Massachusetts Cannabis Control Commission

Independent Testing Laboratory

General Information:

License Number: IL281334

Original Issued Date: 08/25/2020

Issued Date: 08/11/2022

Expiration Date: 08/25/2023

ABOUT THE MARIJUANA ESTABLISHMENT

Business Legal Name: G7 Lab LLC

Phone Number: 978-517-0154 **Email Address:** G7LabLLC@gmail.com

Business Address 1: 160 Ayer Road, Unit 3 **Business Address 2:**

Business City: Littleton **Business State:** MA **Business Zip Code:** 01460

Mailing Address 1: 160 Ayer Road, Unit 3 **Mailing Address 2:**

Mailing City: Littleton **Mailing State:** MA **Mailing Zip Code:** 01460

CERTIFIED DISADVANTAGED BUSINESS ENTERPRISES (DBES)

Certified Disadvantaged Business Enterprises (DBEs): Minority-Owned Business

PRIORITY APPLICANT

Priority Applicant: no

Priority Applicant Type: Not a Priority Applicant

Economic Empowerment Applicant Certification Number:

RMD Priority Certification Number:

RMD INFORMATION

Name of RMD:

Department of Public Health RMD Registration Number:

Operational and Registration Status:

To your knowledge, is the existing RMD certificate of registration in good standing?:

If no, describe the circumstances below:

PERSONS WITH DIRECT OR INDIRECT AUTHORITY

Person with Direct or Indirect Authority 1

Percentage Of Ownership: 60 **Percentage Of Control:** 60

Role: Owner / Partner **Other Role:** President, Chief Executive Officer, Lab director

First Name: Shankar **Last Name:** Gautam **Suffix:**

Gender: Male **User Defined Gender:**

What is this person's race or ethnicity?: Asian (Chinese, Filipino, Asian Indian, Vietnamese, Korean, Japanese)

Specify Race or Ethnicity: Nepali

Person with Direct or Indirect Authority 2

Percentage Of Ownership: 40 **Percentage Of Control:** 40

Role: Owner / Partner **Other Role:** Vice President, Chief Financial Officer

First Name: Pratima **Last Name:** Bhattarai **Suffix:**

Gender: Female **User Defined Gender:**

What is this person's race or ethnicity?: Asian (Chinese, Filipino, Asian Indian, Vietnamese, Korean, Japanese)

Specify Race or Ethnicity: Nepali

ENTITIES WITH DIRECT OR INDIRECT AUTHORITY

No records found

CLOSE ASSOCIATES AND MEMBERS

No records found

CAPITAL RESOURCES - INDIVIDUALS

Individual Contributing Capital 1

First Name: Shankar **Last Name:** Gautam **Suffix:**

Types of Capital: Monetary/Equity **Other Type of Capital:** **Total Value of the Capital Provided:** $40000 **Percentage of Initial Capital:** 10

Capital Attestation: Yes

CAPITAL RESOURCES - ENTITIES

No records found

BUSINESS INTERESTS IN OTHER STATES OR COUNTRIES

No records found

DISCLOSURE OF INDIVIDUAL INTERESTS

No records found

MARIJUANA ESTABLISHMENT PROPERTY DETAILS

Establishment Address 1: 160 Ayer Road, Unit 3

Establishment Address 2:

Establishment City: Littleton **Establishment Zip Code:** 01460

Approximate square footage of the Establishment: 3215 **How many abutters does this property have?:** 8

Have all property abutters have been notified of the intent to open a Marijuana Establishment at this address?: Yes

HOST COMMUNITY INFORMATION

Host Community Documentation:

Document Category	Document Name	Type	ID	Upload Date
Certification of Host Community Agreement	G7 HCA Certification Form.pdf	pdf	5e6acbb0b3c49635509e661e	03/12/2020
Plan to Remain Compliant with Local Zoning	Plan to Remain Compliant with Local Zoning.pdf	pdf	5eb6dd650e32c52d2bdd1117	05/09/2020
Community Outreach Meeting	Community Outreach Documentation	pdf	5eb6dd785f1314349d5f838e	05/09/2020

Documentation	complete G7 Labs LLC.pdf

Total amount of financial benefits accruing to the municipality as a result of the host community agreement. If the total amount is zero, please enter zero and provide documentation explaining this number.: $

PLAN FOR POSITIVE IMPACT

Plan to Positively Impact Areas of Disproportionate Impact:

