Proposed Changes to NCCR Regulation 5

LICENSING, BACKGROUND CHECKS, AND REGISTRATION CARDS

New
~~Deleted~~

5.075 Authority of Board and Executive Director relating to inspections and investigations, summoning of witnesses and issuance of subpoenas, administration of oaths and administration of provisions of chapter.

1. Submission of an application for a license for a cannabis establishment constitutes permission for entry to and reasonable inspection of the cannabis establishment by the Board and Board Agents, with or without notice. An inspector conducting an inspection pursuant to this section does not need to be accompanied during the inspection.
2. The Executive Director may, upon receipt of a complaint against a cannabis establishment, except for a complaint concerning the cost of services, a complaint concerning the efficacy of cannabis or a complaint related to consumer service issues, conduct an investigation during the operating hours of the cannabis establishment, with or without notice, into the premises, facilities, qualifications of personnel, methods of operation, policies, procedures and records of that cannabis establishment or any other cannabis establishment which may have information pertinent to the complaint.
3. Board Agents may enter and inspect any building or premises at any time, with or without notice, to:
    (a) Secure compliance with any provision of the NCCR or Title 56 of NRS;
    (b) Prevent a violation of any provision of the NCCR or Title 56 of NRS; or
    (c) Conduct an unannounced inspection of a cannabis establishment in response to an allegation of noncompliance with the NCCR or Title 56 of NRS.
4. The Board may:
    (a) Summon witnesses to appear and testify on any subject material to its responsibilities
    under this chapter or Title 56 of NRS. No property owner and no officer, director, superintendent, manager or agent of any company or corporation, whose property is wholly in one county, shall be required to appear, without his or her consent, at a place other than the county seat or at the nearest town to his or her place of residence or the principal place of business of such company or corporation. Such summons may be served by personal service by the Executive Director or his or her agent or by the sheriff of the county.
    (b) Except as otherwise provided in this paragraph, issue subpoenas to compel the attendance of witnesses and the production of books and papers and may seek to enforce the subpoenas by petition to any court of competent jurisdiction in the manner provided by law. The Board will not issue a subpoena to compel the production of books and papers that contain individually identifiable health information.
5. Any member of the Board, the Executive Director or any officer of the Board designated by the Board or Executive Director may administer oaths to witnesses.
6. The Board and Board Agents may:

(a) Inspect and examine all premises wherein cannabis is manufactured, sold or distributed;
(b) Inspect all equipment and supplies in, upon or about such premises;
(c) Summarily seize and remove from such premises any cannabis or cannabis products and impound any equipment, supplies, documents or records for the purpose of examination and inspection;
(d) Demand access to and inspect, examine, photocopy and audit all papers, books and records of any applicant or licensee, on his or her premises, or elsewhere as practicable, and in the presence of the applicant or licensee, or his or her agent, relating to the gross income produced by any cannabis establishment, and require verification of income, and all other matters affecting the enforcement of the policy or any of the provisions of this chapter or any chapter of Title 56 of NRS; and
(e) Demand access to and inspect, examine, photocopy and audit all papers, books and records of any affiliate of a licensee whom the Board knows or reasonably suspects is involved in the financing, operation or management of the licensee. The inspection, examination, photocopying and audit may take place on the premises of the affiliate or another location, as practicable, and in the presence of the affiliate or its agent.

7. Board Agents will enter and inspect ~~at least annually~~, with or without notice, each building or the premises of a cannabis establishment to ensure compliance with the provisions of this chapter and Title 56 of NRS. ***All cannabis establishments may be inspected at least annually except that cannabis independent testing laboratories may be inspected at least biennially, with interim follow-up activities at least annually.*** Nothing in this subsection shall be construed to prohibit an appropriate local administrative authority from conducting an inspection of the facilities or operations of a cannabis establishment as provided by the ordinance of a local government.
8. Board Agents will enter and inspect, with or without notice, any building or premises operated by a cannabis establishment within 72 hours after the Board is notified that the cannabis establishment is operating without a license for the cannabis establishment.
9. Board Agents will inspect the medical cannabis establishment and the cannabis establishment of a dual licensee at the same time using the same inspection team to ensure consistency and efficiency. Board Agents will conduct such an inspection in a manner which is not unduly burdensome for the dual licensee.
10 The Board or Board Agents may consult with any person or entity, as needed, in any of the
Board's audits, inspections, and/or investigations. This includes, but is not limited to, allowing
such persons or staff from said entities to accompany Board Agents during inspections, and/or investigations.
11. The Board will administer the provisions of the NCCR and Title 56 of NRS for the protection of the public and in the public interest in accordance with the policy of this State.

Proposed Changes to NCCR Regulation 7

CANNABIS SALES FACILITY

New
~~Deleted~~

7.035 Storage and location of products; disclosure of cannabis testing facility performing quality assurance tests upon request of consumer; approved sources of products for sale; maintenance and availability of certificate of analysis; exemption for industrial hemp.

1. A cannabis sales facility must store all usable cannabis, concentrated cannabis and cannabis products behind a counter or other barrier to ensure a consumer does not have direct access to the cannabis, concentrated cannabis or cannabis products.

2. Upon the request of a consumer, a cannabis sales facility must disclose the name of the cannabis testing facility which performed the required quality assurance tests for the cannabis sales facility and ***provide a copy of*** the corresponding certificate of analysis ***to the consumer.***

3. A cannabis sales facility may only sell usable cannabis obtained from a cannabis cultivation facility in this State.

4. Except as otherwise provided in subsection 6, a cannabis sales facility may only sell concentrated cannabis and cannabis products obtained from a cannabis product manufacturing facility in this State.

