MURIEL BOWSER
MAYOR

JAN 18 2019

The Honorable Phil Mendelson
Chairman, Council of the District of Columbia
John A. Wilson Building
1350 Pennsylvania Avenue, N.W., Suite 504
Washington, D.C. 20004

Dear Chairman Mendelson:

Enclosed for consideration by the Council, is the "Medical Marijuana Testing Laboratory Rulemaking Approval Resolution of 2019."

This resolution would approve proposed rulemaking to amend Title 22-C (Medical Marijuana) of the District of Columbia Municipal Regulations (DCMR) by adding a new chapter 64 (Testing Laboratories.) This rulemaking is necessary to implement regulations governing the registration, regulation, and operation of medical marijuana testing laboratories in the District of Columbia.

I urge the Council to take prompt and favorable action on the enclosed legislation.

Sincerely,

Muriel Bowser
Mayor

MB/cmw

Chairman Phil Mendelson
at the request of the Mayor

A PROPOSED RESOLUTION

IN THE COUNCIL OF THE DISTRICT OF COLUMBIA

Chairman Phil Mendelson, at the request of the Mayor, introduced the following resolution, which was referred to the Committee on _____.

To approve proposed rules to govern the registration, regulation, and operation of medical marijuana testing laboratories in the District of Columbia.

RESOLVED, BY THE COUNCIL OF THE DISTRICT OF COLUMBIA, that this resolution may be cited as the "Medical Marijuana Testing Laboratory Rulemaking Approval Resolution of 2019."

Sec. 2. Pursuant to section 14(b) of the Legalization of Marijuana for Medical Treatment Initiative of 1999 (Act), effective February 25, 2010 (D.C. Law 13-315; 57 DCR 3360), as amended by the Legalization of Marijuana for Medical Treatment Amendment Act of 2010, effective July 27, 2010 (D.C. Law 18-210; D.C. Official Code §§ 7-1671.13(b)), the Council approves the proposed rulemaking adopted by the Department of Health adding amending §§ 5000, 5002, and 5003 of Chapter 50, amending §§ 5101, 5102, 5107, 5108, 5109, and 5110 of Chapter 51, amending §§ 5200 and 5201 of Chapter 52, amending §§ 5301, 5302, and 5303 of Chapter 53, amending §§ 5401, 5402, 5403, 5404, 5407, 5408, 5411, 5412, 5414, 5417, and 5418 of Chapter 54, amending § 5500 of Chapter 55, amending §§ 5600, 5602, 5603, 5605, 5606, 5610, 5613, 5614, 5615, 5617, 5618, 5619, and 5621 of Chapter 56, amending § 5704 of Chapter 57,

amending § 5900 of Chapter 59, and amending § 9900 of Chapter 99 of Title 22-C of the District of Columbia Municipal Regulations, and adding a new chapter 64 (Testing Laboratories) to Title 22-C of the District of Columbia Municipal Regulations to govern the registration, regulation, and operation of medical marijuana testing laboratories in the District of Columbia.

Sec. 3. Fiscal impact.

The Council adopts the fiscal impact statement in the committee report of the Chief Financial Officer as the fiscal impact statement required by section 4(a) of the General Legislative Procedures Act of 1975, approved October 16, 2006 (120 Stat. 2038; D.C. Official Code § 1-301.47(a)).

Sec. 4. The Council shall transmit a copy of this resolution, upon its adoption, to the Mayor, the Director of the Department of Health, and the Administrator of the Office of Documents and Administrative Issuances.

Sec. 5. This resolution shall take effect immediately.

DEPARTMENT OF HEALTH

NOTICE OF PROPOSED RULEMAKING

The Director of the Department of Health, pursuant to Sections 6 and 14 of the Legalization of Marijuana for Medical Treatment Initiative of 1999, effective July 27, 2010 (D.C. Law 18-210; D.C. Official Code §§ 7-1671.05 & 7-1671.13 (2018 Repl.); Section 4902(d) of the Department of Health Functions Clarifications Act of 2001, effective October 3, 2001 (D.C. Law 14-28; D.C. Official Code § 7–731(d) (2018 Repl.)); and Mayor's Order 2011-71, dated April 13, 2011, hereby gives notice of her intent to adopt the following amendments to Subtitle C (Medical Marijuana) of Title 22 (Health) of District of Columbia Municipal Regulations (DCMR) in not less than thirty (30) days from the date of publication of this notice in the *D.C. Register*, and upon the Council's approval of the rulemaking. If the Council does not disapprove of the rules during the thirty (30) day period of review, the rules shall be deemed approved.

The amendments would, within Subtitle C of Title 22 of the DCMR, amend Chapters 50 (Registration, Licensing, and Enforcement of Cultivation Centers and Dispensaries), 51 (Registration and Permit Categories), 52 (Registration Limitations), 53 (General Registration Limitations), 54 (Registration Applications), 55 (Registration Changes), 56 (General Operating Requirements), 57 (Prohibited and Restricted Activities), 59 (Records and Reports), and 99 (Definitions) and add a new Chapter 64 (Testing Laboratories). The purpose of this rulemaking is to implement regulations governing the registration, regulation, and operation of medical marijuana testing laboratories in the District of Columbia.

Chapter 50, REGISTRATION, LICENSING, AND ENFORCEMENT OF CULTIVATION CENTERS AND DISPENSARIES, of Subtitle C, MEDICAL MARIJUANA, of Title 22, HEALTH, of the DCMR is amended as follows:

The title of Chapter 50 is amended to read as Registration, Licensing, and Enforcement of Cultivation Centers, Dispensaries, and Testing Laboratories.

Section 5000, MEASURING DISTANCES, is amended by amending § 5000.1 to read as follows:

5000.1 In establishing the distance between one (1) or more places, (such as the actual distance of a cultivation center, dispensary, or testing laboratory from a school or recreation center, as defined in the Act), the distance shall be measured linearly by the Department and shall be the shortest distance between the property lines of the places.

Section 5002, PERMISSIBLE ACTIVITIES AND LIMITATIONS ON CULTIVATION CENTERS AND DISPENSARIES, is amended as follows:

The title of § 5002 is amended to read as Permissible Activities and Limitations on Cultivation Centers, Dispensaries, and Testing Laboratories.

A new § 5002.3 is added to read as follows:

5002.3 A testing laboratory registered to operate in the District may:

(a) Possess medical marijuana and medical marijuana products for the purpose of testing the contents; and

(b) Collect samples of medical marijuana and medical marijuana products from a cultivation center, and transport the samples from the cultivation center to the testing laboratory for the purpose of testing the samples.

Section 5003, NON-TRANSFERABILITY OF LOCATIONS AND OWNERSHIP, is amended to read as follows:

5003 LOCATIONS AND OWNERSHIP

5003.1 An application for a dispensary, cultivation center, or testing laboratory registration shall identify the proposed location of the dispensary, cultivation center, or testing laboratory by street mailing address, including suite or unit number if applicable. No post office box numbers shall be permitted. An applicant shall not be permitted to alter, change, or substitute the proposed location of the dispensary, cultivation center, or testing laboratory after the application has been submitted.

5003.2 A registration for a dispensary, cultivation center, or testing laboratory shall be issued for the specific location identified on the application, and is valid only for the owner, premises, and name designated on the registration and the location for which it is issued.

5003.3 Repealed.

5003.4 An application for a dispensary, cultivation center, or testing laboratory registration shall clearly identify the individual applicant, partnership or limited liability company applicant, or corporate applicant as required under this subtitle. An applicant shall not be permitted to change the proposed ownership or controlling interest of the entity after the application has been submitted.

5003.5 A registration for a dispensary, cultivation center, or testing laboratory and the authorization to apply for the registration upon approval by the Department, shall be issued for the specific individual applicant, partnership or limited liability company applicant, or corporate applicant as identified in the application.

5003.6 Repealed.

5003.7 A dispensary, cultivation center, or testing laboratory registration shall not be leased, or subcontracted, in whole or in part.

Chapter 51, REGISTRATION AND PERMIT CATEGORIES, of Subtitle C, MEDICAL MARIJUANA, of Title 22, HEALTH, of the DCMR is amended as follows:

Section 5101, RENEWAL PERIODS, is amended by amending §§ 5101.3 and 5101.4 to read as follows:

5101.3 In addition to the initial application, the Mayor shall provide all Advisory Neighborhood Commissions (ANCs) located in the affected ward thirty (30) days for public comment once every three (3) years on an applicant for a dispensary, cultivation center, or testing laboratory's renewal, beginning with the third renewal.

5101.4 The notice to the ANCs set forth in § 5101.3 of this chapter on a third year renewal application shall be provided to the ANCs not later than ninety (90) days before a registration is renewed. The Department shall renew the registration or inform the applicant in writing of his intent not to renew the registration within sixty (60) days following the conclusion of the ANC thirty (30) day comment period.

Section 5102, EXTENSION OF EXPIRATION DATES OF PROTESTED REGISTRATIONS, is amended by amending § 5102.1 to read as follows:

5102.1 Unless a registration is otherwise summarily suspended under this subtitle, the registration of a cultivation center, dispensary, or testing laboratory that has received written notice of the Department's intent not to renew the registration shall continue in effect until such time as the Department has taken final action on the registration.

Section 5107, NOTICE TO ADVISORY NEIGHBORHOOD COMMISIONS, is amended by amending §§ 5107.1 and 5107.2 to read as follows:

5107.1 Upon the initial selection of a completed application by the panel, a third year renewal, or an application to transfer the location of a dispensary, cultivation center, or testing laboratory to a new location, the Director shall give written notice through the mail of the registration application to all ANCs in the affected ward. Notice shall be given by the Director to all ANCs in the affected ward at least ninety (90) days prior to the approval of a location for a dispensary, cultivation center, or testing laboratory, and shall state that the ANCs must submit their comments to the Director not later than thirty (30) days after receiving the notice.

5107 .2 The written notice shall contain the legal and trade name of the applicant, the street address of the establishment for which registration is sought, the type of registration sought, and a description of the nature of the operation the applicant has proposed, including the proposed hours of operation.

Section 5108, POSTED NOTICE TO THE PUBLIC, is amended by amending § 5108.1 to read as follows:

5108.1 The Director shall post two (2) notices indicating that an application for a cultivation center, dispensary, or testing laboratory registration has been filed in conspicuous places on the outside of the establishment's proposed location for the duration of the ANCs thirty (30) day comment period.

Section 5109, COMMENTS FROM ANCS LOCATED IN THE AFFECTED WARD, is amended by amending § 5109.1 to read as follows:

5109.1 Comments submitted by an ANC located in the affected ward for consideration shall relate to the ANC's concerns or support regarding the proposed location including but not limited to:

(a) The potential adverse impact of the proposed location to the neighborhood;

(b) An overconcentration or lack of cultivation centers, dispensaries, or testing laboratories in the affected ward; and

(c) Its proximity to substance abuse treatment centers, day care centers, and halfway houses.

Section 5110, NON-TRANSFERABLE REGISTRATION CARDS, is amended by amending §§ 5110.1 and 5110.2 to read as follows:

5110.1 All persons required to register with the Department shall receive and wear on their person, while working in a restricted access area at a cultivation center, dispensary, or testing laboratory, a non-transferable uniform registration identification card from the Department. It shall be a violation of this subtitle for a person to not wear their non-transferable registration identification card while working in a restricted access area of a cultivation center, dispensary, or testing laboratory.

5110.2 The non-transferable registration card shall be presented by a manager, director, officer, member, incorporator, agent and employee of a cultivation center, dispensary, or testing laboratory to law enforcement or a Department investigator to confirm that the person is authorized to cultivate, dispense, distribute, possess, test, or transport medical marijuana, or manufacture, possess, or distribute paraphernalia.

Chapter 52, REGISTRATION LIMITATIONS, of Subtitle C, MEDICAL MARIJUANA, of Title 22, HEALTH, of the DCMR is amended as follows:

The title of § 5200 is amended to read as Limitation on the Number of Dispensaries, Cultivation Centers, and Testing Laboratories.

Subsections 5200.3 and 5200.4 are amended to read as follows:

5200.3 The number of testing laboratories registered to operate in the District of Columbia shall not exceed two (2).

5200.4 Nothing in this subtitle shall require the Department to issue all of the available registrations to operate a dispensary, cultivation center, or testing laboratory.