Document Category	Document Name	Type	ID	Upload Date
Plan for Positive Impact	G7 Lab LLC - Positive Impact Plan (1).pdf	pdf	5ee1127b2d9da4181de9e4aa	06/10/2020
Other	MRCC PIP letter G7 Lab (1).pdf	pdf	5ee1127c2989d72512a75a01	06/10/2020

ADDITIONAL INFORMATION NOTIFICATION

Notification:

INDIVIDUAL BACKGROUND INFORMATION

Individual Background Information 1

Role: **Other Role:**

First Name: Shankar **Last Name:** Gautam **Suffix:**

RMD Association: Not associated with an RMD

Background Question: no

Individual Background Information 2

Role: **Other Role:**

First Name: Pratima **Last Name:** Bhattarai **Suffix:**

RMD Association: Not associated with an RMD

Background Question: no

ENTITY BACKGROUND CHECK INFORMATION

No records found

MASSACHUSETTS BUSINESS REGISTRATION

Required Business Documentation:

Document Category	Document Name	Type	ID	Upload Date
Secretary of Commonwealth - Certificate of Good Standing	G7 Sec of Commonwealth Certif of Good Standing.pdf	pdf	5e9f02861cdd2e3910a55c3d	04/21/2020
Department of Revenue - Certificate of Good standing	G7 DOR Certif of Good Standing.pdf	pdf	5e9f028c5f1da0353e2b5de2	04/21/2020
Bylaws	G7 Operating Agreement.pdf	pdf	5e9f0314d29ad93571599ba2	04/21/2020
Articles of Organization	Certificate of Organization Sec of Comm G7 reduced.pdf	pdf	5e9f04e22b97cf38fa37897c	04/21/2020
Department of Revenue - Certificate of Good standing	DUA_compliance _signed (1).pdf	pdf	5eb6eef8cb1edf34af2dd8ac	05/09/2020
Articles of Organization	Certificate of Amendment 01272020reduced.pdf	pdf	5ebc1a8e0f6f0d34840b37a9	05/13/2020

Certificates of Good Standing:

Document Category	Document Name	Type	ID	Upload Date
Department of Unemployment Assistance - Certificate of Good standing	DUA attestion signed 060222.jpeg	jpeg	629a4e00eb816b00087109a2	06/03/2022
Secretary of Commonwealth - Certificate of Good Standing	cogs_PDF.pdf	pdf	62adec275871d1000892a504	06/18/2022
Department of Revenue - Certificate of Good standing	COGS_MAREV.pdf	pdf	62be2bea9ff1170008276b59	06/30/2022

Massachusetts Business Identification Number: 001369282

Doing-Business-As Name:

DBA Registration City:

BUSINESS PLAN

Business Plan Documentation:

Document Category	Document Name	Type	ID	Upload Date
Business Plan	Business Plan_CCC Application updated 5-13-2020 with CONFIDENTIAL header (1).pdf	pdf	5ebda4038caba634a8439709	05/14/2020
Plan for Liability Insurance	INSURENCE CERT.pdf	pdf	62adecc0eb816b0008825ef5	06/18/2022
Proposed Timeline	Plan to remain compliant .pdf	pdf	62be2d749ff1170008276be6	06/30/2022

LABORATORY CERTIFICATION

Certifying Body: ISO **ISO 17025 Accreditation Certificate Number:** 1234567

OPERATING POLICIES AND PROCEDURES

Policies and Procedures Documentation:

Document Category	Document Name	Type	ID	Upload Date
Inventory procedures	G7 Lab LLC - Inventory Procedures.pdf	pdf	5ebda4987d78332d19fc7f80	05/14/2020
Maintaining of financial records	G7 Lab LLC - Maintaining of Financial Records.pdf	pdf	5ebda4997dc0413492816c36	05/14/2020
Restricting Access to age 21 and older	G7 Lab LLC - Restricting Access to age 21 or older.pdf	pdf	5ebda49a0e32c52d2bdd1d92	05/14/2020
Security plan	G7 Lab LLC - Security Plan with Floor Plan from Septronics.pdf	pdf	5ebda4c78caba634a843970d	05/14/2020
Storage of marijuana	G7 Lab LLC - Storage.pdf	pdf	5ebda4c91cd17834bad62d61	05/14/2020
Transportation of marijuana	G7 Lab LLC - Transportation of Marijuana.pdf	pdf	5ebda4cb502f482d48990213	05/14/2020
Prevention of diversion	G7 Lab LLC - Prevention of Diversion.pdf	pdf	5ebda4cdcb1edf34af2de4c5	05/14/2020
Record Keeping procedures	G7 Lab LLC - Record Keeping Procedures (1).pdf	pdf	5ebda4d0f16b5934c591b167	05/14/2020
Personnel policies including	G7 Lab LLC - Personnel Policies Including	pdf	5ebdae837dc0413492816c4b	05/14/2020

