March 2020 Draft Rules with changes from the February Draft highlighted in yellow

TITLE 9. HEALTH SERVICES
CHAPTER 17. MEDICAL MARIJUANA PROGRAM

ARTICLE 1. GENERAL

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ARTICLE 1. GENERAL

R9-17-101. Definitions

In addition to the definitions in A.R.S. § 36-2801, the following definitions apply in this Chapter unless otherwise stated:

1. "Accreditation" means approval being deemed as technically competent under ISO 17025 by the:
   a. American Association of Laboratory Accreditation,
   b. Perry Johnson Laboratory Accreditation,
   c. ANSI National Accreditation Board, or
   d. International Accreditation Services, or
   e. NELAC Institute.

#. "Accuracy testing" means a mechanism in which a laboratory performs testing on samples with known characteristics, prepared by the laboratory, to determine a laboratory agent's ability to analyze samples within specific acceptance criteria.

2. "Acquire" means to obtain through any type of transaction and from any source.
3. "Activities of daily living" means ambulating, bathing, dressing, grooming, eating, toileting, and getting in and out of bed.
4. "Amend" means adding or deleting information on an individual's registry identification card that affects the individual's ability to perform or delegate a specific act or function.

#. "Analyte" means a specific substance for which testing is performed by a laboratory.

#. "Applicant" means:
   a. An individual submitting an application for a registry identification card or to amend, change, or replace a registry identification card for a qualifying patient, designated caregiver, dispensary agent, or laboratory agent; or
   b. An individual or entity submitting an application for a dispensary registration certificate, approval to operate a dispensary, laboratory registration certificate, approval to test, or approval to change parameters.

5. "Batch" means:
   a. When referring to cultivated medical marijuana, a specific lot of medical marijuana grown from one or more seeds or cuttings that are planted and harvested at the same time;
   b. When referring to marijuana products, a specific amount of a marijuana product infused, manufactured, or prepared for sale from the same set of ingredients at the same time; and

c. When referring to testing of medical marijuana or a marijuana product, a specific set of samples prepared and tested during the same run using the same equipment.

6. "Batch number" means a unique numeric or alphanumeric identifier assigned to a batch by a dispensary when:
   a. the The batch of medical marijuana is planted, or
   b. The batch of a marijuana product is infused, manufactured, or prepared for sale.
7. "Calendar day" means each day, not including the day of the act, event, or default from which a designated period of time begins to run, but including the last day of the period unless it is a Saturday, Sunday, statewide furlough day, or legal holiday, in which case the period runs until the end of the next day that is not a Saturday, Sunday, statewide furlough day, or legal holiday.
8. "CHAA" means a Community Health Analysis Area, a geographic area based on population, established by the Department for use by public health programs.
9. "Change" means:
   a. When used in relation to a registry identification card, adding or deleting information on an individual's registry identification card that does not substantively affect the individual's ability to perform or delegate a specific act or function;
   b. When used in relation to a place, moving to a different location;
   c. When used in relation to an individual, selecting a different individual to perform specific actions;
   d. When used in relation to parameters, revising a laboratory's standard operating procedures or quality assurance plan, required in R9-17-404.06, due to:
      i. Adding or removing a parameter,
      ii. Altering a testing method, or
      iii. Using a different instrument for performing a test; and
   e. When used in relation to testing results, altering the testing results in any way and for any reason.
10. "Commercial device" means the same as in A.R.S. § 41-2051.
#. "Contaminant" means matter, pollutant, hazardous substance, or other substance that is not intended to be part of dispensed medical marijuana or a marijuana product.
11. "Cultivation site" means the one additional location where marijuana may be cultivated,

infused, or prepared for sale by and for a dispensary.

12. "Current photograph" means an image of an individual, taken no more than 60 calendar days before the submission of the individual's application, in a Department-approved electronic format capable of producing an image that:
    a. Has a resolution of at least 600 x 600 pixels but not more than 1200 x 1200 pixels;
    b. Is 2 inches by 2 inches in size;
    c. Is in natural color;
    d. Is a front view of the individual's full face, without a hat or headgear that obscures the hair or hairline;
    e. Has a plain white or off-white background; and
    f. Has between 1 and 1 3/8 inches from the bottom of the chin to the top of the head.
13. "Denial" means the Department's final decision not to issue a registry identification card, a dispensary registration certificate, a laboratory registration certificate, or an approval of a change of dispensary or a dispensary's cultivation site location, to an applicant because the applicant or the application does not comply with the applicable requirements in A.R.S. Title 36, Chapter 28.1 or this Chapter.
14. "Dispensary" means the same as "nonprofit medical marijuana dispensary" as defined in A.R.S. § 36-2801.
15. "Dispensary agent" means the same as "nonprofit medical marijuana dispensary agent" as defined in A.R.S. § 36-2801.
16. "Edible food product" means a substance, beverage, or ingredient used or intended for use or for sale in whole or in part for human oral consumption.
17. "Enclosed area" when used in conjunction with "enclosed, locked facility" means outdoor space surrounded by solid, 10-foot walls, constructed of metal, concrete, or stone that prevent any viewing of the marijuana plants, and a 1-inch thick metal gate.
18. "Entity" means a "person" as defined in A.R.S. § 1-215.
19. "Generally accepted accounting principles" means the set of financial reporting standards established by the Financial Accounting Standards Board, the Governmental Accounting Standards Board, or another specialized body dealing with accounting and auditing matters.

#. "Geographic area" means the same as in A.R.S. § 36-2803.01.

#. "Holding time" means the number of minutes, hours, or days that a sample is kept

between sampling and the beginning of testing.

20. "In-state financial institution" means the same as in A.R.S. § 6-101.

21. "Laboratory" means the same as "independent third-party laboratory" as defined in A.R.S. § 36-2801.

22. "Laboratory agent" means the same as "independent third-party laboratory agent" as defined in A.R.S. § 36-2801.

23. "Legal guardian" means an adult who is responsible for a minor:

    a. Through acceptance of guardianship of the minor through a testamentary appointment or an appointment by a court pursuant to A.R.S. Title 14, Chapter 5, Article 2; or

    b. As a "custodian" as defined in A.R.S. § 8-201.

#. "Maximum holding time" means the greatest number of minutes, hours, or days that a sample may be kept between sampling and the beginning of testing and still be considered a valid sample.

24. "Medical record" means the same as:

    a. "Adequate records" as defined in A.R.S. § 32-1401,

    b. "Adequate medical records" as defined in A.R.S. § 32-1501,

    c. "Adequate records" as defined in A.R.S. § 32-1800, or

    d. "Adequate records" as defined in A.R.S. § 32-2901.

25. "Out-of-state financial institution" means the same as in A.R.S. § 6-101.

#. "Parameter" means the combination of a particular type of sample with a specific instrument or equipment by which the sample will be tested for a specific analyte or characteristic.

#. "Proficiency testing" means a mechanism in which samples with known characteristics are submitted to a laboratory for analysis to determine a laboratory agent's ability to analyze samples within specific acceptance criteria.

#. "Proficiency testing service" means an independent company or other person acceptable to the Department, based on ISO/IEC 17043:2010 certification, that:

    a. Is the source for samples with known characteristics for proficiency testing, and

    b. Assesses the acceptability of a laboratory agent's results from the samples with known characteristics during proficiency testing.

26. "Private school" means the same as in A.R.S. § 15-101.

27. "Public place":

    a. Means any location, facility, or venue that is not intended for the regular

exclusive use of an individual or a specific group of individuals;

b. Includes, but not is limited to:

i. Airports;

ii. Banks;

iii. Bars;

iv. Child care facilities;

v. Child care group homes during hours of operation;

vi. Common areas of apartment buildings, condominiums, or other multifamily housing facilities;

vii. Educational facilities;

viii. Entertainment facilities or venues;

ix. Health care institutions, except as provided in subsection (24)(c);

x. Hotel and motel common areas;

xi. Laundromats;

xii. Libraries;

xiii. Office buildings;

xiv. Parking lots;

xv. Parks;

xvi. Public transportation facilities;

xvii. Reception areas;

xviii. Restaurants;

xix. Retail food production or marketing establishments;

xx. Retail service establishments;

xxi. Retail stores;

xxii. Shopping malls;

xxiii. Sidewalks;

xxiv. Sports facilities;

xxv. Theaters; and

xxvi. Waiting rooms; and

c. Does not include:

i. Nursing care institutions as defined in A.R.S. § 36-401,

ii. Hospices as defined in A.R.S. § 36-401,

iii. Assisted living centers as defined in A.R.S. § 36-401,

iv. Assisted living homes as defined in A.R.S. § 36-401,

v. Adult day health care facilities as defined in A.R.S. § 36-401,

vi. Adult foster care homes as defined in A.R.S. § 36-401, or

vii. Private residences.

28. "Public school" means the same as "school" as defined in A.R.S. § 15-101.

29. "Registry identification number" means the random 20-digit alphanumeric identifier generated by the Department, containing at least four numbers and four letters, issued by the Department to a qualifying patient, designated caregiver, dispensary, dispensary agent, laboratory, or laboratory agent.

30. "Revocation" means the Department's final decision that an individual's registry identification card, a dispensary registration certificate, or a laboratory registration certificate is rescinded because the individual, the dispensary, or the laboratory does not comply with the applicable requirements in A.R.S. Title 36, Chapter 28.1 or this Chapter.

#. "Sample" means:

a. A representative portion of a larger quantity of medical marijuana or a marijuana product,

b. A specific quantity of a substance or set of substances to be used for testing purposes, or

c. To collect the representative portion in subsection (#)(a).

31. "Working day" means a Monday, Tuesday, Wednesday, Thursday, or Friday that is not a state holiday or a statewide furlough day.

ARTICLE 3. DISPENSARIES AND DISPENSARY AGENTS

R9-17-310. Administration

A. A dispensary shall:

1. Ensure that the dispensary is operating and available to dispense medical marijuana to qualifying patients and designated caregivers:
   a. at At least 30 hours weekly between the hours of 7:00 a.m. and 10:00 p.m.; and
   b. For a dispensary with a dispensary registration certificate issued on or after April 1, 2020, within 18 months after receiving the dispensary registration certificate;
2. Develop, document, and implement policies and procedures regarding:
   a. Job descriptions and employment contracts, including:
      i. Personnel duties, authority, responsibilities, and qualifications;
      ii. Personnel supervision;
      iii. Training in and adherence to confidentiality requirements;
      iv. Periodic performance evaluations; and
      v. Disciplinary actions;
   b. Business records, such as manual or computerized records of assets and liabilities, monetary transactions, journals, ledgers, and supporting documents, including agreements, checks, invoices, and vouchers;
   c. Inventory control, including:
      i. Tracking;
      ii. Packaging;
      iii. Accepting marijuana from qualifying patients and designated caregivers;
      iv. Acquiring marijuana or marijuana products from other dispensaries;
      v. Disposing of unusable marijuana, which may include submitting any unusable marijuana to a local law enforcement agency; and
      vi. Submitting marijuana or marijuana products to a laboratory agent or laboratory for testing;
      v. Providing marijuana or marijuana products to another dispensary; and
      vi. Either:
         (1) Providing samples of marijuana or marijuana products to a laboratory for testing, or
         (2) Allowing a laboratory agent access to medical marijuana or marijuana product to collect samples;

d. Laboratory testing, including:

i. The analytes, including possible contaminants, to be tested for;

ii. The process for separating a batch of marijuana or of a marijuana product until laboratory testing has been completed and testing results received by the dispensary;

iii. The process for collecting samples of medical marijuana or a marijuana product for laboratory testing, including:

(1) The amount to be collected from each batch,

(2) The method for ensuring that a sample collected is representative of the batch,

