



ARIZONA DEPARTMENT  
OF HEALTH SERVICES

Medical Marijuana Testing Advisory Council  
Findings and Recommendations

December 2019



# ARIZONA DEPARTMENT OF HEALTH SERVICES

December 30, 2019

**Re: Medical Marijuana Testing Advisory Council**

Dear Governor Ducey, President Fann, and Speaker Bowers:

On behalf of the Arizona Department of Health Services and the volunteers who comprised the Medical Marijuana Testing Advisory Council (Council), I am pleased to present the Council's Report of Findings and Recommendations as directed by the passage of Senate Bill 1494 in 2019.

Members of the multi-disciplinary Council actively collaborated over the past three months to make recommendations for testing medical marijuana in Arizona. Recommendations within the report pertain to topics including testing and potency standards, procedural requirements for collection and storage, reporting of test results, and remediation and disposal of medical marijuana that fails to meet testing standards. Record of the Council's work is available through the following website:

<https://www.azdhs.gov/licensing/medical-marijuana/index.php#testing-advisory-council>.

I would like to extend my gratitude to the Council for their diligence in completing this task and their interest in this issue.

Sincerely,

A handwritten signature in black ink that reads "Cara M. Christ MD".

Cara M. Christ, MD  
Director

cc: Katie Hobbs, Secretary of State

Douglas A. Ducey | Governor    Cara M. Christ, MD, MS | Director

# Medical Marijuana Testing Advisory Council: Findings and Recommendations

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## Executive Summary

This report encompasses the work of the Medical Marijuana Testing Advisory Council (Council), convened pursuant to Senate Bill 1494 to advise the Director of the Arizona Department of Health Services (ADHS) regarding administration and implementation of a required medical marijuana testing program. Recommendations of the Council focus on testing and potency standards for medical marijuana; procedural requirements for collecting, storing, and testing samples of medical marijuana; reporting testing results; and remediation and disposal requirements for medical marijuana that fails to meet testing standards.

Council members represented numerous groups and organizations as required by Senate Bill 1494, including dispensaries, testing laboratories, trade associations, patients, caregivers, public safety, and healthcare providers. The Council's work included a review of testing programs and requirements in other states, as well as discussion of the current testing landscape within Arizona.

Through a series of meetings held between September and December, 2019, the Council developed the following findings and recommendations:

### Microbial Contamination

- All final products must be tested for *E. coli* prior to sale.
  - Products testing  $\leq 100$  CFU/g pass.
  - Products testing  $> 100$  CFU/g must be remediated or reprocessed as applicable and retested prior to sale.
- All final products must be tested for *Salmonella*. Samples with detectable *Salmonella* will fail and must be destroyed - no remediation possible.
- All inhaled products must either be:
  - Tested for *Aspergillus flavus*, *fumigatus*, *niger*, and *terreus* using molecular methods (PCR, qPCR, DNA microarrays, sequencing). Products  $\leq 1$  CFU pass and no further testing is required. If the result is  $> 1$  CFU, the product must be tested for mycotoxins using HPLC, ELISA, or an in-house developed method that is validated by AOAC Appendix J or K as relevant, or other federal or international standards. Products testing  $\geq 20\mu\text{g/kg}$  (ppm) mycotoxins fail and cannot be remediated.

OR

- Tested for mycotoxins using HPLC, ELISA, or an in-house developed method that is validated by AOAC Appendix J or K as relevant, or other federal or international standards. Products testing  $\geq 20\mu\text{g/kg}$  (ppm) mycotoxins fail and cannot be remediated.
- Microbial testing should be conducted using the Bacteriological Analytical Manual (FDA 2013a) and validated by AOAC Appendix J or K as relevant, or other federal or international standards that meet the criteria.

## Heavy Metals

- Any edible or infused product made from concentrate that has previously passed safety testing is exempt from final testing for solvents, heavy metals, pesticides, fungicides, and growth regulators.
- All final products must be tested for heavy metals as listed below. Products at or below the values listed in the table may be sold.

Heavy Metal	Limit (ppm)
Arsenic	≤0.4
Cadmium	≤0.4
Lead	≤1.0
Mercury	≤1.2

- Heavy metals testing can be conducted using any national, international, or in-house developed method that is validated by AOAC Appendix K or other federal or international standards that meet the method criteria from EPA methods.

