



August 8, 2022

Robert Sachs
Regulation and Licensing Department
Cannabis Control Division

RE: Comments related to proposed rule change for 16.8.6 NMAC

Mr. Sachs,

Below you'll find comments for consideration concerning the proposed rule change to 16.8.6 NMAC. I have also provided a track changes version illustrating the comments as Attachment 1 to these comments.

1. 16.8.6.7A should read: "Except as specified in Subsection (F) or 16.8.6.7..."
2. 16.8.6.7F should read: "Certification to NMED, as specified in Subsections (A) through (E) of 16.8.6.7..."
3. 16.8.6.7G should read: "Class II, III, or IV cannabis manufacturers that were licensed by RLD prior to the effective date of 16.8.6 NMAC..."
4. 16.8.6.7H: Should read "Except as specified in Subsection (F) of 16.8.6.7, class II, III, or IV cannabis manufacturers that were not licensed by RLD prior to the effective date of 16.8.6 NMAC, and that are also engaged in manufacturing cannabis edible products or cannabis edible finished products, shall provide a certification to NMED as specified in Subsections (A) through (E) and apply for a food permit from NMED or a home rule municipality as specified in (G) of 16.8.6.7."
5. Omit all of 16.8.6.8 Operational Plans.

If you have any questions concerning these comments, please contact me at (505) 362-8861 or johnathan.gerhardt@state.nm.us.

Thank you for your consideration.

Best regards,

Johnathan Gerhardt, Program Manager
New Mexico Environment Department

cc: Rebecca Roose, Deputy Secretary, NMED
Andrew Knight, Assistant General Counsel, NMED
Mia Napolitano, Assistant General Counsel, NMED
Bill Chavez, Bureau Chief, NMED

TITLE 16 OCCUPATIONAL AND PROFESSIONAL LICENSING
CHAPTER 8 COMMERCIAL AND MEDICAL CANNABIS
PART 6 HEALTH AND SAFETY, FOOD AND PRODUCT SAFETY, ENVIRONMENTAL
IMPACTS, AND NATURAL RESOURCES

16.8.6.1 ISSUING AGENCY: New Mexico Regulation and Licensing Department, Cannabis Control Division.

[16.8.6.1 NMAC – N, XX/XX/2022]

16.8.6.2 SCOPE: This rule applies to all applicants for licensure pursuant to the Cannabis Regulation Act, the Lynn and Erin Compassionate Use Act or division rules, and where applicable, the general public.

[16.8.6.2 NMAC - N, XX/XX/2022]

16.8.6.3 STATUTORY AUTHORITY: The requirements set forth herein are promulgated by the cannabis control division pursuant to the authority granted under the Cannabis Regulation Act and the licensing provisions of the Lynn and Erin Compassionate Use Act.

[16.8.6.3 NMAC - N, XX/XX/2022]

16.8.6.4 DURATION: Permanent.

[16.8.6.4 NMAC - N, XX/XX/2022]

16.8.6.5 EFFECTIVE DATE: 12/02/2021, unless a later date is cited at the end of a section.

[16.8.6.5 NMAC - N, XX/XX/2022]

16.8.6.6 OBJECTIVE: The objective of Part 6 is to set forth standards related to health and safety, food and product safety, environmental impacts, and natural resources to ensure public health, safety, and well-being. Part 6 is not applicable to personal use of cannabis pursuant to the Cannabis Regulation Act or the Lynn and Erin Compassionate Use Act.

[16.8.6.6 NMAC - N, XX/XX/2022]

16.8.6.7 PREREQUISITE AND RESPONSIBILITY FOR OPERATION:

A. Except as specified in Subsection (F) of 16.8.6.7+, prior to the submission of a license application for a class II, III, or IV cannabis manufacture license, each applicant or licensee engaged in the manufacturing of edible or topical cannabis products or edible or topical cannabis finished products shall provide to NMED a certification that:

(1) the facility where the cannabis manufacturer operates, and the manufacturing equipment used will be constructed and maintained in accordance with the requirements of this part; and

(2) edible and topical cannabis products and edible and topical finished products will be stored, manufactured, packaged, repackaged, labeled, relabeled, tested, reworked, or wasted in accordance with the requirements of this part.

