1. Working group name:

*Laboratory Working Group*

1. Individual sponsor(s):

*Darryl Johnson- Ace Analytical*

*Alec Garcia- 374 Labs*

*Sharryn Cohen - Operating Chemist, Dept. of Agriculture*

*David Grenz- Nevada Department of Agriculture*

1. Describe the recommendation:

*Proposal for Independent Testing Laboratory (ITL) Regulation*

*1. Recommendation that Independent Testing Laboratories ITLs be accredited to the ISO/IEC 17025 standard*

*1.1. Per legislation in SB329 mandate accreditation by 1/1/2019 for existing Laboratories and one year after opening for new laboratories.*

*1.2. Possibly include requirement to follow AOAC International Guidelines for Laboratories Performing Microbiological and Chemical Analyses of Food, Dietary Supplements, and Pharmaceuticals - An Aid to the Interpretation of ISO/IEC 17025:2005*

*2. For the purpose of licensing and registration, the following terms and definitions are used:*

*3. (1) “Accreditation body” is an impartial organization that operates in conformance with the International Organization for Standardization (ISO) / International Electrical Commission standard (ISO/IEC) 17011 and is a signatory to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA) for Testing.*

*4. (2) “Certificate of accreditation” means a certificate issued by an accrediting body for the ITL facility, entity or site to be registered in Nevada.*

*5. (4) “Scope of accreditation” means a document issued by the accreditation body which describes the tests or types of tests performed and materials or products tested and the methods used for testing medical cannabis or products containing medical cannabis for which the accreditation has been granted.*

*6. (5) “Independent Testing Laboratory” or “ITL” means any facility, entity, or site in that offers or performs tests of medical cannabis or products containing medical cannabis, and is free from conflict of interest with of any entity that grows, processes or dispenses cannabis.*

*7.* ***Proposed Laboratory Regulation:***

*8. Independent testing laboratories must follow licensing, accreditation, and management protocols established by the State of Nevada. As a prerequisite for licensing and incorporating the definitions above, we recommend the following regulatory language:*

*9. Laboratory operations that perform testing of Cannabis and Cannabis-derived products for public safety must be licensed by the State and accredited to the ISO/IEC 17025 standard; the assessment and accreditation process must be carried out by an accreditation body that is a signatory to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement operating in conformance with the ISO/IEC 17011 standard.*

***2. Recommendation that ITLs be audited and accredited by NDA and individual cannabis analyst be certified by NDA. Below is a breakout of potential accreditation criteria. NDA will develop a complete accreditation protocol by July 1st Existing ITL’s to receive NDA accreditation prior to January 1st 2018.***

*2.1. The NDA Cannabis Laboratory accreditation program would provide more specific quality standards that labs must operate under and be enforced through more frequent and thorough audits than provided for by ISO CABs.*

*2.1.1. Quality standards shall be established by NDA with the input and advisement of ITLs*

*2.1.1.1. Requirements for quality standards would be establish for both general laboratory requirements as well for each category of methods for each test. (e.g. agar based testing has different QA/QC needs than rehydratable film based methods like 3M Petrifilm or Hardy’s Compact Dry)*

*2.1.2. NDA would also set standardized result reporting requirements*

*2.2. Labs would have a scheduled annual audit by NDA that would include:*

*2.2.1. Record review*

*2.2.2. Laboratory compliance audit*

*2.2.3. On-site verification of individual analysts’ abilities to execute test methods*

*2.2.4. On-site verification of sampling procedure*

*2.3. Labs would be subject to unannounced check audits*

*2.4. Audit procedures and requirements would be set by NDA with input and advisement of ICLs*

*2.5. Cannabis lab analyst would be certified on an individual basis, per method.*

*2.5.1. Lab director would certify training on newly hired analyst*

*2.5.2. New analyst would need to satisfactorily participate in PT and on-site verification before gaining full certification*