Section 5201, REGISTRATION APPLICATIONS NEAR SCHOOLS AND RECREATION CENTERS, is amended by amending § 5201.1 to read as follows:

5201.1 A dispensary, cultivation center, or testing laboratory shall not locate within three hundred feet (300 ft.) of a preschool, primary or secondary school, or recreation center.

Chapter 53, GENERAL REGISTRATION REQUIREMENTS, of Subtitle C, MEDICAL MARIJUANA, of Title 22, HEALTH, of the DCMR is amended as follows:

Section 5300, DENIAL OF REGISTRATION FOR VIOLATIONS OF LAW, is amended by amending § 5300.1 to read as follows:

5300.1 The Director may deny registration to an applicant if evidence shows that the applicant has permitted conduct at the cultivation center, dispensary, or testing laboratory which is in violation of this subtitle.

Section 5301, CERTIFICATE OF OCCUPANCY AND PERMITS, is amended by amending § 5301.1 to read as follows:

5301.1 A registration may not be issued for a cultivation center, dispensary, or testing laboratory unless the applicant obtains a valid certificate of occupancy for the premises in which the business for which the registration is sought is located, and is also the holder of all other licenses and permits required by law or regulation for that business. A registration for a cultivation center, dispensary, or testing laboratory shall not be issued for any premises located within a residentially zoned district.

Section 5302, REGISTRATION APPROVAL BEFORE ISSUANCE OF CERTIFICATE OF OCCUPANY, is amended by amending § 5302.1 to read as follows:

5302.1 The Director is authorized, in its discretion, to approve the granting of a registration for a cultivation center, dispensary, or testing laboratory, subject to all other requirements of the Act or this subtitle, to an applicant prior to the issuance

of a certificate of occupancy for the building in which the registered premises shall be located, if the Director finds to his or her satisfaction the following:

(a) That an applicant for registration has entered into a bona fide agreement with the owner of a building proposed to be constructed or remodeled;

(b) That, under the bona fide agreement, the applicant has agreed to lease, purchase, or otherwise occupy all or a portion of the building for the applicant's use in carrying on the business which would be authorized by the registration;

(c) That the agreement provides that all or the portion ofthe proposed building to be occupied for business purposes registered under this chapter is to be constructed or remodeled in accordance with specifications set forth in the agreement;

(d) That the agreement describes the quarters as reasonably adequate and appropriate for the business to be carried on under the authority of the registration;

(e) A zoning determination letter issued by DCRA, which reflects that the zoning of the premises to be registered will allow the issuance of the registration; and

(f) That the applicant shall not engage in the purchase, sale, possession, or testing of medical marijuana unless and until a certificate of occupancy and all other business licenses have been issued for the business.

Section 5303, FAILURE TO OPEN OR OPERATE, is amended to read as follows:

5303 FAILURE TO OPEN OR OPERATE

5303.1 A registration for a dispensary, cultivation center, or testing laboratory shall be returned to the Director if the dispensary, cultivation center, or testing laboratory fails to open for business within one hundred twenty (120) days after the registration has been issued, except that the Director may grant an extension at his or her discretion for good cause shown.

5303.2 A registration for a dispensary, cultivation center, or testing laboratory shall be returned to the Director if the dispensary, cultivation center, or testing laboratory fails to operate for any reason for more than one hundred twenty (120) consecutive days after it has opened for business.

Chapter 54, REGISTRATION APPLICATIONS, of Subtitle C, MEDICAL MARIJUANA, of Title 22, HEALTH, of the DCMR is amended as follows:

Section 5401, OPEN APPLICATION PERIOD AND REQUIRED LETTER OF INTENT, is amended to read as follows:

5401 OPEN APPLICATION PERIOD AND REQUIRED LETTER OF INTENT

5401.1 Applications for a new cultivation center, dispensary, or testing laboratory registration shall only be accepted by the Director during the open application period as specified by the Director by publishing a Notice in the *D.C. Register*; such period shall not be extended.

5401.2 Prior to the submission of a formal application for a new cultivation center, dispensary, or testing laboratory registration, the prospective applicant shall submit a Letter of Intent to the Director or a designee. The Director shall only accept Letters of Intent during the time period specified by the Director by Notice in the *D.C. Register*; such period shall not be extended.

5401.3 The purpose of the Letter of Intent is to formally notify the Director that an application for a cultivation center, dispensary, or testing laboratory registration will be forthcoming.

5401.4 The Letter of Intent shall include at least the following:

(a) The individual's name, or the organization, corporation, company name of the prospective applicant, and if the applicant is an organization, the full name and title of the primary contact;

(b) The mailing address, which shall not be a post office box number, daytime telephone number, and email address of the applicant or primary contact person if not the same person;

(c) The type of registration the prospective applicant may apply for;

(d) A statement, not to exceed one hundred (100) words, defining the prospective applicant's intent to submit an application for a cultivation center, dispensary, or testing laboratory; and

(e) The dated signature of the prospective applicant.

5401.5 At the start of each open application period for new cultivation center, dispensary, or testing laboratory registrations, the Director shall publish a notice in the *D.C. Register* setting forth the process for submission of the applications, which shall include:

(a) The opening and ending dates for the submission of Letters of Intent to the Director by all individuals and entities who intend to apply for cultivation center, dispensary, or testing laboratory registrations;

(b) The opening and ending dates for the submission of applications for a cultivation center, dispensary, or testing laboratory registration by those individuals and entities that have timely submitted Letters of Intent to the Director, meeting the requirements set forth in § 5401.4 of this chapter;

(c) A statement that only the individuals and entities that timely submit Letters of Intent to the Director, meeting the requirements set forth in § 5401.4 of this chapter, shall be permitted to submit an application for a cultivation center, dispensary, or testing laboratory registration;

(d) The address for submission to the Director; and

(e) The process for obtaining application materials from the Director.

5401.6 The Notice required in § 5401.5 of this chapter shall appear, at a minimum, in the *D.C Register* and on the Department's website.

5401.7 Applicants shall file a separate Letter of Intent and a separate application for each registration sought.

5401.8 An applicant may apply for more than one (1) cultivation center registration or testing laboratory registration, but may apply for only one (1) dispensary registration.

5401.9 An applicant for a testing laboratory shall not apply for or have a cultivation center or dispensary registration.

5401.10 Only the individuals and entities that timely submitted Letters of Intent to the Director, and received a letter of acceptance from the Department, shall be permitted to submit an application for a cultivation center, dispensary, or testing laboratory registration.

Section 5402, SELECTION PROCESS, is amended to read as follows:

5402 SELECTION PROCESS

5402.1 For cultivation center and dispensary registration applicants, a six (6) member panel shall be convened consisting of one (1) representative from the Department, District Department of the Environment (DDOE), Office of the Attorney General (OAG), Department of General Services Protective Services Division (PSD), DCRA, and a consumer representative or patient advocate, selected by the Director, to evaluate and score each application.

5402.2 For testing laboratory applicants, a seven (7) member panel shall be convened consisting of one (1) representative from the Department, DDOE,

OAG, PSD, DCRA, Department of Forensic Science (DFS), and a consumer representative or patient advocate, selected by the Director, to evaluate and score each application.

5402.3 For cultivation center and dispensary registration applicants, each panel member shall score each application on a two hundred and fifty (250) point base scale. An applicant's overall score is based upon the quality of the applicant's submission, and the ANC comments submitted in accordance with § 5109 of this subtitle, by discarding the highest and lowest panel member scores, adding up the four (4) remaining scores, and dividing that total by four (4).

5402.4 For testing laboratory applicants, each panel member shall score each application on a two hundred and fifty (250) point base scale. An applicant's overall score is based upon the quality of the applicant's submission, and the ANC comments, by discarding the highest and lowest panel member scores, adding up the five (5) remaining scores, and dividing that total by five (5).

5402.5 Each applicant may also be considered to receive bonus points as follows:

(a) An applicant for a cultivation center, dispensary, or testing laboratory registration shall receive twenty (20) bonus points if the applicant submits proof of being a certified business enterprise at the time of submission of its application for a registration;

(b) A dispensary applicant may also submit an educational materials plan, which shall be worth up to twenty (20) additional bonus points;

(c) A cultivation center applicant may also submit an environmental plan, which shall be worth up to twenty (20) additional bonus points; and

(d) A testing laboratory applicant may also submit an environmental plan, which shall be worth up to twenty (20) additional bonus points.

5402.6 The maximum points for each criterion are indicated in § 5403 of this subtitle. To be considered eligible for further review, an application must have at least one hundred and fifty (150) points prior to the ANC review. The panel shall set forth through consensus comments the basis of the scoring decision for each criterion.

5402.7 Prior to seeking ANC review, the panel shall calculate a provisional score based upon the then available points and bonus points. Each applicant's provisional score shall be calculated by discarding the highest and lowest panel member scores, adding up the remaining scores, and dividing that total by the number of scores that remain. The provisional scores shall be ranked from highest to lowest and the Panel shall provisionally select not more than the twenty (20) highest ranking cultivation center applicants, and not more than the ten (10) highest ranking dispensary applicants, for ANC review. The provisional selection

decision shall be made in writing to the successful applicants. Notice shall also be provided by the Director to applicants that are not selected. The Notice shall advise the applicants of the following:

(a) The applicant's total score;

(b) Whether or not the applicant achieved the requisite one hundred and fifty (150) points needed to move forward in the selection process;

(c) The summary of the panel's consensus comments that formed the basis for the applicant's score;

(d) Whether the panel's consensus comments were adopted by the Director and are the findings of fact which are the basis of and support the Director's rationale for the decision. If the application was denied, the Notice shall also address whether the consensus comments were adopted by the Director and are the findings of fact which are the basis of and support the Director's rationale for the decision to deny the applicant's registration application, or whether the denial was based upon other reasoning. If based upon another reason, that reason shall be clearly articulated in the notice letter; and

(e) The applicant's right to judicial review in the D.C. Superior Court.

5402.8 The applications provisionally selected by the panel shall be placarded by the Director with notice given to each ANC in the affected Ward, and shall state that the ANCs must submit their comments to the Director not later than thirty (30) days after receiving the notice.

5402.9 The ANC comments received during the comment period shall then be forwarded to the panel, which shall have thirty (30) days to evaluate and score the ANC comments. Only the official comments of the ANC that were voted upon and approved by the ANC as a whole shall be accepted by the panel for scoring. All affected ANCs that do not timely submit comments shall be scored by the panel as if the ANCs submitted neutral comments. The ANC comments shall be worth up to fifty (50) points of the total scoring for each provisionally selected applicant.

5402.10 The panel shall prepare a report of the final proposed selections based upon the applicant scores, and then submit it to the Director. The report shall assign a numerical rank for each applicant based on the application's final score, include a narrative of the basis for each of the panel's final proposed selections that includes the consensus comments that formed the basis of the scoring decision for each criterion, and shall include not more than the ten (10) highest scoring cultivation center applicants, not more than the five (5) highest scoring dispensary applicants, and not more than the five (5) highest scoring testing laboratory

applicants.

5402.11 In the event that two (2) or more applicants for a cultivation center registration receive the same total score, the panel shall give priority in rank to the applicant that received the highest score in the security plan category. In the event that the same two (2) applicants receive the same score in the security plan category, the panel shall give priority in rank to the applicant that received the highest score in the cultivation plan category.

5402.12 In the event that two (2) or more applicants for a dispensary registration receive the same total score, the panel shall give priority in rank to the applicant that received the highest score in the security plan category. In the event that the same two (2) applicants receive the same score in the security plan category, the panel shall give priority in rank to the applicant that received the highest score in the product safety and labeling plan category.

5402.13 In the event that two (2) or more applicants for a testing laboratory registration receive the same total score, the panel shall give priority in rank to the applicant that received the highest score in the laboratory testing plan category. In the event that the same two (2) applicants receive the same score in the laboratory testing plan, the panel shall give priority rank to the applicant that received the highest score in the security plan category.

