

MEETING MINUTES

INDEPENDENT LABORATORY ADVISORY COMMITTEE

The Independent Laboratory Advisory Committee held a public meeting on June 10, 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 Shaloo called the meeting to order at 2:05pm.

Present: Brenda Shaloo, Craig Kovi, Duke Fu, Cindy Orser, Ed Alexander, Nick Malmquist

Teleconference: Darryl Johnson

Absent: none

Brenda Shaloo has background in environmental analytical chemistry, with eight years of experience analyzing marijuana specifically. She is scientific director for NV CannLabs. Duke Fu is CEO of Green Therapeutics, has Doctor of Pharmacy and MBA, former president of Medmen, used to run nuclear pharmaceutical labs. Cindy Orser, PhD scientist, practiced science for twenty-five years, lab director and chief science officer for Digipath Labs for last five years. Craig Kovi was an analytical chemist at two different labs, and currently lab manager at a production facility in Las Vegas. Ed Alexander holds seven licenses, involved in ILAC since its inception, and involved in cannabis for 20 years. Nick Malmquist has PhD in biochemistry and pharmacology, has done biomedical research based on early stage drug discovery, and involved in cannabis for three years on production side (product development and research based in Nevada). Darryl Johnson has PhD bioanalytical chemistry, is scientific director at Ace Analytical. Prior to that, he worked at Center for Disease Control and Prevention in Atlanta. He has worked in cannabis industry for eight years.

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

Mona Lisa Samuelson made public comment in Las Vegas. She thanked committee for the agenda and thought it was the best agenda so far. When committee began its work, patients understood that they could go to ILAC with their issues and misunderstandings. She provided a list of issues that patients would like members to look into. Information from microbiologist included that addressed his concerns with some items on the agenda.

Rene Adler made public comment in Las Vegas. He represented Digipath Labs. He spoke about current regulation regarding testing pesticides in cannabis concentrates. The main problem is to set action limits to minimize consumer risk while maintaining good laboratory practice. No action limits at all is risky and leaves room for liability. Determination of pesticides in cannabis is extremely difficult. To minimize measurement uncertainty between laboratories, a standardized method should be implemented in Nevada based on current methods and evaluated by a third party. A European approach after a study with many laboratories set overall measurement uncertainty of 50%. If pesticide had action limit of 0.5 PPM, it will only fail completely if the residue detected goes over 1.0 PPM. He recommended including common pesticides used in Nevada. Additional information available in handout.

3. Approval of May 6, 2019 meeting minutes

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

4. New ILAC Nominees

Shaloo asked for general discussion of what is needed in the two new members. There are currently three labs represented, four production/cultivation represented. Almost all current members have science-based degrees. Shaloo stated two people on ILAC should not work at the same entity. It would make it difficult for them to do their job without

discussing issues related to ILAC and not violate open meeting law. She is looking for someone non-biased who will look for public health issues and not personal interest.

Alexander stated there are labs and production represented. He is the only dispensary owner on ILAC. He has tried to stay as neutral as possible and made recommendations that went against his interests. ILAC needs to be cognizant of patients having representation, and retail and cultivation should be represented.

Orser commented that one area not represented is safety, for the people that work in the industry and what they are exposed to. Patient advocates should be represented. Shaloo responded that ILAC members must be in the industry. Patient advocates or Department of Taxation employees also can't be members. The nominee with a safety background, Andre Rhodes, would not be eligible unless he is currently employed in the industry.

Darryl Johnson recommended Nikhil Kumar due to his background in microbiology. Shaloo agreed for the same reason. Discussion amongst ILAC members and Department employees regarding whether Kumar was applying to join ILAC or only nominating Trevor Low.

Shaloo asked for additional comments. Alexander stated that he believed that Andre Rhodes is employed at a dispensary in Las Vegas as general manager and is in the industry. Duke Fu confirmed that Rhodes is with Nevada Wellness Center.

Shaloo presented each applicant. Rene Adler has BS in chemical engineering and toxicology background in pesticides; currently working at Digipath Labs. Steven Markle has a BS in biology with a minor in chemistry and previous lab experience includes marijuana lab. Markle is currently with Planet 13 (dispensary, cultivation and production). Andre Rhodes is firefighter currently with Nevada Wellness Center. Trevor Low has BS in chemistry and master's degree in public health and previous lab experience with environmental science and radiochemistry. He is currently at Canalysis Laboratories. Haifei Yin has a BS in chemistry and masters degree in Environmental Chemistry. Yin has background in environmental and pharmaceutical analysis and currently works at RSR Analytical Labs.