B. A certification shall include information specified in Subparagraphs (a) through (i) of Paragraph (1) of Subsection A of 16.8.2.30 NMAC.

C. Any person signing a certification pursuant to this section shall include the following signed statement: “I certify under penalty of law that this document and all attachments were prepared under my direction or supervision in accordance with a system designed to assure that qualified personnel properly gather and evaluate the information submitted. Based on my inquiry of the person or persons who manage the system, or those persons directly responsible for gathering the information, the information submitted is, to the best of my knowledge and belief, true, accurate, and complete. I am aware that there are significant penalties for submitting false information.”

D. NMED shall provide confirmation of receipt to each applicant or licensee that provides a certification.

E. Each applicant or licensee shall provide the NMED confirmation to RLD as specified in Paragraph (1) of Subsection A of 16.8.2.30 NMAC.

F. Certification to NMED, as specified in Subsections (A) through (E) of 16.8.6.7+ shall no longer be required after December 31, 2022.

G. Class II, III, or IV cannabis manufacturers that were licensed by RLD prior to the effective date of 16.8.6.~~NMAC~~, and that are also engaged in manufacturing of cannabis edible products or cannabis edible finished products, shall apply for a food permit from NMED or a home rule municipality by January 1, 2023.

H. Except as specified in Subsection (F) of 16.8.6.~~74~~, class II, III, or IV cannabis manufacturers that were not licensed by RLD prior to the effective date of 16.8.6.~~NMAC~~, and that are also engaged in manufacturing cannabis edible products or cannabis edible finished products, shall provide a certification to NMED as specified in Subsections (A) through (E) and apply for a food permit from NMED or a home rule municipality as specified in (G) of 16.8.6.~~74~~.

I. Beginning April 1, 2023, Class II, III, or IV cannabis manufacturers that manufacturer cannabis edible products or cannabis edible finished products shall not operate without a food permit from NMED or a home rule municipality.

[16.8.6.7 NMAC - N, XX/XX/2022]

~~16.8.6.8~~ ~~OPERATIONAL PLANS:~~

~~A. A licensee shall prepare a written operational plan containing the following information, as applicable, for each edible or topical cannabis product or edible or topical cannabis finished product to be manufactured, labeled, relabeled, packaged, or repackaged:~~

- ~~(1) planned source of cannabis products and ingredients;~~
- ~~(2) names of the ingredient(s);~~
- ~~(3) the final product pH;~~
- ~~(4) the final product water activity (A_w);~~
- ~~(5) names of preservative(s);~~
- ~~(6) the type of packaging to be used that complies with all requirements of section 16.8.3.13 of this part and whether the packaging is integral to product stability;~~
- ~~(7) the intended distribution of the product;~~
- ~~(8) if the product is to be distributed at ambient, refrigerated or frozen temperature;~~
- ~~(9) the expected shelf life during distribution, retail storage, and in the hands of the end user;~~
- ~~(10) how the product should be prepared for consumption;~~
- ~~(11) what mishandling of the product might occur in the merchandising channels or in the hands of the end user;~~
- ~~(12) the proposed recall plan, meeting the requirements of 16.8.2.11 NMAC;~~
- ~~(13) the complete operational procedure for product formulation, including:~~
 - ~~(a) a written, detailed description of the intended manufacturing process, including method of infusion;~~
 - ~~(b) a flow chart illustrating the manufacturing process; and~~
 - ~~(c) identification of critical control points.~~
- ~~(14) written good manufacturing practices (GMPs);~~
- ~~(15) other policies and procedures related to the safe and sanitary operation of the cannabis manufacturer;~~
- ~~(16) proposed product labels that comply with all requirements of section 16.8.3.14 of this part;~~
- ~~(17) proposed record keeping and chain of custody systems;~~
- ~~(18) a description of the batch/lot ID coding system;~~
- ~~(19) proposed pest control plan; and~~
- ~~(20) procedures for remedial measures to bring cannabis products into compliance with division standards; destruction, wastage, or disposal of a tested batch of cannabis products if the testing samples from the tested batch indicate noncompliance with applicable health and safety standards; and destruction, wastage, and disposal of recalled cannabis products.~~