5402.14 Except as provided by § 6000 of this subtitle, the Director shall adopt the panel's report and findings and select the highest scoring applicant for a cultivation center, dispensary, or testing laboratory registration. The selection decision shall be made in writing to the successful applicants. Notice shall also be provided by the Director to applicants that are not selected. The Notice shall advise the applicants of the following:

(a) The applicant's total score;

(b) Whether or not the applicant was selected and deemed eligible for registration;

(c) Whether the applicant(s) that was selected and deemed eligible for registration was the highest scoring applicant(s) or otherwise set forth the ranking of the selected applicant(s);

(c) The summary consensus comments that formed the basis for the applicant's score;

(d) Whether the panel's consensus comments were adopted by the Director and are the findings of fact which are the basis of and support the Director's rationale for the decision. If the application was denied, the Notice shall also address whether the consensus comments and final

ranking were adopted by the Director and are the findings of fact which are the basis of and support the Director's rationale for the decision to deny the applicant's registration application, or whether the denial was based upon other reasoning. If based upon another reason, that reason shall be clearly articulated in the notice letter; and

(e) The applicant's right to judicial review in the D.C. Superior Court.

5402.15 In the event that a selected cultivation center, dispensary, or testing laboratory application is subsequently denied by the Director pursuant to § 6000.2 of this subtitle, the applicant who received the next highest score from the panel who was not initially accepted shall be selected.

5402.16 An applicant submitting a cultivation center or dispensary registration application shall be required to submit the eight thousand dollar ($8,000) nonrefundable application fee at the time the cultivation center or dispensary application is filed with the Director.

5402.17 An applicant submitting a testing laboratory registration application shall be required to submit the three thousand five hundred dollar ($3,500) nonrefundable application fee at the time the testing laboratory application is filed with the Director.

Section 5403, SELECTION CRITERIA, is amended as follows:

Sub-subparagraph 5403.1(a)(2)(B) is amended to read as follows:

5403.1 (a) Dispensary Criteria:

(2) Proposed Staffing Plan and Knowledge of District and federal law relating to marijuana (Up to twenty (20) points):

(B) Measure 2: The applicant shall provide an operations manual that demonstrates compliance with the District's medical marijuana rules. The operations manual shall also contain information demonstrating the applicant's knowledge of the District and federal laws and regulations relating to medical marijuana. The applicant shall also submit a notarized written statement on a form provided by the Mayor indicating that they have read the Act and this subtitle and have knowledge of District and federal law relating to marijuana. (up to ten (10) points);

A new subparagraph 5403.1(a)(9) is added to read as follows:

5403.1 (a) Dispensary Criteria:

(9) Certified Business Enterprise (twenty (20) bonus points):

(A) Measure 1: The applicant shall provide documentation, at the time the application is submitted, that it is registered as a certified business enterprise (CBE) by the Department of Small and Local Business development.

Sub-subparagraph 5403.1(b)(2)(B) is amended to read as follows:

5403.1 (b) Cultivation Center Criteria:

(2) Proposed Staffing Plan and Knowledge of District and federal law relating to marijuana (Up to twenty (20) points):

(B) Measure 2: The applicant shall provide an operations manual that demonstrates compliance with the District's medical marijuana rules. The operations manual shall also contain information demonstrating the applicant's knowledge of the District and federal laws and regulations relating to medical marijuana. The applicant shall also submit a notarized written statement on a form provided by the Mayor indicating that they have read the Act and this subtitle and have knowledge of District and federal law relating to marijuana. (up to ten (10) points);

A new subparagraph 5403.1(b)(9) is added to read as follows:

5403.1 (b) Cultivation Center Criteria:

(9) Certified Business Enterprise (twenty (20) bonus points)

(A) Measure 1: The applicant shall provide documentation, at the time the application is submitted, that it is registered as a certified business enterprise (CBE) by the Department of Small and Local Business development.

A new paragraph 5403.1(c) is added to read follows:

5403.1 (c) Testing Laboratory Criteria:

(1) Suitability of the Proposed facility (Up to fifty (50) points)

(A) Measure 1: The applicant demonstrates that the proposed

facility is suitable for testing medical marijuana in an environmentally safe manner, and is adequate in size to accommodate testing and sample retention. (up to twenty-five (25) points); and

(B) Measure 2: The applicant demonstrates that the proposed facility is suitable to meet the cultivation centers' needs for testing a variety of medical marijuana products in a timely manner, and maintaining documented chain of custody (up to twenty-five (25) points);

(2) Proposed Staffing Plan (Up to forty (40) points):

(A) Measure 1: The applicant fully describes a staffing plan that will provide and ensure that personnel meets the requisite qualifications set forth in the regulations, and has demonstrated knowledge, experience, training, and certification to perform in the designated positions and roles and to conduct the required analytical processes, operations, and testing; ensure quality control and quality assurance, adequate staffing and experience during business hours, and adequate security and theft prevention; and maintain chain of custody, and confidential information. (up to twenty (20) points); and

(B) Measure 2: The applicant shall provide an operations manual that demonstrates compliance with the District's medical marijuana rules. The operations manual shall also fully describe a plan to provide and ensure that a system is in place to evaluate and document personnel's competency in performing authorized tests, and to evaluate and document that personnel demonstrate acceptable performance on precision, accuracy, specificity, reportable ranges, blanks, and unknown challenge samples. (up to twenty (20) points).

(3) Laboratory testing plan (Up to fifty (50) points)

(A) Measure 1: Applicant demonstrates knowledge, experience, training, and applicable certifications in laboratory testing techniques. (up to twenty (20) points);

(B) Measure 2: Applicant demonstrates knowledge of and fully describes plan to provide and ensure quality assurance, quality control, proficiency testing, analytical processes, chain of custody, sample retention, space, recordkeeping,

results reporting, and corrective action protocols (up to twenty (20) points); and

(C) Measure 3: Applicant fully describe the method(s) used to test medical marijuana and medical marijuana products, and report testing results; this includes but is not limited to SOPS (up to ten (10) points);

(4) Security Plan (Up to thirty (30) points): The applicant shall submit a security plan which shall include the following:

(A) Measure 1: The applicant's security plan fully demonstrates the applicant's ability to prevent the theft or diversion of medical marijuana and how the plan will assist with MPD and Department enforcement. Specifically, it shall evidence compliance with all items and include all submittals required in § 5405.2 and § 5610 of this subtitle. (up to ten (10) points);

(B) Measure 2: The applicant demonstrates that its plan for record keeping, tracking and monitoring inventory, and security and other policies and procedures will discourage unlawful activity (up to ten (10) points);

(C) Measure 3: The applicant's security plan shall describe the enclosed, locked facility that will be used to secure or store medical marijuana, including when the location is closed for business, and its security measures, and the steps taken to ensure that medical marijuana is not visible to the public. (up to five (5) points); and

(D) Measure 4: The security plan describes how it intends to prevent the diversion of medical marijuana and includes the applicant's after action plan for any incidents that may trigger enforcement under District of Columbia law or regulations. The plan shall also describe the applicant's plan to coordinate with and dispose of unused or surplus medical marijuana with MPD. (up to five (5) points);

(5) Knowledge of District and federal law relating to marijuana. (Up to ten (10) points:

(A) Measure 1: The applicant shall demonstrate knowledge of the District and federal laws and regulations relating to medical marijuana. The applicant shall also submit a notarized written statement on a form provided by the

Mayor indicating that they have read the Act and this title and have knowledge of District and federal law relating to marijuana. (up to ten (10) points);

(6) Applicant's business plan and services to be offered (Up to twenty (20) points):

(A) Measure 1: The applicant shall provide a business plan that describes how the testing laboratory will operate on a long-term basis. This shall include the applicant providing a detailed description about the amount and source of the equity and debt commitment for the proposed testing laboratory that demonstrates the immediate and long-term financial feasibility of the proposed financing plan, the relative availability of funds for capital and operating needs, and the financial capability to undertake the project. (up to five (5) points);

(B) Measure 2: The applicant or its directors, officers, members, or incorporators demonstrate experience in business management and/or having medical industry or laboratory experience. (up to ten (10) points); and

(C) Measure 3: The business plan demonstrates a start-up timetable which provides an estimated time from registration of the testing laboratory to full operation, and the assumptions used for the basis of those estimates. (up to five (5) points);

(7) Advisory Neighborhood Commission comments (Up to fifty (50) points);

(A) Measure 1: The ANCs' concerns or support regarding the potential adverse impact of the proposed location to the neighborhood. (up to twenty (20) points);

(B) Measure 2: The ANCs' concerns or support regarding an overconcentration or lack of testing laboratories and the number of cultivation centers in the affected ward. (up to ten (10) points); and

(C) Measure 3: The ANCs' concerns or support regarding the proposed location's proximity to substance abuse treatment centers, day care centers, and halfway houses. (up to twenty (20) points);

(8) Environmental Plan (Up to twenty (20) bonus points):

(A) Measure 1: The applicant demonstrates an environmental plan of action to minimize the carbon footprint, environmental impact, and resource needs for the testing of medical marijuana. (up to ten (10) bonus points); and

(B) Measure 2: The applicant describes any plans for: (1) the use of alternative energy; (2) the treatment of waste water and runoff; (3) scrubbing or treatment of exchanged air; and (4) the co-location of testing laboratories. (Up to ten (10) bonus points)

(9) Certified Business Enterprise (up to twenty (20) bonus points)

(A) Measure 1: The applicant provides documentation that they are registered as a certified business enterprise (CBE) by the Department of Small and Local Business development, at the time they submit an application. (Twenty (20) bonus points).

Section 5404, APPLICATION FORMAT AND CONTENTS, is amended to read as follows:

5404 APPLICATION FORMAT AND CONTENTS

5404.1 The business application of a person or entity applying for a cultivation center, dispensary, or testing laboratory registration shall include:

(a) In the case of an individual applicant, the trade name of the business, if applicable, and the name and address of the individual; in the case of a partnership or limited liability company applicant, the trade name of the business, if applicable, and the names and addresses of each member of the partnership or limited liability company; and in the case of a corporate applicant, the legal name, trade name, place of incorporation, principal place of business, and the names and addresses of each of the corporation's principal officers, directors, and shareholders holding, directly or beneficially, one percent (1%) or more of its common stock;

(b) The name and address of the owner of the establishment for which the registration is sought and the premises where it is located;

(c) Whether registration is sought for a cultivation center, dispensary, or testing laboratory;

(d) A certified surveyor's report setting forth the proximity of the cultivation center, dispensary, or testing laboratory to the nearest public or private, preschool, primary or secondary school or recreation center, and the name of the school or recreation center;

(e) The size and design of the cultivation center, dispensary, or testing laboratory;

(f) A detailed description of the nature of the proposed operation, including the following:

(1) The location of all restricted access areas; and

(2) The hours during which the cultivation center, dispensary, or testing laboratory plans to operate;

(g) An affidavit that complies with D.C. Official Code § 47-2863;

(h) Documents or other written statements or evidence establishing to the satisfaction of the Director that the person applying for the registration meets all of the qualifications set forth in § 5400.1 of this subsection;

(i) The applicant shall sign a written statement on a form provided by the Director attesting that the applicant assumes any and all risk or liability that may result under District of Columbia and federal laws from the operation of a medical marijuana cultivation center, dispensary, or testing laboratory. The applicant shall further acknowledge that it understands that the medical marijuana laws and enforcement thereof by the District of Columbia and the Federal government are subject to change at any time and that the District of Columbia shall not be liable as a result of these changes;

(j) A notarized affidavit attesting to the fact that the applicant is the true and actual owner of the business for which the registration is sought; the applicant intends to carry on the business for the entity identified in the application and not as the agent of any other individual, partnership, association, or corporation not identified in the application; and the registered establishment will be managed by the applicant in person or by a registered manager approved by the Director;

(k) The applicant shall sign a written statement on a form provided by the Director attesting that the applicant understands and is aware that a cultivation center's, dispensary's, or testing laboratory's registration may be revoked at any time for the convenience of the District pursuant to § 6002 of this subtitle; and

(l) The applicant shall submit a written and detailed plan for closure of its cultivation center, dispensary, or testing laboratory.

5404.2 The applicant shall sign a notarized statement certifying that the application is complete and accurate. Any person who knowingly makes a false statement on an application, or in any accompanying statement under oath that the Department may require, shall be guilty of the offense of making false statements. The making of a false statement, whether made with or without the knowledge or consent of the applicant, shall, in the discretion of the Director, constitute sufficient cause for denial of the application or revocation of the registration. The making of false statements shall also constitute the basis for a criminal offense under D.C. Official Code § 22-2405.