5. ~~Except as otherwise provided in subsection 6, a~~ ***A*** cannabis sales facility may not sell a product other than usable cannabis, concentrated cannabis or cannabis products which contain any level of THC or CBD without the approval of the appropriate Board Agent. Each cannabis sales facility shall maintain a file which contains a certificate of analysis for any such approved product at the cannabis sales facility and shall make the file available for review upon request.

6. The provisions of subsection 4 does not apply to industrial hemp, as defined in NRS 557.040, which is certified and registered with the State Department of Agriculture.

Proposed Changes to NCCR Regulation 11

CANNABIS INDEPENDENT TESTING LABORATORY

New
~~Deleted~~

11.010 Employment, qualifications and duties of scientific director; inspection of testing laboratory upon appointment of new director.

1. Each cannabis independent testing laboratory must employ a scientific director who must *reside in Nevada, and shall be* responsible for:

(a) Establishing and maintaining a quality control and quality assurance program that ensures the quality of the cannabis independent testing laboratory's services, and that is capable of identifying any failure of quality when it occurs;

(b) Ensuring safety and hazardous substance control in the laboratory;

~~(b)~~ *(c)* Supervising all staff of the cannabis independent testing laboratory; ~~and~~

(d) Ensuring laboratory employees meet or exceed the requirements for education and experience as provided in ASTM D8347 21a: "Standard Guide for Requirements for Analytical Laboratory Related Professions Within the Cannabis and Hemp Industries";

(e) Reviewing all new technical policies and procedures, as well as substantial changes to existing technical policies and procedures, prior to implementation. These reviews must be documented and may not be delegated;

(f) Ensuring technical policies and procedures are reviewed at least biennially thereafter, with documentation of this review. This review may be delegated to a knowledgeable person, and must ensure technical policies and procedures are complete, current, and scientifically valid and relevant; and

~~(c)~~ *(g)* Actively participating in the operation of the cannabis independent testing laboratory to the extent necessary to assure compliance with the NCCRs and Title 56 of NRS.

2. The scientific director of a cannabis independent testing laboratory must have earned:

(a) A doctorate degree in science from an accredited college or university and have at least 2 years of post-degree laboratory experience;

(b) A master's degree in science from an accredited college or university and have at least 4 years of post-degree laboratory experience; or

(c) A bachelor's degree in science from an accredited college or university and have at least 6 years of post-degree laboratory experience.

3. If a scientific director is no longer employed by a cannabis independent testing laboratory, the cannabis independent testing laboratory shall not be permitted to conduct any testing. An interim director that meets the minimum qualifications may be appointed for no more than ~~90~~ *60* days *unless an extension is granted by the appropriate board agent*.

4. A cannabis independent testing laboratory shall immediately inform the Board upon the appointment of a new scientific director *or interim director.*

5. A scientific director shall be available to the personnel of a testing laboratory, in person or by telephonic or other electronic means, for any necessary consultation.

6. The scientific director must be on the premises of the testing laboratory at least ~~5~~ *10* workdays each month. *If circumstances temporarily prevent the scientific director from*

meeting this requirement, the laboratory shall appoint an interim director who meets the minimum qualifications for the necessary length of time, not to exceed 60 days.
(Amended: 8/2021)

11.015 ~~Requirements for testing laboratory to handle, test or analyze cannabis.~~ ***Cannabis Independent Testing Laboratory- Safety Program***
A cannabis independent testing laboratory shall implement a safety program which meets all applicable requirements of Laboratory Safety Guidance published by the Occupational Safety and Health Administration of the United States Department of Labor.

11.020 Agreement to become accredited within 1 year after licensure; provision of annual inspection report to Board; inspection by accrediting organization is not substitute for inspection by Board.

1. Each cannabis independent testing laboratory must agree to become accredited pursuant to standard ISO/IEC 17025 of the International Organization for Standardization within 1 year after licensure. The scope of accreditation must cover all analytes pursuant to NCCR 11.050.
2. Each cannabis independent testing laboratory that claims to be accredited must provide the Board with copies of each annual inspection report from the accrediting organization, including, without limitation, any deficiencies identified in and any corrections made in response to the report. ***The final inspection report must be provided to the Board within 2 business days of receipt.***
3. Inspection by an accrediting organization is not a substitute for inspection by the Board or Board Agents.

11.025 Adherence to general laboratory standards, practices, procedures and programs; inspection by Board or authorized third party; adoption of publications by reference.

1. Each cannabis independent testing laboratory must:
   (a) Follow the most current version of the Cannabis Inflorescence: Standards of Identity, Analysis, and Quality Control monograph published by the American Herbal Pharmacopoeia.
   (b) Follow the Recommendations for Regulators — Cannabis Operations published by the American Herbal Products Association.
   (c) Be accredited pursuant to standard ISO/IEC 17025 of the International Organization for Standardization by an impartial organization that operates in conformance with standard ISO/IEC 17011 of the International Organization for Standardization and is a signatory to the Mutual Recognition Arrangement of the International Laboratory Accreditation Cooperation.
   (d) Follow the Guidelines for Laboratories Performing Microbiological and Chemical Analyses of Food, Dietary Supplements, and Pharmaceuticals — An Aid to the Interpretation of ISO/IEC 17025:2005 (2015) published by AOAC International.
2. Each cannabis independent testing laboratory shall demonstrate proficiency in testing samples using the analytical methods approved by the Board or the appropriate Board Agent by participating in the approved proficiency testing program for all required analytes within 6 months after the date upon which the cannabis independent testing laboratory is issued a license.