Shaloo began with recommendations: Stephen Markle and Nikhil Kumar. If Kumar in not applying, then she recommended Trevor Low or Haifei Yin.

Ed Alexander stated that since it not recommended to have two people from same lab, is there any nominee that should be eliminated because they currently work with an ILAC member. Shaloo responded that Rene Adler because he works with Cindy Orser at Digipath.

Response received from Nikhil Kumar who would like to be considered for nomination to ILAC. Shaloo stated she would recommend Stephen Markle and Nikhil Kumar. Duke Fu recommended Nikhil Kumar and Andre Rhodes. Cindy Orser recommended Nikhil Kumar and Andre Rhodes. Craig Kovi recommended Nikhil Kumar and Stephen Markle. Darryl Johnson recommended Nikhil Kumar and Stephen Markle. Ed Alexander recommended Nikhil Kumar and Stephen Markle. Nick Malmquist recommended Nikhil Kumar and Trevor Low.

Shaloo gave count of votes: four members recommended Stephen Markle, two members recommended Andre Rhodes, seven members recommended Nikhil Kumar and one recommended Trevor Low.

Shaloo made motion to approve recommendations. Orser seconded. Department asked if there were additional names that ILAC would like to nominate. Shaloo responded that the only other eligible candidate was Haifei Yin. Shaloo asked for approval on recommendations. Approved.

5. ILAC working with Governor's Advisory Panel

Ed Alexander reached out to contacts provided by Ky Plaskon and there was some confusion between the Cannabis Control Board and the Department of Taxation in regards to who was dealing with cannabis currently. There was language added to SB533. They were not able to identify ILAC because ILAC is tasked thru statute and not thru regulations. The language added recommended inclusion of existing working groups in the Cannabis Control Board. It is being well received that ILAC will have involvement with the Cannabis Control Board as it moves forward.

Shaloo asked for discussion. Shaloo asked to see the language in SB533. Alexander responded that session closed last week and he could send a copy SB533 to the members. He will continue to work with having communications with ILAC

and Cannabis Control Board. Now the session is over, there will be more time for people to figure out the details. He will have an update at the next ILAC meeting.

Shaloo made motion to close discussion. Malmquist seconded. Discussion closed.

6. Revisions to ILAC Bylaws

Cindy Orser presented proposed changes to the Bylaws. First revision was move the oversight and reporting of ILAC to Department of Taxation (previously under Division of Public and Behavioral Health). Next revision was to update the list of marijuana and cannabis products under ILAC advisement. The existing list was marijuana, edible marijuana products and marijuana infused products. Proposed expanding to include usable marijuana flower and trim, extracts, isolates, distillates, edible marijuana products, marijuana-infused products and topicals (under Article III).

One of the duties assigned to ILAC was to determine acceptable tolerance limits of residual solvents or gas in finished medical marijuana extract. Orser was alerted by the Department this has not been done for ethanol. This is an existing assigned duty. Orser proposed recommending acceptable PPM for cannabis extract of residual pesticides in finished medical marijuana products. Also proposed to advise on appropriate application of “measurement uncertainty” on the Certificate of Analysis for cannabis products. This is a requirement for labs under ISO 17025 2017 updated guidelines. Labs are required to determine measurement uncertainty for every analyte tested in the lab and there needs to be guidance on how that will be reflected on the certificate of analysis. At Digipath, the certificate of analysis says that they have determined the measurement uncertainty for all of these analytes and the data is available if anyone wants to look at it. Orser recommended that one way to include the measurement uncertainty is to give a range of values, and not an absolute number. Orser wanted ILAC to provide oversight to recreational cannabis market in addition to medical. However, ILAC operates under statute that does not include adult use.

Shaloo commented that the language is specific in Article VII. She would rather have more general wording and not just specific things to work on. For example to work with Department of Taxation to determine list of things to discuss. In Article II Section B, there is a reference to a policy manual that ILAC is to assist in creating and updating. To her knowledge, this has not been worked on or created; proposed removal of section. If Department of Taxation does want ILAC to create a policy manual, then ILAC will need to determine what it will look like and be worked on by working group. There was discussion at last meeting regarding minimum number of members needed for a quorum (in Article VI Section B). Shaloo worried that it will be difficult to meet quorum requirements with a larger number of ILAC members. In Article VII section A, Shaloo recommended a change to show that groups may be composed of a single member. Bylaws further state that working groups can be assigned to former members of ILAC and the public. Shaloo recommended that they only be assigned to current ILAC members.