5404.3 An applicant for a dispensary, cultivation center, or testing laboratory registration shall advise the Department, in the application, as to the source of the funds used to acquire or develop the business for which the registration is sought, and shall provide documentation concerning the source of such funds and copies of closing documents in connection with the purchase of a registered business upon request of the Department.

5404.4 Repealed.

5404.5 An applicant for a cultivation center, dispensary, or testing laboratory registration shall also file with the Department plans and specifications for the interior of the building if the building to be occupied is in existence at the time of the application. If the building is not in existence, the applicant shall file a plot plan and a detailed sketch for the interior and the architect's drawing of the building to be constructed.

5404.6 The application for an operator of a cultivation center, dispensary, or testing laboratory registration shall specifically recite verbatim each of the following notices:

(a) **Limitation of Liability** – The District of Columbia shall not be liable to registrant, its employees, agents, business invitees, licensees, customers, clients, family members or guests for any damage, injury, accident, loss, compensation or claim, based on, arising out of or resulting from registrant's participation in the District of Columbia's medical marijuana program, including but not limited to the following: arrest and seizure of persons and/or property, prosecution pursuant to federal laws by federal prosecutors, interruption in registrant's ability to operate its medical marijuana cultivation center, dispensary and/or testing laboratory; any fire, robbery, theft, mysterious disappearance or any other casualty; the actions of any other registrants or persons within the cultivation center, dispensary, or testing laboratory. This Limitation of Liability provision

shall survive expiration or the earlier termination of this registration if such registration is granted;

(b) **Indemnification, Hold Harmless and Defense Obligations** – Registrant hereby indemnifies and holds the District of Columbia, its officers, directors, employees, affiliates and agents ("Indemnified Parties") harmless and shall defend the Indemnified Parties (with counsel satisfactory to District of Columbia) from and against any and all losses, costs, damages, liabilities, expenses, claims and judgments (including, without limitation, attorney's fees and court costs) suffered by or claimed against the Indemnified Parties, directly or indirectly, based on, arising out of or resulting from:

(1) Registrant's establishment and operation of a cultivation center, dispensary, or testing laboratory in the District's medical marijuana program;

(2) The negligence or willful misconduct of registrant or its employees, contractors, agents, licensees, guests or invitees;

(3) Any breach or default by registrant in the performance or observance of its covenants or obligations under this registration; or

(4) Any violations of law by of registrant or its employees, contractors, agents, licensees, guests or invitees; and

(c) **Federal Prosecution** - The United States Congress has determined that marijuana is a controlled substance and has placed marijuana in Schedule I of the Controlled Substance Act. Growing, distributing, and possessing marijuana in any capacity, other than as a part of a federally authorized research program, is a violation of federal laws. The District of Columbia's law authorizing the District's medical marijuana program will not excuse any registrant from any violation of the federal laws governing marijuana or authorize any registrant to violate federal laws.

5404.7 As part of the registration process, every applicant for a cultivation center, dispensary, or testing laboratory registration shall sign a written statement attesting to the following:

(a) The applicant acknowledges receipt and advisement of the notices set forth in § 5404.6 of this subtitle;

(b) The applicant agrees to and accepts the limitation of liability against the District, and the requirement to indemnify, hold harmless, and defend the District, as set forth in § 5404.6 of this subtitle;

(c) The applicant assumes any and all risk or liability that may result under District of Columbia or federal laws arising from the possession, use, cultivation, administration, dispensing, or testing of medical marijuana;

(d) The applicant understands that the medical marijuana laws and enforcement thereof by the District of Columbia and the Federal government are subject to change at any time; and

(e) The applicant chooses to sign this attestation willingly and without reservation and is fully aware of its meaning and effect.

5404.8 Execution of the attestation set forth in § 5404.7 of this subtitle shall be a required element of each application for a cultivation center, dispensary, or testing laboratory registration.

5404.9 The Director shall not permit any applicant for a cultivation center, dispensary, or testing laboratory to make any additions, changes, alterations, amendments, modifications, corrections, or deletions to the application package once it has been submitted to the Department; however, an applicant may be permitted to modify the location of the premises identified on the application pursuant to § 6001.9 of this subtitle.

Section 5407, CULTIVATION CENTER AND DISPENSARY REGISTRATION ISSUANCE, is amended to read as follows:

5407 CULTIVATION CENTER, DISPENSARY, AND TESTING LABORATORY REGISTRATION ISSUANCE

5407.1 A registration for a cultivation center, dispensary, or testing laboratory shall not be issued by the Department until all approvals or assessments required under this subtitle have been obtained from MPD or its designee, DCRA, and the Department.

Section 5408, DIRECTOR, OFFICER, MEMBER, INCORPORATOR, AND AGENT REGISTRATION REQUIREMENTS, is amended by amending § 5408.2 to read as follows:

5408.2 An applicant for a non-profit or for-profit corporation, partnership, or limited liability company shall identify all of its directors, officers, members, or incorporators on its registration application. An applicant for a dispensary, cultivation center, or testing laboratory may submit simultaneously registration applications for individual directors, officers, members, incorporators and agents at the time its dispensary, cultivation center, or testing laboratory registration application is filed.

Section 5411, CRIMINAL BACKGROUND CHECKS, is amended by amending § 5411.2 to read as follows:

5411.2 No director, officer, member, incorporator, agent, manager, or employee of a dispensary, cultivation center, or testing laboratory who has access to the medical marijuana at the dispensary, cultivation center, or testing laboratory shall have a felony conviction. However, an individual shall not be disqualified solely for a felony conviction of possession with intent to distribute marijuana that occurred before July 17, 2014.

Section 5412, REGISTRATION PROHIBITED IN RESIDENTIAL USE DISTRICT, is amended by amending § 5412.1 to read as follows:

5412.1 No registration shall be issued to a cultivation center, dispensary, or testing laboratory located in a residential-use district as defined in the Zoning Regulations and shown in the official atlases of the Zoning Commission for the District.

Section 5414, RENEWAL PROCESS, is amended by amending § 5414.1 to read as follows:

5414.1 The Director shall provide all ANCs in the affected ward with a thirty (30) day comment period prior to renewing a cultivation center, dispensary, or testing laboratory application for a third time. If proper notice has been given to all ANCs in the affected ward, and no objection to the renewal is filed, the Director shall approve the registration application unless the Director finds the applicant's record of compliance warrants denying the renewal application or there is another legal basis for denial.

Section 5417, DENIED OR WITHDRAWN APPLICATIONS, is repealed.

Section 5418, LIMITATIONS ON SUCCESSIVE APPLICATIONS AFTER DENIAL, is amended by amending § 5418.1 to read as follows:

5418.1 A second and each subsequent registration application for a cultivation center, dispensary, or testing laboratory that has had its registration revoked by the Director shall not be considered for the same person or persons within five (5) years of the Director's revocation.

Chapter 55, REGISTRATION CHANGES, of Subtitle C, MEDICAL MARIJUANA, of Title 22, HEALTH, of the DCMR is amended as follows:

Section 5500, TRADE NAMES AND CORPORATE NAMES, is amended to read as follows:

5500 TRADE NAMES AND CORPORATE NAMES

5500.1 No dispensary, cultivation center, or testing laboratory registered under the Act shall utilize any name other than that of an individual, including a corporate or trade name, without first obtaining approval from the Department for use of the corporate or trade name.

5500.2 A dispensary, cultivation center, or testing laboratory registered under the Act may file a written request with the Department to add an additional trade name at a location currently authorized for the sale or testing of medical marijuana. The Department, in its discretion, may approve the use of an additional trade name. Any additional trade name approved by the Department shall appear on the establishment's written registration.

5500.3 A dispensary, cultivation center, or testing laboratory registered under the Act shall not use or display a trade name, corporate name, or sign bearing the words "pharmacy", "apothecary", "drug store", or other phrase that implies that the practice of any health profession occurs on the premises.

5500.4 Any trade name requested by an applicant shall not be identical or confusingly similar to one currently used under a previously issued or existing registration.

5500.5 The Mayor shall provide written notice to MPD of any Department approved trade name changes. Such notice shall contain both the previous and current Department approved trade name.

5500.6 Repealed.

Chapter 56, GENERAL OPERATING REQUIREMENTS, of Subtitle C, MEDICAL MARIJUANA, of Title 22, HEALTH, of the DCMR is amended as follows:

Section 5600, INSTRUCTION TO REGISTRANTS, is amended by amending § 5600.1 to read as follows:

5600.1 The Department shall develop and furnish to registrants, at the time of issuance of registration, written information describing the laws and regulations applicable to the dispensary, cultivation center, or testing laboratory's day-to-day operations.

Section 5602, HOURS OF OPERATION AND SALE, is amended by amending §§ 5602.2 and 5602.3 to read as follows:

5602.2 A registered cultivation center or testing laboratory shall not be open to the public.

5602.3 In the event that a registered cultivation center and registered dispensary are located in the same building, the portion of the building occupied by the cultivation center shall be closed to the public.

New §§ 5602.4 through 5602.9 are added to read as follows:

5602.4 A cultivation center may operate its business twenty-four (24) hours a day.

5602.5 A testing laboratory may operate on any day and at any time except between the hours of 9:00 p.m. and 5:00 a.m.

5602.6 A registered cultivation center or its contracted agent may deliver to medical marijuana dispensaries on any day and at any time except between the hours of 9:00 p.m. and 7:00 a.m.

5602.7 A registered testing laboratory or its contracted agent may collect medical marijuana samples from a cultivation center on any day and at any time except between the hours of 9:00 p.m. and 5:00 a.m.

5602.8 A registered cultivation center or testing laboratory shall permit only a registered director, officer, member, incorporator, agent, manager, employee, or government or law enforcement official on the registered premises.

5602.9 The Department may further limit the hours of operation for a cultivation center, dispensary, or testing laboratory on a case-by-case basis as a condition of registration in response to written comments received from an ANC in the affected ward, or as the result of the dispensary, cultivation center, or testing laboratory's failure to comply with the Act, or this subtitle.

Section 5603, LOCKING AND SECURING OF MEDICAL MARIJUANA DURING NON-OPERATING HOURS, is amended by amending §§ 5603.1 and 5603.2 to read as follows:

5603.1 A registered dispensary, cultivation center, or testing laboratory shall keep all medical marijuana located on the premises in a separate storage area which is securely closed and locked during all hours when the establishment is prohibited from operating or is closed. The storage area shall have a volumetric intrusion detection device(s) installed and connected to the facility intrusion detection system.

5603.2 A cultivation center, dispensary, or testing laboratory shall be required to install and use a safe for overnight storage of any processed marijuana, transaction records, and cash on the registered premises. The safe shall be a UL listed burglar-proof safe with a minimum rating of TL-30. Safes weighing less than seven hundred fifty pounds (750 lb.) shall be installed in a steel clad concrete block or otherwise securely anchored to a fixed part of the facility structure.

Section 5605, DESTRUCTION AND DISPOSAL OF UNUSED OR SURPLUS MEDICAL MARIJUANA AND REPORTING THEFT, is amended to read as follows:

5605 DESTRUCTION AND DISPOSAL OF UNUSED OR SURPLUS MEDICAL MARIJUANA AND REPORTING THEFT

5605.1 A cultivation center, dispensary, or testing laboratory shall destroy or dispose of unused or surplus medical marijuana and its by-products by providing it to MPD for destruction.

5605.2 All unused or surplus medical marijuana and its by-products shall be weighed and documented and submitted to MPD on a form provided by MPD prior to being delivered to MPD by the cultivation center, dispensary, or testing laboratory for destruction.

5605.3 A cultivation center or dispensary that has had its registration renewal denied, or revoked, or is going out of business may obtain approval from the Department by submitting a written request to sell and transport medical marijuana to another cultivation center or dispensary. The Department shall notify MPD of such approval prior to any medical marijuana being transported to another cultivation center or dispensary.

5605.4 A cultivation center, dispensary, or testing laboratory shall report any stolen or lost medical marijuana by filing a police report, by calling 911, or in person with the Police District where the registered business resides either in person or in writing within twenty-four (24) hours of becoming aware of the theft or loss.