## Pesticides, Fungicides, Herbicides, and Growth Regulators

- Any edible or infused product made from concentrate that has previously passed safety testing is exempt from final testing for solvents, heavy metals, pesticides, fungicides, and growth regulators.
- All final products must be tested for pesticides, fungicides, and growth regulators listed in Table 2 within the Oregon Health Authority's Technical Report ([OHA 8964](#))<sup>1</sup>. Products at or below the values listed in the table may be sold.
- Pesticide, fungicide, herbicide, and growth regulator testing can be conducted using any national, international, or in-house developed method that is validated by AOAC Appendix K or other federal or international standards that meet the method criteria from EPA methods.

## Residual Solvents

- Any edible or infused product made from concentrate that has previously passed safety testing is exempt from final testing for solvents, heavy metals, pesticides, fungicides, and growth regulators.

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<sup>1</sup> Farrer DG. Technical Report: Oregon Health Authority's process to decide which types of contaminants to test for in cannabis. Oregon Health Authority. 2015 December. <https://www.oregon.gov/oha/ph/preventionwellness/marijuana/documents/oha-8964-technical-report-marijuana-contaminant-testing.pdf>. Accessed 29 Nov. 2019.

**Residual Solvents (cont.)**

- All final extracted products must be tested for residual solvents referenced below. Products at or below the values listed in the table may be sold.

Solvent	Limit (ppm)	Solvent	Limit (ppm)
Acetone	≤1000	Heptanes	≤5000
Acetonitrile	≤410	Hexane	≤290
Benzene	≤2	Isopropyl Acetate	≤5000
Butane	≤5000	Methanol	≤3000
Chloroform	≤60	Pentane	≤5000
Dichloromethane	≤600	2-Propanol (IPA)	≤5000
Ethanol	≤5000	Propane	≤5000
Ethyl Acetate	≤5000	Toluene	≤890
Ethyl Ether	≤5000	Xylenes	≤2170

- Residual solvent testing should be conducted using any EPA, AOAC, or in-house developed method that is validated by AOAC Appendix K or other federal or international standards that meet the EPA criteria.

**Potency**

- All products must be tested for THC-A, Δ9-THC, CBD-A, CBD, and any label claims specific to cannabinoids.
- Total THC and CBD shall be reported as follows:
  - Total THC = (Δ9-THC + (THC-A × 87.7%))
  - Total CBD = (CBD + (CBD-A × 87.7%))
- Potency of all products must test +/- 20% of label claim or be repackaged to meet actual concentration.
- Potency reporting should include, at minimum:
  - For anything over 10% cannabinoid - one decimal place (i.e., to 12.3%)
  - For anything under 10% but above 0.1% - two decimal places (i.e., to 0.01%)
  - For anything under 0.01% - three decimal places (i.e., to 0.012%)
- For edibles, report potency in milligrams (mg) with two significant figures.
- Potency reporting should note that results are “below the level of quantitation” (<LOQ) when applicable.
- Potency testing can be conducted by AHP or in-house methods that are validated by AOAC Appendix K or other federal or international standards that meet the criteria.

### **Sample Collection**

- Utilize ANSI Z1.4 / AQL General Inspection Level II.
- Utilize number of containers per production batch to set the lot size for the sample set.
- Utilize top, middle, bottom, star pattern or sample thief sampling with composite quartering to arrive at the most homogeneous sample possible.
- Total sample size to be taken would be a minimum of 4 grams of material per production batch for potency and 12 grams of material per production batch for patient safety to allow duplicate testing, as necessary.

### **Reporting Results**

- Laboratories should be required to, at a minimum, produce a technical report, or other summary report that is consistent with ISO accreditation, detailing laboratory testing results. Requirements for a summary report of laboratory analysis should be revisited once the Council reconvenes in six months per a subsequent recommendation.

### **Remediation**

- Unless explicitly stated otherwise, all products can be remediated.

### **Retesting**

- Rules should allow for product retesting to verify safety testing results.
- Retesting for remediated production batches will follow the same procedure as initial testing.

### **Disposal**

- Laboratories must maintain policies and procedures to render waste unusable and unrecognizable.