~~B. Prior to adding new edible or topical cannabis products or edible or topical cannabis finished products, or changing the stated process for any existing product in the product line, a licensee shall:~~

- ~~(1) for a new product, prepare a written operational plan as specified in Section 9 of this part;~~
- ~~and~~
- ~~(2) for an existing product for which a change will be made in the manufacturing process, update the existing operational plan.~~

~~C. — A licensee shall have an edible cannabis finished product operational procedure approved by a process authority to verify all critical factors of public health significance are addressed when the product is determined to require a product assessment as determined by table A or table B as follows:~~

~~Table A. Interaction of pH and A_w for control of spores in FOOD heat treated to destroy vegetative cells and subsequently packaged~~

A_w values	pH: 4.6 or less	pH: >4.6—5.6	pH: >5.6
<0.92	non-TCS food*	non-TCS food	non-TCS food
>0.92—0.95	non-TCS food	non-TCS food	PA**
>0.95	non-TCS food	PA	PA

~~* TCS FOOD means TIME/TEMPERATURE CONTROL FOR SAFETY FOOD~~

~~** PA means Product Assessment required~~

~~Table B. Interaction of pH and A_w for control of vegetative cells and spores in FOOD not heat treated or heat treated but not PACKAGED~~

A_w values	pH: <4.2	pH: 4.2—4.6	pH: >4.6—5.0	pH: >5.0
<0.88	non-TCS food*	Non-TCS food	non-TCS food	non-TCS food
0.88—0.90	non-TCS food	non-TCS food	non-TCS food	PA**
>0.90—0.92	non-TCS food	non-TCS food	PA	PA
>0.92	non-TCS food	PA	PA	PA

~~* TCS FOOD means TIME/TEMPERATURE CONTROL FOR SAFETY FOOD~~

~~** PA means Product Assessment required~~

~~D. — The licensee shall maintain current operational plans on the licensed premises during all hours of operation and shall, upon request, make them available for review by the division. [16.8.6.8 NMAC—N, XX/XX/2022]~~

~~16.8.6.9~~**16.8.6.8 MANAGEMENT AND PERSONNEL:**

A. Adoption of food code parts 2-1, 2-3 and 2-4 and section 2-103.11. Except as otherwise provided, parts 2-1, 2-3 and 2-4 and section 2-103.11 of the 2017 United States food and drug administration model food code is hereby adopted and incorporated in its entirety.

B. A licensee shall have written procedures for employees to follow when responding to vomiting or diarrheal events that involve the discharge of vomitus or fecal matter onto surfaces in the edible cannabis manufacturing facility. The procedures shall be maintained onsite and address the specific actions employees must take to minimize the spread of contamination and the exposure of employees, consumers, food, and surfaces to vomitus or fecal matter.

C. Except as otherwise provided, the licensee shall be the person in charge or shall designate a person in charge and shall ensure that a person in charge is present at the cannabis manufacturer facility during all hours of operation.

D. If edible or topical cannabis products or edible or topical cannabis finished products are manufactured as part of a vertically integrated cannabis establishment or integrated cannabis microbusiness that is the legal responsibility of the same licensee and that are located on the same licensed premises, the licensee may designate a single person in charge who is present on the licensed premises during all hours of operation.

E. The person in charge shall have the education, training, or experience necessary to supervise the production of clean and safe edible or topical cannabis products or edible or topical cannabis finished products and ensure the cannabis manufacturer remains in compliance with this part, division rules, and the act at all times.

F. Personal care items on the premises shall be stored in a manner to protect edible and topical cannabis products, edible and topical cannabis finished products, other ingredients, equipment, and utensils from contamination at all times.