5605.5 For purposes of this section, "unused or surplus medical marijuana" shall be defined as any harvested or unharvested marijuana, both processed and unprocessed, which is possessed by a cultivation center, dispensary, or testing laboratory and includes:

(a) Any marijuana plants possessed by a cultivation center in excess of the authorized plant limitation;

(b) Any marijuana that has spoiled or is unusable for medical purposes;

(c) Any marijuana possessed by a dispensary in excess of the amount needed to supply all of the dispensary's qualified patients for a one (1) month period;

(d) Any marijuana that has or appears to have been tampered with; and

(e) Any marijuana that has completed testing at a testing laboratory, or unused sample materials.

5605.6 The Department, in its discretion, may allow a dispensary to possess a surplus of medical marijuana for a period of time, if it is shown that the surplus is needed to adequately serve the patient population.

Section 5606, NOTICE OF CRIMINAL CONVICTION OF DIRECTOR, OFFICER, MEMBER, INCORPORATOR, AGENT OR EMPLOYEE, is amended by amending § 5606.1 to read as follows:

5606.1 A registered dispensary, cultivation center, or testing laboratory shall immediately notify the Department in writing if the registration holder discovers that any director, officer, member, incorporator, agent, or employee has at any time prior to or during his or her employment been convicted of a felony. For purposes of this section, "immediately" shall mean notifying the Department within seven (7) days of discovering the criminal conviction.

Section 5610, ELECTRONIC RECORDING SECURITY AND ALARM SYSTEM, is amended to read as follows:

5610 ELECTRONIC RECORDING SECURITY AND ALARM SYSTEM

5610.1 A dispensary, cultivation center, or testing laboratory shall be required to operate and maintain in good working order a twenty-four (24) hour, seven (7) days a week, a closed circuit television (CCTV) surveillance system on the premises that complies with the following minimum standards:

(a) Visually records and monitors all building entrances and exits, all parking lot areas, rear alley areas immediately adjacent to the building, and covers the entire inside of the facility, including all limited access areas, and including all areas where medical marijuana is cultivated, stored, dispensed, tested, or destroyed. Fixed cameras shall be installed to provide a consistent recorded image of these areas. The cultivation center, dispensary, or testing laboratory shall instruct the company or individuals installing the surveillance cameras to maximize the quality of facial and body images and to avoid backlighting and physical obstructions;

(b) Cameras installed outdoors and in low-light interior areas shall be day/night cameras with a minimum resolution of six hundred (600) lines per inch (analog) or D1 (IP) and a minimum light factor requirement of seven tenths (0.7) LUX. The installation of additional lighting may be required to increase picture clarity and brightness. Cameras shall be calibrated and focused to maximize the quality of the recorded image;

(c) The recording device shall be a digital video recorder that meets the following minimum standards:

(1) Displays a date and time stamp on all recorded video; and

(2) Can produce a video disc (CD/DVD) directly from the DVR unit using an installed media recording drive. The video on the disc

shall be viewable on any Windows PC, and include any required player software on the disc;

(d) A display monitor with a minimum screen size of twelve inches (12 in.) shall be connected to the electronic recording security system at all times;

(e) Electronic recording security systems are required to be maintained in good working order at all times. The owner of a cultivation center, dispensary, or testing laboratory shall instruct each manager, employee, or agent overseeing the functioning of the video recording security system to immediately report any malfunctioning or technical problems with the system;

(f) Security recordings shall meet the following minimum requirements:

(1) The recorded image resolution shall be at least D1; and

(2) The recorded image frame rate shall be at least three (3) frames per second during alarm or motion based recording.

(g) Security recordings shall be retained by the cultivation center, dispensary, or testing laboratory for a minimum of thirty (30) days. The recording system for the security cameras must be located in a locked, tamper-proof compartment. A cultivation center, dispensary, or testing laboratory shall be prohibited from taping over existing security video from the last thirty (30) days; and

(h) Upon request, the recording shall be turned over to MPD or the Department.

5610.2 A dispensary, cultivation center, or testing laboratory shall install, maintain, and use a professionally monitored robbery and burglary alarm system; which meets the following requirements:

(a) The control panel shall be a UL listed burglar alarm control panel;

(b) The system shall report to a UL listed central monitoring station;

(c) A test signal shall be transmitted to the central station every twenty-four (24) hours;

(d) At a minimum, the system shall provide coverage of all facility entrances and exits, rooms with exterior windows, rooms with exterior walls or walls shared with other facility tenants, roof hatches, skylights, and storage room(s) that contain safe(s);

(e) The system shall include at least one (1) holdup alarm for staff use; and

(f) The system shall be inspected, and all devices tested annually by a qualified alarm vendor.

5610.3 A dispensary, cultivation center, or testing laboratory shall maintain for a period of three (3) years reports of incidents that triggered an alarm. Such reports shall be made available to the Department during any inspection of the facility. A dispensary, cultivation center, or testing laboratory shall notify the Department by electronic means within twenty-four (24) hours of any incident in which a theft, burglary, robbery, or break in occurred, whether or not items were actually removed from the facility. The facility manager shall follow up the initial notice with a written report describing in detail the factual circumstances surrounding the incident and include an inventory of all stolen items, if applicable.

Section 5613, TEMPORARY SURRENDER OF REGISTRATION— SAFEKEEPING, is amended by amending §§ 5613.1, 5613.3, and 5613.4 to read as follows:

5613.1 A registered cultivation center, dispensary, or testing laboratory that discontinues its operations for any reason shall surrender its registration to the Department for safekeeping within three (3) calendar days of discontinuing its operations. The Department shall hold the registration for one hundred twenty (120) days or until the establishment resumes business whichever occurs first. If the registrant has not initiated proceedings to resume operations within one hundred twenty (120) days, the Department shall deem the registration abandoned and cancel the registration.

5613.3 This section shall not relieve a registered cultivation center, dispensary, or testing laboratory from the responsibility for renewing the registration upon its expiration.

5613.4 If a cultivation center, dispensary, or testing laboratory notifies the Department that the establishment has ceased to do business under the registration or if the Department cancels the registration under this section, the registration shall be marked as "cancelled."

Section 5614, CO-LOCATION AND INTEGRATION, is amended to add new §§ 5614.3 and 5614.4 to read as follows:

5614.3 Nothing in this title shall preclude two (2) or more testing laboratories from locating in the same building, provided that they maintain:

(a) Separate books, equipment, staff, and records; and

(b) Their own secure and distinct registered premises that is separated, at minimum, by a fixed boundary.

5614.4 A testing laboratory shall not be located in the same building as a cultivation center or dispensary.

Section 5615, POINT-OF-SALE SYSTEM, is amended to read as follows:

5615 SEED-TO-SALE TRACKING SYSTEM

5615.1 The Department may require a dispensary, cultivation center, and testing laboratory to purchase and participate in a seed-to-sale tracking system as determined by the Department for purposes of:

(a) Tracking, in real-time, all medical marijuana plants and products from cloning or seed through cultivation, testing, transportation, and sale or destruction;

(b) Tracking and verifying all purchases and sales; and

(c) Tracking and verifying all District of Columbia and non-resident patient purchases to confirm and ensure the identity of the patients, the validity of the patient's authorization to purchase, and ensuring that the patients do not purchase more than four ounces within a thirty day period.

Section 5617, OUTDOOR LIGHTING REQUIREMENTS, is amended by amending § 5617.1 to read as follows:

5617.1 A cultivation center, dispensary, or testing laboratory shall be required for security purposes to have sufficient lighting outside of the registered business each day between sunset and sunrise that adequately illuminates the cultivation center, dispensary, or testing laboratory and its immediate surrounding area, including storage areas, parking lots, entry areas such as the front façade, and any adjoining public sidewalk.

Section 5618, MINIMUM STAFFING LEVELS, is amended by adding a new § 5618.3 to read as follows:

5618.3 A testing laboratory shall be staffed with at least two (2) persons when employees are present inside of the testing laboratory.

Section 5619, LIMITED ACCESS AREAS, is amended by amending §§ 5619.1 through 5619.3 to read as follows:

5619.1 Medical marijuana shall only be grown, cultivated, stored, weighed, displayed, packaged, sold, possessed for sale, or tested only in a limited access area under

the control of the cultivation center, dispensary, or testing laboratory. A cultivation center, dispensary, or testing laboratory shall permit only those persons registered with the Department to enter the limited access area.

5619.2 A limited access area, including all areas of ingress and egress, shall be designated by the cultivation center, dispensary, or testing laboratory on its application. The limited access area shall be either a building, room, or other contiguous area upon the registered premises.

5619.3 A cultivation center, dispensary, or testing laboratory shall post a sign provided by the Department at all areas of ingress and egress identifying the limited access area.

Section 5621, TRANSPORT OF MEDICAL MARIJUANA, is amended to read as follows:

5621 TRANSPORT OF MEDICAL MARIJUANA

5621.1 A cultivation center shall obtain from the Department a transport permit to transport medical marijuana within the District of Columbia to registered dispensaries. An original transport permit shall be required for each vehicle being designated by the cultivation center or its contracted agent to be authorized to deliver medical marijuana to registered dispensaries.

5621.2 A testing laboratory shall obtain from the Department a transport permit to transport medical marijuana within the District of Columbia from a cultivation center to the testing laboratory. An original transport permit shall be required for each vehicle being designated by the testing laboratory or its contracted agent to be authorized to transport medical marijuana from a cultivation center to a testing laboratory.

5621.3 A cultivation center, testing laboratory, or its contracted agent shall not transport medical marijuana within the District of Columbia without an original transport permit. A cultivation center or testing laboratory shall permit only an employee, director, officer, member, incorporator, or agent registered with the Department or its contracted agent to transport medical marijuana to a registered dispensary.

5621.4 Upon demand by an MPD officer or Department investigator, the registered person in charge of the transportation for the cultivation center or testing laboratory, or its contracted agent shall exhibit to the MPD officer or Department investigator an original transport permit.

Chapter 57, PROHIBITED AND RESTRICTED ACTIVITIES, of Subtitle C, MEDICAL MARIJUANA, of Title 22, HEALTH, of the DCMR is amended as follows:

Section 5704, PLANT LIMITATIONS, is amended by amending § 5704.1 to read as follows:

5704.1 A cultivation center shall be permitted to possess and cultivate up to one thousand (1,000) living marijuana plants at any one (1) time for the sole purpose of producing medical marijuana in a form permitted under this subtitle. A dispensary shall not be permitted to possess or sell marijuana plants. It shall be a violation of this subtitle for a dispensary to possess or sell marijuana plants or for a cultivation center to sell marijuana plants to a dispensary.

Chapter 59, RECORDS AND REPORTS, of Subtitle C, MEDICAL MARIJUANA, of Title 22, HEALTH, of the DCMR is amended as follows:

Section 5900, CULTIVATION CENTER BOOKS AND RECORDS, is amended by amending paragraphs 5900.1(e) and (f), and adding a new paragraph 5900.1(g) to read as follows:

5900.1 Each registered cultivation center shall keep and maintain upon the registered premises true, complete, legible, and current books and records, including the following:

(e) The quantity and form of medical marijuana maintained at the cultivation center on a daily basis;

(f) The amount of plants being grown at the cultivation center on a daily basis; and

(g) The results of the testing laboratory analysis for five (5) years from the date of the test.

A new chapter 64, TESTING LABORATORIES, of Subtitle C, MEDICAL MARIJUANA, of Title 22, HEALTH, of the DCMR is added to read as follows:

CHAPTER 64 TESTING LABORATORIES

6400 APPLICABILITY

6400.1 The provisions of this chapter shall apply to an individual or entity that is registered by the Department, or applying for a registration, to test medical marijuana and medical marijuana products.

6400.2 The provisions of this chapter do not apply to the in-house testing by a cultivation center of its own cultivated crop or products. However, a cultivation center shall not sell any of its cultivated crop or products until the crop or products have been tested and certified by an independent testing laboratory registered by the Department to test medical marijuana and medical marijuana products.

6401 GENERAL PROVISIONS

6401.1 A testing laboratory shall not be owned or operated, in whole or in part, by a director, officer, member, incorporator, agent, or employee of a cultivation center or dispensary.

6401.2 No owner, member, manager, employee, or agent of a testing laboratory shall have an ownership interest in, or a direct or indirect financial interest in, a dispensary or cultivation center.