*2.5.3. Lab analyst could lose certification by failing PT or on-site. Typically, two strike system unless clear inability is demonstrated during on-site. Certification can only be regained through the event it was lost (i.e. if you lose certification due to failed PT, you must pass PT to regain certification)*

***3. Recommendation the ITLs be required to participate in Proficiency Testing and NDA Round Robin events.***

*3.1. Continue the use of current PT provider with NDA provided Round Robin testing event*

*3.2. Goal is to transition to PT event(s) that meets the following:*

*3.2.1. All labs have contemporaneous participation in the same event*

*3.2.2. PT samples are in matched matrix so that laboratory sample preparation and extraction can be assessed*

*3.2.3. PT participation moves from per laboratory basis to per analyst basis*

*3.2.3.1. Cost is an important consideration in the per analyst consideration, can explore feasibility with NDA Round Robin by analyst*

*3.3. Possible transition from existing PT structure to NDA providing proficiency testing using cannabis matrix with sample preparation methods polished through round robin events once NDA is ready.*

*4.* ***Recommendation that NDA collect and test surveillance samples***

*4.1. NDA would randomly collect surveillance samples of lots of product recently sampled by laboratories.*

*4.2. NDA would test these samples and compare results to ITL results*

*4.3. Significant discrepancies would be investigated to determine a cause.*

*4.4. Goal is to prevent sample tampering by producers and prevent inadvertent or fraudulently inaccurate test results from ITLs. Additionally, NDA’s testing would generate data that to help revise test requirements and limits in addition to a statistically significant sample size.*

*5.* ***Recommendation that a tiered enforcement system be codified***

*5.1. Goal is to give laboratory compliance enforcement “teeth” so that repeated violations or exceptionally egregious violations result in actionable enforcement against offending laboratories.*

*5.2. Minor or repeated violations by labs would be sent a warning letter or administered fines (This is public record and maybe require if be posted online)*

*5.3. Continued violation or egregious violations (e.g. intentional fraud) would result in loss or suspension of license (important choice between “MAY” or “SHALL” suspend or revoke license…)*

*5.4. Some repeat or serious violations or failure could just result in only a particular analyst being de-certified for some or all testing, or the lab losing certification for a particular method until satisfactory corrective action is submitted and approved.*

1. Which guiding principle(s) does this recommendation support?

*Guiding Principle 1 - Promote the health, safety, and well-being of Nevada’s communities*

*Guiding Principle 2 - Be responsive to the needs and issues of consumers, non-consumers, local governments and the industry*

*Guiding Principle 7 - Take action that is faithful to the text of Question 2*

1. What provision(s) of Question 2 does this recommendation apply to?

*Sec 2 (c) – Cultivating, manufacturing, testing, transporting, and selling marijuana will be strictly controlled through state licensing and regulations*

*Sec 2 (g) – Marijuana sold in the state will be tested and labeled*

*Sec 5 (f) – Requirements for the testing and labeling of marijuana and marijuana products sold by marijuana establishments including a numerical indication of potency based on the ration of THC to the weight of a product intended for oral consumption*

1. What issue(s) does the recommendation resolve?

*Addresses the requirements for quality lab results which promote the health and safety of the consumer*

1. Was there dissent in the group regarding this recommendation? If yes, please provide a summary of the dissenting opinion regarding the recommendation.

*No dissent*

1. What action(s) will be necessary to adopt the recommendation? Will statute, policy, regulations, etc. need to be addressed?

*Regulations from the Medical Marijuana program will need to be amended*

1. Additional information (cost of implementation, priority according to the recommendations, etc).

*A consolidated budget has been submitted for the anticipated services that will be provided by the Department of Agriculture.*

*This recommendation will require Laboratory’s to become ISO 17025 accredited. This process typically involves considerable man hours by the laboratory to implement and $10,000+ for the actual accreditation by an independent third party accreditor. The Dept. of Agriculture will also incur additional costs if they will implement the round-robin proficiency testing in the future.*