3. The Board may require an independent third party to inspect and/or monitor the analytical testing methodologies and technical competence of the cannabis independent testing laboratory on an ongoing basis.

4. Each cannabis independent testing laboratory shall:

(a) Adopt and follow minimum good laboratory practices which must, at a minimum, satisfy the OECD Series on Principles of Good Laboratory Practice (GLP) and Compliance Monitoring published by the Organisation for Economic Co-operation and Development.

(b) Become certified by the International Organization for Standardization and agree to have the inspections and reports of the International Organization for Standardization made available to the Board or Board Agents.

(c) Maintain internal standard operating procedures. A copy of these procedures shall be provided promptly to the Board or Board Agents upon request.

(d) Maintain a quality control and quality assurance program.

5. The Board Agents or an independent third party authorized by the Board may conduct an inspection of the practices, procedures and programs adopted, followed and maintained pursuant to subsection 4 and inspect all records of the cannabis independent testing laboratory.

6. A cannabis independent testing laboratory must use, when available, testing methods that have undergone validation by the Official Methods of Analysis of AOAC International, the Performance Tested Methods Program of the Research Institute of AOAC International, the Bacteriological Analytical Manual of the Food and Drug Administration, the International Organization for Standardization, the United States Pharmacopeia, the Microbiology Laboratory Guidebook of the Food Safety and Inspection Service of the United States Department of Agriculture, ***the Elemental Analysis Manual for Food and Related Products of the Food and Drug Administrations, the Pesticide Analytical Manual of the Food and Drug Administration,*** or an equivalent third-party validation study approved by the Board. If no such testing method is available, a cannabis independent testing laboratory may use an alternative testing method or a testing method developed by the cannabis independent testing laboratory upon demonstrating the validity of the testing method to and receiving the approval of the Board.

7. All quality assurance tests pursuant to NCCR 11.050 ***shall meet the AOAC Cannabis SMPRs for the adopted reference method, and*** shall be validated or verified ***according to, as applicable:*** ~~by the cannabis independent testing laboratory observing the guidelines of the most recent version of standard~~

(a) ASTM D8282: "Standard Practice for Laboratory Test Method Validation and Method Development", published by the American Society for Testing and Materials (ASTM) and available at **www.astm.org**. ~~, or any subsequent standard as approved by the appropriate Board Agent.~~

(b) AOAC - Appendix J: Guidelines for Validation of Microbiological Methods for Food and Environmental Surfaces, 2012, which is available at http://www.eoma.aoac.org/app_j.pdf;

(c) AOAC - Appendix K: Guidelines for Dietary Supplements and Botanicals, 2013, which is available at http://www.eoma.aoac.org/app_k.pdf; ~~***or***~~

(d) Standard ISO/IEC 16140-3 "Microbiology of the Food Chain- Method Validation-Part 3: Protocol for the verification of reference methods and validated alternative methods in a single laboratory", published by the International Organization for Standardization. A copy of that publication may be obtained from

the American National Standards Institute at the Internet address: https://webstore.ansi.org/Standards/ISO/isofdis161402020-2424064; or

(e) Any subsequent standard as approved by the appropriate Board agent.

8. The Board hereby adopts by reference:

(a) The Cannabis Inflorescence: Standards of Identity, Analysis, and Quality Control monograph published by the American Herbal Pharmacopoeia. A copy of that publication may be obtained from the American Herbal Pharmacopoeia, P.O. Box 66809, Scotts Valley, California 95067, or at the Internet address **http://www.herbal-ahp.org/;**

(b) The OECD Series on Principles of Good Laboratory Practice (GLP) and Compliance Monitoring published by the Organisation for Economic Co-operation and Development. A copy of that publication may be obtained free of charge from the Organisation for Economic Co-operation and Development at the Internet address **http://www.oecd.org/env/ehs/testing/oecdseriesonprinciplesofgoodlaboratorypracticeglpandcompliancemonitoring.htm;**

(c) Standard ISO/IEC 17025 published by the International Organization for Standardization. A copy of that publication may be obtained from the American National Standards Institute at the Internet address ~~https://webstore.ansi.org/RecordDetail.aspx?sku=ISO%2fIEC+17025%3a2005~~ ***https://webstore.ansi.org/Standards/ISO/isoiec170252017;***

(d) The Guidelines for Laboratories Performing Microbiological and Chemical Analyses of Food, Dietary Supplements, and Pharmaceuticals — An Aid to the Interpretation of ISO/IEC 17025:20~~05~~***17A*** (20~~15~~***18***) published by AOAC International. A copy of that publication may be obtained from AOAC International at the Internet address **https://www.aoac.org/aoac-accreditation-guidelines-for-laboratories-alacc/;**

(e) ASTM D8282: "Standard Practice for Laboratory Test Method Validation and Method Development", published by the American Society for Testing and Materials (ASTM) and available at www.astm.org;

(f) ASTM D8347 21a: "Standard Guide for Requirements for Analytical Laboratory Related Professions Within the Cannabis and Hemp Industries", published by the American Society for Testing and Materials (ASTM) and available at www.astm.org;

(g) AOAC - Appendix J: Guidelines for Validation of Microbiological Methods for Food and Environmental Surfaces, 2012, which is available at http://www.eoma.aoac.org/app_j.pdf;

(h) ASTM D8244-20: "Standard Guide for Analytical Operations Supporting the Cannabis Industry", published by the American Society for Testing and Materials (ASTM) and available at www.astm.org;