(3) The packaging of the sample,

(4) The method for documenting chain of custody for the sample, and

(5) Methods to deter tampering with the sample and to determine whether tampering has occurred;

vi. The process for submitting samples of medical marijuana or a marijuana product to a laboratory agent or laboratory for testing or retesting; and

v. Actions to be taken on the basis of laboratory testing results;

e. Remediation, including:

i. Criteria for when a batch of medical marijuana or marijuana product can be remediated;

ii. The process by which each type of medical marijuana or marijuana product is remediated, including the methods for remediation and subsequent retesting; and

iii. Documentation of the remediation process;

f. Disposal of marijuana or a marijuana product, including:

i. Destroying a batch of marijuana or a marijuana product that does not meet the requirements in Table 3.1 and documenting the destruction,

ii. Submitting marijuana that is not usable marijuana to a local law enforcement agency and documenting the submission, or

iii. Otherwise disposing of marijuana or a marijuana product and documenting the method of disposal, the laboratory agent overseeing the disposal, and the date of disposal;

d.g. Qualifying patient records, including purchases, denials of sale, any delivery

options, confidentiality, and retention; and

e.h. Patient education and support, including the development and distribution of materials on:

i. Availability of different strains of marijuana and the purported effects of the different strains;

ii. Information about the purported effectiveness of various methods, forms, and routes of medical marijuana administration;

iii. Information about laboratory testing, the analytes for which the dispensary receives testing results, the right to receive a copy of the final report of testing specified in R9-17-404.06 upon request, and how to read and understand the final report of testing;

iii.iv. Methods of tracking the effects on a qualifying patient of different strains and forms of marijuana; and

iv.v. Prohibition on the smoking of medical marijuana in public places;

3. Maintain copies of the policies and procedures at the dispensary and provide copies to the Department for review upon request;
4. Review dispensary policies and procedures at least once every 12 months from the issue date of the dispensary registration certificate and update as needed;
5. Employ or contract with a medical director;
6. Ensure that each dispensary agent has the dispensary agent's registry identification card in the dispensary agent's immediate possession when the dispensary agent is:
   a. Working or providing volunteer services at the dispensary or the dispensary's cultivation site, or
   b. Transporting marijuana for the dispensary;
7. Ensure that a dispensary agent accompanies any individual other than another dispensary agent associated with the dispensary when the individual is present in the enclosed, locked facility where marijuana is cultivated by the dispensary;
8. Not allow an individual who does not possess a dispensary agent registry identification card issued under the dispensary registration certificate to:
   a. Serve as a principal officer or board member for the dispensary,
   b. Serve as the medical director for the dispensary,
   c. Be employed by the dispensary, or
   d. Provide volunteer services at or on behalf of the dispensary;
9. Provide written notice to the Department, including the date of the event, within 10

working days after the date, when a dispensary agent no longer:

a. Serves as a principal officer or board member for the dispensary,

b. Serves as the medical director for the dispensary,

c. Is employed by the dispensary, or

d. Provides volunteer services at or on behalf of the dispensary;

10. Document and report any loss or theft of marijuana from the dispensary to the appropriate law enforcement agency;

11. Maintain copies of any documentation required in this Chapter for at least 12 months after the date on the documentation and provide copies of the documentation to the Department for review upon request;

12. Post the following information in a place that can be viewed by individuals entering the dispensary:

a. If applicable, the dispensary's approval to operate;

b. The dispensary's registration certificate;

c. The name of the dispensary's medical director and the medical director's professional license number on a sign at least 20 centimeters by 30 centimeters;

d. The hours of operation during which the dispensary will dispense medical marijuana to a qualifying patient or a designated caregiver; and

e. A sign in a Department-provided format that contains the following language:

i. "WARNING: There may be potential dangers to fetuses caused by smoking or ingesting marijuana while pregnant or to infants while breastfeeding," and

ii. "WARNING: Use of marijuana during pregnancy may result in a risk of being reported to the Department of Child Safety during pregnancy or at the birth of the child by persons who are required to report;"

13. Not lend any part of the dispensary's income or property without receiving adequate security and a reasonable rate of interest;

14. Not purchase property for more than adequate consideration in money or cash equivalent;

15. Not pay compensation for salaries or other compensation for personal services that is in excess of a reasonable allowance;

16. Not sell any part of the dispensary's property or equipment for less than adequate consideration in money or cash equivalent; and

17. Not engage in any other transaction that results in a substantial diversion of the dispensary's income or property.

B. If a dispensary cultivates marijuana, the dispensary shall cultivate the marijuana in an enclosed, locked facility.

R9-17-317. Product Labeling and Analysis

A. A dispensary shall ensure that medical marijuana or a marijuana product provided by the dispensary to a qualifying patient or a designated caregiver is labeled with:

1. The dispensary's registry identification number;
2. The amount, strain, and batch number of the medical marijuana or marijuana product;
3. The form of the medical marijuana or marijuana product;
4. As applicable, the weight of the medical marijuana or marijuana product;
5. Beginning November 1, 2020, and in compliance with Table 3.1, the potency of the:
   a. Medical marijuana, based on laboratory testing results; or
   b. Marijuana product, based on laboratory testing results;
6. The following statement: "ARIZONA DEPARTMENT OF HEALTH SERVICES' WARNING: Marijuana use can be addictive and can impair an individual's ability to drive a motor vehicle or operate heavy machinery. Marijuana smoke contains carcinogens and can lead to an increased risk for cancer, tachycardia, hypertension, heart attack, and lung infection. KEEP OUT OF REACH OF CHILDREN";
7. If not cultivated by the dispensary, whether the medical marijuana was obtained from a qualifying patient, a designated caregiver, or another dispensary;
8. If not infused or prepared for sale by the dispensary, whether the marijuana product was obtained from another dispensary;
9. For a marijuana product, the ingredients in order of abundance;
10. The date of manufacture, harvest, or sale;
6. A list of all chemical additives, including nonorganic pesticides, herbicides, and fertilizers, used in the cultivation and production of the medical marijuana; and
11. The registry identification number of the qualifying patient.

B. If a dispensary provides medical marijuana cultivated, or a marijuana product infused or prepared for sale, by the dispensary to another dispensary, the dispensary shall ensure that:

1. the The medical marijuana or marijuana product is labeled with:
   a. The dispensary's registry identification number;
   b. The amount, strain, and batch number of the medical marijuana or marijuana product; and
   c. The date of harvest or sale; and

4. A list of all chemical additives, including nonorganic pesticides, herbicides, and fertilizers, used in the cultivation of the medical marijuana.

2. A copy of laboratory testing results for the medical marijuana or marijuana product is provided to the receiving dispensary.

C. If medical marijuana is provided as part of an edible food product, a dispensary shall, in addition to the information in subsection (A), include on the label the total weight of the edible food product.

D. A dispensary shall provide to the Department upon request a sample of the dispensary's medical marijuana inventory of sufficient quantity to enable the Department to conduct an analysis of the medical marijuana. **[Moved to next Section]**

R9-17-317.01. Analysis of Medical Marijuana or a Marijuana Product

A. Beginning on November 1, 2020, before offering a batch of medical marijuana or of a marijuana product for sale or dispensing, a dispensary shall ensure that each batch of medical marijuana or marijuana product is tested in compliance with requirements in R9-17-404.03, R9-17-404.04, and Table 3.1.

B. A dispensary shall ensure that:

1. Until laboratory testing has been completed and testing results received by the dispensary that comply with requirements in R9-17-404.03, R9-17-404.04, and Table 3.1, a batch of marijuana or of a marijuana product is stored in a location away from medical marijuana and marijuana products offered for dispensing or for sale to another dispensary;
2. Samples of each batch of medical marijuana or marijuana product are collected according to ANSI/ASQ Standard Z1.4 (2018), General Inspection Level II, incorporated by reference, including no future editions, and available at https://asq.org/quality-resources/z14-z19, including:
   a. Use, as applicable, of one of the following sampling methods:
      i. Top, middle, and bottom sampling using a sample thief, a device consisting of two nested tubes with one or more aligned slots through which a sample may be collected and then sealed into the inner tube by rotating the outer tube;
      ii. Star pattern sampling from the top, middle, and bottom of each storage container;
      iii. Collecting discrete incremental units of a batch, such as every tenth unit or every twentieth drop; or

iv. Quartering until the sample reaches the size specified in subsection (B)(3); and

b. For sampling methods specified in subsections (B)(2)(a)(i) through (iii), quartering the volume of the aggregated samples collected to obtain the size specified in subsection (B)(3);

3. The minimum size of the sample provided to a laboratory for testing is 16 grams;

4. Each sample in subsection (B)(3) is packaged in a container made of the same material that would be used, as applicable, for:

a. Sale or transfer to another dispensary,

b. Storage at a dispensary prior to dispensing, or

c. Dispensing;

5. Each packaged sample is labeled with the:

a. The dispensary's registry identification number;

b. The amount, strain, and batch number of the medical marijuana or marijuana product;

c. The storage temperature for the medical marijuana or marijuana product; and

d. The date of sampling;

6. A packaged sample in subsection (B)(4) is submitted to a laboratory that:

a. Has a laboratory registration certificate issued by the Department, and

b. Is approved by the Department to test for the analyte for which testing is being requested;

7. The samples in subsection (B)(4) are tested for each analyte specified in Table 3.1;

8. Only batches of marijuana or marijuana products for which laboratory testing results in subsection (B)(7) are in compliance with the requirements in R9-17-404.03, R9-17-404.04, and Table 3.1 are offered for sale or dispensing; and

9. Any batch of marijuana or marijuana product that does not comply with the requirements in R9-17-404.03, R9-17-404.04, and Table 3.1 is remediated, if applicable, or destroyed according to policies and procedures.

C. A dispensary may request retesting by the same laboratory of a sample that does not comply with the requirements in Table 3.1 to assess the accuracy of the laboratory's testing result.

D. A dispensary shall ensure that remediation of a batch of marijuana or of a marijuana product that has undergone laboratory testing and does not comply with the requirements in R9-17-404.03, R9-17-404.04, and Table 3.1:

1. Is performed according to policies and procedures,

2. Uses a method that is appropriate to address an analyte not in compliance with Table 3.1, and

3. Does not introduce or produce a substance in a concentration that is known to be harmful to humans.

E. If a batch of medical marijuana I or a marijuana product is remediated, a dispensary shall submit samples from the remediated batch for laboratory testing according to subsection (B).

