

**Summary of Medical Cannabis Program Rule Amendments for
Public Hearing January 16, 2020**

7.34.2 NMAC:

7.34.2.7 NMAC: Amendments to definitions; identical to proposed amendments of 7.34.3.7 and 7.34.4.7 NMAC.

7.34.3 NMAC:

7.34.3.7 NMAC: Amendments to definitions; identical to proposed amendments of 7.34.2.7 and 7.34.4.7 NMAC.

7.34.4 NMAC:

7.34.4.7 NMAC: Amendments to definitions; identical to proposed amendments of 7.34.2.7 and 7.34.3.7 NMAC.

“Adequate supply”: Modified to more closely reflect statutory definition.

“Batch”: Removed reference to “homogenous” in response to public comment, and substituted with text proposed in public comment, to identify a “batch” as having come from the same cultivation area, at the same time, and having been subject to the same agricultural practices (including pesticides).

“Cannabis establishment”: Added statutory definition, based on public comment.

“Hemp”: Added statutory definition, based on public comment.

“Manufacture”: Modified to more closely reflect statutory definition, based on public comment.

“Permanent structure”: Added definition. The expression “permanent structure” is used in new text, discussed below, that modifies a passage concerning the cleaning of surfaces in buildings operated by LNPPs, which is added in response to public comment.

“Produce”: Added statutory definition, based on public comment.

“Recall”: Definition added, in response to public comment.

7.34.4.8 NMAC:

(F): Added “grandfathering” text from statute, in response to public comment. This text would allow a licensed non-profit producer to continue operating at a location that is within 300 feet of a school, church, or daycare center if the producer’s location existed at the location prior to the establishment of the school, church, or daycare center within the 300 foot boundary. For consistency, identical text is also included in the passages of the rule that apply the 300-foot standard to locations of manufacturers, laboratories, and couriers.

(Q)(3): Added provision to clarify that an employee who cannot produce a Department-issued identification card on request shall not remain on an LNPP’s licensed premises. A similar requirement was also included in sections regarding each of the other cannabis establishments.

(R)(2): Added text to specify that the Medical Cannabis Program will identify materials that remain to be submitted for completion of an incomplete LNPP application for amended licensure, and that the LNPP will have 30 days to either submit the required materials or otherwise contact the Department regarding the application before the application is closed as incomplete.

(X): Included provision that the Department may require that an LNPP operate dispensaries in certain geographical locations as a precondition of initial licensure. This provision was modified to apply to initial licensure, in response to public comment.

7.34.4.9 NMAC:

(A)(2): Clarified that equipment, implements, and fixtures that are used for the production of cannabis shall be used exclusively for that purpose. This edit was made in response to public comment.

(A)(3): Replaced reference to “premises” with “licensed property”. This edit was made in response to public comment seeking clarification.

Removed reference to manufacturing being conducted indoors. This provision is more appropriately suited for the manufacturing section, and is contained within Section 15(A)(3).

(A)(11): Clarified the “washable, wipeable, and non-absorbent” surfaces requirement to exclude earthen floors, and to reference “permanent structures”. These edits are made in response to public comments.

(A)(31): Added provision to prohibit the combination of hemp, hemp extract, and hemp derived products with usable cannabis that is sold or distributed in the Medical Cannabis Program, and identified hemp paper and hemp seed oil as exceptions. The Department is proposing to prohibit the combination of hemp products with medical cannabis products, in order to ensure quality and adherence to NMDOH testing requirements for all medical cannabis products sold, and also to limit the potential for illegal inversion of marijuana and marijuana products that are produced outside of the Medical Cannabis Program. Hemp seed oil is also exempted from this prohibition in recognition of the fact that cannabis seeds do not contain significant quantities of THC, and therefore do not present concerns regarding inversion.

7.34.4.10 NMAC:

Clarified that dried usable cannabis that is destined to be converted into a cannabis derived product is not required to be tested prior to the conversion. This edit was made in response to public comment.

(C)(2), Table 2: Corrected typo in headings and footnote, to change “mg/kg” to “µg/kg”. The measure was correctly identified as parts-per-billion (ppb) in the footnote, but was incorrectly indicated.