### **Additional Recommendations**

- The Council should be reconvened at six and 12 months to review the recommended testing parameters and action levels, as well as other items discussed by the Council.
- ADHS may waive testing requirements of this section in whole or in part if ADHS determines that the number of labs approved to conduct a given test is insufficient for all testing samples to be appropriately processed. ADHS may also adopt and enforce a staggered random testing schedule for the sampling and testing of dried, usable cannabis and concentrated cannabis-derived products.

## **1.0 Statutory Authority and Council Activity**

### **1.1 Statutory Authority for the Council**

Senate Bill 1494<sup>2</sup> amended Arizona Revised Statutes, Title 36, Chapter 28.1, in a number of ways, including instituting a requirement for medical marijuana and marijuana products to be tested for unsafe levels of various contaminants and to confirm potency prior to selling or dispensing for medical use beginning November 1, 2020, and requiring the Arizona Department of Health Services (ADHS) to adopt rules to certify and regulate independent third-party laboratories that analyze cultivated medical marijuana.

In addition, S.B. 1494 directed the ADHS Director to establish a Medical Marijuana Testing Advisory Council (Council). The Council was charged with assisting and making recommendations to the Director regarding administering and implementing Chapter 28.1, specifically in regards to the following items:

1. Establish a required testing program.
2. Testing and potency standards for medical marijuana.
3. Procedural requirements for collecting, storing, and testing samples of medical marijuana.
4. Reporting results to patients and ADHS.
5. Remediation and disposal requirements for medical marijuana that fails to meet testing standards.
6. Additional items as necessary.

### **1.2 Council Membership**

In accordance with S.B. 1494, the Council was comprised of the following members (named list is available in Appendix 1), appointed by the ADHS Director and chaired by the Director's designee:

1. The president or executive director of a statewide nonprofit association representing the marijuana dispensaries, or the person's designee.
2. The president or executive director of a statewide nonprofit cannabis testing association, or the person's designee.
3. The president or executive director of a medical marijuana trade association that does not primarily consist of dispensaries or cannabis laboratory testing facility owners, or the person's designee.
4. A representative of a nonprofit medical marijuana dispensary who is employed by the dispensary to cultivate medical marijuana and who has at least three years of medical marijuana cultivation experience.
5. A representative of an Arizona-based nonprofit medical marijuana dispensary that produces medical marijuana concentrates and that has been regularly sending products for testing who has at least three years of medical marijuana extraction experience.

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<sup>2</sup> "SB 1494 - Arizona Legislature." <https://www.azleg.gov/legtext/54leg/1R/laws/0318.pdf>. Accessed 29 Nov. 2019.

6. A representative of an Arizona-based nonprofit medical marijuana dispensary that is primarily focused in producing medical marijuana edibles who has at least three years of medical marijuana edible production experience.
7. An owner of an Arizona-based cannabis testing laboratory.
8. A laboratory scientist who holds a doctorate or a bachelor of science degree and who has at least three years of experience in cannabis laboratory testing.
9. A registered qualifying patient.
10. A registered designated caregiver.
11. A representative of the department of public safety.
12. A licensed health care provider who specializes in treating substance use disorders and who has at least five years of experience.

Council members were selected through an online application process published on the ADHS website. Applicants were asked to designate the Council position they were applying to fill, provide a brief statement on their relevant experience and interest in serving on the Council, attest that they met the requirements of the position for which they were applying and would attend Council meetings, and submit a current resume.

### **1.3 Record of Business**

The Council prepared agendas and kept a record of each meeting through complete meeting recordings in compliance with Arizona's Open Meeting Law (A.R.S. Title 38, Chapter 3, Article 3.1). A [Council website](#)<sup>3</sup> was developed to serve as a repository for all information reviewed, presented, and discussed. Agendas and meeting recordings are included on the Council website. The initial Council meeting took place on September 26, 2019, and seven Council meetings occurred in total.

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<sup>3</sup> "ADHS - Medical Marijuana - Home." <https://www.azdhs.gov/licensing/medical-marijuana/index.php#testing-advisory-council>. Accessed 29 Nov. 2019.