F. A dispensary shall provide to the Department upon request a sample of the dispensary's inventory of medical marijuana or a marijuana product of sufficient quantity to enable the Department to conduct an analysis of the medical marijuana or marijuana product. **[Moved from 317]**

Table 3.1. Analytes

Key:

CAS Number = Chemical Abstract Services Registry number
CFU = Colony-forming unit, a method to estimate the number of viable bacteria or fungal cells in a sample

A. Microbial Contaminants

Analyte	Maximum Allowable Contaminants	Required Action
Escherichia coli	100 CFU/g	Remediate and retest, or Destroy
Salmonella spp.	Detectable	Destroy
Aspergillus flavus *Aspergillus fumigatus* *Aspergillus niger* *Aspergillus terreus*	Inhalable: Detectable	Remediate and retest, Remediate and use for preparing an extract or a concentrate, or Destroy
Mycotoxins: Aflatoxin B1, B2, G1, and G2 Ochratoxin A	Marijuana product prepared from an extract or concentrate of medical marijuana: ≥ 20 µg/kg (ppb) of total aflatoxins or of ochratoxin	Destroy

B. Heavy Metals

Analyte	Maximum Allowable Concentration	Required Action
Arsenic	0.4 ppm	Remediate and retest, or Destroy
Cadmium	0.4 ppm	
Lead	1.0 ppm	
Mercury	1.2 ppm	

C. Residual Solvents

Analyte	CAS Number	Maximum Allowable Concentration	Required Action
Acetone	67-64-1	1,000 ppm	Remediate and retest, or Destroy
Acetonitrile	75-05-8	410 ppm	
Benzene	71-43-2	2 ppm	
Butanes (measured as the cumulative residue of n-butane and iso-butane)	106-97-8 and 75-28-5, respectively	5,000 ppm	
Chloroform	67-66-3	60 ppm	
Dichloromethane	75-09-2	600 ppm	
Ethanol	64-17-5	5,000 ppm	
Ethyl Acetate	141-78-6	5,000 ppm	
Ethyl Ether	60-29-7	5,000 ppm	
Heptane	142-82-5	5,000 ppm	
Hexanes (measured as the cumulative residue of n-hexane, 2-methylpentane, 3-methylpentane, 2,2-dimethylbutane, and 2,3-dimethylbutane)	110-54-3, 107-83-5, 96-14-0, 75-83-2, and 79-29-8, respectively	290 ppm	
Isopropyl Acetate	108-21-4	5,000 ppm	
Methanol	67-56-1	3,000 ppm	
Pentanes (measured as the cumulative	109-66-0, 78-78-4, and	5,000 ppm	

residue of n-pentane, iso-pentane, and neo-pentane)	463-82-1, respectively		
2-Propanol (IPA)	67-63-0	5,000 ppm	
Propane	74-98-6	5,000 ppm	
Toluene	108-88-3	890 ppm	
Xylenes (measured as the cumulative residue of 1,2-dimethylbenzene, 1,3-dimethylbenzene, and 1,4-dimethylbenzene, and the non-xylene, ethyl benzene)	1330-20-7 (95-47-6, 108-38-3, and 106-42-3, respectively, and 100-41-4)	2,170 ppm	

D. Pesticides, Fungicides, Herbicides, Growth Regulators

Analyte	CAS Number	Maximum Allowable Concentration	Required Action
Abamectin	71751-41-2	0.5 ppm	Remediate and retest, or Destroy
Acephate	30560-19-1	0.4 ppm	
Acequinocyl	57960-19-7	2.0 ppm	
Acetamiprid	135410-20-7	0.2 ppm	
Aldicarb	116-06-3	0.4 ppm	
Azoxystrobin	131860-33-8	0.2 ppm	
Bifenazate	149877-41-8	0.2 ppm	
Bifenthrin	82657-04-3	0.2 ppm	
Boscalid	188425-85-6	0.4 ppm	
Carbaryl	63-25-2	0.2 ppm	
Carbofuran	1563-66-2	0.2 ppm	
Chlorantraniliprole	500008-45-7	0.2 ppm	
Chlorfenapyr	122453-73-0	1.0 ppm	
Chlorpyrifos	2921-88-2	0.2 ppm	
Clofentezine	74115-24-5	0.2 ppm	
Cyfluthrin	68359-37-5	1.0 ppm	
Cypermethrin	52315-07-8	1.0 ppm	
Daminozide	1596-84-5	1.0 ppm	
DDVP (Dichlorvos)	62-73-7	0.1 ppm	
Diazinon	333-41-5	0.2 ppm	
Dimethoate	60-51-5	0.2 ppm	
Ethoprophos	13194-48-4	0.2 ppm	
Etofenprox	80844-07-1	0.4 ppm	
Etoxazole	153233-91-1	0.2 ppm	
Fenoxycarb	72490-01-8	0.2 ppm	
Fenpyroximate	134098-61-6	0.4 ppm	
Fipronil	120068-37-3	0.4 ppm	
Flonicamid	158062-67-0	1.0 ppm	
Fludioxonil	131341-86-1	0.4 ppm	
Hexythiazox	78587-05-0	1.0 ppm	
Imazalil	35554-44-0	0.2 ppm	
Imidacloprid	138261-41-3	0.4 ppm	

Kresoxim-methyl	143390-89-0	0.4 ppm	
Malathion	121-75-5	0.2 ppm	
Metalaxyl	57837-19-1	0.2 ppm	
Methiocarb	2032-65-7	0.2 ppm	
Methomyl	16752-77-5	0.4 ppm	
Methyl parathion	298-00-0	0.2 ppm	
MGK-264	113-48-4	0.2 ppm	
Myclobutanil	88671-89-0	0.2 ppm	
Naled	300-76-5	0.5 ppm	
Oxamyl	23135-22-0	1.0 ppm	
Paclobutrazol	76738-62-0	0.4 ppm	
Permethrins (measured as the cumulative residue of cis- and trans-isomers)	52645-53-1 (54774-45-7 and 51877-74-8)	0.2 ppm	
Phosmet	732-11-6	0.2 ppm	
Piperonyl_butoxide	51-03-6	2.0 ppm	
Prallethrin	23031-36-9	0.2 ppm	
Propiconazole	60207-90-1	0.4 ppm	
Propoxur	114-26-1	0.2 ppm	
Pyrethrins (measured as the cumulative residue of pyrethrin 1, cinerin 1 and jasmolin 1)	8003-34-7 (121-21-1, 25402-06-6, and 4466-14-2)	1.0 ppm	
Pyridaben	96489-71-3	0.2 ppm	
Spinosad	168316-95-8	0.2 ppm	
Spiromesifen	283594-90-1	0.2 ppm	
Spirotetramat	203313-25-1	0.2 ppm	
Spiroxamine	118134-30-8	0.4 ppm	
Tebuconazole	107534-96-3	0.4 ppm	
Thiacloprid	111988-49-9	0.2 ppm	
Thiamethoxam	153719-23-4	0.2 ppm	
Trifloxystrobin	141517-21-7	0.2 ppm	

E. Potency

Analyte	Labelling	Required Action
Tetrahydrocannabinolic acid (THC-A)	Label claim is not within +/- 20 % of tested value	Revise label as necessary
Delta-9-tetrahydrocannabinol (Δ9-THC)		
Cannabidiolic acid (CBD-A)		
Cannabidiol (CBD)		

ARTICLE 4. LABORATORIES AND LABORATORY AGENTS

R9-17-402. Applying for a Laboratory Registration Certificate

A. To apply for a laboratory registration certificate, an applicant shall submit to the Department the following:

1. An application in a Department-provided format that includes:
   a. The physical address of the laboratory;
   b. The distance to the closest private school or public school from the laboratory;
   b.c. The following information for the laboratory applying:
      i. The legal name of the laboratory,
      ii. Type of business organization,
      iii. Mailing address,
      iv. Telephone number, and
      v. E-mail address;
   c.d. The name of the owner designated to submit laboratory agent registry identification card applications on behalf of the laboratory;
   d.e. The name, residence address, and date of birth of each owner;
   f. The identifying number on the applicable card or document in subsection (A)(4)(d)(i) through (v);
   e.g. The name, residence address, and date of birth of the technical laboratory director designated according to R9-17-404(3);
   h. For each parameter for which approval for testing is being requested:
      i. The type of sample,
      ii. The analyte to be tested for,
      iii. The instruments and equipment to be used for testing, and
      iv. The software to be used at the laboratory for instrument control and data reduction interpretation;
   f.i. The name, residence address, and date of birth of each laboratory agent other than an owner or the technical laboratory director, if applicable;
   g. For each laboratory agent, an attestation signed and dated by the laboratory agent that the laboratory agent has not been convicted of an excluded felony offense as defined in A.R.S. § 36-2801;
   h. Policies and procedures that comply with the requirements in this Chapter that contain:

i. A quality assurance program and standards;

ii. Inventory control;

iii. A chain of custody and sample requirement process;

iv. A records retention process;

v. Security;

vi. A process to ensure marijuana or marijuana products test results are accurate, precise, and scientifically valid before reporting the results; and

vii. A process for disposal of marijuana or marijuana products that are submitted to the laboratory for testing;

i.j. Whether the laboratory agrees to allow the Department to submit supplemental requests for information;

j.k. An attestation that the information provided to the Department to apply for a laboratory registration certificate is true and correct; and

k.l. The signatures of the owner of the laboratory, according to R9-17-401(A), and the technical laboratory director and the date the owner each signed;

2. Policies and procedures that comply with the requirements in this Chapter that contain:

a. A quality assurance program and standards;

b. Inventory control;

c. A chain of custody and sample requirement process;

d. A records retention process;

e. Security;

f. A process to ensure marijuana or marijuana products testing results are accurate, precise, and scientifically valid before reporting the results; and

g. A process for disposal of marijuana or marijuana products that are submitted to the laboratory for testing; **[Includes the excess of the sample submitted and what was prepared but not used for testing]**

2.3. If the entity applying applicant is one of the business organizations in R9-17-401(A)(2) through (7), a copy of the business organization's articles of incorporation, articles of organization, or partnership or joint venture documents that include:

a. The name of the business organization,

b. The type of business organization, and

c. The names and titles of the individuals in R9-17-401(A);

3.4. For each owner:

a. An attestation signed and dated by the owner that the owner has not been

convicted of an excluded felony offense as defined in A.R.S. § 36-2801;

b. An attestation signed and dated by the owner that the owner does not have a direct or indirect familial or financial relationship with or interest in a dispensary, related medical marijuana business entity, or management company;

b.c. An attestation signed and dated by the owner that the laboratory will not test marijuana or marijuana products for:

i. A dispensary, related medical marijuana business entity, or management company that the owner has a direct or indirect familial or financial relationship with or interest in; or

ii. A a designated caregiver who the owner has a direct or indirect familial or financial relationship with;

d. An attestation signed and dated by the owner pledging not to divert marijuana to any individual who or entity that is not allowed to possess marijuana pursuant to A.R.S. Title 36, Chapter 28.1;

e. A copy the owner's:

i. Arizona driver's license issued on or after October 1, 1996;

ii. Arizona identification card issued on or after October 1, 1996;

iii. Arizona registry identification card;

iv. Photograph page in the owner's U.S. passport; or

v. Arizona driver's license or identification card issued before October 1, 1996 and one of the following for the owner:

(1) Birth certificate verifying U.S. citizenship,

(2) U. S. Certificate of Naturalization, or

(3) U. S. Certificate of Citizenship; and

c.f. For the Department's criminal records check authorized in A.R.S. §§ 36-2804.01 and 36-2804.07:

i. The owner's fingerprints on a fingerprint card that includes:

(1) The owner's first name; middle initial, if applicable; and last name;

(2) The owner's signature;

(3) If different from the owner, the signature of the individual physically rolling the owner's fingerprints;

(4) The owner's residence address;

(5) If applicable, the owner's surname before marriage and any

names previously used by the owner;

(6) The owner's date of birth;

(7) The owner's Social Security number;

(8) The owner's citizenship status;

(9) The owner's gender;

(10) The owner's race;

(11) The owner's height;

(12) The owner's weight;

(13) The owner's hair color;

(14) The owner's eye color; and

(15) The owner's place of birth; or

ii. If the fingerprints and information required in subsection (A)(3)(c)(i) (A)(4)(f)(i) were submitted to the Department as part of an application for a designated caregiver registry identification card, dispensary agent registry identification card, or laboratory agent registry identification card within the previous six months, the registry identification number on the registry identification card issued to the owner as a result of the application;

4.5. If zoning restrictions have been enacted, a sworn statement signed and dated by the individual or individuals in R9-17-401(A) certifying that the laboratory is in compliance with any local zoning restrictions;

5.6. A copy of documentation issued by the local jurisdiction to the laboratory authorizing occupancy of the building as a laboratory, such as a certificate of occupancy, a special use permit, or a conditional use permit;

6. The distance to the closest private school or public school from the laboratory;

7. A site plan drawn to scale of the laboratory location showing streets, property lines of the contiguous premises, buildings, parking areas, outdoor areas if applicable, fences, security features, fire hydrants if applicable, and access to water mains;

8. A floor building plan drawn to scale of the building where the laboratory is located showing the:

a. Layout and dimensions of each room,;

b. Name and function of each room,;

#. Fire ratings of the materials used for ceilings, walls, doors, and floors of rooms used to store flammable substances;

#. Location of each fire protection device;

#. Layout of heating, air conditioning, exhaust, and ventilation systems;

#. Location and layout of refrigerated rooms or freezer rooms;

c. Location of each hand washing sink, safety shower, other water supply, or plumbing fixture;

#. Location of fixed or movable equipment and instruments that require dedicated electrical, water, vacuum, gas, or other building systems;

d. Location of each toilet room security measures or equipment to protect from diversion of marijuana or marijuana products,; and

e. Means of egress;

9. Documentation of accreditation;

10. The laboratory's Transaction Privilege Tax Number issued by the Arizona Department of Revenue; and

11. The applicable fee in R9-17-102 for applying for a laboratory registration certificate.

B. Within 72 hours after an owner receives a laboratory registration certificate pursuant to an application submitted according to subsection (A), the owner shall apply for a laboratory agent registry identification card, according to R9-17-405, for each laboratory agent, including an owner or a technical laboratory director.