6401.3 A testing laboratory registration shall be valid for one (1) year, and may be renewed as set forth in § 5101.1 of this subtitle.

6401.4 A testing laboratory shall not handle, test, or analyze medical marijuana in the District of Columbia unless the laboratory has been issued a medical marijuana registration by the Department.

6401.5 Medical marijuana products shall be sold only after a representative sample has been tested by a registered testing laboratory and the test results have been uploaded to the District of Columbia's electronic tracking system, which verify the medical marijuana sample has received passing results.

6401.6 No testing laboratory shall operate without a registration issued by the Department.

6401.7 A testing laboratory shall not cultivate, process, manufacture, distribute, provide, or sell medical marijuana in any form.

6401.8 A testing laboratory shall not permit the consumption of medical marijuana in any form on the premises.

6401.9 A testing laboratory shall not share a facility with a cultivation center or dispensary.

6401.10 A testing laboratory shall not falsify, change, modify, or otherwise alter in any way the results of quantitative or other analyses performed on medical marijuana samples or the corresponding certificates of analysis.

6401.11 A testing laboratory shall not employ any sampling methods that do not ensure that a random sample is collected for analysis, or that could provide results that are not representative of a batch or lot from which a sample is taken.

6401.12 A testing laboratory shall not prepare medical marijuana samples in such a manner as to provide results that are not representative of a batch or lot from which a sample is taken.

6401.13 A testing laboratory shall not store medical marijuana in quantities greater than

that which is necessary to perform required analysis.

6401.14 A testing laboratory shall not transport medical marijuana in quantities greater than that which is necessary to perform required analysis.

6401.15 A testing laboratory shall not perform analysis on any medical marijuana that has not been obtained from a cultivation center or dispensary registered by the Department.

6401.16 A testing laboratory shall not perform analysis on any medical marijuana that has not been identified in the inventory tracking system.

6401.17 A testing laboratory shall not endorse, advertise, or make claims on behalf of any cultivation center, dispensary, brand or strain of medical marijuana, or brand or type of medical marijuana product.

6401.18 A testing laboratory shall not publish or otherwise release to the public the results of any tests performed pursuant to this subtitle, except aggregated data obtained as part of a research plan that has been approved by the Department.

6401.19 A testing laboratory shall comply with all applicable public health, fire, safety laws and regulations.

6402 **TESTING LABORATORY REGISTRATION APPLICATION REQUIREMENTS AND SELECTION PROCESS**

6402.1 An applicant for a testing laboratory registration shall meet the general qualifications set forth in § 5400 of this subtitle.

6402.2 An applicant for a testing laboratory registration shall be independent from all other persons and entities involved in the medical marijuana industry in the District of Columbia, including but not limited to:

(a) A medical marijuana dispensary;

(b) A medical marijuana cultivation center;

(c) A provider of health care who currently provides or has provided medical marijuana recommendations within the most recent five (5) years; or

(d) Any other person or entity that may benefit from the cultivation, manufacture, dispensing, sale, purchase, or use of medical marijuana.

6402.3 Applications for a new testing laboratory registration shall only be accepted by the Director during the open application period as specified by the Director by publishing a Notice in the *D.C. Register*; such period shall not be extended.

6402.4 Prior to the submission of a formal application for a new testing laboratory registration, the prospective applicant shall submit a Letter of Intent to the Director or a designee, following the process set forth in § 5401 of this subtitle. The Director shall only accept Letters of Intent during the time period specified by the Director by Notice in the *D.C. Register*, such period shall not be extended.

6402.5 Applications for a new testing laboratory registration shall be selected pursuant to the selection process and selection criteria set forth in Chapter 54 of this subtitle.

6402.6 In addition to the requirements in § 5404 of this subtitle, an application for a testing laboratory shall also contain the following:

(a) A proposed staffing plan;

(b) A proposed security plan containing the criteria set forth in § 6402.7;

(c) A written statement regarding the suitability of the proposed facility;

(d) A laboratory testing plan that demonstrates the applicant's knowledge, experience, training, and applicable certifications in laboratory testing techniques, and ability to provide and ensure quality assurance, quality control, proficiency testing, analytical processes, chain of custody, sample retention, space, recordkeeping, results reporting, and corrective action protocols;

(e) A proposed plan and timeline for obtaining accreditation;

(f) A notarized written statement from the applicant that he or she has read the Act and this subtitle and has knowledge of the District and federal laws and regulations relating to medical marijuana.

6402.7 An applicant for a testing laboratory registration shall file a written security plan with the Department. The written security plan shall address, at a minimum, the following elements:

(a) Evidence that the space will comply with all security system requirements set forth in § 5610 of this subtitle;

(b) A site plan showing the entire structure the testing laboratory, including the street(s), parking lot(s), other tenants within the facility, and any other entities that physically border the testing laboratory;

(c) A floor plan of the testing laboratory detailing the location of the following:

(1) All entrances and exits to the testing laboratory;

(2) The location of any windows, skylights, and roof hatches;

(3) The location of all cameras, and their field of view;

(4) The location of all alarm inputs (door contacts, motion detectors, duress/hold up devices) and alarm sirens;

(5) The location of the digital video recorder and alarm control panel; and

(6) Restricted and public areas;

(d) The type of security training provided for, and completed by, establishment personnel, including:

(1) Conflict resolution training and other security training to be provided by staff; and

(2) Procedures for handling violent incidents, other emergencies, and calling the Metropolitan Police Department;

(e) How the applicant intends to use and maintain an incident log;

(f) The number and location of cameras used by the establishment;

(g) Security measures taken by the applicant to prevent individuals from entering the limited access area portion of the registered premises;

(h) The applicant's closing procedures after the cessation of business each day;

(i) The applicant's plan to prevent theft or the diversion of medical marijuana, including maintaining all medical marijuana in a secure, locked room that is accessible only to authorized persons;

(j) The type of alarm system and outdoor lighting to be used by the applicant; and

(k) The applicant's procedures for obtaining, transporting, posting test results, and disposing of medical marijuana samples.

6402.8 Upon receipt of a written security plan for an initial testing laboratory application, the Director shall forward the security plan electronically to MPD or its designee

for an assessment. MPD or its designee shall complete its assessment of the security plan within twenty-one (21) days of receipt from the Director. The Department shall not issue a testing laboratory registration until MPD or its designee completes its security plan assessment and submits that assessment in writing to the Department.

6402.9 After completion of the MPD or the designee assessment, the entire application package shall be submitted to the panel.

6402.10 For purposes of this subsection, the Chief of Police may select a designee from outside of the MPD.

6404 ACCREDITATION, CERTIFICATION AND INSPECTION

6404.1 A testing laboratory registrant shall be accredited pursuant to standard ISO/IEC 17025 of the International Organization for Standardization by a nonprofit, impartial organization that operates in conformance with standard ISO/IEC 17011 of the International Organization for Standardization and is a signatory to the Mutual Recognition Arrangement of the International Laboratory Accreditation Cooperation.

6404.2 A testing laboratory registrant shall obtain the accreditation required by § 6404.1 of this subtitle within six (6) months after being issued a registration by the Department.

6404.3 The Department may suspend or revoke the registration of a testing laboratory that fails to obtain the accreditation required by § 6404.1 of this subtitle within six (6) months after being issued a registration by the Department.

6404.4 A registered testing laboratory shall remain in good standing with a Department approved proficiency testing program.

6404.5 The Department shall conduct unannounced compliance inspections of registered testing laboratories on at least an annual basis.

6404.6 The Department shall conduct investigations within seventy-two (72) hours of receiving a complaint against a registered testing laboratory.

6405 RECORDS RETENTION

6405.1 A testing laboratory shall create, and maintain for not less than five (5) years, and make them immediately available to the Department upon request, records of the testing it conducted on medical marijuana and medical marijuana products, which shall include:

(a) The time, date, and location the sample was obtained;

(b) A description of the sample, including the amount;

(c) What tests were conducted on each sample;

(d) The results of the tests; and

(e) The time, date, and method of disposal or destruction of the sample after testing was completed, and the amount of sample disposed of or destroyed.

6405.2 A testing laboratory shall maintain the following records for not less than five (5) years, and make the records immediately available to the Department upon request:

(a) Test results;

(b) Quality control and quality assurance records;

(c) Standard operating procedures;

(d) Chain-of-custody records;

(e) Proficiency testing records;

(f) Analytical data to include printouts generated by the instrumentations;

(g) Accession numbers;

(h) Specimen type;

(i) Raw data of calibration standards and curves, controls and subject results;

(j) Final and amended reports;

(k) Acceptable reference range parameters;

(l) The identity of the analyst; and

(m) The date of the analysis.

6406 LABORATORY PERSONNEL QUALIFICATIONS AND DUTIES

6406.1 All testing laboratory personnel shall be registered with the Department.

6406.2 All testing laboratory personnel shall:

(a) Pass a criminal background check pursuant to § 5411 of this subtitle; and

(b) Sign an attestation stating that they do not have any conflicts of interest with any other registered medical marijuana facility or personnel.

6406.3 A testing laboratory shall be staffed with at least the following personnel who shall meet the following requirements and perform the following duties:

(a) Laboratory Director:

(1) Shall have earned a Doctor of Medicine degree (M.D.), Doctor of Osteopathic Medicine degree (D.O.), or doctorate degree in chemical, physical, biological or clinical laboratory sciences from a college or university that at the time of the awarding of the degree was accredited by an accrediting body recognized by the United States Department of Education, and have at least two (2) years of post-degree laboratory experience;

(2) Shall be responsible for the overall operation of the testing laboratory, including but not limited to:

(A) Ensuring that the testing laboratory achieves and maintains quality standards;

(B) Analytical operation;

(C) Quality of the results;

(D) Supervising all laboratory personnel;

(E) Recordkeeping;

(F) Reporting results and data; and

(G) Ensuring compliance with all regulatory requirements; and

(3) May also serve in any other personnel role;

(b) Technical Supervisor:

(1) Shall have earned at least:

(A) A master's degree in medical technology, clinical laboratory science, or chemical, physical or biological science from a college or university that at the time of the awarding of the degree was accredited by an accrediting

body recognized by the United States Department of Education, and have at least two (2) years of post-degree training and experience in high-complexity testing; or

(B) A bachelor's degree in medical technology, clinical laboratory science, or chemical, physical or biological science from a college or university that at the time of the awarding of the degree was accredited by an accrediting body recognized by the United States Department of Education, and have at least four (4) years of post-degree training and experience in high-complexity testing;

(2) Shall be responsible for, including but not limited to:

(A) Supervising laboratory personnel (with the exception of The Laboratory Director);

(B) Ensuring appropriate testing methods are performed;

(C) Ensuring equipment is operational, clean, and certified;

(D) Verifying and ensuring the accuracy of test results; and

(E) Training and competency assessments of laboratory personnel; and

(3) May also serve in the roles of Quality Assurance Manager, Testing Personnel and Collection Specialist;

(c) Quality Assurance Manager:

(1) Shall have earned at least:

(A) A master's degree or bachelor's degree in clinical laboratory science, medical technology, or chemical, physical or biological science from a college or university that at the time of the awarding of the degree was accredited by an accrediting body recognized by the United States Department of Education, and have at least one (1) year of post-degree training and experience in high-complexity testing; or

(B) An associate's degree in medical laboratory technology from a college or university that at the time of the awarding of the degree was accredited by an accrediting body recognized by the United States Department of Education,

and have at least two (2) years of post-degree training and experience in high-complexity testing;

(2) Shall be responsible for, but not limited to:

(A) Implementing standard operating procedures (SOPs) for the testing laboratory;

(B) Ensuring that SOPs are followed; and

(C) Conducting quality assurance assessments;

(3) May also serve in the roles of Testing Personnel and Collection Specialist, if he or she meets the qualifications;

(d) Testing Personnel:

(1) Shall have earned at least a master's degree or bachelor's degree in clinical laboratory science, medical technology, or chemical, physical or biological science from a college or university that at the time of the awarding of the degree was accredited by an accrediting body recognized by the United States Department of Education;

(2) Shall be responsible for testing medical marijuana samples as set forth in § 6409 of this subtitle, and providing accurate results; and

(3) May also serve in the role of the Collection Specialist.