Alexander commented that the Bylaws have amended sections to include both medical and adult use regulations. He thought that it might be necessary to remove all references to 453D and potentially remove references to adult-use testing because that is not what ILAC is tasked with. He would like to know what the State thinks regarding these references in the Bylaws. If allowed to keep oversight over adult use then there needs to be consistency throughout all the articles in the Bylaws. In regards to the amount of members for a quorum, he thought that it is designed to be a majority of the members and does not think that we can choose a smaller number.

Malmquist asked in reference to working groups, if there is only one member involved and they meet with members of the public, is it not still subject to open meeting law requirements? Plaskon responded that if there is more than one committee member, then it is subject to open meeting law requirements. If there is only one committee member then it is not subject to open meeting law. Plaskon commented that maybe they should not be called working groups. Shaloo recommended keeping them called working groups since that is what the Bylaws already states.

Malmquist commented that Article VII states that work groups may take action with a majority of members present might not fit in. It further states that working groups are subject to the open meeting law requirements, which goes against what Ky Plaskon just stated. Shaloo commented that Article VII section C should be amended to say only one member present otherwise it becomes subject to open meeting law.

There was discussion of Article VIII section B in regards to State employees working with ILAC. Shaloo asked if this needed to be amended. Plaskon responded that it does not need to be amended; State employees are allowed to work with ILAC members and provide information. Shaloo responded that she thought the wording needed to be changed because

State employees cannot be ILAC members. Alexander asked if section should be removed. Orser agreed. Malmquist stated that unless state employees need it to assist ILAC. Plaskon responded no, state employees did not need it. Shaloo commented that the Department would need to give approval for any recommended changes made to the Bylaws.

Shaloo went through each recommendation. Orser's recommendations included changing all references to Department of Taxation instead of Department of Public and Behavioral Health, expanding oversight to include medical marijuana and adult-use, update list of marijuana to include all of the marijuana advertised, propose to add three sections (Shaloo recommended keeping it more general). Shaloo recommended striking policy manual section, changing quorum to four members and not a majority (needs clarification), change working groups to include one member, strike article VIII section C referring to Taxation employees.

Shaloo made motion to forward these changes to the Department of Taxation for review and approval. Malmquist asked if there would be an updated copy of the Bylaws presented before they take action. Shaloo responded that she hoped the State take the recommendations, provide updated bylaws for next meeting, and then ILAC members review at the next meeting. Alexander stated that he thought the Bylaws should be kept generic so that it does not need to be amended every time there is something new. Some of the proposed changes are too specific (for example the wording could be "all marijuana products as defined in NRS 453D or amended thereafter"). Orser responded there needed to be a balance because if it is too wide open, some things may not be addressed. Ultimately, it is up to the Department.

Shaloo made motion again to forward the recommendations to the Division. Orser seconded. Approved.

7. Tracking Department of Taxation's actions from ILAC recommendations.

Shaloo worked with Ky Plaskon on system of how the Department responds to recommendations. A working group will be assigned to an ILAC member. The member will attempt to work with experts outside of ILAC and possible help from Department of Taxation. Member will compile non-biased information and present to ILAC members. The ILAC members will present working group findings to Ky Plaskon and ILAC members one week prior to next scheduled meeting so there is time to review and be prepared to discuss. Each working group assigned will be designated as an agenda item on the next scheduled ILAC meeting. Based on the discussion, ILAC members may choose to make recommendations for the action of the Department of Taxation. The following scheduled ILAC meeting agenda will include a section designated for a representative from the Department of Taxation to discuss what action if any was taken. If there was not time for the Department to review, they will still need to address the ILAC and provide status. Then ILAC can discuss if further changes need to be made. The ILAC may then choose to close discussion, discuss further, make additional recommendations or open up as a working group again.

Shaloo made motion to close discussion. Cindy Orser seconded. Discussion closed.

8. ILAC working with Department of Agriculture

Malmquist contacted employees at Department of Agriculture via email. Response received was "I appreciate you reaching out to Department of Agriculture staff regarding ILAC involvement. However, we are currently addressing cannabis testing/action limits for pesticides internally and we are going to pass on getting involved with ILAC at this time." Department of Agriculture is not interested in getting involved with an intellectual exchange with ILAC.