(C)(3), Table 3: Corrected typo in heading and footnote, to change “mg/g” to “µg/g”. The measure was correctly identified as parts-per-million (ppm) in both locations, but was incorrectly indicated. Also switched positions of ortho-xylene and meta-xylene within the table, so that the method reporting level for ortho-xylene is 100 ppm and that of meta-xylene (reported together with para-xylene) is 200 ppm. This correction was made in response to public comment.

Lowered action levels for multiple targeted residual solvent compounds. Having lower action levels ensures safer, cleaner products, and in some ways can make laboratory analysis less expensive, insofar as labs won't have to buy a wider range of reference materials.

(C)(4): Specified that an LNPP may test for the quantity of CBN, CBGA, CBG, CBC, and THCV, at the LNPP's option, but is not required to test for those cannabinoids. This had been implied in other passages of the rule, but the previous text of this passage incorrectly indicated that testing for these substances was mandatory.

(C)(4)(a): Included text to specify that a cannabis-derived product will be deemed non-homogenous if 10% of the infused portion of the product contains more than 20% of the total THC contained in the product. This text was proposed in public comment.

(C)(5), Table 5: Corrected typo in heading and footnote, to change "mg/g" to "µg/g". The measure was correctly identified as parts-per-million (ppm) in both locations, but was incorrectly indicated.

Lowered method reporting level for arsenic from 1.0 µg/g to 0.2 µg/g. This revision was made to correct a typographical error.

(C)(6), Table 6: Corrected typo in headings and footnote, to change "mg/kg" to "µg/kg". The measure was correctly identified as parts-per-billion (ppb) in the footnote, but was incorrectly indicated.

(C)(7), Table 7:

Created separate designations for "concentrated cannabis-derived products" (CCDPs) and "non-concentrated cannabis-derived products" (NCCDPs). This edit was made in response to public comments expressing concern that the rule would require 10 grams of concentrates to be sampled for microbiological testing. The rule as revised would require that only 1 gram of concentrate be sampled for microbiological testing.

Specified in the footnote the combined test sample sizes for CCDPs, NCCDPs, and dried usable cannabis.

(F)(3): Included text clarifying that an LNPP or manufacturer may not remediate edible cannabis derived products such as brownies, cookies, candies, and similar products.

7.34.4.14 NMAC:

(B)(8): Included grandfathering provision, discussed above, in passage regarding application of 300-foot rule to manufacturer locations.

(B)(25): Added application requirement that manufacturer applications include a written statement of the days and hours that the manufacturer will operate.

(C): Added exception to the "addictive substance" requirement, to exempt sugar. This edit was made in response to public comment.

(E): Added provision to clarify that an employee who cannot produce a Department-issued identification card on request shall not remain on a manufacturer's licensed premises.

(F)(2): Added text to specify that the Medical Cannabis Program will identify materials that remain to be submitted for completion of an incomplete manufacturer application for amended licensure, and that the manufacturer will have 30 days to either submit the required materials or otherwise contact the Department regarding the application before the application is closed as incomplete.

7.34.4.15 NMAC:

(A)(2): Clarified that equipment, implements, and fixtures that are used for the manufacture of cannabis-derived products shall be used exclusively for that purpose. This edit was made in response to public comment.

(A)(5): Included grandfathering provision, discussed above, in passage regarding application of 300-foot rule to manufacturer locations.

(A)(36): Added requirement that the Department must be notified of any changes to the days or hours of a manufacturer's business operations.

(A)(37): Added requirement that manufacturer staff tasked with conducting compressed gas extraction must be appropriately trained prior to conducting extraction activities.

(A)(38): Added requirement, reflecting standard discussed above, that manufacturers must not combine hemp or hemp-derived products with usable cannabis intended to be sold or distributed in the Medical Cannabis Program.

(A)(39): Added requirement that cannabis and cannabis-derived products that are kept in manufacturing areas must at all times be clearly segregated from hemp and hemp-derived products.

(C): Added requirement that certain edible products containing THC must be imprinted with a universal THC symbol or a comparable symbol denoting THC content. This is a safety feature intended to alert consumers that a product contains THC, and is a fairly common requirement in other cannabis programs.

