testing requirements on a case by case basis, it appears that there is not a need to include any new specific analytes. However, personal philosophies on approaches to risk dictate perspectives on the proper action. In general, the American philosophy is to prove that it is dangerous. The competing approach is to prove that it is safe. By requiring products to only be tested for process solvents, the assumption is that nothing ever goes wrong. Do we want to build redundancy into our system designed to protect consumers or do we want to address the current approach? The screening of USP 467 or some modified list and limits would ensure that the products do not contain any of those potentially harmful chemicals above accepted limits. This monitors the entire industry and production process as a safety net. This is the final check that can catch any contamination of the USP listed solvents.

Reviewing other states regulations shows that the adoption of the USP 467 list and limits with some modifications. Kovl's initial recommendation options are to adopt the screening of the class 1, 2, and 3 solvents in the USP 467 as an industry safety net. We can come up with a short list of the solvents most likely to be used in the industry and screen for those. We can keep the current list that Nevada has and strengthen the approval process for solvents outside of that list that are petitioned for use.

Kovl supports the first option, to screen for the solvents as a safety net in addition to an improved solvent list limits the potential for contaminated products to each consumer. Even if testing for every analyte is not substantiated, there is value provided to the consumer and public. Thorough testing allows for confidence in industry and a more complete consumer protection from accidents. Do we prioritize consumer safety and confidence or do we balance the approach to streamline industry.

Shalloo opened the topic for discussion. Orser thought it was odd that Nevada has such a short list of solvents that are tested for. She favored adopting the list and limits that California is using. Kovl added that California uses the USP for ingestible products and the OSHA short term exposure limits for inhalable products. The short term exposure limits are below the USP limits. The USP limits have a ten gram daily dose. The short term exposure limits may be a closer fit for the way cannabis is used.

Malmquist asked if there was any data on results from solvent testing, to see if there members on the list that don't show up at all because they aren't involved in the process. He supports safety and doesn't think there should be things on the list that don't appear.

Shalloo asked if there is any advisement from the State or rules on the purity of butane that is used? Kovl responded that the purity should be 99% or greater. Malmquist agreed that was correct purity and added that for hydrocarbon extractions, a mixture of hydrocarbons can be used but they must all be 99% purity or greater. Shalloo commented that the purity that is used limits the other compounds from showing up. The problem is that just because we say that you can't use it, doesn't mean that people don't. Shalloo stated that the State was asking specifically about ethanol and Shalloo has clients that ask for product to be tested for ethanol because the are using it for extraction purposes or it used to clean equipment. Shalloo does see high levels of ethanol, but it is not something that is reported at this point. Shalloo thinks ethanol should be added. In Arizona, the alcohol board got involved if there was a certain amount of alcohol in the product.

Malmquist stated that he was involved in creating products with flavorings using alcohol. There are different limits for alcohol in confections for different states.

Alexander asked if there is a short term exposure limit for any of the pesticides or PGRs that are on the list? He would like the State of Nevada and ILAC to look at adopting the same short term exposure limit standard for some of the other products tested. Also asked if one of the labs represented on ILAC of what the financial impact there will be to the end user if the change is made from the three solvents to 22 solvents. Kovl responded that he would look into the short term exposure limits for pesticides. In regards to cost, the USP provides standard mixtures that make it easy to test for the whole suite of chemicals, which can make it more practical than individual tests because you can screen for them all at the same time. Alexander asked that worst case there is neutral financial impact for testing more and the best case scenario is that there may be savings in testing for the whole suite. Kovl responded that using the mixtures can have savings, and added that there is progressive testing regiment which USP recommends.

Orser stated that it would add to the expense for evaluating residual solvents, there is more reporting and more analysis and proficiency testing. There would be more work and more expense for the labs.

Johnson stated ethanol would be the one to look at. There is cost involved in maintaining standards. You can take regulatory approach and say what the limits can be. Some of the issues could be taken care of by setting guidance on solvents with the correct purity. Consumer safety is most important. But with the cost involved, he is not convinced that Nevada needs to monitor everything at this time when ethanol is the main peak seen.

Shalloo agreed that ethanol is the main peak seen outside of the list. She wanted to keep the working group open have Kovl look into ethanol specifically and come up with some levels of safety that can be recommended. Kovl stated that USP defines ethanol as class 3 which is a lower toxicity. That was defined as 5000ppm limit. Ethanol is one of the least toxic, but most commonly found.

Malmquist would like to know if this is a question of safety or purity? Would it be possible to obtain anonymous results from labs within the state of the amount of ethanol found in different products. Kovl will try to pull that information together.

Shalloo moved to close discussion. Kovl seconded. Discussion closed.

11. Standardized Decision Rule

Darryl Johnson was to present this topic. Topic delayed to next meeting.

12. Assignment of Tasks

Shalloo stated no new tasks to assign. The microbiology testing standards, residual solvents, standardized decision rule, and the governor's advisory panel tasks are all kept open. Shalloo will also speak with the Department regarding pesticides and that may be a topic on the next agenda. Shalloo asked for any additional topics to address. There were none.

Shalloo moved to close discussion. Orser seconded. Discussion closed.

13. Public Comment (no action may be taken)

Mona Lisa Samuelson stated that ILAC does have a voice on the Cannabis Compliance Board. It is included in the bill that was passed. There will be a subcommittee to research efficacy of testing labs and have asked for an ILAC member to set on that committee. Samuelson welcome Nikhil Kumar to the committee. She would have liked the Bylaws to include patients on the ILAC. Samuelson stated that ten grams is not an excessive serving size for a medical marijuana patients.

Rene Adler stated that the acute daily intake was handed out at the last meeting and the calculations were in there. The calculations were based on European studies and ten grams was the magic number that they came up with.

Randy Gardner with Certified AG Lab made public comment. Ethanol at 5000 ppm is 0.5%. Ethanol is used in cough medicine. He is not sure of the risk to cannabis with ethanol. If it not allowed at 5000 ppm in the oil, so you can't make confection out of that, then can you not use the flavor if it has that? It is adding more analysis for something that is not a huge health risk.

Jason Strull with 374 Labs made comment regarding residual solvents. Strull stated that he thought California did the time weighted average as opposed to short term exposure limit. The main difference is the short term exposure limit is fifteen minutes, where one was working in an environment with solvent. He does not know if that is accurate for the usage in this industry and people are exposed to it. He has been working with lab in California, and the ethylene oxide has been challenging to keep in the standards. If Nevada is modelled after California, he would not include that compound. He would try to organize the limits better. If a facility is using solvents purchased from a place such as Home Depot, that is where the contaminants can be introduced. He supports patient safety and the industry, but recommends a common sense approach. Labs can screen for anything, but their concern is the detection limits being so close to the LOQ.

Ed Alexander made public comment regarding cartridges. He dealt with the largest manufacturer of cartridges in the world. Since California enacted regulations, the five largest customers of this manufacturer are black market producers. The four largest customers in the State of Nevada are black market producers. As the price associated with regulated cannabis continues to increase, clients are pushed to acquiring product from the black market. In the effort to make everyone more safe than they need to be, we are also pushing people in the direction of a less safe product as the black market is thriving. We must be aware of this unintended consequence of over-regulating the industry.

14. Adjournment

Shalloo made motion to adjourn. Orser seconded. Meeting adjourned at 3:20 pm.