(i) WHO Expert Committee on Specifications for Pharmaceutical Preparations: fifty-fourth report. Geneva: World Health Organization; 2020 (WHO technical report series; no. 1025). Annex 4: Good Chromatography Practices, available at https://www.who.int/publications/m/item/trs-1025-annex-4-gmp;

(j) The OECD Guidance Document for Single Laboratory Validation of Quantitative Analytical Methods - Guidance Used in Support of Pre-And-Post-Registration Data Requirements for Plant Protection and Biocidal Products published by the Organisation for Economic Co-operation and Development. A copy of that publication may be obtained free of charge from the Organisation for Economic Co-operation and Development at the Internet address:

https://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=ENV/JM/MONO(2014)20&doclanguage=en; and
(k) AOAC - Appendix K: Guidelines for Dietary Supplements and Botanicals, 2013, which is available at http://www.eoma.aoac.org/app_k.pdf.

11.030 Establishment of policies for adequate chain of custody and requirements for samples of products provided to testing laboratory. Each cannabis independent testing laboratory must establish ***and follow*** policies for an adequate chain of custody and sample identification requirements for samples of products provided to the cannabis independent testing laboratory for testing or research purposes, including, without limitation, policies and requirements for:

1. Issuing instructions for the minimum sample and storage requirements;
2. Ensuring positive identification of the cannabis or cannabis product by verifying the accuracy of the seed-to-sale tracking information present on the source package immediately prior to sample collection.
~~2.~~ ***3.*** Documenting the condition of the external package and integrity seals utilized to prevent contamination of, or tampering with, the sample;
~~3.~~ ***4.*** Documenting the condition and amount of the sample ~~provided~~ at the time of ***collection or*** receipt;
~~4.~~ ***5.*** Documentation of any pertinent sample identifiers, including but not limited to product type, product name, strain name, seed-to-sale tracking number, batch/lot number and production run number as appropriate;
~~5.~~ ***6.*** Documenting all persons handling the original samples, aliquots and extracts;
~~6.~~ ***7.*** Providing adequate identification on sample containers throughout all phases of testing, including, but not limited to aliquots, dilutions, tubes, slides, culture plates, extracts, data files, images, and other secondary samples created during the processing or testing of a sample. The sample identifier(s) on any sample container must be indelible, legible, and able to withstand all stages of processing and conditions of storage;
~~7.~~ ***8.*** Documenting all transfers of samples, aliquots and extracts referred to another cannabis independent testing laboratory for additional testing or whenever requested by a client;
~~8.~~ ***9.*** Maintaining a current list of authorized cannabis establishment agents and restricting entry
to the laboratory to only those authorized;
~~9.~~ ***10.*** Securing the cannabis independent testing laboratory during nonworking hours;
~~10.~~ ***11.*** Securing short- and long-term storage areas when not in use;
~~11.~~ ***12.*** Utilizing a secured area to log-in and aliquot samples;
~~12.~~ ***13.*** Ensuring samples are stored appropriately; and
~~13.~~ ***14.*** Documenting the disposal of samples, aliquots and extracts.

***

11.045 Limited testing for research and development purposes.

1. A cannabis cultivation facility or a cannabis production facility may conduct operations and request limited laboratory testing by a cannabis independent testing laboratory for research and development purposes.

2. A cannabis cultivation facility or cannabis production facility described in subsection 1 shall:

(a) Notify the appropriate Board Agent of its intent to conduct research and development on a form prescribed by the Board by electronic mail before sending a sample to a cannabis independent testing laboratory;

(b) Receive approval from the appropriate Board Agent for the requested research and development studies.

(c) Quarantine each batch, lot or production run in a separate quarantine area and label each batch, lot or production run with a distinctive label containing "R&D QUARANTINE" as a header and footer in ***at least*** 20-point white font and a red background;

(d) Account for all cannabis subject to quarantine pursuant to paragraph (b) in the seed-to-sale tracking system;

(e) Limit all research and development operations to clearly segregated and designated areas or rooms marked "R&D CULTIVATION AREA" or "R&D PRODUCTION AREA" on ***at least*** 8 1/2 by 11-inch signs with a red background and white lettering, posted at the entrance to the area or room and along the walls of the area or room, with a minimum of one sign for every 300 square feet of the area or room; and

(f) Perform research and development operations in a grow room only if the plants used for such operations are designated and separated from other plants.

3. A cannabis cultivation facility or cannabis production facility operating as described in subsection 1 may request limited testing protocols from a cannabis independent testing laboratory for research and development purposes. A cannabis independent testing laboratory shall not perform any laboratory tests on research and development samples which were not specifically indicated as part of the approved study.

a. The Board may draft a policy allowing for licensees to apply for a variance on testing requirements under certain conditions.

4. A cannabis independent testing laboratory that performs testing for a cannabis cultivation facility or cannabis production facility described in subsection 1 shall report the results of the testing to the cannabis establishment and to the Board ~~by electronic mail~~ ***in a manner prescribed by the Board***. The cannabis independent testing laboratory shall clearly mark the test results with "R&D TESTING ONLY -- NOT FOR RESALE" on the top of each page of the report in 20-point white font and a red background.

5. A batch, lot or production run produced for research and development purposes pursuant to this section which fails quality assurance testing need not be destroyed.

6. A batch, lot or production run originally produced for research and development purposes pursuant to this section may not be sold to a cannabis sales facility until the batch, lot or production run has undergone and passed all testing required by NCCR 6.100. ***The cannabis independent testing laboratory who performed the limited testing on a lot or production run in accordance with subsection 3 must be the same laboratory who performs the final testing of that lot or production run.***

7. A batch, lot or production run which fails quality assurance testing under research and development provisions may not be remediated without Board approval.