B.C. A change in location of the laboratory's physical address or ownership requires a new application to be submitted according to subsection (A).

D. A separate laboratory registration certificate is required for each noncontiguous portion of a laboratory.

R9-17-402.01. Applying for Approval for Testing

To apply for approval for testing, an applicant shall submit to the Department, at least 60 calendar days before the expiration of the initial laboratory registration certificate for the laboratory, the following:

1. An application in a Department-provided format that includes:

a. The name and registry identification number of the laboratory;

b. The physical address of the laboratory;

c. The name of the applicant;

d. The name of the technical laboratory director designated according to R9-17-404(3);

e. The name, address, and date of birth of or the laboratory agent registry identification card number for each laboratory agent;

f. For each parameter for which approval for testing is being requested:
   i. The type of sample,
   ii. The analyte to be tested for,
   iii. The instruments and equipment to be used for testing, and
   iv. The software to be used at the laboratory for instrument control and data reduction interpretation;
g. The laboratory's proposed hours of operation;
h. Whether the laboratory agrees to allow the Department to submit supplemental requests for information;
i. Whether the laboratory is ready for an inspection by the Department;
j. If the laboratory is not ready for an inspection by the Department, the date the laboratory will be ready for an inspection by the Department;
k. An attestation that the information provided to the Department to apply for approval to operate the laboratory is true and correct; and
l. The signatures of the owner of the laboratory, according to R9-17-401(A), and the technical laboratory director and the date each signed;

2. For each parameter listed according to subsection (1)(f):
   a. The limit of quantitation;
   b. A copy of current accreditation;
   c. A copy of a proficiency testing report, if applicable, or accuracy testing documentation; and
   d. A copy of the standard operating procedure; and

3. If different from the building plan submitted according to R9-17-402(A)(8), a building plan drawn to scale of the building where the laboratory is located showing the:
   a. Layout and dimensions of each room;
   b. Name and function of each room;
   #. Fire ratings of the materials used for ceilings, walls, doors, and floors of rooms used to store flammable substances;
   #. Location of each fire protection device;
   #. Layout of heating, air conditioning, exhaust, and ventilation systems;
   #. Location and layout of refrigerated rooms or freezer rooms;
   c. Location of each sink, safety shower, other water supply, or plumbing fixture;
   #. Location of fixed or movable equipment and instruments that require dedicated electrical, water, vacuum, gas, or other building systems;

d. Location of security equipment to protect from diversion of marijuana or marijuana products; and

e. Means of egress.

R9-17-403. Renewing a Laboratory Registration Certificate

To renew a laboratory registration certificate, a laboratory an applicant shall submit to the Department, at least 30 calendar days before the expiration date of the laboratory's current laboratory registration certificate, but no more than 90 days before the expiration date of the laboratory's current laboratory registration certificate, the following:

1. An application in a Department-provided format that includes:
   a. The physical address of the laboratory;
   b. The following information for the laboratory:
      i. The legal name of the laboratory,
      ii. The registry identification number for the laboratory,
      iii. Type of business organization,
      iv. Mailing address,
      v. Telephone number, and
      vi. E-mail address;
   c. The name of the owner designated to submit laboratory agent registry identification card applications on behalf of the laboratory;
   d. The name, residence address, and date of birth of each owner;
   e. The name, residence address, and date of birth of the technical laboratory director designated according to R9-17-404(3);
   f. The name, residence address, and date of birth of each laboratory agent, if applicable;
   g. For each laboratory agent, an attestation signed and dated by the laboratory agent that the laboratory agent has not been convicted of an excluded felony offense as defined in A.R.S. § 36-2801;
   g. Whether the applicant is requesting the same parameters for which the laboratory is currently approved, including the same:
      i. Analytes,
      ii. Instruments and equipment to be used for testing, and
      iii. Software to be used at the laboratory for instrument control and data reduction interpretation;

h. For each new parameter for which approval for testing is being requested:

i. The type of sample,

ii. The analyte to be tested for,

iii. The instruments and equipment to be used for testing, and

iv. The software to be used at the laboratory for instrument control and data reduction interpretation;

h.i. Whether the laboratory agrees to allow the Department to submit supplemental requests for information;

i.j. An attestation that the information provided to the Department to renew the laboratory registration certificate is true and correct; and

j.k. The signatures of the each owner of the laboratory, according to R9-17-401(A), and the technical laboratory director and the date the owner each signed;

2. For each owner:

a. An attestation signed and dated by the owner that the owner has not been convicted of an excluded felony offense as defined in A.R.S. § 36-2801; and

b. An attestation signed and dated by the owner that the laboratory will not test medical marijuana and medical marijuana products for:

i. A dispensary, related medical marijuana business entity, or management company that the owner has a direct or indirect familial or financial relationship with or interest in; or

ii. A designated caregiver who the owner has a direct or indirect familial or financial relationship with;

3. If zoning restrictions have been enacted, a sworn statement signed and dated by the owner in R9-17-401(A) certifying that the laboratory is in compliance with any local zoning restrictions;

4. A copy of documentation issued by the local jurisdiction to the laboratory authorizing occupancy of the building as a laboratory, such as a certificate of occupancy, a special use permit, or a conditional use permit; and

3. For each new or current parameter, documentation of current accreditation;

4. For each new parameter for which approval for testing is being requested:

a. The limit of quantitation;

b. A copy of a proficiency testing report, if applicable, or accuracy testing documentation; and

c. A copy of the standard operating procedure;

5. If a change has been made to the standard operating procedure for a current parameter, a copy of the revised standard operating procedure;

6. If a change has been made in the quality assurance plan for a current parameter required in R9-17-404.03 or R9-17-404.04, a copy of the revised standard operating procedure and

5.7. The applicable fee in R9-17-102 for applying to renew a laboratory registration certificate.

R9-17-404. Administration

A laboratory An owner of a laboratory with a laboratory registration certificate shall:

1. Comply with the:
   a. Quality assurance requirements in A.A.C. R9-14-615(B) and (C) R9-17-404.05,
   b. Operation requirements in A.A.C. R9-14-616 R9-17-404.06, and
   c. Laboratory records and reports requirements in A.A.C. R9-15-617(1) through (7) R9-17-404;
2. Maintain accreditation for each approved parameter;
3. Designate in writing a technical laboratory director who shall:
   a. Has knowledge and experience in overseeing a laboratory as documented by:
      i. A doctoral degree in chemistry, biochemistry, microbiology, or a similar laboratory science;
      ii. A master's degree in chemistry, biochemistry, microbiology, or a similar laboratory science and at least two years of experience working in a laboratory and providing laboratory testing; or
      iii. A bachelor's degree in chemistry, biochemistry, microbiology, or a similar laboratory science and at least four years of experience working in a laboratory and providing laboratory testing; and
   b. Is responsible for:
      a.i. Ensure Ensuring that all services and tests provided by the laboratory are performed in compliance with the requirements in this Article,;
      b.ii. Direct and supervise Directing and supervising services and tests provided by the laboratory;
      iii. and be responsible for Overseeing the work of all personnel in the laboratory,;
      iv. Providing ongoing training to laboratory agents, as applicable to the functions performed by a laboratory agent; and

c.v. Be responsible for Ensuring safety and hazardous substance control in the laboratory;

4. Notify the Department in writing within 20 business working days after any change in the technical laboratory director, providing the name and contact information for the new technical laboratory director;

5. Develop, document, and implement policies and procedures regarding:

a. Job descriptions and employment contracts, including:

i. Personnel duties, authority, responsibilities, and qualifications;

ii. Personnel supervision;

iii. Ongoing training, applicable to the functions performed by a laboratory agent;

iii.iv. Training in and adherence to confidentiality requirements;

iv.v. Periodic performance evaluations, including proficiency testing or accuracy testing, as applicable, on a rotating basis among all laboratory agents performing similar functions; and

v. Disciplinary actions;

b. Business records, such as manual or computerized records of assets and liabilities, monetary transactions, journals, ledgers, and supporting documents, including agreements, checks, invoices, and vouchers;

c. Inventory control, including:

i. Tracking;

ii. Accepting marijuana or marijuana products for testing;

iii. Testing marijuana and marijuana products; and

iv. Disposing of marijuana or marijuana products, including the method of destruction, whether destroyed marijuana or marijuana products were tested, if not tested, the reason and whether any unusable marijuana or marijuana products were submitted to a local law enforcement agency;

d. Standard operating procedures, including:

i. The review and updating of standard operating procedures;

ii. Requirements for a laboratory agent to review current, new, or updated standard operating procedures applicable to the functions performed by the laboratory agent; and

iii. Documenting the review of standard operating procedures by applicable laboratory agents;

d.e. Laboratory records, including:

i. submissions Submission of medical marijuana and marijuana products for testing,;

ii. The chain of custody for a sample accepted by the laboratory for testing;

iii. The storage of a submitted sample prior to testing to maintain the integrity of the sample and analyte;

iv. The process for selecting a portion of a submitted sample for testing;

v. ensuring Ensuring testing results are accurate, precise, and scientifically valid before reporting the results,;

vi. reporting Reporting of testing results,;

vii. confidentiality Confidentiality,; and

viii. retention Retention;

e.f. A quality assurance program and standards;

f. A chain of custody and sample process;

g. A records retention process; and

h. Security;

6. Review and document the review of laboratory policies and procedures at least once every 12 months after the issue date of the laboratory registration certificate and update as needed;

7. Ensure that each laboratory agent has the laboratory agent's registry identification card in the laboratory agent's immediate possession when the laboratory agent is working or providing volunteer services related to marijuana or marijuana products testing at the laboratory;

8. Ensure that a laboratory agent accompanies any individual other than another laboratory agent associated with the laboratory when the individual is present in the area of the laboratory where marijuana or marijuana products are being tested or stored for testing;

9. Not allow an individual who does not possess a laboratory agent registry identification card issued under the laboratory registration certificate to:

a. Serve as an owner for the laboratory,

b. Be employed by the laboratory, or

c. Provide volunteer services at or on behalf of the laboratory;

10. Provide written notice to the Department, including the date of the event, within 10 working days after the date, when a laboratory agent no longer:

a. Serves as an owner for the laboratory,

b. Is employed by the laboratory, or

c. Provides volunteer services at or on behalf of the laboratory;

11. Document and report any loss or theft of marijuana or marijuana products from the laboratory to the appropriate law enforcement agency; and

12.11. Maintain Unless otherwise specified, maintain copies of any documentation required in this Chapter for at least 12 months after the date on the documentation and provide copies of the documentation to the Department for review upon request.

R9-17-404.01. Compliance Monitoring

A. Submission of an application for a laboratory registration certificate constitutes permission for:

1. The Department's entry to and inspection of the laboratory, and
2. The Department to conduct proficiency testing according to R9-17-404.02.