## 2.0 Establishment of a Testing Program

Senate Bill 1494 required ADHS to adopt rules to certify and regulate independent third-party laboratories that will be responsible for testing medical marijuana and specified several requirements laboratories must meet in order to be certified. These include, in summary:

1. Meeting requirements established by ADHS, including reporting and health and safety requirements.
2. Not having any direct or indirect familial or financial relationships with or interest in a nonprofit medical marijuana dispensary or related medical marijuana business entity or designated caregiver.
3. Having a quality assurance program and standards.
4. Having an adequate chain of custody and sample requirement policies.
5. Having an adequate records retention processes.
6. Establishing procedures to ensure results are accurate, precise, and scientifically valid.
7. Being accredited by a national or international accreditation association or similar accrediting entity as determined by ADHS.
8. Establishing policies and procedures for disposal and reverse distribution of samples.

To expedite the certification of independent third-party laboratories, ADHS promulgated an initial set of rules<sup>4</sup>, effective August 27, 2019, creating a process for laboratories to apply for certification. Once certified, laboratory staff would be eligible to apply for laboratory agent cards as required by S.B. 1494 and could then begin the process of accreditation for the various methods that will be utilized to test medical marijuana and marijuana products by November 1, 2020.

The recommendations contained within this report will help inform an amended set of rules ADHS will issue to further stipulate the requirements of Arizona's medical marijuana testing program. Laboratories will be required to demonstrate validation of each method they will be utilizing to test medical marijuana and marijuana products before they will be certified to utilize that method and report out results. ADHS provides information about active rulemakings on ADHS's [Administrative Council and Rules website](#)<sup>5</sup>.

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<sup>4</sup> "Authenticated PDF - Arizona Secretary of State." 20 Sep. 2019, [https://apps.azsos.gov/public\\_services/register/2019/38/contents.pdf](https://apps.azsos.gov/public_services/register/2019/38/contents.pdf). Accessed 29 Nov. 2019.

<sup>5</sup> "ADHS - Administrative Rules - Rulemakings In Progress - Medical Marijuana (Exempt)." <https://www.azdhs.gov/director/administrative-counsel-rules/rules/index.php#rulemakings-active-medical-marijuana>. Accessed 29 Nov. 2019.

### 3.0 Testing and Potency Standards for Medical Marijuana

ADHS State Public Health Laboratory staff conducted an extensive review of medical marijuana testing programs throughout the United States, compiling their findings into a series of tables and summary documents. The majority of this information was presented to Council members at their initial meeting to provide them with background information, best practices, and evidence based practices (where available) to consider as they made recommendations to ADHS.

The information contained within the [presentation](#)<sup>6</sup> from the September 26, 2019 Council meeting, as well as supporting documents<sup>7,8,9,10,11,12,13,14</sup> posted on the website, serve as the reference base for subsequent Council discussion and ADHS consideration.

Council members provided additional information and expertise to inform discussions and final recommendations of the Council. All information presented and reviewed by the Council is contained as a document or within an audio recording posted on the Council's [website](#).<sup>15</sup>

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<sup>6</sup> "9/26/19 Meeting Presentation."

<https://www.azdhs.gov/documents/licensing/medical-marijuana/testing-advisory-council/9-26-19-mmta-c-meeting-presentation.pdf>. Accessed 29 Nov. 2019.

<sup>7</sup> "Summary of 50 State Review for Medical Marijuana Laboratory Testing Advisory Committee."

<https://www.azdhs.gov/documents/licensing/medical-marijuana/testing-advisory-council/50-state-review.pdf>. Accessed 29 Nov. 2019.

<sup>8</sup> "Compiled State Heavy Metals Standards Review."

<https://www.azdhs.gov/documents/licensing/medical-marijuana/testing-advisory-council/compiled-state-metals-limits.xlsx>. Accessed 29 Nov. 2019.

<sup>9</sup> "Compiled Microbial Standards Review."

<https://www.azdhs.gov/documents/licensing/medical-marijuana/testing-advisory-council/compiled-state-micro-limits.xlsx>. Accessed 29 Nov. 2019.

<sup>10</sup> "Compiled State Pesticides/Fungicides/Herbicides/Growth Regulators Review."

<https://www.azdhs.gov/documents/licensing/medical-marijuana/testing-advisory-council/compiled-state-pesticides-limits.xlsx>. Accessed 29 Nov. 2019.