11.050 Required quality assurance tests; submission of wet cannabis for testing.

1. Each cannabis independent testing laboratory must use the sampling protocols and the general body of required quality assurance tests for usable cannabis, as received, concentrated cannabis and cannabis products set forth in this section. Such tests may include moisture content, potency analysis, foreign matter inspection, microbial screening, pesticide and other chemical residue and metals screening and residual solvents levels. A cannabis independent testing laboratory may request permission from the appropriate Board Agent to obtain additional sample material for the purposes of completing required quality assurance tests but may not use such material for the purposes of resampling or repeating quality assurance tests. A cannabis independent testing laboratory may retrieve samples from the premises of another cannabis establishment and transport the samples directly to the cannabis independent testing laboratory. A cannabis independent testing laboratory transporting samples may make multiple stops if:

(a) Each stop is for the sole purpose of retrieving a sample from a cannabis establishment; and

(b) All samples remain secured at all times.

2. The tests required pursuant to subsection 1 by a cannabis independent testing laboratory are as follows:

<<Testing Table here>>

3. A sample of usable cannabis must be at least ~~10~~ 20grams. A sample of a production run must be the lesser of 1 percent of the total product weight of the production run or 25 units of product, but not less than 5 grams of the production run. Before testing, all samples must be homogenized by the testing laboratory using a homogenization process which has been approved by the appropriate Board Agent and in a manner that prevents contamination of test samples or analytical portions.

4. The analytical portion that is used for the purposes of ~~any~~ ***each*** microbial test must be a minimum of one gram, unless otherwise approved by the Board.

5. A cannabis establishment shall not submit wet cannabis to a cannabis independent testing laboratory for testing unless the wet cannabis is destined for extraction and weighed within 2 hours after harvest. The plant must not undergo any further processing, including, without limitation, drying the plant and subsequently selling separately the cannabis bud and cannabis trim from the plant, before being weighed.

6. As used in this section, "as received" means the unaltered state in which a sample was collected, without any processing or conditioning, which accounts for all mass, including moisture content. A cannabis independent testing laboratory shall not report the results of usable cannabis on a dry weight basis.

7. A cannabis independent testing laboratory shall provide the final certificate of analysis to the Board and to the cannabis establishment from which the sample was collected within 2 business days after obtaining the results.

8. The certificate of analysis shall include a photo of the product, as received.

9. The certificate of analysis is valid for 1 year from the test date for cannabis and cannabis products unless a shorter shelf-life is specified by the board.

11.053 Requirements for instrument calibration and quality control.

1. A cannabis independent testing laboratory shall ensure that all instruments and equipment used for testing cannabis and cannabis products are:

(a) Set up, tuned, and calibrated according to the laboratory's validated methods, and

(b) Applicable for the analytes to be tested.

2. A cannabis independent testing laboratory meet the following requirements related to calibration and standards:

(a) A minimum of:

(1) Five standards shall be used for an average response factor or for a linear model.

(2) Six standards shall be used for a quadratic model.

(b) The calibration curve must not be forced through the origin.

(c) At least one calibration standard shall be at or below the limit of quantitation.

(d) One standard for each analyte shall be at or near the State action level, where State action levels are applicable.

(e) One calibration standard must be a mid-level standard.

(f) A minimum of one calibration standard must be between the mid-level standard and highest-level standard.

(g) The correlation coefficient (r) for standard concentration to instrument response is greater than or equal to 0.995.

3. A cannabis independent testing laboratory may not:

(a) Remove data points from within a calibration range while still retaining the extreme ends of the calibration range.

(b) Use non-linear calibrations to compensate for detector saturation or to avoid proper instrument maintenance.

(c) Apply a calibration fit which was not validated for that method.

4. For test methods using internal standards for calibration, the following requirements must be met:

(a) For chromatographic methods, internal standards must:

(1) Have retention times similar to the analytes being tested for; and

(2) Not interfere with any of the analytes; and

(3) Have similar chemical properties as the analytes being tested for

(b) For heavy metals testing, the internal standards must:

(1) Be appropriate for the analyte and the instrumental method used; and

(2) Not interfere with any of the analytes

5. A cannabis independent testing laboratory shall implement and adhere to the following quality control (QC) practices:

(a) Initial calibration verification:

(1) Must be prepared from a different source than that from which the initial calibration standards were obtained or from a different lot of standards from the same source.

(2) Must be run at the beginning of the analytical sequence.

(b) Continuing calibration verification:

(1) Must be prepared from the same source calibration standard used to prepare the calibration curve.

(2) Shall be included in an analytical batch at the following frequency, at minimum:

(I) After every 20 injections and
(II) At the end of the analytical sequence.

(c) The following acceptance criteria shall not be exceeded for any quality control samples in an analytical batch, including calibration verification samples:

(1) For potency testing, 80% - 120% recovery of the true value;
(2) For testing for terpenes, pesticides, herbicides, plant growth regulators, 75% - 125% recovery of the true value;
(3) For testing for residual solvents, 75% - 125% recovery of the true value; and
(4) For heavy metals testing, 90% - 110% recovery of the true value;
(5) More stringent criteria shall be used where required by a specific analytical method.

(d) An independent testing laboratory may not report sample results which are associated with QC that has exceeded the tolerance limits specified in this section.