(e) Collection Specialist:

(1) Shall have earned at least:

(A) A master's degree or bachelor's degree in clinical laboratory science, medical technology, or chemical, physical or biological science from a college or university that at the time of the awarding of the degree was accredited by an accrediting body recognized by the United States Department of Education; or

(B) An associate's degree in medical laboratory technology from a college or university that at the time of the awarding of the degree was accredited by an accrediting body recognized by the United States Department of Education;

(2) Shall be responsible for:

(A) The selection and collection of representative samples from cultivation centers;

(B) Maintaining chain of custody; and

(C) Ensuring aseptic sampling techniques are used; and

(3) Shall not serve in any other personnel role unless he or she meets the educational and training requirements for that role as set forth in this subtitle.

6407 STANDARD OPERATING PROCEDURE REQUIREMENTS

6407.1 A testing laboratory shall have a written manual of standard operating procedures, with detailed instructions for performing each testing method the testing laboratory uses and the minimum standards for each test. The written manual of standard operating procedures must be available to each employee at the testing laboratory at all times.

6407.2 A testing laboratory shall establish, maintain, implement, and comply with the policies and procedures contained in its manual of standard operating procedures. At a minimum, a facility's standard operating procedures shall include policies and procedures that:

(a) Designate areas in the facility that are compartmentalized based on function, including any areas to which access is restricted, and including areas that segregate samples awaiting analysis from those samples being analyzed or prepared for analysis, to prevent cross-contamination;

(b) Provide best practices for safe, secure, and proper testing of medical marijuana;

(c) Establish training and safety policies and procedures to ensure that any person involved in analytical testing of medical marijuana:

(1) Has been fully trained in the safe operation and maintenance of any and all instrumentation that will be used in the testing of medical marijuana, with supporting documentation of the training;

(2) Has been fully trained in the safe use, handling, and storage of any and all chemicals that will be used in the testing of medical marijuana, in accordance with OSHA protocols, with supporting documentation of the training;

(3) Has direct access to applicable safety data sheets and labels; and

(4) Has been fully trained regarding compliance with the District's laws and regulations;

(d) Ensure the chain of custody for all medical marijuana will be documented in the inventory tracking system;

(e) Ensure the facility will be maintained with adequate lighting, ventilation, temperature, sanitation, equipment, and security for the testing of medical marijuana, including requiring that the testing laboratory shall:

(1) Keep the facility free of debris, dust, rodents, insects, birds, and animals of any kind, and any other potential contaminants;

(2) Use chemicals, cleaning solutions, and other sanitizing agents generally accepted for laboratory use, and store them in a manner that protects against contamination;

(3) Maintain a cleaning and equipment maintenance log at the facility, including any preventive and routine maintenance plans and corresponding records, and whether the maintenance is performed by laboratory staff or by service contract with third-parties or the original equipment manufacturer;

(4) Routinely calibrate its scales, balances, or other weight and/or mass measuring devices using "National Institute of Standards and Technology" (NIST)-traceable reference weights, at least once each calendar year; and

(5) Standardize all analytical test instrumentation using reference materials traceable to reference material producers accredited to ISO/IEC 17034 "General Requirements for the Competence of Reference Material Producers" or the national metrology institute (NMI), where available;

(f) Address the analysis, storage, sample inventory tracking, and transportation of plant material, medical marijuana extract, and medical marijuana products; and

(g) Address the following:

(1) Sample Collection;

(2) Sample preparation for each matrix that will be tested;

(3) Reagent, solution, and reference standard preparation;

(4) Instrument setup, if applicable;

(5) Standardization of volumetric reagent solutions, if applicable;

(6) Data acquisition;

(7) Calculation of results;

(8) Identification criteria;

(9) Quality control frequency;

(10) Quality control acceptance criteria; and

(11 Corrective action protocol.

6407.4 The Laboratory Director shall approve, sign, and date each standard operating procedure and each revision to any standard operating procedure.

6407.5 A testing laboratory shall establish and maintain procedures to document a clear and unbroken chain of custody at all stages from sampling to destruction, which shall include:

(a) Documenting each person handling the original samples, aliquots, and extracts;

(b) Documenting any transfer of samples, aliquots, and extracts to another testing facility for additional testing or transfer at the request of the marijuana cultivation facility that provided the testing sample;

(c) Maintaining a current list of authorized persons and restricting entry to the marijuana testing facility to those authorized persons;

(d) Securing the marijuana testing facility during non-working hours;

(e) Using a secured area to log in and aliquot samples; and

(f) Documenting the disposal of samples, aliquots, and extracts.

6407.6 A testing laboratory shall establish and maintain sample requirement procedures that include:

(a) Issuing instructions for the minimum sample requirements and storage requirements;

(b) Documenting the condition of the external package and integrity seals utilized to prevent contamination of or tampering with the sample;

(c) Documenting the condition and amount of sample provided at the time the sample is received at the marijuana testing facility;

(d) Securing short-term and long-term storage areas when not in use; and

(e) Ensuring samples are stored appropriately.

6408.4 A testing laboratory shall document the chain of custody of each sample in the Department's medical marijuana inventory tracking system.

6409 TESTING REQUIREMENTS AND METHODOLOGIES:

6409.1 Each testing laboratory shall:

(a) Follow the most current version of the "*Cannabis Inflorescence: Standards of Identity, Analysis, and Quality Control*" monograph published by the American Herbal Pharmacopoeia;

(b) Follow the most current version of "*Recommendations for Regulators -- Cannabis Operations*" published by the American Herbal Products Association;

(c) Follow most current version of the "*Guidelines for Laboratories Performing Microbiological and Chemical Analyses of Food, Dietary Supplements, and Pharmaceuticals – An Aid to the Interpretation of ISO/IEC 17025:2005 (2015")* published by AOAC International;

(d) Adopt and follow most current version of the minimum good laboratory practices which must, at a minimum, satisfy the "*OECD Series on Principles of Good Laboratory Practice (GLP) and Compliance Monitoring*" published by the Organization for Economic Co-operation and Development;

(e) Maintain internal standard operating procedures; and

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

6409.2 A testing laboratory shall use, when available, testing methods that have undergone validation by the "Official Methods of Analysis of AOAC International," the Performance Tested Methods Program of the Research Institute of AOAC International, the "Bacteriological Analytical Manual" of the Food and Drug Administration, the International Organization for Standardization, the

United States Pharmacopeia, the "Microbiology Laboratory Guidebook" of the Food Safety and Inspection Service of the United States Department of Agriculture or an equivalent third-party validation study approved by the Department.

6409.3 A testing laboratory shall test and analyze a statistically representative sample from each batch of medical marijuana or medical marijuana products for, at minimum:

(a) Moisture content;

(b) Water activity;

(c) Cannabinoid potency, including, at minimum, the levels of the following:

(i) Delta-9-tetrahydrocannabinolic acid (THCA);

(ii) Delta-9-tetrahydrocannabinol (THC);

(iii) Cannabidiolic acid (CBDA);

(iv) Cannabidiol (CBD); and

(v) Cannabinol (CBN);

(d) Foreign matter contamination;

(e) Microbial contamination;

(f) Mycotoxin contamination;

(g) Heavy metal contamination, including, at minimum, arsenic, cadmium, lead, and mercury;

(h) Pesticide and fertilizer residue,

(i) Residual solvents;

(j) Cannabinoid and Terpene Profile;

(k) Product Assessment (for edible products);

(l) Homogeneity (for edible products); and

(m) Any other items requested by or approved by the Department.

6409.4 All samples shall be personally selected and collected by the testing laboratory personnel on site at the cultivation center.

6409.5 The samples personally selected and collected by the testing laboratory shall include, at a minimum:

(a) One (1) testable sample of the final product of flower, from each harvest for every strain of medical marijuana grown by the cultivation center; and

(b) One (1) testable sample of each type of product produced from each batch of medical marijuana, such as but not limited to, the following:

(1) Tincture;

(2) Topical;

(3) Shatter;

(4) Oils;

(5) Edibles;

(6) Wax;

(7) Kief; and

(8) Hash.

6409.6 A testing laboratory shall timely upload into the tracking system the test results for each batch of medical marijuana or medical marijuana product tested.

6409.7 The testing laboratory may retest or reanalyze the sample or a different sample from the same batch by following its standard operating procedures to confirm or refute the original result, upon request by the cultivation center or upon request by the Department at the cultivation center's expense.

6409.8 A testing laboratory shall implement an acceptable method of testing, such as, but not limited to:

(a) Gas Chromatography;

(b) Gas Chromatography Mass Spectrometry;

(c) Immunoassays;

(d) Thin Layer Chromatography;

(d) High Performance Liquid Chromatography; and

(e) Liquid Chromatography Mass Spectroscopy.

6409.9 A testing laboratory using Gas Chromatography shall perform and maintain records of the following, which shall be readily available to the staff operating the equipment:

(a) Document the conditions of the gas chromatograph, including the detector response;

(b) Perform and document preventive maintenance as required by the manufacturer;

(c) Document the performance of new columns before use;

(d) Use an internal standard for each qualitative and quantitative analysis that has similar chemical and physical properties to that of the compound identified;

(e) Establish criteria of acceptability for variances between different aliquots and different columns; and

(f) Document the monitoring of the response (area or peak height) of the internal standard to ensure consistency overtime of the analytical system.

6409.10 A testing laboratory using Gas Chromatography Mass Spectrometry shall perform and maintain records of the following, which shall be readily available to the staff operating the equipment:

(a) Perform and document preventive maintenance as required by the manufacturer;

(b) Document the changes of septa as specified in the standard operating procedure;

(c) Document liners being cleaned or replaced as specified in the standard operating procedure;

(d) Maintain records of mass spectrometer tuning;

(e) Establish written criteria for an acceptable mass spectrometer tune;

(f) Document corrective actions if a mass spectrometer tune is unacceptable;

(g) Monitor analytic analyses to check for contamination and carry-over;

(h) Use selected ion monitoring within each run to assure that the laboratory compares ion ratios and retention times between calibrators, controls and samples for identification of an analyte;

(i) Use an internal standard for qualitative and quantitative analysis that has similar chemical and physical properties to that of the compound identified and is isotopically labeled when available or appropriate for the assay;

(j) Document the monitoring of the response (area or peak height) for the internal standard to ensure consistency overtime of the analytical system;

(k) Define the criteria for designating qualitative results as positive;

(l) Ensure that when a library is used to qualitatively match an analyte, the relative retention time and mass spectra from a known standard or control shall be run on the same system before reporting the results; and

(m) Evaluate the performance of the instrument after routine and preventive maintenance (such as clipping or replacing the column or cleaning the source) prior to analyzing subject samples.

6409.11 A testing laboratory using Immunoassays shall perform and maintain records of the following, which shall be readily available to the staff operating the equipment:

(a) Perform and document preventive maintenance as required by the manufacturer;

(b) Validate any changes or modifications to a manufacturer's approved assays or testing methods when the sample being tested is not included in the list of samples approved for assaying or testing by the manufacturer; and

(c) Define acceptable separation or measurement units (absorbance intensity or counts per minute) for each assay, which shall be consistent with the manufacturer's instructions.

6409.12 A testing laboratory using Thin Layer Chromatography shall perform and maintain records of the following, which shall be readily available to the staff operating the equipment:

(a) Apply unextracted standards to each thin layer chromatographic plate;

(b) Include in its standard operating procedures the preparation of mixed solvent systems, spray reagents and designation of their lifetimes;

(c) Include in its standard operating procedures the storage of unused thin layer chromatographic plates;

(d) Evaluate, establish, and document acceptable performance for new thin layer chromatographic plates before placing them into service;

(e) Verify that the spotting technique used precludes the possibility of contamination and carry-over;

(f) Measure all appropriate R_f values for qualitative identification purposes;

(g) Use and record sequential color reactions, when applicable;

(h) Maintain a copy of the developer TLC plates for each bath of samples analyzed; and

(i) Analyze an appropriate matrix blank with each batch of samples analyzed.

6409.13 A testing laboratory using High Performance Liquid Chromatography shall perform and maintain records of the following, which shall be readily available to the staff operating the equipment:

(a) Perform and document preventive maintenance as required by the manufacturer;

(b) Monitor and document the performance of the HPLC instrument each day of testing;

(c) Document the performance of new columns before use;

(d) Create standard operating procedures for acceptability when eluting solvents are recycled;

(e) Use an internal standard for each qualitative and quantitative analysis that has similar chemical and physical properties to that of the compound identified when available or appropriate for the assay; and

(f) Document the monitoring of the response (area or peak height) of the internal standard to ensure consistency overtime of the analytical system.