Shaloo commented that if Department of Agriculture is not willing to be involved with ILAC, there is not much to be done. Shaloo asked for clarification regarding Department of Agriculture's work on pesticides and if they will share their findings. Karalin Cronkhite responded that they would share action levels for pesticides.

Alexander stated that under 453D, the Department of Agriculture has the responsibility for setting limits. It is interesting that the group tasked with this will choose to not deal with the working group also tasked with it. They do not have the option to not work with ILAC. Part of the adult use language had the responsibility for the MRLs and action limits given to the Department of Agriculture.

Shaloo stated that as long as they provide the information to Department of Taxation and it is then forwarded to ILAC then recommendations could still be made based on the information provided. It is not an ideal situation but one that can be worked through.

Orser stated that they used to work with ILAC before and used to attend meetings. Alexander commented that the situation changed when they made a budgetary proposal for funding needed to work with the Department, but that was denied. Shaloo asked if there was any reason given and Malmquist responded that he gave their full response.

Shaloo commented that there would be a working group on pesticides and would like to get a copy of the presentation that Department of Agriculture made. The presentation will be provided to the members. The Department may be able to request a presentation on proposed action limits, and a copy may be provided to ILAC members for review prior to the presentation.

Alexander mentioned that cultivation and production facilities are petitioning the Department of Agriculture in regards to allowable action limits for pesticides. The entity that has the authority to set the limits needs to be defined so that ILAC is not working on something that the Department Agriculture may be responsible for determining. Shaloo stated this is something that will be tasked to one of the work groups.

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

9. Assignment of tasks.

9.1 ILAC working with Department of Taxation to create a list of items that need to be addressed. Assigned to Nick Malmquist. Shaloo contacted Kimberly Wayman and David Witkowski to determine some of the items that will be assigned as tasks. They are looking for about ten items to address.

9.2 Determination of tolerance limits for pesticides in concentrates. Assigned to Cindy Orser. The presentation made by Department of Agriculture will be forwarded to Orser. Shaloo would like to get a toxicologist involved to ensure that human consumption levels are addressed to avoid a public health issue. Alexander commented in regards to the mention of a range of allowable uncertainty, there should be consistency in how limits are set (a range vs. a set limit). He also supported involvement of a toxicologist. Orser clarified that measurement uncertainty applied to any analytical measurement. Measurement uncertainty is something that must be determined and it is usually a very small number when dealing with numbers such as 0.5 PPM. Malmquist added that in Alexander's mention of having a range applied to other measurements as well on lab work. Orser advocated for the approach on the Certificate of Analysis to have plus or minus that incorporates actual uncertainty.

9.3 Working with Department of Agriculture to review current microbiology testing standards. Assigned to Duke Fu. This will need a different approach since the Department of Agriculture is not willing to work with ILAC. Shaloo spoke to Department of Taxation and wanted powdery mildew (how to detect) and 3M plating dilutions (inconsistencies in how labs are plating dilutions), testing of Aspergillus (determine a different correlation perhaps). Darryl Johnson asked if Kumar would be willing to work on this with Duke Fu. Plaskon stated that Fu could freely work with Kumar until he is a member of ILAC. The three tasks assigned to Duke Fu could also be split up amongst other members if it is too much for one member to work on. Alexander asked if this task should be tabled until a decision is made in regards to Kumar joining ILAC. Duke Fu wanted to have conversation with Kumar while he could, and then possibly split up these tasks later.

9.4 Working with Governor's Advisory Panel to determine ILAC's role in new advisory structure. Assigned to Ed Alexander. No additional discussion.

9.5 Determination if ethanol should be added to the residual solvent testing list. Assigned to Craig Kovi. Malmquist recommended action limits reflect level of toxicity or harmfulness considering the delivery method. Orser stated USP has solvent limits for inhalable levels versus ingested. Malmquist asked if those were for items directly inhaled or combusted and then inhaled. Orser did not know, but added that California has two categories depending on how the product is used and recommended looking at California's inhalable limits. Malmquist commented that sometimes California sets limits that are lower than larger regulatory bodies. Orser added that there are many states now (Massachusetts, Oregon, California, and Colorado for example) and there is a lot of data to compare. Shaloo added that she just listed ethanol but can be opened up to include others solvents. Alexander stated it would be helpful to get the USP list as it may potentially address all the solvents.