11.060 Performance of testing to verify homogeneity of potency of edible cannabis products.

1. Except as otherwise provided in subsection 2, a cannabis independent testing laboratory shall perform testing to verify the homogeneity of the potency of an edible cannabis product by testing multiple samples from a single production run.
2. A cannabis independent testing laboratory that tests an edible cannabis product which has previously had the homogeneity of the potency of the edible cannabis product verified by a cannabis independent testing laboratory and which has not undergone a change in recipe may verify the homogeneity of the edible cannabis product by testing one or more single units or servings from a production run of the edible cannabis product.
3. The cannabis independent testing laboratory will verify the homogeneity of the potency of the edible cannabis product only if:

(a) The concentration of THC ~~and weight~~ of each sample is within 15 percent above or below the intended concentration of THC ~~and weight~~; and

(b) The concentration of THC of each sample must not exceed the THC limits for sale in NCCR 9.045 section 2.

~~(b) No combination of samples which comprise 10 percent or less of the cannabis product contain 20 percent or more of the total THC in the cannabis product.~~

11.065 Use of approved pesticides by cannabis establishment; performance of pesticide residue analysis by testing laboratory.

1. A cannabis establishment shall only use a pesticide in the cultivation or production of cannabis or cannabis products if the pesticide appears on the list of pesticides published by the State Department of Agriculture pursuant to NRS 586.550.
2. When performing pesticide residue analysis pursuant to NCCR 11.050, a cannabis independent testing laboratory shall analyze for the pesticides which occur on the list of pesticides published by the State Department of Agriculture pursuant to NRS 586.550 at the detection levels specified by the State Department of Agriculture and for any other substances required by the Board. If:

(a) A pesticide which occurs on the list of pesticides published by the State Department of Agriculture pursuant to NRS 586.550 is detected at a level which exceeds the level specified by the State Department of Agriculture; or

(b) A pesticide which does not occur on the list of pesticides published by the State Department of Agriculture pursuant to NRS 586.550 is detected in any amount which is

positively ~~verified~~ ***identified by the cannabis independent testing laboratory***, the pesticide residue analysis is failed.

11.070 Testing: Selection of representative samples and random samples; segregation period for entire lot; duties of testing laboratory; disposal of lot if sample fails test; release of lot if sample passes test; filing of electronic copy of certificate of analysis for tests performed by testing laboratory; grounds for disciplinary action for failure to comply.

1. Immediately before packaging:

(a) Usable cannabis for sale to a cannabis sales facility, cannabis production facility or another cannabis cultivation facility, a cannabis cultivation facility shall segregate all harvested cannabis into homogenized lots of flower and trim, respectively, and allow a cannabis independent testing laboratory to select a homogenous representative sample for testing from each lot the cannabis cultivation facility has segregated. The cannabis testing laboratory which performs the test must collect the samples. If the cannabis cultivation facility has segregated the lot of harvested cannabis into packages or container sizes smaller than the entire lot, the cannabis cultivation facility must present all packages comprising the lot to the cannabis independent testing laboratory, and the testing laboratory must sample and test each package containing harvested cannabis from the lot.

(b) Concentrated cannabis or cannabis products, a cannabis production facility shall ***segregate concentrated cannabis or cannabis products into production runs and*** allow a cannabis independent testing laboratory to ***randomly*** select a ~~random~~ ***homogeneous representative*** sample ***for testing*** from each ~~lot or~~ production run ~~for testing by the cannabis independent testing laboratory~~. The cannabis independent testing laboratory performing the testing must collect the samples. ***If a production run of concentrated cannabis or cannabis products is stored in multiple containers, the cannabis production facility must present all containers comprising the production run to the cannabis independent testing laboratory, and the testing laboratory must sample and test each container which comprises the production run.***

(c) The cannabis independent testing laboratory must follow aseptic sampling procedures in accordance with ASTM D8334 Standard Practice for Sampling of Cannabis/Hemp Post-Harvest Batches for Laboratory Analyses when collecting samples for testing. Sampling equipment such as tongs or calipers must be used for sampling cannabis and cannabis products. The sampling equipment must be aseptically cleaned between the sampling of different lots or production runs (or more times, if determined necessary by the sample collector) using ethanol, 70 % or equivalent.

(d) The sample collector will wear new aseptic gloves before sampling a different lot or production run (or more frequently, if determined necessary by the sample collector).

(e) The sample aliquot(s) shall be taken from multiple areas of each container or tray (i.e., the upper, middle, and lower sections), such that the samples taken are representative of the entire lot or production run. In the case of large bales or bags, samples must be taken from a depth of at least 10 cm [3.9 in.].

(f) The sample collector shall take extreme care if sampling from multiple sites in one day to ensure contaminants (such as microorganisms, insects, residues, etc.), pathogens, or other organisms or substances are not transferred between facilities.

(g) The field balance used for sampling must meet the following requirements, at minimum:

(1) Must be capable of weighing 65 % of specimen weight or 0.1 g [0.000220462 lb], whichever is less.

(2) Must be calibrated to include the range of specimen weight.

(~~c~~ *h*) The cannabis independent testing laboratory selecting a sample shall seal the sample within the package to ensure sample integrity. The sample shall be collected in a tamper resistant package or in a package that is sealed with tamper resistant tape immediately after the sample is placed in the package.

(~~d~~ *i*) The cannabis independent testing laboratory shall ensure the seed-to-sale identification tag is affixed to the sample package. The batch, lot or production run number and the weight or quantity of the sample shall be documented on the sample package and on the chain of custody.

2. A cannabis independent testing laboratory that collects a sample pursuant to this section shall test the sample as provided in NCCR 11.050.