6409.14 A testing laboratory using Liquid Chromatography Mass Spectroscopy shall perform and maintain records of the following, which shall be readily available to the staff operating the equipment:

(a) Perform and document preventive maintenance as required by the manufacturer;

(b) Maintain records of mass spectrometer tuning;

(c) Document corrective actions if a mass spectrometer tune is unacceptable;

(d) Use an internal standard with each qualitative and quantitative analysis that has similar chemical and physical properties to that of the compound identified and is isotopically labeled when available or appropriate for the assay;

(e) Document the monitoring of the response (area or peak height) of the internal standard to ensure consistency overtime of the analytical system;

(f) Compare two transitions and retention times between calibrators, controls and samples within each run;

(g) Document and maintain records when changes in source, source conditions, eluent, or column are made to the instrument; and

(h) Evaluate the performance of the instrument when changes in source, source conditions, eluent, or to a column are made prior to reporting test results.

6409.15 A testing laboratory shall determine if the following pesticides are within the acceptable limit using the following chart:

Table A. Insecticide Critical Limits in Parts Per Million (PPM)

Insectide	Critical Limit
Acetamiprid	0.2
Abamectin	0.5
Aldicarb	0.4
Bifenazate	0.2
Carbofuran	0.2
Chlorantraniliprole	0.2
Chlorpyrifos	0.2
Cyfluthrin	1.0
DDVP	0.1

(Dichlorvos)	
Diazinon	0.2
Dimethoate	0.2
Fenpyroximate	0.5
Fipronil	0.4
Flonicamid	1.0
Imidacloprid	0.4
Malathion	0.2
Methiocarb	0.2
Methomyl	0.4
Naled	0.5
Oxamyl	1.0
Permethrin	0.5
Phosmet	0.2
Piperonyl butoxide	1.0
Pyrethrins	1.0
Spinosad	0.2
Spiromesifen	0.2
Spirotetramat	0.2
Thiacloprid	0.2
Thiamethoxam	0.2

6409.16 A testing laboratory shall determine if the following plant growth regulators are within the acceptable limit using the following chart:

Table B. Plant Growth Regulator Critical Limits in Parts Per Million (PPM)	
Plant Growth Regulator	**Critical Limit**
Ancymidol	0.2
Carbaryl	0.2
Daminozide (Alar)	0.1
Ethephon	1.0
Flurprimidol	0.2
Paclobutrazol	0.4

6409.17 A testing laboratory shall determine if the following fungicides are within the acceptable limit using the following chart:

Table C. Fungicide Critical Limits in Parts Per Million (PPM)

Fungicide	Critical Limit
Azoxystrobin	0.2
Bifenthrin	0.2
Boscalid	0.4
Fludioxonil	0.4
Imazalil	0.2
Kresoxim-methyl	0.4
Metalaxyl	0.2
Myclobutanil	0.2
Propiconazole	0.4
Trifloxystrobin	0.2

6409.18 A testing laboratory shall determine if the following acaricides are within the acceptable limit using the following chart:

Table D. Acaricide Critical Limits in Parts Per Million (PPM)	
Acaricide	**Critical Limit**
Clofentezine	0.2
Etoxazole	0.2

6409.19 A testing laboratory shall determine if the following ovicide is within the acceptable limit using the following chart:

Table E. Ovicide Critical Limits in Parts Per Million (PPM)	
Ovicide	**Critical Limit**
Hexythiazox	1.0

6409.20 A testing laboratory shall determine if the following residual solvents are within the acceptable limit using the following chart:

Table F. Residual Solvents Critical Limits in Parts Per Million (PPM)	
Solvent	**Critical Limit**
Benzene	2

Butanes	5000
Ethanol	5000
Heptanes	5000
Hexanes	290
Propanes	5000
Toluene	< 890
Total Xylenes	< 2170

6409.21 A testing laboratory shall determine if the following microbial impurities are within the acceptable limit using the following chart:

Table G. Microbiological Impurity Critical Limits in Colony Forming Units (CFU/g)	
Microbiological Impurity	**Critical Limit**
E. coli	< 100
Salmonella spp.	0
Total Aerobic Microbial Count	100,000
Total Yeast and Mold Count	10,000

6409.22 A testing laboratory shall determine if the following heavy metals are within the acceptable limit using the following chart:

Table I. Heavy Metal Critical Limits in Parts Per Million (PPM)	
Heavy Metal	**Critical Limit**
Arsenic	0.4
Barium	60.0
Cadmium	0.4
Chromium	0.6
Lead	< 1.0
Mercury	0.2
Selenium	26.0
Silver	1.4

6409.23 A testing laboratory shall determine if the Water Activity (A_w) of a sample is within an acceptable limit. For purposes of this section, the A_w of a sample shall be acceptable if it is below $0.65A_w$.

6409.24 A testing laboratory shall determine if an edible is a potentially hazardous food by using the following charts:

Table J. Interaction of pH and A_w for control of spores in food heat-treated to destroy Vegetative cells and subsequently packaged

A_w values	pH values		
	4.6 or less	> 4.6 – 5.6	> 5.6
≤0.92	Non-PHF*/non-TCS food**	Non-PHF/non-TCS food	Non-PHF/non-TCS food
> 0.92 - .95	Non-PHF/non-TCS food	Non-PHF/non-TCS food	PA***
> 0.95	Non-PHF/non-TCS food	PA	PA

* PHF means Potentially Hazardous Food
** TCS Food means Time/Temperature Control for Safety Food
*** PA means Product Assessment required

TABLE K. INTERACTION OF pH AND A_W FOR CONTROL OF VEGETATIVE CELLS AND SPORES IN FOOD NOT HEAT-TREATED BUT NOT PACKAGED

A_w values	pH values			
	< 4.2	4.2 – 4.6	> 4.6 – 5.0	> 5.0
< 0.88	non-PHF*/non-TCS food**	non-PHF/ non-TCS food	non-PHF/ non- TCS food	non-PHF/ non –TCS food
0.88 – 0.90	non-PHF/ non-TCS food	non-PHF/ non-TCS food	non-PHF/ non-TCS food	PA***
> 0.90 – 0.92	non-PHF/non-	non-PHF/		

	TCS food	non-TCS food	PA	PA
> 0.92	non-PHF/non-TCS food	PA	PA	PA
* PHF means Potentially Hazardous Food ** TCS FOOD means Time/Temperature Control for Safety Food *** PA means Product Assessment required				

6410 RESULT REPORTING

6410.1 A testing laboratory shall issue results for each sample tested which shall address the following:

(a) Whether the chemical profile of the medical marijuana sample conforms to the accepted variety for the following compounds:

(1) Delta-9-tetrahydrocannabinol (THC);

(2) Delta-9-tetrahydrocannabinolic acid (THCA);

(3) Cannabidiol (CBD);

(4) Cannabidiolic acid (CBDA);

(5) The terpenes described in the most current version of the cannabis inflorescence monograph published by the American Herbal Pharmacopeia (AHP);

(6) Cannabigerol (CBG); and

(7) Cannabinol (CBN);

(b) That the presence of the following contaminants do not exceed the levels as provided in § 6409 of this subtitle;

(1) Heavy metals; and

(2) Pesticide residue;

(c) The presence of microbial impurities, including but not limited to:

(1) The total aerobic microbial count (TAMC);

(2) The total combined yeast and molds count (TYMC);

(3) Pseudomonas aeruginosa (P. aeruginosa);

(4) Aspergillus spp;

(5) Staphylococcus aureus (S. aureus);

(6) Aflatoxin B_1, B_2, G_1 and G_2; and

(7) Ochratoxin A;

(d) Whether the batch is within specification for the characteristics of:

(1) Odor;

(2) Appearance;

(3) Fineness; and

(4) Moisture content.

6410.2 The testing laboratory shall enter results into the Department's electronic tracking system within twenty-four (24) hours from the date of the test.

6410.3 The level of contaminants in medical marijuana and medical marijuana products shall not exceed the standards provided in this subtitle, and if any of the standards are exceeded, the cultivation center shall not sell or otherwise transfer any portion of the batch of medical marijuana or medical marijuana products to a dispensary.

6410.4 In the event the testing laboratory results determine that the sample does not meet the standards required in this subtitle, the cultivation center may seek approval from the Department to reprocess the batch and/or harvest. If written approval is granted by the Department, the cultivation center may:

(a) Reprocess the batch and/or harvest according to their SOPs; and

(b) Have the reprocessed product tested by the same testing laboratory.

6410.5 Upon receiving notification in the tracking system that the batch failed to pass testing, a cultivation center shall immediately quarantine the non-conforming batch until any reprocessing and testing is performed; or until the batch is destroyed by MPD.

6410.6 For purposes of this section, quarantine means that the batch shall be separated from all other inventory and the quarantine status shall be indicated in the

tracking system. The quarantine shall be lifted only by the Department in writing, and only upon receipt of test results in the inventory tracking system documenting that the batch conforms to the required testing standards.

6410.7 The testing laboratory shall notify the Department of results that do not meet the standards and specifications set forth in this subtitle within twenty-four (24) hours of completion of analysis.

6410.8 A cultivation center shall release a batch and/or harvest for sale only if the results from the laboratory testing facility have determined that the sample has met the standards and specifications set forth in this subtitle.

Chapter 99, DEFINITIONS, of Subtitle C, MEDICAL MARIJUANA, Title 22, HEALTH, of DCMR is amended as follows

Section 9900, DEFINITIONS, is amended as follows:

Subsection 9900.1 is amended by adding the following new definitions to appear in alphabetical order.

Acaricide – A substance poisonous to ticks or mites.

Batch – (a) A quantity of usable medical marijuana from a harvest lot; or

(b) A quantity of cannabinoid concentrate or extract or cannabinoid product from a process lot.

Chain of custody – Procedures employed by a testing laboratory to record the possession of samples from the time of sampling through destruction.

Fungicide – A chemical that destroys fungus.

Ovicide – A substance that kills eggs.

Pesticide – A substance used to destroy insects or other organisms harmful to plants.

Plant Growth Regulator – A substance used to alter the plants' characteristics.

Potentially Hazardous Food- food that contains moisture or protein that is capable of supporting the rapid and accelerating growth of infectious or toxigenic microorganisms.

Product Assessment – Test to determine if an edible is a Potentially Hazardous Food.

TCS Food – A food that requires time and temperature control in order to ensure food safety.

Testable Sample – A representative sample that is large enough in quantity to perform all of the required tests.

Testing Laboratory – An entity that is not owned or operated by a director, officer, member, incorporator, agent, or employee of a cultivation center or dispensary, and is registered by the Department to test medical marijuana and medical marijuana products that are to be sold.

Water Activity – The available water ratio for microorganisms or bacteria to grow, expressed on a scale of 0 to 1, where 1 is pure water.

All persons desiring to comment on the subject matter of this proposed rulemaking action shall submit written comments, not later than thirty (30) days after the date of publication of this notice in the *D.C. Register*, to Phillip Husband, General Counsel, Department of Health, Office of the General Counsel, 899 North Capitol Street, N.E., 6th Floor, Washington, D.C. 20002. Copies of the proposed rules may be obtained between the hours of 8:00 a.m. and 4:00 p.m. the address listed above, or by contacting Angli Black, Paralegal Specialist, at Angli.Black@dc.gov, (202) 442-5977.

GOVERNMENT OF THE DISTRICT OF COLUMBIA
Office of the Attorney General

Legal Counsel Division

MEMORANDUM

TO: Alana Intrieri
Executive Director
Office of Policy and Legislative Affairs

FROM: Janet M. Robins
Deputy Attorney General
Legal Counsel Division

DATE: December 13, 2018

SUBJECT: Legal Sufficiency Review of the "Medical Marijuana Testing Laboratory Rulemaking Approval Resolution of 2019"
(AR-18-571)

This is to Certify that this Office has reviewed the above-referenced legislation and that we have found it to be legally sufficient. If you have any questions in this regard, please do not hesitate to call me at 724-5524.

Janet M. Robins