7.34.4.16 NMAC:

(B): Changed previous 8-point type standard to 1/16th of an inch. The font size requirement has been effectively reduced, in response to public comment. It has also been converted to a specific measurement in recognition of the fact that point sizes are not necessarily fixed sizes.

(B), (C): Removed and modified various labeling requirements in response to public comments. The Department received several comments that the previously proposed contents of the label were too numerous to fit onto a label. In response, the Department has proposed to require less information on the product labels, and to have the removed information included in the drug information sheets, detailed at subsection C.

(E): Moved text regarding vaporization products warning label above, to subsection (B)(13).

Included reference to potential recall in subsection regarding failure to comply with packaging or labelling requirements. The recall section is located at section 24.

7.34.4.17 NMAC:

(C)(17): Included reference to “continuing demonstration of capability”. This expression has been included within Section 19, to distinguish from initial demonstrations of capability. This is in response to public comment.

(C)(18): Included grandfathering provision, discussed above, in passage regarding application of 300-foot rule to laboratory locations.

(E): Replaced references to “program manager” with “program director or designee”, here and in other passages of the rule that referenced a “program manager”. These edits were made in response to public comment.

(G): Added provision to clarify that an employee who cannot produce a Department-issued identification card on request shall not remain on a laboratory’s licensed premises.

(J): Added text to specify that the Medical Cannabis Program will identify materials that remain to be submitted for completion of an incomplete laboratory application for amended licensure, and that the laboratory will have 30 days to either submit the required materials or otherwise contact the Department regarding the application before the application is closed as incomplete.

7.34.4.18 NMAC:

(D)(3)(b), (O): Replaced previous destruction text at (D)(3)(b) with a reference to wastage requirements of the rule. A similar edit was also made at section 18(O), which had referenced destruction of excess cannabis, but which is deleted in deference to the wastage requirements at section 11. These revisions were made in response to public comment.

7.34.4.19 NMAC:

(F): Includes references to new expression, “continuing demonstration of capability”. An initial demonstration of capability is required before a laboratory begins to conduct a given test, after there’s been a change in method or instrumentation, when a new instrument is installed, and whenever the method hasn’t been performed in a 12-month period. In contrast, a continuing demonstration of capability is required as part of the renewal licensure process. The creation and inclusion of references to a “continuing demonstration of capability” were made in response to public comment regarding the use of the expression “initial demonstration of capability”.

(G): Added text requiring that a laboratory utilize internal standards to ensure proper measurement of analyte quantification.

(H): Clarified that the action levels for each and every analysis must be followed in accordance with the testing requirements of the rule.

7.34.4.20 NMAC:

(B)(20): Included grandfathering provision, discussed above, in passage regarding application of 300-foot rule to courier locations.

(E): Added provision to clarify that an employee who cannot produce a Department-issued identification card on request shall not remain on a courier’s licensed premises.

(G)(2): Added text to specify that the Medical Cannabis Program will identify materials that remain to be submitted for completion of an incomplete courier application for amended licensure, and that the courier will have 30 days to either submit the required materials or otherwise contact the Department regarding the application before the application is closed as incomplete.

7.34.4.22 NMAC:

(C)(2): Included grandfathering provision, discussed above, in passage regarding application of 300-foot rule to LNPP locations.

(H)(3)(f): Added requirement that applicants for LNPP licensure must undergo training that addresses robbery awareness and conflict de-escalation for all employees. This provision is intended to ensure greater education and awareness among LNPPs of robbery threats, and to promote the adoption of de-escalation methods in addressing theft, thereby reducing potential threats to employees and customers.

(H)(3)(g): Added requirement that LNPP employees must undergo general food safety training. This is a requirement for manufacturers, but is equally important for LNPPs, which commonly sell cannabis-infused food products.

7.34.4.24 NMAC:

Added new section to address product recalls. This section would require LNPPs and manufacturers to create and implement written procedures for recalling cannabis and cannabis products that are sold or otherwise distributed to qualified patients, primary caregivers, or other cannabis establishments. The licensee must notify the Department within 24 hours of initiating a product recall, and the Department may order the immediate recall of a product if it deems it necessary to protect public health and safety.