G. A licensee shall:

(a) immediately contact the division to report an illness of an employee or conditional employee as specified under Subsection A of this section;

(b) immediately discontinue operations and notify the division if an imminent health hazard may exist as specified in 16.8.3.17 NMAC;
[16.8.6.9 NMAC - N, XX/XX/2022]

~~16.8.6.10~~**16.8.6.9 EDIBLE AND TOPICAL CANNABIS MANUFACTURER REQUIREMENTS:**

A. Adoption of 21 CFR 117. Except as otherwise provided, Subpart F and the sections, specified in paragraphs 1-7 of this subsection, of Subparts A and B of the United States code of federal regulations, title 21, part 117 are hereby adopted and incorporated in their entirety:

- (1) 117.3 Definitions;
- (2) 117.20 Plant and grounds;
- (3) 117.35 Sanitary operations;
- (4) 117.37 Sanitary facilities and controls;
- (5) 117.40 Equipment and utensils;
- (6) 117.80 Processes and controls; and
- (7) 117.110 Defect action levels and Subpart F.

B. Modifications. Except as otherwise provided, the following modifications are made to the incorporated subparts of 21 CFR 117:

(1) 117.301: All records required by this part are subject to all requirements of this subpart;

(2) 117.315(c): Offsite storage of records is permitted if such records can be retrieved and provided onsite within 24 hours of request for official review. Electronic records are considered to be onsite if they are accessible from an onsite location; and

(3) 117.320: All records required by this part must be made promptly available to the division for official review and copying upon oral or written request.

C. Omissions. Except as otherwise provided, the following omissions are made to the incorporated subparts of 21 CFR 117:

- (1) 117.310;
- (2) 117.315(d);
- (3) 117.325;
- (4) 117.335; and
- (5) The following terms are omitted from section 117.3 Definitions:
 - (a) Allergen;
 - (b) Food;
 - (c) Food-contact surfaces;
 - (d) Lot;
 - (e) Manufacturing/processing; and
 - (f) Packing.

D. Adoption of food code parts 4-5, 4-6 and 4-7. Except as otherwise provided, parts 4-5, 4-6, and 4-7 of the 2017 United States food and drug administration model food code is hereby adopted and incorporated in its entirety.

E. Modifications. Except as otherwise provided, the following modifications are made to the incorporated subparts of the 2017 United States food and drug administration model food code:

(1) 4-603.12 Precleaning.

(a) Food or cannabis product debris on equipment and utensils shall be scraped over a waste disposal unit or garbage receptacle or shall be removed in a warewashing machine with a prewash cycle.

(b) If necessary, for effective cleaning, utensils and equipment shall be pre-flushed, presoaked, or scrubbed with abrasives. Ethyl alcohol (ethanol) or isopropyl alcohol (isopropanol) are acceptable for pre-flushing or presoaking.

F. Omissions. Except as otherwise provided, the following omissions are made to the incorporated subparts of the 2017 United States food and drug administration model food code:

- (1) 4-502.12;

- (2) 4-502.13(B);
- (3) 4-502.14;
- (4) 4-602.11(A)(1);
- (5) 4-602.11(B);
- (6) 4-602.11(D)(3); and
- (7) 4-602.11(E)(2)-(3).

G. Cannabis Product Ingredient Source.

(1) Ingredients shall be received from sources as specified in 7.6.2 NMAC.

(2) Cannabis products, ingredients, and edible or topical cannabis finished products intended for human consumption shall be transported under conditions that will protect against allergen cross-contact and against biological, chemical (including radiological), and physical contamination of the cannabis products, ingredients, and cannabis finished products, as well as against deterioration of the cannabis products, ingredients, and cannabis finished products and the container in accordance with the New Mexico Food Service Sanitation Act and the New Mexico Food Act.

H. The current 21 CFR 111 and United States federal food, drug, and cosmetic act, title 21, chapter 9 and 7.6.2 NMAC are hereby adopted as a technical reference and interpretation guide.
[16.8.6.10 NMAC – N, XX/XX/2022]

~~16.8.6.11~~**16.8.6.10 WATER SUPPLY AND SEWAGE:**

A. Drinking water shall be obtained from an approved source that is:

- (1) a public water system; or
- (2) a non-public water system that is constructed, maintained, and operated according to law.

B. A drinking water system shall be flushed and disinfected before being placed in service after construction, repair, or modification and after an emergency situation, such as a flood, that may introduce contaminants to the system.