3. From the time that a lot or production run has been homogenized for sample testing and eventual packaging and sale to a cannabis sales facility, cannabis production facility or, if applicable, another cannabis cultivation facility, the cannabis establishment which provided the sample shall segregate and withhold from use the entire lot or production run, except the samples that have been removed by the cannabis independent testing laboratory for testing, until the cannabis independent testing laboratory provides the certificate of analysis from its tests and analysis. During this period of segregation, the cannabis establishment which provided the sample shall maintain the lot or production run in a secure, clearly designated, cool and dry location so as to prevent the cannabis from becoming contaminated or losing its efficacy. Under no circumstances shall the cannabis establishment which provided the sample sell the cannabis or cannabis products, as applicable, to a cannabis sales facility, cannabis production facility or, if applicable, another cannabis cultivation facility before the time that the cannabis independent testing laboratory has completed its testing and analysis and provided the certificate of analysis to the cannabis establishment which provided the sample.

4. Except as otherwise provided in subsection 5, a cannabis independent testing laboratory shall ~~immediately return or~~ dispose of any sample received pursuant to this section upon the completion of any testing, use or research. ~~If a cannabis independent testing laboratory disposes of a sample received pursuant to this section, the~~ ***The*** cannabis independent testing laboratory shall document the disposal of the sample using its seed-to-sale tracking system pursuant to NCCR 6.080 and 6.082.

5. A cannabis independent testing laboratory shall keep ~~any~~ ***all*** sample***s*** ~~which fails testing, or which is collected by the Board for confirmation testing~~ for 30 days after ~~failure or~~ collection. A sample which is kept pursuant to this subsection must be stored in a manner approved by the appropriate Board Agent. A cannabis independent testing laboratory shall dispose of a sample kept pursuant to this subsection after 30 days have elapsed after ~~failure or~~ collection.

6. Except as otherwise provided in NCCR 11.075, if a sample provided to a cannabis independent testing laboratory pursuant to this section does not pass the testing required by NCCR 11.050, the cannabis establishment which provided the sample shall dispose of the entire lot or production run from which the sample was taken and document the disposal of the sample using its inventory control system pursuant to NCCR 6.080 and 6.082.

7. If a sample provided to a cannabis independent testing laboratory pursuant to this section passes the testing required by NCCR 11.050, the cannabis independent testing laboratory shall release the entire lot or production run for immediate manufacturing, packaging and labeling for sale to a cannabis sales facility, a cannabis production facility or, if applicable, another cannabis cultivation facility.

8. A cannabis establishment shall not use more than one cannabis independent testing laboratory to test the same lot or production run of cannabis without the approval of the appropriate Board Agent.

9. A cannabis independent testing laboratory shall file with the Board, in a manner prescribed by the Board, an electronic copy of the certificate of analysis for all tests performed by the cannabis independent testing laboratory, regardless of the outcome of the test, including all testing required by NCCR 11.050 to 11.065, inclusive, at the same time that it transmits those results to the facility which provided the sample. ***The cannabis independent testing laboratory shall not provide preliminary test results to a cannabis cultivation facility or cannabis production facility, including any of their employees or representatives, prior to submitting the Certificate of Analysis to the Board.*** ~~The cannabis independent testing laboratory shall transmit an electronic copy of the certificate of analysis for each test to the Board by electronic mail at:~~

~~(a) If the test was passed, **cannabislabpass@ccb.nv.gov**; or~~

~~(b) If the test was failed, **cannabislabfail@ccb.nv.gov.**~~

10. ~~An electronic mail message transmitted pursuant to subsection 9 must be formatted as follows:~~

~~(a) The subject line of the electronic mail message must be the name of the cannabis establishment from which the sample was collected.~~

~~(b)~~ The name of the electronic file containing the certificate of analysis must be:

(1) Except as otherwise provided in subparagraph (2) or (3), the ~~Facility~~ ***cannabis establishment*** ID assigned by the Board to the cannabis independent testing laboratory, followed by an underscore, followed by the ~~four-digit identifier~~ ***cannabis establishment ID*** assigned by the Board to the cannabis establishment from which the sample was collected, followed by ***an underscore, followed by the identification number assigned to the test sample within the seed-to-sale tracking system. Followed by an underscore, followed by the product name assigned to the test sample within the seed-to-sale tracking system.*** ~~:~~

~~(I) If the sample was from a production run, the production run number; or~~

~~(II) If the sample was not from a production run, the batch number, followed by an underscore, followed by the lot number.~~

(2) If the certificate of analysis is from a retesting of a previously failed sample, an underscore followed by the word "Retest" must be appended to the end of the name of the electronic file.

(3) If the certificate of analysis has been amended, an underscore followed by the word "Amended" must be appended to the end of the name of the electronic file.

(c) If the certificate of analysis has been amended, the electronic copy of the certificate of analysis must state "Amended" in 20-point bold red font at the center of the top of the first page of the report and must contain a statement of the reason for the amendment that clearly and completely describes the change in 10-point ***red*** font.

11. The Board will take immediate disciplinary action against any cannabis establishment which fails to comply with the provisions of this section or falsifies records related to this section, including, without limitation, revoking the license of the cannabis establishment.

12. A cannabis independent testing laboratory may subcontract its testing of cannabis or cannabis products only to another cannabis independent testing laboratory. ***The name and cannabis establishment ID of the cannabis testing laboratory which performed the subcontracted testing must be indicated on the final Certificate of Analysis in at least 8-point font.***

13. The Board may publish on their website all Certificates of Analysis issued to them in the preceding time.

(Amended: 8/2021)

11.075 Testing: Authorized use of cannabis upon failure of microbial screening; automatic failure to pass; request for retest; retest for pesticide residue must be performed by State Department of Agriculture; effect of passing or failing retest.