B. The Department shall conduct:

1. An initial laboratory inspection; and
2. A follow-up laboratory inspection, at least annually.

C. The Department shall comply with A.R.S. § 41-1009 in conducting a laboratory inspection or investigation.

D. The Department shall not accept allegations of a laboratory's noncompliance with A.R.S. Title 36, Chapter 28.1 or this Chapter from an anonymous source.

E. If the Department receives an allegation of a laboratory's noncompliance with A.R.S. Title 36, Chapter 28.1 or this Chapter, the Department may conduct an unannounced inspection of the laboratory.

F. If the Department determines that a laboratory is not in compliance with the requirements of A.R.S. Title 36, Chapter 28.1, or this Chapter, the Department:

1. Shall provide the owner, according to R9-17-401(A), and technical laboratory director with a written notice that includes the specific rule or statute that was violated; and
2. May:
   a. Take an enforcement action as described in R9-17-410; or
   b. Require that the technical laboratory director submit to the Department, within 30 calendar days after written notice from the Department, a corrective action plan to address issues of compliance that do not directly affect the health or safety of a qualifying patient or laboratory agent that:
      i. Describes how each identified instance of noncompliance will be corrected and reoccurrence prevented, and

ii. Includes a date for correcting each instance of noncompliance that is appropriate to the actions necessary to correct the instance of noncompliance.

G. Under A.R.S. § 41-1009(G) and (I), the Department's decision regarding whether a technical laboratory director may submit a corrective action plan on behalf of a laboratory or whether a deficiency has been corrected or has been corrected within a reasonable period of time is not an appealable agency action as defined by A.R.S. § 41-1092.

R9-17-404.02. Proficiency Testing; Accuracy Testing

A. At least once in each 12-month period, and more often if requested by the Department, a technical laboratory director shall have at least one laboratory agent, selected according to policies and procedures, participate in proficiency testing provided by the Department or a proficiency testing service that:

1. Includes at least one proficiency testing sample for each parameter for which the laboratory has been approved or is requesting approval and for which proficiency testing samples are available;
2. Demonstrates the laboratory agent's competence in testing for the parameter; and
3. If the laboratory has been approved or has requested approval to test an analyte by different methods, may use the same proficiency testing sample for each method.

B. If a proficiency testing sample is not available for a specific parameter, a technical laboratory director shall have at least one laboratory agent, selected according to policies and procedures, participate in accuracy testing for the parameter.

C. To demonstrate competence in testing for a parameter, test results reported for the parameter shall be within acceptance limits established by the Department, according to R9-17-404.03 or R9-17-404.04, or the proficiency testing service, as applicable.

D. A technical laboratory director shall ensure that:

1. Each sample for proficiency testing accepted at the laboratory is analyzed at the laboratory;
2. Each sample for accuracy testing is analyzed at the laboratory;
3. Each sample for proficiency testing or accuracy testing is tested within the maximum holding times allowed for the parameter, according to R9-17-404.03 or R9-17-404.04, using the same procedures and techniques employed for routine sample testing, and calculating the holding time from the time the sample seal is broken or as indicated in the instructions accompanying the sample;

4. A proficiency testing service provides the results for each proficiency testing sample directly to the laboratory and the Department;
5. If proficiency testing is provided by the Department, the laboratory submits to the Department payment for the actual costs of the materials for proficiency testing; and
6. If proficiency testing is not provided by the Department, the laboratory selects a proficiency testing service and contracts with and pays the proficiency testing service directly for proficiency testing.

E. The Department may submit blind proficiency testing samples to a laboratory at any time during the certification period.

R9-17-404.03. Method Criteria and References for Chemical Analyses

A. In addition to the definitions in A.R.S. § 36-2801 and R9-17-101, the following definitions apply in this Section unless otherwise stated:

#. "Limit of quantitation" means the lowest concentration of an analyte that may be detected and the concentration of the analyte reliably and accurately determined.

#. "Matrix" means the specific components of a sample, other than the analyte being tested for.

#. "Mid-level standard" means a standard that is between the highest concentration and lowest concentration of standards containing the same substances that are used as a reference when testing for the concentration of an analyte.

#. "Response factor" means the ratio between a signal produced by an analyte relative to a signal produced by an internal standard.

#. "Retention time" means the length of time taken by an analyte to pass through a chromatography column.

#. "Standard" means a sample of known concentration and containing specific substances that is used as a reference when testing for the concentration of an analyte.

B. To perform laboratory testing using chemical analytical methods for any of the analytes in Table 3.1, a laboratory may use:

1. An established national or international chemical method; or
2. A laboratory-developed method that was validated according to:
   a. AOAC - Appendix K: Guidelines for Dietary Supplements and Botanicals, 2013, which is incorporated by reference, includes no future editions or amendments, and is available at http://www.eoma.aoac.org/app_k.pdf;

b. USDA - Guidelines for the Validation of Chemical Methods for the FDA FVM Program, 2nd Edition, April 2015, which is incorporated by reference, includes no future editions or amendments, and is available at https://www.fda.gov/media/81810/download; or

c. ICH – Validation of Analytical Procedures: Text and Methodology Q2(R1) 2005, which is incorporated by reference, includes no future editions or amendments, and is available at https://database.ich.org/sites/default/files/Q2_R1__Guideline.pdf or https://www.fda.gov/regulatory-information/search-fda-guidance-documents/q2-r1-validation-analytical-procedures-text-and-methodology.

C. A technical laboratory director shall ensure that all instruments and equipment used for testing medical marijuana or a marijuana product by chemical analytical methods are:

1. Set up, tuned, and calibrated according to:
   a. Manufacturer's acceptance criteria, or
   b. Criteria validated according to subsection (B), as applicable;
2. Monitored and maintained according to AOAC - Guidelines for Laboratories Performing Microbiological and Chemical Analyses of Food, Dietary Supplements, and Pharmaceuticals, Appendix A: Equipment, August 2018, which is incorporated by reference, includes no future editions or amendments, and is available at https://www.aoac.org/aoac-accreditation-guidelines-for-laboratories-alacc; and
3. Applicable for the analytes to be tested.

D. A technical laboratory director shall ensure that for an initial demonstration of capability:

1. Before implementing a method, at least four replicate reference samples for each analyte are:
   a. Spiked into a clean matrix with, as applicable, an amount at or near the maximum allowable concentration for the analyte in Table 3.1 or the mid-level standard for potency testing; and
   b. Taken through the entire sample preparation and analysis process;
2. Whenever a significant change to instrumentation or to a standard operating procedure occurs, the laboratory demonstrates, as specified in subsection (D)(1), that acceptable precision and bias can still be obtained by the changed conditions; and
3. Whenever a new laboratory agent who will be performing testing on medical marijuana or marijuana products is being trained, the laboratory agent demonstrates, as specified in subsection (D)(1), acceptable precision and bias.

E. For potency testing or testing for pesticides, fungicides, herbicides, growth regulators, or residual solvents, a technical laboratory director shall ensure that:

1. For establishing the retention time for an analyte, the retention time is determined by three injections, over the course of a 72-hour period, of a standard at or near, as applicable:
   a. The maximum allowable concentration in Table 3.1 for the analyte; or
   b. The mid-level standard for potency testing; and
2. The width of the retention time window for each analyte is defined as ±3 times the standard deviation of the mean absolute retention time that was established during the 72-hour period or 0.1 minutes, whichever is greater.

F. A technical laboratory director shall ensure that:

1. The laboratory complies with the following requirements related to calibration and standards:
   a. Except as specified in subsection (F)(1)(c), a minimum of:
      i. Five standards are used for an average response factor or for a linear model,
      ii. Six standards are used for a quadratic model, and
      iii. Seven standards are used for a cubic model;
   b. An X-value of zero is not included as a calibration point;
   c. A calibration curve for heavy metal testing includes a minimum of three standards and a calibration blank;
   d. One standard is at or near the limit of quantitation;
   e. As applicable, one standard for each analyte is at or near the:
      i. Maximum allowable concentration in Table 3.1 for the analyte, or
      ii. Mid-level standard for potency testing; and
   f. One standard is above the maximum allowable concentrations in Table 3.1 for an analyte;
2. The acceptance criteria for testing is one of the following, as applicable:
   a. The maximum relative standard deviation for the average calibration factor, for an external calibration model, or the response factor, for an internal calibration model, is no more than 20%; and
   b. For linear and non-linear calibration models, the coefficient of determination (r^2) is greater than or equal to 0.99;
3. For chromatographic testing methods using internal standards for calibration:

a. The relative retention time of each analyte to the internal calibration standard is within 0.06 units;

b. The areas of the peaks for the internal standards in any sample are between 50 and 200% of the area of the peak of the internal standard in subsection (F)(1)(e) used for calibration; and

c. The internal standards:

i. Have retention times similar to the analytes being tested for,

ii. Do not interfere with any of the analytes, and

iii. Have similar chemical properties as the analytes being tested for; and

4. For methods testing for heavy metals, the internal standards:

a. Are appropriate for the analyte, and

b. Do not interfere with any of the analytes.

G. To obtain an acceptable calibration, a technical laboratory director:

1. May use any of the following options:

a. Perform instrument maintenance to optimize analyte responses, as long as all resulting calibration models meet the acceptance criteria appropriate for the analyte;

b. If the problem appears to be associated with a single standard:

i. Reanalyze that one standard, at the time of calibration and before any samples are analyzed, to rule out problems due to random error: and

ii. Recalculate and reevaluate the standard against the acceptance criteria;

c. Narrow the calibration range by replacing one or more of the calibration standards at the upper or lower ends of the curve;

d. Narrow the calibration range by removing data points from either extreme end of the range and recalculating the calibration function; or

e. Perform a new initial calibration according to subsection (F); and

2. May not:

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

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

H. A technical laboratory director shall ensure that for initial calibration verification:

1. Standards are prepared from a different source or, if there is not another source from which the standards may be obtained, from a different lot of standards from the same

source than the source from which the initial calibration standards specified in subsection (F)(1) were obtained and must be at or near, as applicable, the maximum allowable concentrations for an analyte in Table 3.1 or the mid-level standard for potency testing; and

2. The following acceptance criteria are used:
   a. For potency testing, 80 to 120% recovery of true value;
   b. For testing for pesticides, fungicides, herbicides, growth regulators, or residual solvents, 70 to 130% recovery of the true value; and
   c. For heavy metal testing, 90 to 110% recovery of the true value.

I. A technical laboratory director shall ensure that for the limit of quantitation:

1. The limit of quantitation is initially verified by the analysis of at least seven replicate samples, spiked at the limit of quantitation, and processed through all preparation and analysis steps of the method;
2. The signal to noise ratio of the replicate samples in subsection (I)(1) is at least 5:1;
3. The mean recovery of the replicate samples in subsection (I)(1) is ± 35% of the true value;
4. The relative standard deviation of the replicate samples in subsection (I)(1) is less than 20%;
5. The limit of quantitation is, as applicable, no greater than:
   a. Half the maximum allowable concentrations for an analyte in Table 3.1, or
   b. 1.0 mg/g for each analyte for potency testing;
6. Any changes to specific sample amounts, dilutions, or volumes employed are reflected in the limit of quantitation stated on a sample report; and
7. Documentation of the current limit of quantitation is maintained for each analyte for each instrument.