C. Except as specified under Subsection D of this section:

(1) Water from a public water system shall meet the construction and drinking water quality standards specified in 20.7.10 NMAC; and

(2) Water from a non-public water system shall meet:

- (a) the construction requirements and drinking water quality standards of a non-community water system as specified in 20.7.10 NMAC; and
- (b) the drinking water source setback requirements as specified in 20.7.3 NMAC.

D. A non-drinking water supply shall be used only if its use is approved and shall be used only for nonculinary purposes such as air conditioning, non-cannabis equipment cooling, and fire protection.

E. Except when used as specified in Subsection D of this section, water from a non-public water system shall meet the sampling requirements of a non-community water system as specified in 20.7.10 NMAC.

F. The most recent sample report for the non-public water system shall be retained on file in the cannabis manufacturer facility or the report shall be maintained as specified by state water quality regulations.

G. Water shall be received from the source through the use of:

- (1) an approved public water main; or
- (2) one or more of the following that shall be constructed, maintained, and operated

according to law:

- (a) Non-public water main, water pumps, pipes, hoses, connections, and other appurtenances;
- (b) Water transport vehicles; or
- (c) Water containers.

H. Sewage shall be disposed of according to LAW. Liquid waste systems shall meet the requirements of 20.7.3 NMAC.

[16.8.6.11 NMAC - N, XX/XX/2022]

~~16.8.6.12~~**16.8.6.11 EDIBLE AND TOPICAL CANNABIS FINISHED PRODUCT TESTING:**

A. Edible and topical cannabis finished products shall meet the requirements specified in division rules related to testing prior to being transported or transferred from the licensed premises, distributed, sold or otherwise made available to consumers.

B. Edible and topical cannabis finished products that do not meet the requirements of Subsection A of this section shall:

- (1) be segregated;
- (2) reworked, remediated or reconditioned as specified in division rules related to testing; or
- (3) destroyed, wasted, and disposed of in accordance with the wastage requirements of the

division.

[16.8.6.12 NMAC – N, XX/XX/2022]

~~16.8.6.13~~16.8.6.12 **EDIBLE AND TOPICAL CANNABIS FINISHED PRODUCT TESTING**

LABORATORIES: Testing required by the division shall be conducted by a division-approved cannabis testing laboratory that has no direct ownership or financial interest in the facility for which the testing is being conducted.

[16.8.6.13 NMAC - N, XX/XX/2022]

~~16.8.6.14~~16.8.6.13 **CEASING OPERATIONS AND REPORTING:**

A. Except as specified in Subsections B and C of this section, a licensee shall immediately discontinue operations if an imminent health hazard may exist because of an emergency such as a fire, flood, extended interruption of electrical or water service, sewage backup, misuse of poisonous or toxic materials, onset of an apparent foodborne or cannabis-borne illness outbreak, gross insanitary occurrence or condition, or other circumstance that may endanger public health, employees, or the environment.

B. A licensee need not discontinue operations in an area of a cannabis manufacturer facility that is unaffected by the imminent health hazard.

C. Considering the nature of the potential hazard involved and the complexity of the corrective action needed, the division may allow the licensee to continue operations in the event of an extended interruption of electrical or water service if:

- (1) a written emergency operating plan has been approved by the division (NMED);
- (2) immediate corrective action is taken by the licensee to eliminate, prevent, or control any food safety risk and imminent health hazard associated with the electrical or water service interruption; and
- (3) the division (NMED) is informed upon implementation of the written emergency operating plan.

D. If operations are discontinued as specified in Subsection A of this section or otherwise according to law, the licensee shall obtain approval from the division (NMED) before resuming operations.

[16.8.6.14 NMAC - N, XX/XX/2022]

~~16.8.6.15~~16.8.6.14 **SEVERABILITY:** If any part or application of this rule is held to be invalid, the remainder or its application to other situations or persons shall not be affected. Any section of this rule legally severed shall not interfere with the remaining protections and duties provided by this rule.

[16.8.6.16 NMAC – N, XX/XX/2022]

History of 16.8.6 NMAC: [RESERVED]