7.34.4.28 NMAC:

Specified that the reciprocity provisions will become effective on July 1, 2020. One concern raised in public comments was that it is not yet clear how the registration of reciprocal participants will work in the context of the BioTrack tracking system. The Department is working with BioTrack to incorporate reciprocal participant registration and sales into the BioTrack system, but anticipates that it will take until July for the system to be updated and any bugs to be worked out.

7.34.4.30 NMAC:

(B): Required that manufacturers maintain sales records, in addition to LNPPs. Also, removed reference to the word “confidential” in reference to sales records. Sales records may be deemed confidential in accordance with applicable laws, such as HIPAA or the Lynn and Erin Compassionate Use Act at NMSA 1978, § 26-2B-7(H), depending on individual facts and circumstances. However, the passage as previously written could give the impression that all sales records are always confidential, which is incorrect. For example: a manufacturer’s sales to an LNPP would not necessarily be deemed confidential in-and-of themselves.

Clarified that the Department shall have access to the financial records of producers, manufacturers, laboratories, and couriers.

(C): Added manufacturers, laboratories, and couriers to the “monitoring visit” provisions that currently apply to LNPPs.

(D): Substituted existing references to qualified patients and primary caregivers with a reference to personal production license holders. Suspension of patients and primary caregivers is addressed separately within the patient rule at 7.34.3 NMAC, whereas this rule concerns producers (including PPL holders) and cannabis establishments.

Other Public Comments:

Below are the Department's responses to various public comments that were not otherwise addressed via the edits described above.

7.34.4.8 NMAC:

1. Some commenters stated that requiring amendment to licensure whenever the membership of an LNPP's board of directors changes is too onerous. The Department disagrees. The Department does not deem this requirement to be especially onerous, and here as well, the Department considers this information to be valuable and important for purposes of tracking the management of a licensed producer.
2. The Department received public comment expressing that amendments should not be required for "any physical modification or addition to the facility", and that this should instead be required only for modifications that add or remove space to areas where cannabis is dispensed, stored, or produced, etc. The Department is concerned that such a standard would be too restrictive. Fundamentally, the Program is interested not only in the size and location of producer locations, but in how producer operations are conducted.
3. The Department received comments about amendment to licensure being required for any change in ownership of facilities. Commenters suggested that an LNPP that rents property should not be required to report changes in ownership of that property, and that LNPPs shouldn't have to disclose the identities of persons who have only an indirect interest in facility ownership. The Department believes that recording the ownership of premises occupied by an LNPP is important, irrespective of whether an LNPP leases the property.
4. One commenter suggested that the proposed 120-day retention of cannabis destruction is too burdensome, and that digital storage is too costly. The Department finds the proposed 120-day retention period to be reasonable and appropriate to accomplish the Department's objectives. Also, upon information and belief, digital storage is relatively inexpensive, and should by no means be cost prohibitive.
5. The Department received comment criticizing the inclusion of a restriction prohibiting LNPP production facilities from being located within 300 feet of a school, church, or daycare center. The commenter argued that the NM Legislature did not extend the 300-foot rule to production facilities, but only to "distribution" locations. The commenter also argued that the 300-foot provision should not apply to laboratory or manufacturer locations. The Department considers the production of cannabis and the manufacture of cannabis-derived products to be part of the distribution chain, and believes that the 300-foot requirement, as applied to production and manufacturing facilities, therefore falls within the statutory provision at NMSA 1978, § 26-2B-7(A)(6)(b). However, regardless of whether these locations fall within the statutory mandate, the Department believes that the 300-foot requirement, as applied to LNPP production locations, manufacturer locations, and laboratory locations, is an appropriate standard and can be required by the Department consistent with the Department's statutory authority to identify requirements for the licensure of

producers, manufacturers, and laboratories. See NMSA 1978, § 26-2B-7(A)(5). Note, however, that the Department has proposed, consistent with the exception that was recently included in the statute, to include a “grandfathering” provision that would allow any such licensee to continue operating at a location that falls within the 300-foot distance, provided that the school, church, or daycare center was established within the 300-foot boundary after the licensee became licensed to operate at the location.

6. One commenter criticized the proposed rule provisions that would prohibit employees of licensees from being under the influence of drugs while at work. The commenter suggested that employees should be allowed to use cannabis at work. The Department has proposed to prohibit employees of cannabis establishments from being under the influence of drugs or alcohol while at work. Allowing employees to be under the influence of drugs or alcohol while at work would pose obvious health and safety risks, and the Department does not intend to allow it.