<sup>11</sup> "Compiled State Solvent Review."

<https://www.azdhs.gov/documents/licensing/medical-marijuana/testing-advisory-council/compiled-state-solvent-limits.xlsx>. Accessed 29 Nov. 2019.

<sup>12</sup> Farrer DG. Technical Report: Oregon Health Authority's process to decide which types of contaminants to test for in cannabis. Oregon Health Authority. 2015 December.

<https://www.oregon.gov/oha/ph/preventionwellness/marijuana/documents/oha-8964-technical-report-marijuana-contaminant-testing.pdf>. Accessed 29 Nov. 2019.

<sup>13</sup> Holmes M, Vyas JM, Steinbach W, McPartland J. Microbiological Safety Testing of Cannabis. Cannabis Safety Institute. 2015 May.

<https://www.azdhs.gov/documents/licensing/medical-marijuana/testing-advisory-council/microbiological-safety-testing-of-cannabis.pdf> Accessed 29 Nov. 2019.

<sup>14</sup> "Arizona Proposed Pesticides."

<https://azdhs.gov/documents/licensing/medical-marijuana/testing-advisory-council/12-10-19-arizona-proposed-pesticides.pdf>. Accessed 9 Dec. 2019.

<sup>15</sup> "ADHS - Medical Marijuana - Home."

<https://www.azdhs.gov/licensing/medical-marijuana/index.php#testing-advisory-council>. Accessed 29 Nov. 2019.

Council members were asked to make recommendations about the parameters that should be tested for within each testing category, the safety levels that should be set above which a product must be remediated or disposed, and test method options that should be used.

### **3.1 Microbial Contamination**

Council members considered a variety of microbial contaminants to include in Arizona's marijuana testing program including *E. coli*, *Salmonella*, *Aspergillus*, mycotoxins, aflatoxins, yeast and mold, and other bacterial pathogens.

The final recommendations of the Council related to microbial contaminants are:

- All final products must be tested for *E. coli* prior to sale.
  - Products testing  $\leq 100$  CFU/g pass.
  - Products testing  $> 100$  CFU/g must be remediated or reprocessed as applicable and retested prior to sale.
- All final products must be tested for *Salmonella*. Samples with detectable *Salmonella* will fail and must be destroyed - no remediation possible.
- All inhaled products must either be:
  - Tested for *Aspergillus flavus*, *fumigatus*, *niger*, and *terreus* using molecular methods (PCR, qPCR, DNA microarrays, sequencing). Products  $\leq 1$  CFU pass and no further testing is required. If the result is  $> 1$  CFU, the product must be tested for mycotoxins using HPLC, ELISA, or an in-house developed method that is validated by AOAC Appendix J or K, as relevant, or other federal or international standards. Products testing  $\geq 20\mu\text{g/kg}$  (ppm) mycotoxins fail and cannot be remediated.

OR

- Tested for mycotoxins using HPLC, ELISA, or an in-house developed method that is validated by AOAC Appendix J or K, as relevant, or other federal or international standards. Products testing  $\geq 20\mu\text{g/kg}$  (ppm) mycotoxins fail and cannot be remediated.
- Microbial testing should be conducted using the Bacteriological Analytical Manual (FDA 2013a) and validated by AOAC Appendix J or K, as relevant, or other federal or international standards that meet the criteria

### 3.2 Heavy Metals

In their discussion of heavy metals testing, Council members considered testing requirements in other states, including which elements are included in other states' regulations and the safety levels set for each of these limits.

The final recommendations of the Council related to heavy metals are:

- Any edible or infused product made from concentrate that has previously passed safety testing is exempt from final testing for solvents, heavy metals, pesticides, fungicides, and growth regulators.
- All final products must be tested for heavy metals as listed below. Products at or below the values listed in the table may be sold.

Heavy Metal	Limit (ppm)
Arsenic	≤0.4
Cadmium	≤0.4
Lead	≤1.0
Mercury	≤1.2

- Heavy metals testing can be conducted using any national, international, or in-house developed method that is validated by AOAC Appendix K or other federal or international standards that meet the method criteria from EPA methods

### 3.3 Pesticides, Herbicides, Fungicides, Growth Regulators

The Council had access to multiple resources in their consideration of which pesticides, herbicides, fungicides, and growth regulators to include in Arizona's testing program including other states' regulations and a proposal from a local scientist reviewing a variety of compounds and summarizing their frequency of use, toxicity classification, and clinical evidence.