J. Except as provided in subsection (P), a technical laboratory director shall ensure that for batch analysis:

1. Continuing calibration verification standards:
   a. Are prepared from the same calibration standard source used to prepare the standards specified in subsection (F)(1):
      i. Initially, with a concentration at or near, as applicable, the maximum allowable concentration for an analyte in Table 3.1 or the mid-level standard for potency testing; and

ii. Subsequently, with a concentration between the highest concentration and lowest concentration of standards for the analytes in the batch;

b. Have the following acceptance criteria:

i. For potency testing, 80 - 120% recovery of true value;

ii. For testing for pesticides, fungicides, herbicides, growth regulators, or residual solvents, 70 - 130% recovery of the true value; and

iii. For heavy metal testing, 90 - 110% recovery of the true value;

2. If internal standards are used in continuing calibration verification, the acceptability criteria of the internal standards is determined as follows:

a. For testing for pesticides, fungicides, herbicides, growth regulators, or residual solvents by mass spectrometry, if the area of the peak for an internal standard is different by a factor of two from the area of the respective standard in subsection (F)(1)(e), for the most recent initial calibration sequence, according to subsection (F):

i. The mass spectrometer is inspected for malfunctions and corrected, and

ii. Reanalysis of the continuing calibration verification meets acceptance criteria in subsection (J)(1)(b)(ii) before any samples are tested; and

b. For heavy metal testing:

i. The intensity of an internal standard is monitored for each analysis to ensure that the intensity does not vary by more than ± 30%, with respect to the intensity during the initial calibration in subsection (F); and

ii. If the intensity of an internal standard is outside the range also observed in the calibration blank required in subsection (F)(1)(c):

(1) Testing is stopped until the problem is corrected, the instrument is recalibrated, and the new calibration is verified;

(2) Reanalysis of the continuing calibration verification meets acceptance criteria in subsection (J)(1)(b)(iii) before any samples are tested; and

(3) The affected samples are retested; and

3. The frequency of continuing calibration verification is as follows:

a. For potency testing, heavy metal testing, or testing for pesticides, fungicides, herbicides, growth regulators, or residual solvents by a method other than mass spectrometry:

i. At the beginning of the test;

ii. After every 20 samples, not counting a quality control sample, such as a sample required in subsection (K); and

iii. At the end of the test; and

b. For testing for pesticides, fungicides, herbicides, growth regulators, or residual solvents by mass spectrometry:

i. At the beginning of the testing,

ii. After every 12 hours of running, and

iii. At the end of the run.

K. Except as provided in subsection (P), a technical laboratory director shall ensure that for batch analysis:

1. A method blank, with a matrix similar to each type of sample matrix to be tested within the batch:

a. Contains the same internal standards as the samples in the batch,

b. Is prepared and tested with each batch, and

c. Produces results below the limit of quantitation;

2. Except as provided in subsection (R), a laboratory control sample and duplicate:

a. Are prepared at or near, as applicable, the maximum allowable concentrations for an analyte in Table 3.1 or the mid-level standard for potency testing;

b. Are carried through all stages of sample preparation and included with each analytical batch of up to 20 samples; and

c. Have the following acceptance criteria:

i. For potency testing, 80 - 120% recovery of true value;

ii. For testing for pesticides, fungicides, herbicides, growth regulators, or residual solvents, 70 - 130% recovery of the true value; and

iii. For heavy metal testing, 80 - 120% recovery of the true value;

3. The relative percent difference for the laboratory control sample and duplicate, calculated on the basis of concentration or amount, is no more than 20%; and

4. A matrix spike:

a. Is prepared at or near, as applicable, the maximum allowable concentrations for an analyte in Table 3.1 or the mid-level standard for potency testing;

b. Is carried through all stages of sample preparation and included with each analytical batch of up to 20 samples for each matrix type; and

c. Has either the following acceptance criteria or acceptance criteria within statistically derived limits developed by the laboratory:

i. For potency testing, 80 - 120% recovery of true value;

ii. For testing for pesticides, fungicides, herbicides, growth regulators, or residual solvents, 70 - 130% recovery of the true value; and

iii. For heavy metal testing, 75 - 125% recovery of the true value.

L. A technical laboratory director shall ensure that:

1. Except as provided in subsection (P), for potency testing or testing for pesticides, fungicides, herbicides, growth regulators, or residual solvents by mass spectrometry, the relative intensities of the characteristic ions agrees within 30% of the relative intensities of these ions in the reference spectrum; and
2. For heavy metal testing, the intensity of each internal standard is monitored for each analysis to ensure that the intensity does not vary more than ±30%, with respect to the intensity of the internal standard during the initial calibration specified in subsection (F).

M. A technical laboratory director shall ensure that the resolution of chromatographic peaks in potency testing or testing for pesticides, fungicides, herbicides, growth regulators, or residual solvents by a method other than mass spectrometry is maintained so that the height of the valley between the two chromatographic peaks is less than 50% of the average of the two peak heights.

N. A technical laboratory director shall ensure that confirmation for testing for pesticides, fungicides, herbicides, growth regulators, or residual solvents by a method other than mass spectrometry:

1. Is performed using:
   a. A second column:
      i. That has a stationary phase dissimilar to the stationary phase in the primary column, and
      ii. From which the analyte is eluted in a different order than from the primary column;
   b. A different instrument type, such as gas chromatography followed by mass spectrometry;
   c. Gas chromatography with two different types of detectors; or
   d. Other recognized confirmation techniques;
2. Meets the applicable criteria in subsections (D) through (M); and
3. Includes as part of the confirmation of the analyte:
   a. An evaluation of the agreement of the quantitative values of the results from both methods of testing; and
   b. Determination of the relative percent difference between the values.

O. If the relative percent difference between the values obtained according to subsection (N) is more than 40%, a technical laboratory director shall ensure that:

1. The chromatograms are checked to see if an obviously overlapping peak is causing an erroneously high result, and the chromatographic conditions are reviewed; and
2. Either:
   a. If a problem is found with one of the tests, the result from the other test is reported; and
   b. If there is no evidence of a chromatographic problem, the higher result is reported.

P. A technical laboratory director may release testing results that are scientifically valid and defensible, according to R9-17-404.06(B)(3), with the following data qualifier notations if:

1. The target analyte detected in the calibration blank required in subsection (F)(1)(c) or the method blank specified in subsection (K)(1) is at or above the limit of quantitation, but the sample result:
   a. For potency testing, is below the limit of quantitation – B1; or
   b. When testing for pesticides, fungicides, herbicides, growth regulators, heavy metals, or residual solvents, is below the maximum allowable concentration in Table 3.1 for the analyte – B2;
2. The limit of quantitation and the sample results were adjusted to reflect sample dilution D1;
3. The relative intensity of a characteristic ion in a sample analyte exceeded the acceptance criteria in subsection (L)(1) with respect to the reference spectra, indicating interference – I1;
4. When testing for pesticides, fungicides, herbicides, growth regulators, heavy metals, or residual solvents, the percent recovery of a laboratory control sample is greater than the acceptance limits in subsection (K)(2)(c), but the sample's target analytes were not detected above the maximum allowable concentrations in Table 3.1 for the analytes in the sample – L1;
5. The recovery from the matrix spike in subsection (K)(4) was:
   a. High, but the recovery from the laboratory control sample in subsection (K)(2) was within acceptance criteria – M1,
   b. Low, but the recovery from the laboratory control sample in subsection (K)(2) was within acceptance criteria – M2, or

c. Unusable because the analyte concentration was disproportionate to the spike level, but the recovery from the laboratory control sample in subsection (K)(2) was within acceptance criteria – M3;

6. The analysis of a spiked sample required a dilution such that the spike recovery calculation does not provide useful information, but the recovery from the associated laboratory control sample in subsection (K)(2) was within acceptance criteria – M4;

7. The analyte concentration was determined by the method of standard addition, in which the standard is added directly to the aliquots of the analyzed sample – M5;

8. The relative percent difference for the laboratory control sample and duplicate exceeded the limit in subsection (K)(3), but the recovery in subsection (K)(2) was within acceptance criteria – R1;

9. The relative percent difference for a sample and duplicate exceeded the limit in subsection (O) – R2; or

10. The recovery from continuing calibration verification standards exceeded the acceptance limits in subsection (J)(1)(b), but the sample's target analytes were not detected above the maximum allowable concentrations in Table 3.1 for the analytes in the sample – V1.

Q. A technical laboratory director shall include in the final report of testing, according to R9-17-404.06(B)(3)(d)(ii), the following data qualifier notations if:

1. Sample integrity was not maintained – Q1; or

2. The sample is heterogeneous, and sample homogeneity could not be readily achieved using routine laboratory practices – Q2.

R. For batch analysis of samples to determine potency, a technical laboratory director may check precision by using either a duplicate laboratory control sample or a duplicate sample prepared from the medical marijuana or marijuana product being tested, according to requirements in subsections (K)(2) and (3).

S. A technical laboratory director shall ensure that the reporting units for:

1. Pesticides, fungicides, herbicides, growth regulators, heavy metals, or residual solvents is in parts per million (ppm); and

2. Potency is in percent relative to the bulk plant material (w/w) for:

a. Total tetrahydrocannabinol, the sum of tetrahydrocannabinolic acid (THC-A), multiplied by 0.877, and delta-9-tetrahydrocannabinol (Δ9-THC); and

b. Total cannabidiol, the sum of cannabidiolic acid (CBD-A), multiplied by 0.877, and cannabidiol (CBD).

R9-17-404.04. Method Criteria and References for Analyses for Microbial Contaminants

A. To perform laboratory testing for the microbial contaminants in Table 3.1, a laboratory shall use an applicable method:

1. Described in:
    a. The Bacteriological Analytical Manual (BAM), 2019, which is incorporated by reference, includes no future editions or amendments, and is available at https://www.fda.gov/food/laboratory-methods-food/bacteriological-analytical-manual-bam; or
    b. AOAC Official Methods of Analysis, 21st Edition, 2019, which is incorporated by reference, includes no future editions or amendments, and is available at https://www.aoac.org/official-methods-of-analysis-21st-edition-2019; and
2. Validated according to, as applicable:
    a. AOAC - Appendix J: Guidelines for Validation of Microbiological Methods for Food and Environmental Surfaces, 2012, which is incorporated by reference, includes no future editions or amendments, and is available at http://www.eoma.aoac.org/app_j.pdf; or
    b. AOAC - Appendix K: Guidelines for Dietary Supplements and Botanicals, 2013, which is incorporated by reference, includes no future editions or amendments, and is available at http://www.eoma.aoac.org/app_k.pdf.

B. A technical laboratory director shall ensure that all instruments and equipment used for testing medical marijuana or a marijuana product for microbial contaminants are:

1. Set up, calibrated, and verified according to:
    a. Manufacturer's acceptance criteria; and
    b. Requirements for the specific method, as specified in subsection (A)(1)(a) or (b), as applicable;
2. Monitored and maintained according to AOAC - Guidelines for Laboratories Performing Microbiological and Chemical Analyses of Food, Dietary Supplements, and Pharmaceuticals, Appendix A: Equipment, August 2018, which is incorporated by reference, includes no future editions or amendments, and is available at https://www.aoac.org/aoac-accreditation-guidelines-for-laboratories-alacc; and
3. Applicable for the analytes to be tested.

C. A technical laboratory director shall ensure that:

1. The organisms required as controls are checked, as appropriate for their application:
    a. To ensure there is no contamination with other organisms,

b. For verification of biochemical or other biological characteristics, and

c. To ascertain the number of organisms; and

2. Documentation of the following is maintained:

a. Checking required in subsection (C)(1), and

b. Traceability of the organisms in subsection (C)(1) from date of possession.

D. A technical laboratory director shall ensure that for an initial demonstration of capability:

1. Before implementing a method, at least four replicate reference samples for each analyte are:

a. Spiked with control organisms at an amount allowing for quantitation, and

b. Taken through the entire sample preparation and analysis process;

2. Whenever a significant change to instrumentation or to a standard operating procedure occurs, the laboratory demonstrates, as specified in subsection (D)(1), that acceptable precision and bias can still be obtained by the changed conditions; and

3. Whenever a new laboratory agent who will be performing testing on medical marijuana or marijuana products is being trained, the laboratory agent demonstrates, as specified in subsection (D)(1), acceptable precision and bias.