7.34.4.9 NMAC:

1. The Department received public comment expressing disagreement with the notion of prohibiting hemp production on the same premises as medical cannabis. As noted above, for purposes of clarification, the reference to “premises” has been modified to state “licensed property”. The prohibition against hemp production on LNPP licensed property is based on several concerns of the agency. Hemp and marijuana are both of cannabis, with the only true distinction being the quantity of THC contained in each. It is virtually impossible to discern between hemp and marijuana by visual inspection. NM law allows hemp growers licensed by the NM Department of Agriculture to grow hemp (defined as containing no more than three-tenths of a percent of THC on a dry weight basis). However, cannabis that tests above the 0.3 % threshold is marijuana, and must be destroyed by the hemp grower, in accordance with the hemp rules. See 21.20.2.9(C) NMAC; 21.20.2.12 NMAC. The Department is concerned that LNPPs that grow hemp on property licensed by the Department may be inclined to convert such marijuana into medical cannabis, rather than destroying it. Such a practice (known as “inversion”) is not only illegal, but presents additional risks, including but not limited to subverting medical cannabis testing requirements. The Department intends to prohibit the production of hemp on LNPPs’ licensed premises to limit the risk of inversion and to provide greater clarity to Department employees and law enforcement who visit LNPP grow locations regarding the plants and plant material that falls within an LNPP’s licensed grow operations.
2. One commenter suggested that the Department define “chemical or biological hazards”, as that expression is used in Section 9. However, the Department cannot create a definition that identifies every substance or circumstance that may present a threat, and the Department does not consider the expression “chemical or biological hazards” to be especially ambiguous. In essence, this provision is intended to address threats that could reasonably result in the contamination of cannabis with other substances, whether they be chemical or biological in nature.

7.34.4.10 NMAC:

1. The Department received several public comments regarding the proposed sampling requirements. Commenters stated that the identified sampling sizes are too large, particularly with respect to cannabis concentrates. Some commenters contended that the Department should not dictate sample sizes at all, but should leave it to laboratories to decide. Other commenters expressed agreement with the proposed standards. The sample sizes identified in the proposed rule, as

amended, are consistent with U.S. Pharmacopeia USP 2023 standards for nonsterile supplements (botanicals and extracts, etc.), and the Department considers the Pharmacopeia standards to be appropriate. Also, as noted above, the sample sizes have been amended to clarify that concentrates do not require a 10-gram sample for microbiological testing, and that a one-gram sample is sufficient. This was one of the more prominent concerns raised in public comment.

2. Some commenters suggested that the tests could be accomplished by laboratories using smaller sample sizes. However, in proposing the sample sizes, the Department attempted not only to identify quantities that are sufficient to conduct a test, but to identify sizes that are sufficiently large to be *representative* of the batch from which the sample was taken. Adopting smaller sample sizes would be contrary to this goal. Although some commenters criticized the sampling quantities as wasteful, the Department believes that they are necessary to assure appropriate testing, and to thereby promote the health and safety of qualified patients.
3. One commenter expressed that setting sample sizes, without controlling how material is sampled, accomplishes nothing. The Department believes that both sample sizes and sample collection methods are important, and it has for that reason proposed rule provisions that address both topics. The procedures for testing identified at Section 10(E) include sample section requirements that state that an LNPP and a manufacturer shall collect and submit for testing samples that are representative of the batch being tested, and authorize the department to order that modification be made to sampling collection practices if the Department has reason to believe that samples previously taken were not representative of a batch.
4. Some commenters proposed that sampling should be done by laboratories alone, and not by LNPPs or manufacturers, who may have an incentive to take non-representative samples. The Department understands the concerns that have been raised, and the Department may revisit this proposal at some point in the future. However, at this time the Department does not intend to require that sampling be conducted by laboratory personnel. It is not yet clear what logistical impacts such a requirement would have on LNPP and manufacturer testing, or whether the existing laboratories would even have the resources to conduct sampling at all of the current grow facilities in the state. While requiring that sampling be done by laboratories might be advantageous, it is not the only method available to ensure that sampling is conducted in a fair and representative manner. It is also worth noting that the proposed rule incorporates a component for quality assurance testing to be conducted by NMDOH, which may aid in identifying deficiencies in producers' and manufacturers' sampling methods.