The final recommendations of the Council related to pesticides, herbicides, fungicides, and growth regulators are:

- Any edible or infused product made from concentrate that has previously passed safety testing is exempt from final testing for solvents, heavy metals, pesticides, fungicides, and growth regulators.

- All final products must be tested for pesticides, fungicides, and growth regulators listed in Table 2 within the Oregon Health Authority's Technical Report ([OHA 8964](#))<sup>16</sup>. Products at or below the values listed in the table may be sold.

**Table 2. Pesticide analytes and their action levels**

Analyte	Chemical Abstract Services (CAS) Registry number	Action level ppm	Analyte	Chemical Abstract Services (CAS) Registry number	Action level ppm
Abamectin	71751-41-2	0.5	Imazalil	35554-44-0	0.2
Acephate	30560-19-1	0.4	Imidacloprid	138261-41-3	0.4
Acequinocyl	57960-19-7	2	Kresoxim-methyl	143390-89-0	0.4
Acetamiprid	135410-20-7	0.2	Malathion	121-75-5	0.2
Aldicarb	116-06-3	0.4	Metalaxyl	57837-19-1	0.2
Azoxystrobin	131860-33-8	0.2	Methiocarb	2032-65-7	0.2
Bifenazate	149877-41-8	0.2	Methomyl	16752-77-5	0.4
Bifenthrin	82657-04-3	0.2	Methyl parathion	298-00-0	0.2
Boscalid	188425-85-6	0.4	MGK-264	113-48-4	0.2
Carbaryl	63-25-2	0.2	Myclobutanil	88671-89-0	0.2
Carbofuran	1563-66-2	0.2	Naled	300-76-5	0.5
Chlorantraniliprole	500008-45-7	0.2	Oxamyl	23135-22-0	1
Chlorfenapyr	122453-73-0	1	Paclobutrazol	76738-62-0	0.4
Chlorpyrifos	2921-88-2	0.2	Permethrins*	52645-53-1	0.2
Clofentezine	74115-24-5	0.2	Phosmet	732-11-6	0.2
Cyfluthrin	68359-37-5	1	Piperonyl butoxide	51-03-6	2
Cypermethrin	52315-07-8	1	Prallethrin	23031-36-9	0.2
Daminozide	1596-84-5	1	Propiconazole	60207-90-1	0.4
DDVP (Dichlorvos)	62-73-7	0.1	Propoxur	114-26-1	0.2
Diazinon	333-41-5	0.2	Pyrethrins†	8003-34-7	1
Dimethoate	60-51-5	0.2	Pyridaben	96489-71-3	0.2
Ethoprophos	13194-48-4	0.2	Spinosad	168316-95-8	0.2
Etofenprox	80844-07-1	0.4	Spiromesifen	283594-90-1	0.2
Etoazole	153233-91-1	0.2	Spirotetramat	203313-25-1	0.2
Fenoxycarb	72490-01-8	0.2	Spiroxamine	118134-30-8	0.4
Fenpyroximate	134098-61-6	0.4	Tebuconazole	80443-41-0	0.4
Fipronil	120068-37-3	0.4	Thiacloprid	111988-49-9	0.2
Flonicamid	158062-67-0	1	Thiamethoxam	153719-23-4	0.2
Fludioxonil	131341-86-1	0.4	Trifloxystrobin	141517-21-7	0.2
Hexythiazox	78587-05-0	1			

\* Permethrins should be measured as cumulative residue of cis- and trans-permethrin isomers (CAS numbers 54774-45-7 and 51877-74-8).

† Pyrethrins should be measured as the cumulative residues of pyrethrin 1, cinerin 1 and jasmolin 1 (CAS numbers 121-21-1, 25402-06-6, and 4466-14-2 respectively).

Pesticides, continued

Technical report: Oregon Health Authority's process to determine which types of contaminants to test for in cannabis products, and levels for action — 8

- Pesticide, fungicide, herbicide, and growth regulator testing can be conducted using any national, international, or in-house developed method that is validated by AOAC Appendix K or other federal or international standards that meet the method criteria from EPA methods.