9.6 Determination of the standard decision rule (per ISO 17025.2017 requirements) for each mandated analysis. Assigned to Darryl Johnson. Shaloo would like to determine the decision rule that all labs must follow in method

development or measurement uncertainty. Johnson commented that an issue is trying to find the balance between the practical and compliance. Shalloo added her ISO auditor gave her a basic paper about decision rules that she will share with Johnson. Orser wrote an article about the importance of measurement uncertainty in cannabis testing and she can share that. Alexander stated that in the past working with the Department of Agriculture, there was discussion of standard suppliers. One of the challenges was there are potentially different measurements of uncertainty with the standards supplied to the labs. There had been discussion of mandating the standards being used in the labs so that when there was an issue with the test, it was known that labs were using the same standards and potentially there was not an allowable deviation from the standard manufacturer. This is potentially a complicated issue, with ILAC possibly dictating to the labs when they have their own methods. Johnson liked the recommendations and asked for comment on the initial discussion as he thought there was an issue where the state could not dictate or recommend specific brands to the labs. Alexander responded that the discussion occurred when 453D was being created and the topic was tabled. He thought that ILAC should be able to make a recommendation because from his recollection, there was a large deviation between manufacturers. Orser knows of many colleagues that have experiences with deviations in the standards they use. Shalloo thought that based on what the manufacturer claimed the percentage purity that the standard was, it will directly affect how tight the decision rule or measurement uncertainty becomes. It will force labs to use the tighter percentages because that way the decision rule will fit the means of what is standardized. There needs to be working room and tight enough limits to alleviate outlier standards. Alexander asked Orser to share the data on the deviation of cannabinoids. We are currently telling patients there is a level of certainty in products, but that may not be accurate if there is a 30% deviation.

Shalloo made motion to close discussion. Seconded by Orser. Discussion closed.

10. Public comment (no action may be taken on this item of the agenda)

Mona Lisa Samuelson made public comment in Las Vegas. She took offense that ILAC wanted to exclude the public from work groups, since there is trouble compiling non-biased information because members are mostly industry, cannot talk to each other, and will not allow subject matter experts from the public to be involved. Ed Alexander also thought there should be non-industry input. She hoped the Department of Taxation considered those. The determination of tolerance limits for pesticides and concentrates is worrisome because why are we determining new levels of pesticides in concentrates. Why would it be different from what is allowed in flower. ILAC is supposed to be determining safety levels. The public has every reason and need to be involved. Even if they don't meet the requirements to be an ILAC member, they know people and have been there since the beginning. She brought information from a leading microbiologist in regards to testing standards for cannabis (agenda item 9.3). It is important to not exclude public input.

Chao-Hsiung Tung from G3 Labs made public comment in Las Vegas. In regards to policy manual, all of the numbers issued by the department are policy. The compilation of the policy is the policy manual. If this item is removed from Bylaws, it may cause a problem for the Department. Article VIII Section B is a protection provided to committee members to compensate for the hours that committee members will work. He suggested consulting with the Attorney General's office on this matter. In regards to pesticides, pesticides levels by definition of the NRS, anything related to pesticides is domain of Department of Agriculture. He suggested caution with stepping on their toes, even if they don't want to do it, they have the final authority.

Randy Gardner with Certified Ag Lab made public comment in Carson City. He collected about thirty standards from different providers and those deviated 15%. Glenn Miller had called one of the providers and they said that the best they could do was 15%. They recalibrate and run out of standards and then have to buy new ones. The batches bought at different times aren't guaranteed to be the same. He did not know what the difficulty is. He has been in the lab business for over thirty years and a lot of big projects in California. One of the things that they do is field duplicates and often the acceptance window is 20%-30% (with dissolved metals). If he gets 30 PPM and someone else gets 20 PPM, that is considered acceptable. EPA methodologies will show relatively large RPD acceptance (there are a lot of variables). He agreed that it would be nice to get everyone doing close to the same thing.

El Alexander stated ILAC has tried to give public reasonable expectation of safety. The analytical uncertainty needs to be presented to the general public so that they are aware that there is an acceptable level of allowed deviation. He does not want the public to lose faith if there is a level of uncertainty in the product.

11. Adjournment

Meeting adjourned at 3:37 PM.