7.34.4.11 NMAC:

1. The Department received a public comment that asked what constitutes a “designated holding area” for purposes of the wastage section, and whether such an area could be a locked box, or whether it needed to be a separate room on the premises. The Department responds that a designated holding area can be a room, a locked box, or some other form of holding area, so long as the holding area is secured.

7.34.4.12 NMAC:

1. The Department received many public comments regarding the proposed testing standards. The testing standards include new tables that specify action levels for the various tests, and propose new testing requirements for testing for the presence of heavy metals, certain pesticides, and moisture content.
2. Several of the testing-related comments focused on perceived added costs of conducting additional testing. The Department anticipates that the actual costs of testing will be substantially less than has been represented in the public comment. The costs of testing are expected to be spread out across many tests of many batches of cannabis, which should in turn substantially reduce the costs per test. As production of cannabis continues to increase, the number of batches, and consequently the number of tests, is expected to continue to rise. While the Department anticipates that there will be some increase to testing costs for producers, that cost will be diluted by the volume of tests. Ultimately, it is the Department's view that the benefit of added testing (and added assurance for patients that they are purchasing a safe product) substantially outweighs concerns about added costs.
3. One commenter expressed concern about the provision stating that "repeated failures" of tests could lead to disciplinary action, and notes that all LNPPs are bound to have some repeated failures of testing. While the Department understands the concern raised, the Department believes that the inclusion of this provision is appropriate. Repeated failures may or may not raise significant public health and safety concerns, and the Department intends to assess individual facts and circumstances in determining whether to take action against a licensee. To the extent that repeated failures of tests can be attributed to substandard practices of an LNPP, those repeated testing failures will be more likely to lead to disciplinary action.
4. One commenter suggested that the Department should conduct all of the random sampling and testing of cannabis derived products, and argued that LNPPs and manufacturers cannot be trusted to do it themselves. The Department does not possess the infrastructure or resources sufficient to conduct this testing at the present time, although (as noted) the proposed rule does incorporate a quality assurance testing component.
5. Some commenters suggested that microbiological testing is only necessary with respect to aspergillus. Again, the Department has based the testing standards on the U.S. Pharmacopeia provisions concerning nonsterile supplements, which are familiar industry standards, and the Department believes that they are appropriate. Also, the Department is concerned that laboratories may not be able to adequately speciate between different molds, which is part of why the proposed rule was written to address combined yeast and mold.
6. One commenter proposed that the action levels for microbiological testing, solvent testing, and heavy metals testing should be increased, to reflect Colorado's standards. Again, the Department is basing the testing standards primarily on the USP 2023 standards for nonsterile supplements, and it believes that the identified standards are appropriate. Having lower action levels ensures safer, cleaner products. As noted above, the Department has proposed to lower the action levels for residual solvents for the same reason.
7. One laboratory representative argued that mycotoxin testing should be eliminated, because the laboratory had ever detected mycotoxins, and because this appeared to be consistent with laboratories' experiences in other jurisdictions. Particularly considering that the Department is proposing new standards for how tests are conducted, and considering that those standards exclude

ELISA as an approved testing method, the Department believes it would be premature to remove mycotoxin testing from the rule. If mycotoxins are not present in cannabis harvested by NM producers, then testing under the new testing standards should reflect that, and the Department can revisit the suggested removal of mycotoxin testing at a later date.