<sup>16</sup> Farrer DG. Technical Report: Oregon Health Authority's process to decide which types of contaminants to test for in cannabis. Oregon Health Authority. 2015 December. <https://www.oregon.gov/oha/ph/preventionwellness/marijuana/documents/oha-8964-technical-report-marijuana-contaminant-testing.pdf>. Accessed 29 Nov. 2019.

### 3.4 Residual Solvents

In their discussion of testing requirements for residual solvents, Council members considered testing requirements in other states, including which solvents are included in other states' regulations and the safety levels set for each of these limits. Council members also discussed which solvents have been seen within Arizona products.

The final recommendations of the Council related to residual solvents are:

- Any edible or infused product made from concentrate that has previously passed safety testing is exempt from final testing for solvents, heavy metals, pesticides, fungicides, and growth regulators.
- All final extracted products must be tested for residual solvents referenced below. Products at or below the values listed in the table may be sold.

Solvent	Limit (ppm)	Solvent	Limit (ppm)
Acetone	≤1000	Heptanes	≤5000
Acetonitrile	≤410	Hexane	≤290
Benzene	≤2	Isopropyl Acetate	≤5000
Butane	≤5000	Methanol	≤3000
Chloroform	≤60	Pentane	≤5000
Dichloromethane	≤600	2-Propanol (IPA)	≤5000
Ethanol	≤5000	Propane	≤5000
Ethyl Acetate	≤5000	Toluene	≤890
Ethyl Ether	≤5000	Xylenes	≤2170

- Residual solvent testing should be conducted using any EPA, AOAC, or in-house developed method that is validated by AOAC Appendix K or other federal or international standards that meet the EPA criteria.

### 3.5 Potency

Council members engaged in extensive discussion about potency testing, including discussion about which cannabinoids to include in a required testing program and the values at which potency should be reported.

The final recommendations of the Council related to potency are:

- All products must be tested for THC-A,  $\Delta$ 9-THC, CBD-A, CBD, and any label claims specific to cannabinoids.
- Total THC and CBD shall be reported as follows:
  - Total THC = ( $\Delta$ 9-THC + (THC-A  $\times$  87.7%))
  - Total CBD = (CBD + (CBD-A  $\times$  87.7%))
- Potency of all products must test +/- 20% of label claim or be repackaged to meet actual concentration.
- Potency reporting should include, at minimum:
  - For anything over 10% cannabinoid - one decimal place (i.e., to 12.3%)
  - For anything under 10% but above 0.1% - two decimal places (i.e., to 0.01%)
  - For anything under 0.01% - three decimal places (i.e., to 0.012%)
- For edibles, report potency in milligrams (mg) with two significant figures.
- Potency reporting should note that results are “below the level of quantitation” (< LOQ) when applicable.
- Potency testing can be conducted by AHP or in-house methods that are validated by AOAC Appendix K or other federal or international standards that meet the criteria.

### 3.6 Other Testing Standards

In addition to discussion regarding required testing for microbial contamination, heavy metals, pesticides, fungicides, herbicides, growth regulators, residual solvents, and potency, the Council discussed the value of recommending requirements for other kinds of testing. Items discussed included aflatoxins, total yeast and mold, *Pseudomonas aeruginosa*, *Listeria*, toxigenic *E. coli*, other bacterial pathogens besides *Salmonella*, terpenes, water activity, and filth and foreign material. Ultimately, the Council decided against making recommendations regarding these items at this time, but approved a motion to reconvene in six and twelve months to reconsider many of these.

## **4.0 Procedural Requirements for Sample Collection and Storage**

Council members reviewed sample collection requirements from other states and a proposal from a Director of Quality at a local dispensary prior to making recommendations related to sampling. The Council discussed giving ADHS the discretion to move a licensee to a different AQL Inspection Level dependent on their compliance history. The Council also discussed the need to maintain samples in a manner to prevent degradation prior to testing.

Final recommendations for sample collection were:

- Utilize ANSI Z1.4 / AQL General Inspection Level II.
- Utilize number of containers per production batch to set the lot size for the sample set.
- Utilize top, middle, bottom, star pattern or sample thief sampling with composite quartering to arrive at the most homogeneous sample possible.
- Total sample size to be taken would be a minimum of 4 grams of material per production batch for potency and 12 grams of material per production batch for patient safety to allow duplicate testing, as necessary.