1. Upon approval of the appropriate Board Agent, a lot or production run of cannabis that fails a residual solvents, pH, water activity (aw), homogeneity, or microbial screening test may be remediated or used to make an extract. After processing, the remediated lot or extract must pass all required quality assurance tests. Processes for treatment or remediation of cannabis must be pre-approved by the appropriate board agent.

(a) The cannabis establishment must maintain documentation of post-harvest treatment or remediated lots, including the date and method of treatment or remediation. All post-harvest treatment or remediation processes must be pre-approved by the appropriate Board agent.

2. If a sample from a cannabis production facility fails a quality assurance test, the entire production run from which the sample was taken automatically fails the quality assurance test.

3. At the request of a cannabis cultivation facility or a cannabis production facility, the appropriate Board Agent may, on a case-by-case basis, authorize a retest to validate the results of a failed test. The cannabis cultivation facility or cannabis production facility is responsible for all costs involved in a retest performed pursuant to this section.

4. A cannabis cultivation facility or a cannabis production facility may not request a retest pursuant to this section if the lot or production run has undergone any type of remediation since the time samples were initially taken for testing. ***A cannabis independent testing laboratory may not retest a lot, production run or test sample of cannabis or cannabis products, or implement internal retesting procedures for cannabis or cannabis products, without approval by the Board or the appropriate Board Agent.***

5. A cannabis cultivation facility or a cannabis production facility shall submit a request for retesting to the appropriate Board Agent in writing and on a form designated by the Board.

6. If the appropriate Board Agent grants a request for retesting, the Board Agent will select the cannabis independent testing laboratory that will perform the retest.

7. Except as otherwise provided in this subsection, a cannabis cultivation facility or a cannabis production facility may submit a request for retesting of not more than 50 lots or production runs each calendar year. For any subsequent failure of a quality assurance test in a calendar year, the facility shall request permission from the Board for an additional 50 tests, destroy the lot or the entire production run, or request to send the lot or production run to extraction or remediation. The Board may extend authority to the Executive Director of the CCB to approve such requests. If the additional 50 retests are approved, a cannabis cultivation facility or a cannabis production facility must obtain the results of two retests in the category which failed, from two different cannabis independent testing laboratories. For the retested lot or production run to be approved for sale, both retests must provide passing results. If both retests provide passing results, the certificate of analysis with the higher quantifiable results will be recorded. If it is not clear which certificate has higher results, the appropriate board agent will select the one to be recorded. No more than one such request for additional tests is permitted within a calendar year. A lot which only fails a quality assurance test for moisture content must not be counted for the purpose of this subsection.

(a) To request permission from the Board for an additional 50 tests, a cannabis cultivation facility or a cannabis production facility must file a petition with the Board which must include the following:

(1) Request for the additional 50 tests;

(2) List the prior 50 lots or production runs that failed, what they failed for, and which cannabis independent testing laboratory performed the test; and

(3) List whether the prior 50 lots or production runs passed pursuant to a retest, and which cannabis independent testing laboratories performed the retests.

8. A failed quality assurance test for pesticide residue must be retested by the State Department of Agriculture unless otherwise approved by the Board or appropriate Board Agent.

9. If a sample passes the same quality assurance test upon retesting, the cannabis cultivation facility or cannabis production facility need not destroy the lot or production run and may sell the lot or production run to a cannabis cultivation facility, cannabis sales facility or cannabis production facility, as applicable.

10. If a sample fails the same quality assurance test upon retesting, the Board Agent denies a request for retesting or a cannabis cultivation facility or a cannabis production facility does not request retesting after a sample fails a quality assurance test, the facility shall destroy the entire lot or production run from which the sample was taken.

(Amended: 8/2021)

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11.085 Random quality assurance compliance checks; costs for screening or testing.

1. Upon the request of the Board, a cannabis facility must provide a cannabis independent testing laboratory designated by the Board with a sample of cannabis or a cannabis product in an amount determined by the cannabis independent testing laboratory to be sufficient for random quality assurance compliance checks in a secure manner such that the cannabis independent testing laboratory can confirm that it has received and is testing the correct sample.

2. The cannabis independent testing laboratory that receives a sample pursuant to subsection 1 shall, as directed by the Board:

(a) Screen the sample for pesticides, chemical residues, herbicides, growth regulators and unsafe levels of metals;

(b) Perform any other quality assurance test deemed necessary by the Board; and

(c) Report its results to the Board.

3. ***The responsibility*** ~~cannabis cultivation facility or cannabis production facility is responsible~~ for all costs involved in screening or testing performed pursuant to this section ***shall be borne in accordance with the following:***

(a) If the testing is performed as a consequence of an investigation of a cannabis cultivation facility, the costs shall be borne by the cannabis cultivation facility even if the investigation does not lead to a substantiated violation of the law;

(b) If the testing is performed as a consequence of an investigation of a cannabis production facility, the costs shall be borne by the cannabis production facility even if the investigation does not lead to a substantiated violation of the law; or

(c) If the testing is performed as a consequence of an investigation of a cannabis independent testing facility, the costs shall be borne by the cannabis independent testing laboratory even if the investigation does not lead to a substantiated violation of the law.

4. A cannabis cultivation facility, cannabis production facility, or cannabis independent testing laboratory who is responsible for costs of testing pursuant to subsection 3 must remit payment for the costs to the cannabis independent testing laboratory that performed the testing within 30 days of receipt of the invoice.