8. Some commenters suggested that mycotoxins degrade from the heat of smoking or decarboxylation, and that mycotoxin testing is therefore unnecessary. Even assuming that this is the case, there are various means of ingesting cannabis and cannabis-derived products, and patients may not be smoking or otherwise burning the product.
9. Some commenters suggested that yeast and mold testing is unnecessary, but that if it is continued, the action level for yeast and mold should be relaxed. Once again, the standard proposed in the rule is based on the USP 2023 standards for testing for yeast and molds in nonsterile supplements, and the Department deems these standards to be appropriate. In fact, the proposed yeast and mold standards are somewhat less stringent than the ones that are currently proposed by the USP, and the Department considers the action levels to represent an appropriate “middle ground”.
10. Some of the commenters suggested that it is unnecessary to test for heavy metals in cannabis. Some suggested that a preferred alternative would be to require periodic testing of soil. The Department disagrees. Heavy metals can originate in soil, but they can also be found in water and water systems. Several LNPPs licensed in New Mexico conduct their grow facilities in industrial or formerly industrial locations, which present unique threats of heavy metals contamination. Cannabis is also demonstrated to be effective at filtering metals, and thus the risk of heavy metals contamination is somewhat higher with respect to cannabis than other plants. Processes that are used to concentrate THC can also increase the concentration of heavy metals in a product, just as they can tend to increase the concentration of pesticides and other contaminants. For these reasons, the Department considers heavy metals testing to be reasonable and appropriate, and notes that heavy metals testing, like the other tests identified in the rule, is a common testing requirement among states that have medical or recreational cannabis programs.
11. One commenter claimed that it did not make sense to require testing for pesticides that producers know that they have not used on cannabis plants. This comment suggests that the Department, rather than relying on testing, should take producers at their word that they are not utilizing certain pesticides. It also assumes that all non-profit producers have an exhaustive knowledge of the contents of every substance that they use when cultivating cannabis, which may or may not be true, depending on the facts and circumstances. The pesticide testing requirements will help to ensure that prohibited pesticides are not utilized, and that if they are utilized accidentally, the prohibited pesticide will appear in test results. As the recent health outbreak concerning the vaping of THC and other products has made clear, the burning of pesticide residue on cannabis products can pose serious dangers to public health.
12. One commenter suggested that quality assurance testing by the Department should be struck, because cannabis is a biological material that is not uniform in its composition. The Department recognizes that quality assurance testing may be of greater or lesser value depending on the circumstances; but the Department believes that it is important to have quality assurance processes in place that enable the independent evaluation of the testing conducted of an LNPP’s or manufacturer’s products. Quality assurance testing can potentially identify or indicate deficiencies throughout the chain of a given testing scheme. To the extent that samples from the same batch return dissimilar results, this could also indicate deficiencies in an LNPP or manufacturer’s sampling

protocol. The Department believes that quality assurance testing is valuable, and intends to adopt it.

13. Some commenters expressed support for random testing of finished cannabis-derived products (i.e., end products testing) by LNPPs and manufacturers, whereas others argued that it is not justified, that food products would only become contaminated by improper hygiene, and that hygiene can be regulated without requiring laboratory testing. The Department considers the proposed end products testing standards to be reasonable and appropriate. Randomized end products testing is the only mechanism to determine whether the THC content of a cannabis product is homogenous in distribution, in accordance with the proposed rule. THC homogeneity is not assured by adherence to hygiene standards. Further, in proposing the end products testing standards, the Department took care to propose standards that would be of minimal impact to LNPPs and manufacturers. The Department believes that these testing requirements are not particularly onerous for licensees, particularly in consideration of the medical nature of this program, and the Department believes that these tests may prove valuable in identifying gaps in the tests previously conducted of dried cannabis or concentrates utilized in cannabis food products.
14. Some commenters suggested that the Department should not mandate that certain technologies be used for testing, and that ELISA is a reliable testing method. By requiring the use of certain technologies in testing, the Department is attempting to assure the reliability of test results, and to create more uniform standards in how tests are conducted. ELISA (enzyme-linked immunosorbent assay) is a good example of why the Department is doing this, as the Department does not agree with the commenter that ELISA is a reliable method for testing for mycotoxins. As was noted prior to the first hearing: upon information and belief, ELISA is only accurate in testing for one type of mycotoxin that is tested under the rule (aflatoxin B1); and ELISA tends to undermeasure for the other three mycotoxins. ELISA tends to over-measure for ochratoxin B and ochratoxin C, which can then be reported as a false positive for ochratoxin A. ELISA is notorious for reporting false negatives and false positives.
15. A commenter suggested that the proposed remediation standards are too restrictive, and that the rule should allow for additional remediation processes, including the use of ultraviolet (UV) light. In proposing to restrict the methods and circumstances in which remediation of cannabis and cannabis products can occur, the Department has sought to address its concern that producers and manufacturers may currently be utilizing unreliable remediation methods. The proposed rule does not authorize the use of UV light as a remediation method, because the Department finds that UV light is not efficacious and is not a reliable method for the removal of microbiological contaminants. The proposed rule allows remediation through the use of extraction and distillation methods for cannabis and cannabis products that have failed the microbiological test or residual solvent test. These methods are proposed because the Department finds that they are effective at remediating the identified contaminants. The Department finds that remediation would be inappropriate for cannabis that has failed tests other than the microbiological and residual solvent tests.
16. A commenter expressed that “moisture content” is not an appropriate methodology, and that the Department should use “water activity” instead. The rule proposes testing for moisture content, which is intended to ensure that LNPPs do not sell cannabis flower that contains a significant amount of water. Patients commonly pay for cannabis flower by weight, and the evaporation of water from the product can mean a significant decrease in the weight of the product after it is sold.