E. A technical laboratory director shall ensure that each batch of media or reagent:

1. Is examined to ensure it is suitable for use;

2. If externally prepared, has a certificate of meeting quality control standards, issued by the manufacturer;

3. If internally prepared, has documentation of:

a. Instructions for preparation;

b. Traceability to dehydrated media or reagent concentrate;

c. Sterility, including, as applicable:

i. Autoclave records showing the date, run number, autoclave identifier, nature of the material being autoclaved, time at desired temperature, and name of the laboratory agent starting the autoclave; and

ii. For another sterilization method, records showing the date, type of sterilization method, nature of the material being sterilized, confirmation of the sterilization as applicable to the method, and name of the laboratory agent initiating the sterilization method;

d. Checking for the following, as applicable, including the name of the laboratory agent who performed the check and date of the check:

i. pH,

ii. Appearance,

iii. Fill volumes,

iv. Batch size, and

v. Quantity; and

4. Undergoes quality control verification, as applicable, including the name of the laboratory agent who performed the verification and date of verification, for:

a. The ability of media to sustain growth of the organism for which the media will be used;

b. If applicable, the ability of media to select for specific organisms or characteristics of an organism;

c. The ability of a reagent to function as intended; and

d. Sterility of the media or reagent before use.

F. If test kits or other identification systems are used for laboratory testing, a technical laboratory director shall ensure that:

1. Each lot of test kits or other identification systems undergoes quality control verification, including the name of the laboratory agent who performed the verification and date of verification, for:

a. Having a certificate of meeting quality control standards, issued by the manufacturer; and

b. Passing a visual inspection of physical characteristics; and

2. If an identification system is intended to speciate organisms, the identification system is tested with at least one control organism appropriate for the identification system to confirm acceptability.

G. A technical laboratory director shall ensure that:

1. For testing for *Escherichia coli* with a plating method, if the colony count for *Escherichia coli* on a plated sample is below the maximum allowable contaminants in Table 3.1, but the colony count for all organisms on the plate is above the counting range for the size of the plate used, the sample is diluted and replated so that the colony count for all organisms on the plate is within the counting range for the size of the plate used;

2. For testing for *Aspergillus* with a plating method:

a. One of the following plating media is used:

i. Malt extract agar, BAM Media M182;

ii. Dichloran rose bengal chloramphenicol agar, BAM Media M183: or

iii. Potato dextrose agar with rose bengal and chloramphenicol; and

b. Petrifilm™, Simplate™, or another pre-made plate that is unsuitable for growing spreading molds is not used; and

3. For testing for mycotoxins by any method, at least a 0.5 g sample is tested.

H. A technical laboratory director shall ensure that:

1. The reporting units for *Escherichia coli* are colony forming units per gram (CFU/g);
2. Reporting for *Salmonella* is "Detected" or "Not detected";
3. Reporting for *Aspergillus* is "Detected" or "Not detected"; and
4. Reporting for mycotoxins includes:
   a. Total aflatoxins in units of micrograms per kilogram (µg/kg), and
   b. Ochratoxin A in units of micrograms per kilogram (µg/kg).

R9-17-404.05. Quality Assurance

A. An owner holding a laboratory registration certificate or applicant shall ensure that the analytical data produced at the owner's or applicant's laboratory are of known and acceptable precision and accuracy, as prescribed by the method criteria for each analyte in R9-17-404.03 or R9-17-404.04, and are scientifically valid and defensible.

B. An owner holding a laboratory registration certificate or applicant shall establish, implement, and comply with a written quality assurance plan that contains the following and is available at the laboratory for Department review:

1. A title page identifying the laboratory and date of review and including the technical laboratory director's signature of approval;
2. A table of contents;
3. An organization chart or list of the laboratory personnel, including names, lines of authority, and identification of principal quality assurance personnel;
4. A copy of the current laboratory registration certificate and a list of approved parameters;
5. A statement of quality assurance objectives, including data quality objectives with precision and accuracy goals and the criteria for determining the acceptability of each testing;
6. Specifications for:
   a. Sample containers,
   b. Preparation of sample containers,
   c. Preservation of samples, and
   d. Maximum holding times allowed;
7. A procedure for documenting laboratory receipt of samples and tracking of samples

during laboratory testing;

8. A procedure for analytical instrument calibration, including frequency of calibration and complying with the requirements for calibration in subsection (D);
9. A procedure for testing data reduction and validation and reporting of final results, including the identification and treatment of data outliers, the determination of the accuracy of data transcription, and all calculations;
10. A statement of the frequency of all quality control checks;
11. A statement of the acceptance criteria for all quality control checks;
12. Preventive maintenance procedures and schedules;
13. Assessment procedures for data acceptability, including appropriate procedures for manual integration of chromatograms and when manual integration is inappropriate;
14. Corrective action procedures to be taken when results from analytical quality control checks are unacceptable, including steps to demonstrate the presence of any interference if the precision, accuracy, or limit of quantitation of the reported testing result is affected by the interference; and
15. Procedures for chain-of-custody documentation, including procedures for the documentation and reporting of any deviation from the sample handling or preservation requirements.

C. An owner holding a laboratory registration certificate or applicant shall ensure that a laboratory's written quality assurance plan is a separate document available at the laboratory and includes all of the components required in subsection (B), but an owner or applicant may satisfy the components required in subsections (B)(3) through (15) through incorporating by reference provisions in separate documents, such as standard operating procedures.

D. An owner holding a laboratory registration certificate or applicant shall:

1. Have available at the laboratory all methods, equipment, reagents, and supplies necessary for the testing for which the owner or applicant is approved or is requesting approval;
2. Use only reagents of a grade equal to or greater than that required by the method criteria in R9-17-404.03 or R9-17-404.04, and document the use of the reagents;
3. Maintain and require each laboratory agent performing testing on medical marijuana or a marijuana product to comply with a complete and current standard operating procedure that meets the requirements for each method, as specified in R9-17-404.03 or R9-17-404.04, which shall include at least:
   a. A description of all procedures to be followed when the method is performed;
   b. A list of the concentrations for calibration standards, check standards, and spikes;

c. Requirements for instrumental conditions and set up;

d. A requirement for frequency of calibration;

e. The quantitative methods to be used to calculate the final concentration of an analyte in samples, including any factors used in the calculations and the calibration algorithm used; and

f. Requirements for preventative maintenance;

4. Calibrate each instrument as required by the standard operating procedure, as specified in R9-17-404.03 or R9-17-404.04, for which the equipment is used;

5. Maintain calibration documentation, including documentation that demonstrates the calculations performed using each calibration model;

6. Develop, document, and maintain a current limit of quantitation, as specified in R9-17-404.03, for each compliance parameter for each instrument;

7. For each parameter tested at the laboratory use the quality control acceptance criteria specified according to R9-17-404.03, R9-17-404.04, and Table 3.1;

8. Discard or segregate all expired standards or reagents;

9. Maintain a record showing the traceability of reagents; and

10. Ensure that a calibration model is not used or changed to avoid necessary instrument maintenance.

E. Except as provided in subsection (F), an owner holding a laboratory registration certificate or applicant shall ensure that each laboratory standard operating procedure is a separate document available at the laboratory and includes all of the components required in subsection (D)(3).

F. An owner holding a laboratory registration certificate or applicant may satisfy the components required in subsections (D)(3)(e) and (f) through incorporating by reference provisions in separate documents, such as other standard operating procedures.

R9-17-404.06. Operations

A. A technical laboratory director shall ensure that:

1. A sample of medical marijuana or a marijuana product accepted at the technical laboratory director's laboratory is analyzed at the laboratory;

2. If an instrument or equipment used for testing medical marijuana or a marijuana product has a mechanism to track any changes made to testing results, the tracking mechanism is activated; **[This pertains to the audit trail – see also (B)(1)(h)…]**

3. The facility and utilities required to operate equipment and perform testing of medical marijuana or marijuana products are maintained;

4. Environmental controls are maintained within the laboratory to ensure that laboratory environmental conditions do not affect analytical results beyond quality control limits established for the methods performed at the laboratory;
5. Storage, handling, and disposal of hazardous materials at the laboratory are in accordance with all state and federal regulations;
6. The laboratory complies with all applicable federal, state, and local occupational safety and health regulations; and
7. The following information is maintained for all laboratory agents providing supervisory, quality assurance, or analytical functions related to testing of medical marijuana or a marijuana product:
    a. A summary of each laboratory agent's education and professional experience;
    b. Documentation of each laboratory agent's applicable certifications and specialized training;
    c. Information related to the laboratory agent's registry identification card;
    d. Documentation of each laboratory agent's review of the quality assurance plan required under R9-17-404.05(B) and the methods and laboratory standard operating procedures for all testing of marijuana or marijuana products performed by the laboratory agent or for which the laboratory agent has supervisory or quality assurance responsibility;
    e. Documentation of each laboratory agent's completion of training on the use of equipment and of proper laboratory technique, including the name of the laboratory agent, the name of the instructor, the duration of the training, and the date of completion of the training;
    f. Documentation of each laboratory agent's completion of training classes, continuing education courses, seminars, and conferences that relate to the testing procedures used by the laboratory agent for testing of marijuana or marijuana products;
    g. Documentation of each laboratory agent's completion of initial demonstration of capability, as required in R9-17-404.03(D)(3) or R9-17-404.04(D)(3), for each approved method performed by the laboratory agent;
    h. Documentation of each laboratory agent's performance of proficiency testing or accuracy testing, as applicable; and
    i. Documentation of each laboratory agent's completion of training related to instrument calibration that includes:

i. Instruction on each calibration model that the laboratory agent will use or for which the laboratory agent will review data;

ii. For each calibration model in subsection (A)(7)(i), description of the specific aspects of the calibration model that might compromise the data quality, such as detector saturation, lack of detector sensitivity, the calibration model's not accurately reflecting the calibration points, inappropriate extension of the calibration range, weighting factors, and dropping of mid-level calibration points without justification; and

iii. Instruction that a calibration model shall not be used or changed to avoid necessary instrument maintenance.

B. A technical laboratory director shall ensure that:

1. A testing record for marijuana or marijuana products contains:

a. Sample information, including the following:

i. A unique sample identification assigned at the laboratory;

ii. A description of the marijuana or marijuana product from which the submitted sample was taken, including the amount, strain, and batch number;

iii. The sample collection date and time; and

iv. The type of testing to be performed;

b. A picture of the sample as submitted;

c. The name and registry identification number of the dispensary, qualifying patient, or designated caregiver submitting the sample to the laboratory;

d. If applicable, name and the registry identification number of the dispensary agent submitting the sample to the laboratory on behalf of a dispensary;

e. The date and time of receipt of the sample at the laboratory;

f. The name and registry identification number of the laboratory agent who received the sample at the laboratory;

g. The dates and times of testing, including the date and time of each critical step;

h. Whether testing results related to a sample were changed;

i. If testing results related to a sample were changed, what was changed, the name of the laboratory agent who changed the testing results, the time and date the data were changed, and why the testing results were changed;

j. If testing results were changed due to retesting:

i. What was used or done to the sample, and

ii. The original and changed testing results;

k. The actual results of testing, including all raw data, work sheets, and calculations performed;

l. The actual results of quality control data validating the test results, including the calibration and calculations performed;

m. The name of each laboratory agent who performed the testing; and

n. A copy of the final report;

2. A testing result for medical marijuana or a marijuana product that is known to be inaccurate is not reported; and

3. A final report of testing of marijuana or marijuana products contains:

a. The name, address, and telephone number of the laboratory;

b. The registry identification number assigned to the laboratory by the Department;

c. Actual scientifically valid and defensible results of testing of a sample of medical marijuana or a marijuana product in appropriate units of measure, obtained in accordance with R9-17-404.03, R9-17-404.04, and the quality assurance plan;

d. Either:

i. A statement that testing results were obtained according to requirements in the quality assurance plan in R9-17-404.05, in the applicable standard operating procedure, and in R9-17-404.03 or R9-17-404.04; or

ii. A description of any variances from the requirements in the quality assurance plan in R9-17-404.05, the applicable standard operating procedure, R9-17-404.03, or R9-17-404.04, and the reason for the variance;

e. A list of each method used to obtain the reported results;

f. Sample information, including the following:

i. The unique sample identification assigned at the laboratory;

ii. A picture of the sample as submitted;

iii. A description of the marijuana or marijuana product from which the submitted sample was taken, including the amount, strain and batch number;

iv. The sample collection date and time;

v. The name and registry identification number of the dispensary, qualifying patient, or designated caregiver submitting the sample to the laboratory; and

vi. If applicable, name and the registry identification number of the dispensary agent submitting the sample to the laboratory on behalf of a dispensary;

g. The date of testing for each parameter reported;

h. The date of the final report; and

i. The technical laboratory director's or designee's signature.