## **5.0 Reporting Results**

Council members considered multiple methods for reporting results. One option discussed was to require certified independent third-party laboratories to provide two distinct reports regarding results of their testing: a technical report and a certificate of analysis intended to be a patient-friendly summary. Additional discussion occurred regarding the format of reporting and included suggestions of a QR code or something similar to be included on product packaging that would provide test results.

The final recommendations of the Council related to reporting results are that laboratories should be required to, at a minimum, produce a technical report, or other summary report that is consistent with ISO accreditation, detailing laboratory testing results.

## **6.0 Remediation and Retesting**

Council members discussed the appropriateness of remediation and retesting and the circumstances under which each should be allowed. In general, prior Council recommendations around specific safety testing included language detailing when remediation would be allowed.

The final recommendations of the Council related to remediation are that unless explicitly stated otherwise, all products can be remediated.

The final recommendations of the Council related to retesting are:

- Rules should allow for product retesting to verify safety testing results.
- Retesting for remediated production batches will follow the same procedure as initial testing.

## **7.0 Disposal**

Council members discussed current methods of disposal within laboratories and considered information from other states on disposal requirements.

The final recommendations of the Council related to disposal are that laboratories must maintain policies and procedures to render waste unusable and unrecognizable.

## **8.0 Additional Council Recommendations**

In addition to the Council's explicit charge of making recommendations regarding establishing a required testing program, testing and potency standards for medical marijuana, procedural requirements for collecting, storing, and testing samples of medical marijuana, reporting results to patients and ADHS, and remediation and disposal requirements for medical marijuana that fails to meet testing standards, the Council also had the ability to discuss additional recommendations. Through its discussion, Council members were aware that some of the recommendations would require a statutory change prior to implementation.

Additional recommendations made by the Council are:

- The Medical Marijuana Testing Advisory Council should be reconvened at six and twelve months to review the recommended testing parameters and action levels as well as other items discussed by the Council.
- ADHS may waive testing requirements of this section in whole or in part if ADHS determines that the number of labs approved to conduct a given test is insufficient for all testing samples to be appropriately processed. ADHS may also adopt and enforce a staggered random testing schedule for the sampling and testing of dried, usable cannabis and concentrated cannabis-derived products.

## Appendix 1 - Council Roster

The Medical Marijuana Testing Advisory Council, established pursuant to S.B. 1494, is comprised of the following individuals:

Council Member	Council Position
Steve Cottrell	Designee of a medical marijuana trade association (A.R.S. 36-2821 (A)(3))
Joseph DeMenna	Registered qualifying patient (A.R.S. 36-2821 (A)(9))
Vince Figarelli	Representative of the Department of Public Safety (A.R.S. 36-2821 (A)(11))
Stephen Grams	Licensed healthcare provider specializing in treating substance use disorders (A.R.S. 36-2821 (A)(12))
George Griffeth	Designee of a statewide nonprofit cannabis testing association (A.R.S. 36-2821 (A)(2))
Tabitha Hauer	Owner of an Arizona-based cannabis testing laboratory (A.R.S. 36-2821 (A)(7))
R.D. Hendrickson	Representative of an Arizona-based nonprofit medical marijuana dispensary primarily focused on producing medical marijuana edibles (A.R.S. 36-2821 (A)(6))
Ryan Hurley	Designee of a statewide nonprofit dispensary association (A.R.S. 36-2821 (A)(1))
Hope Jones	Laboratory scientist with three years experience in cannabis laboratory testing (A.R.S. 36-2821 (A)(8))
Matthew LaScala	Representative of an Arizona-based nonprofit medical marijuana dispensary who is employed to cultivate medical marijuana (A.R.S. 36-2821 (A)(4))
Blake Jay Neri	Registered designated caregiver (A.R.S. 36-2821 (A)(10))
Jessica Rigler (Chairperson)	ADHS Director's designee
Murray Stein	Representative of an Arizona-based nonprofit medical marijuana dispensary that produces concentrates (A.R.S. 36-2821 (A)(5))