7.34.4.14 NMAC:

1. The Department received comment that the proposed increase to the annual manufacturer license fee, from the current \$1,000 to \$5,000, is too high. The Department believes that the proposed \$5,000 fee is fair and appropriate. The Department finds that the current \$1,000 fee is too small, especially in light of the significant cost borne by NMDOH in terms of man hours in reviewing manufacturers' licensure applications. The proposed \$5,000 fee is also based in part on a review of licensure fees that are charged to manufacturers in other states, and appears to be generally consistent with what other states charge.
2. One commenter criticized the inclusion of hazard analysis critical control point plans (HACCPs) in the manufacturer application requirements. The commenter suggested that a single HACCP would cost \$25,000. The Department disagrees. An HACCP is essentially a written plan that identifies biological, chemical, and physical hazards that exist in the production and distribution of a product. The Department has no reason to believe that the creation of these plans will be cost prohibitive, and the Department finds that the proposed HACCP requirement has the potential to be very beneficial to promoting public health and safety.

7.34.4.16 NMAC:

1. The Department received a comment that the warning that is required to be included on labels for vaping products should specify that the recent outbreak of vaping-related injuries was not caused by anything intrinsic to cannabis. The investigation of vaping-related injuries is ongoing, and the Department is unable to render any such conclusions at this time.

7.34.4.19 NMAC:

1. The Department received a comment stating that the ownership disclosures for laboratories should only apply to ownership above a certain percentage. The comment suggested that requiring detailed disclosures regarding laboratory ownership could negatively impact access to funding streams. The Department does not see why this would be the case; but in any event, the Department believes it is important to know who has an ownership interest in a licensed laboratory.
2. A commenter suggested that requiring Initial Demonstrations of Capability (IDCs) as part of the renewal licensing process is unnecessary. As noted above, the Department has modified the proposed rule to rename the IDC to be submitted at the time of renewal as a "Continuing Demonstration of Capability" (CDC). The Department believes it is important for a laboratory to demonstrate proficiency in testing with each licensing cycle. The Department is also concerned that laboratories may in some cases make changes to their testing processes without informing the Department of the change. Requiring a CDC at the time of renewal provides assurance to the Department that a laboratory's testing methods remain accurate, and that the laboratory continues to adhere to Department rules.
3. A commenter also offered that requiring initial demonstrations of capability (IDCs) whenever equipment is moved is unnecessary. The Department disagrees. Laboratory testing equipment is extremely sensitive, and removing an instrument from one location to another can impact the instrument's calibration.

7.34.4.27 NMAC:

1. The Department received comments from licensed non-profit producers, requesting clarification regarding how the registration process for reciprocal participants will work in practice. As noted above, the Department is proposing to include a July 1, 2020 start date for implementation of reciprocity, in order to address implementation concerns related to the inventory and sales tracking system known as “BioTrack”. Once BioTrack has been updated to include functions to enable registration of and sales to reciprocal participants, the Department anticipates that reciprocal participants will be able to register with any given licensed non-profit producer, and will subsequently be able to purchase from any licensed non-profit producer. Registration will require that a non-profit producer input the reciprocal participant’s contact information and out-of-state medical cannabis registration information into the tracking system. That information will subsequently be available to other non-profit producers through the BioTrack system. The system will also keep track of the quantities (units) of cannabis and cannabis products that are sold to a reciprocal participant.