R9-14-404.07. Adding or Removing Parameters for Testing

A. During the term of a laboratory registration certificate, an owner may request to have one or more parameters:

1. Added to the laboratory registration certificate, or
2. Removed from the laboratory registration certificate.

B. To request a change to one or more parameters, an applicant shall submit to the Department:

1. The following information in a Department-provided format:
   a. The name, address, and telephone number of the applicant;
   b. The name, address, and telephone number of the laboratory for which the change is requested; and
   c. Identification of each parameter requested to be added or removed;
2. The following for each parameter requested to be added:
   a. The limit of quantitation, if applicable;
   b. A copy of current accreditation;
   c. A copy of a proficiency testing report, if applicable, or accuracy testing documentation; and
   d. A copy of the standard operating procedure; and
3. If applicable, any changes to the quality assurance plan in R9-17-404.05(B) made due to the addition or removal of the parameter.

C. The Department may conduct a laboratory inspection during the substantive review period for a request to have one or more parameters added to a laboratory registration certificate.

D. The Department shall process a request to have one or more parameters added to a laboratory registration certificate as provided in R9-17-107.

R9-17-407. Inventory Control System

A. A laboratory shall designate in writing a laboratory agent who has oversight of the laboratory's marijuana inventory control system.

B.A. A laboratory shall not accept submissions of marijuana or marijuana products for testing from an individual who or entity that is not allowed to possess marijuana pursuant to A.R.S. Title 36, Chapter 28.1.

B. A technical laboratory director laboratory shall designate in writing a laboratory agent who has oversight of the laboratory's marijuana inventory control system.

C. A laboratory technical laboratory director shall establish and implement an inventory control system for the laboratory's marijuana and marijuana products that documents:

1. Each day's beginning marijuana and marijuana products inventory, marijuana and marijuana products submitted for testing, disposal of tested or unusable marijuana or marijuana products, and ending marijuana and marijuana products inventory;
2. The chain of custody for each sample of medical marijuana or a marijuana product submitted to the laboratory for testing;
3. Any damage to a sample's container or possible tampering; and
2.4. As applicable, for submissions of marijuana and marijuana products for testing:
    a. A description of the submitted marijuana or marijuana products including the amount, strain and batch number;
    b. The name and registry identification number of the dispensary that submitted the marijuana or marijuana products;
    c. The name and registry identification number of the dispensary agent that submitted the marijuana or marijuana products;
    d. The name and registry identification number of the qualifying patient that submitted the marijuana or marijuana products;
    e. The name and registry identification number of the designated caregiver that submitted the marijuana or marijuana products;
    f. The name and registry identification number of the laboratory agent receiving the marijuana or marijuana products on behalf of the laboratory; and
    g. The date of acquisition;
    h. The date of each test; and
    i. The test results.

D. The individual designated in subsection (A) shall conduct and document an audit of the laboratory's inventory that is accounted for according to generally accepted accounting principles at least once every 30 calendar days.

1. If the audit identifies a reduction in the amount of marijuana or marijuana products in the laboratory's inventory not due to documented causes, the laboratory technical laboratory

director shall determine where the loss has occurred and take and document corrective action.

2. If the reduction in the amount of marijuana or marijuana products in the laboratory's inventory is due to suspected criminal activity by a laboratory agent, the laboratory technical laboratory director shall report the laboratory agent to the Department and to the local law enforcement authorities and document the report.

E. A laboratory shall:

1. Maintain the documentation required in subsections (C) and (D) at the dispensary for at least five years after the date on the document, and
2. Provide the documentation required in subsections (C) and (D) to the Department for review upon request.

R9-17-408. Security

A. Except as provided in R9-17-404(8), a laboratory shall ensure that access to the area of the laboratory where marijuana or marijuana products are being tested or stored for testing is limited to a laboratory's owners and authorized laboratory agents.

B. A laboratory agent may transport marijuana or marijuana products submitted for testing to a laboratory.

C. Before transportation to a laboratory, a laboratory agent shall:

1. Complete a trip plan that includes:
   a. The name of the laboratory agent in charge of transporting the marijuana or marijuana products;
   b. The date and start time of the trip;
   c. A description of the marijuana or marijuana products being transported;
   d. Any anticipated stops during the trip, including the locations of the stops; and
   d.e. The anticipated route of transportation; and
2. Provide a copy of the trip plan in subsection (C)(1) to the laboratory.

D. During transportation to the laboratory, a laboratory agent shall:

1. Carry a copy of the trip plan in subsection (C)(1) with the laboratory agent for the duration of the trip;
2. Use a vehicle without any medical marijuana identification;
3. Have a means of communication with the laboratory; and
4. Ensure that the marijuana or marijuana products are not visible.

E. After transportation, a laboratory agent shall enter the end time of the trip and any changes to the

trip plan on the trip plan required in subsection (C)(1).

F. If a dispensary agent transports medical marijuana or a marijuana product to a laboratory for testing, the laboratory shall require that a copy of the trip report be provided by the dispensary before accepting the medical marijuana or marijuana product for testing.

F.G. A laboratory shall:

1. Maintain the documents required in subsection (C)(2) and (E), subsections (C)(2), (E), and (F); and
2. Provide a copy of the documents required in subsection (C)(2) and (E) subsections (C)(2), (E), and (F) to the Department for review upon request.

G.H. To prevent unauthorized access to marijuana or marijuana products at the laboratory for testing, the laboratory shall have the following:

1. Security equipment to deter and prevent unauthorized entrance into limited access areas that include:
    a. Devices or a series of devices to detect unauthorized intrusion, which may include a signal system interconnected with a radio frequency method, such as cellular, private radio signals, or other mechanical or electronic device;
    b. Exterior lighting to facilitate surveillance;
    c. Electronic monitoring including:
        i. At least one 19-inch or greater call-up monitor;
        ii. A video printer capable of immediately producing a clear still photo from any video camera image;
        iii. Video cameras:
            (1) Providing coverage of all entrances to and exits from limited access areas and all entrances to and exits from the building, capable of identifying any activity occurring in or adjacent to the building; and
            (2) Having a recording resolution of at least 704 x 480 or the equivalent;
        iv. A video camera in each area of the laboratory where marijuana or marijuana products are being tested or stored for testing capable of identifying any activity occurring within the area in low light conditions;
        v. Storage of video recordings from the video cameras for at least 30 calendar days;
        vi. A failure notification system that provides an audible and visual

notification of any failure in the electronic monitoring system; and

vii. Sufficient battery backup for video cameras and recording equipment to support at least five minutes of recording in the event of a power outage; and

d. Panic buttons in the interior of each building; and

2. Policies and procedures that:

a. Restrict access to the areas of the laboratory that contain marijuana or marijuana products and, if applicable, to authorized individuals only;

b. Provide for the identification of authorized individuals; and

c. Prevent loitering.

R9-17-409. Physical Plant

A. A laboratory shall ensure that designated storage areas for marijuana or marijuana products or materials used in direct contact with marijuana or marijuana products are:

1. separate Separate from storage areas for toxic or flammable materials; and are maintained

2. Maintained in a manner to prevent:

1.a. Microbial contamination and proliferation, and

2.b. Contamination or infestation by insects or rodents.

B. A laboratory shall ensure that a designated storage area for medical marijuana or a marijuana product is:

1. At an appropriate temperature for the medical marijuana or marijuana product, as specified on the packaged sample;

2. Monitored to ensure that a:

a. Room temperature storage area is maintained between 15°C and 30°C,

b. Refrigerated storage area is maintained between 2°C and 8°C, and

c. Freezer storage area is maintained at less than -20°C; and

3. Labelled to indicate the temperature range and types of medical marijuana or marijuana product to be store in the storage area.

C. A laboratory shall ensure that a designated area for testing medical marijuana or a marijuana product for microbial contaminants is maintained in a manner to prevent exposure of the medical marijuana or marijuana product to external microbial contaminants.

D. A laboratory shall ensure that a designated area for testing medical marijuana or a marijuana product for pesticides, fungicides, herbicides, growth regulators, heavy metals, or residual solvents is maintained in a manner to prevent exposure of the medical marijuana or marijuana

product to external contamination.

R9-17-410. Denial or Revocation of a Laboratory Registration Certificate

A. The Department shall deny an application for a laboratory registration certificate if:

1. The physical address of the laboratory is within 500 feet of a private school or a public school that existed before the date the laboratory submitted the initial laboratory registration certificate application;
2. An owner:
   a. Has been convicted of an excluded felony offense, or
   b. Is under 21 years of age;
3. The application or the laboratory does not comply with the requirements in A.R.S. Title 36, Chapter 28.1 and this Chapter;
4. The laboratory acquires marijuana or marijuana products from an individual who or entity that is not allowed to possess marijuana pursuant to A.R.S. Title 36, Chapter 28.1;
5. The laboratory diverts marijuana or marijuana products to an individual who or entity that is not allowed to possess marijuana pursuant to A.R.S. Title 36, Chapter 28.1;
6. An owner has any direct or indirect familial or financial relationship with or interest in a nonprofit medical marijuana dispensary or related medical marijuana business entity or management company, or any direct or indirect familial or financial relationship with a designated caregiver for whom the laboratory is testing marijuana and marijuana products for medical use in this state; or
7. The laboratory fails to maintain accreditation.

B. The Department may deny an application for a laboratory registration certificate if an owner of the laboratory provides false or misleading information to the Department.

C. The Department shall revoke a laboratory's registration certificate if:

1. The laboratory acquires marijuana or marijuana products from an individual who or entity that is not allowed to possess marijuana pursuant to A.R.S. Title 36, Chapter 28.1;
2. The laboratory diverts marijuana or marijuana products to an individual who or entity that is not allowed to possess marijuana pursuant to A.R.S. Title 36, Chapter 28.1;
3. An owner has been convicted of an excluded felony offense;
4. An owner has any direct or indirect familial or financial relationship with or interest in a nonprofit medical marijuana dispensary or related medical marijuana business entity or management company, or any direct or indirect familial or financial relationship with a designated caregiver for whom the laboratory is testing marijuana and marijuana products

for medical use in this state; or

5. The laboratory fails to maintain accreditation.

D. The Department may deny an application for a laboratory registration certificate or revoke a laboratory registration certificate if the laboratory does not:

1. Comply with:

a. the The requirements in A.R.S. Title 36, Chapter 28.1 and this Chapter; or

b. The provisions in a corrective action plan submitted according to R9-17-404.01(E)(2)(b); or

2. Implement the policies and procedures or comply with the statements provided to the Department with the laboratory's application.

E. If the Department denies a laboratory registration certificate application, the Department shall provide notice to the applicant that includes:

1. The specific reason or reasons for the denial, and
2. All other information required by A.R.S. § 41-1076.

F. If the Department revokes a laboratory registration certificate, the Department shall provide notice to the laboratory that includes:

1. The specific reason or reasons for the revocation; and
2. The process for requesting a judicial review of the Department's decision pursuant to A.R.S. Title 12, Chapter 7, Article 6.