background checks	Background Checks.pdf			
Qualifications and training	Qualifications and Training combined.pdf	pdf	5edff5eb31143018002523b5	06/09/2020
Quality control and testing	Quality Control and Testing Procedures combined.pdf	pdf	5edff6782989d72512a757f1	06/09/2020
Diversity plan	G7 Lab LLC - Diversity Plan (1).pdf	pdf	5ee112bd1c2dbc24d01a11f2	06/10/2020

ATTESTATIONS

I certify that no additional entities or individuals meeting the requirement set forth in 935 CMR 500.101(1)(b)(1) or 935 CMR 500.101(2)(c)(1) have been omitted by the applicant from any marijuana establishment application(s) for licensure submitted to the Cannabis Control Commission.: I Agree

I understand that the regulations stated above require an applicant for licensure to list all executives, managers, persons or entities having direct or indirect authority over the management, policies, security operations or cultivation operations of the Marijuana Establishment; close associates and members of the applicant, if any; and a list of all persons or entities contributing 10% or more of the initial capital to operate the Marijuana Establishment including capital that is in the form of land or buildings.: I Agree

I certify that any entities who are required to be listed by the regulations above do not include any omitted individuals, who by themselves, would be required to be listed individually in any marijuana establishment application(s) for licensure submitted to the Cannabis Control Commission.: I Agree

Notification:

I certify that any changes in ownership or control, location, or name will be made pursuant to a separate process, as required under 935 CMR 500.104(1), and none of those changes have occurred in this application.: I Agree

I certify that to the best knowledge of any of the individuals listed within this application, there are no background events that have arisen since the issuance of the establishment's final license that would raise suitability issues in accordance with 935 CMR 500.801.: I Agree

I certify that all information contained within this renewal application is complete and true.: I Agree

ADDITIONAL INFORMATION NOTIFICATION

Notification:

COMPLIANCE WITH POSITIVE IMPACT PLAN

Progress or Success Goal 1

Description of Progress or Success: Positive Impact plan assessment.

G7 Lab LLC fully intendeds to donate respective intended amounts to the institutions listed below as a part of G7 Lab LLC positive impact plan after receiving final License from CCC and commence full operations. Please attached letters.

Year 2021 and Year 2022(up to June) Intended donation $2500.00/year

1. MRCC Donation-$0
2. Cannabis Center of Excellence INC-$0

Because of numerous huddles and extenuating circumstances caused by the unforeseen Corona Virus pandemic and multiple delays of lab buildout and instrument validation caused by supplies and material backlog G7 lab LLC has not been able to donate as intended to above parties.

COMPLIANCE WITH DIVERSITY PLAN

Diversity Progress or Success 1

Description of Progress or Success: Diversity Plan Assessment

G7 Lab LLC Diversity plan Qualitative and Quantitative Metrics is to achieve a diverse workplace consituting of at least 10% women and minorities.

Year :2021 :Goal 10% Women or Minority.

Year: 2022 Upto June :Goal 10 % Women or Minority

Goal Achieved 33.3 % women 100% Minority

HOURS OF OPERATION

Monday From: Open 24 Hours	**Monday To:** Open 24 Hours
Tuesday From: Open 24 Hours	**Tuesday To:** Open 24 Hours
Wednesday From: Open 24 Hours	**Wednesday To:** Open 24 Hours
Thursday From: Open 24 Hours	**Thursday To:** Open 24 Hours
Friday From: Open 24 Hours	**Friday To:** Open 24 Hours
Saturday From: Open 24 Hours	**Saturday To:** Open 24 Hours
Sunday From: Open 24 Hours	**Sunday To:** Open 24 Hours

Cannabis Control Commission
COMMONWEALTH OF MASSACHUSETTS

Host Community Agreement Certification Form

The applicant and contracting authority for the host community must complete each section of this form before uploading it to the application. Failure to complete a section will result in the application being deemed incomplete. Instructions to the applicant and/or municipality appear in italics. Please note that submission of information that is "misleading, incorrect, false, or fraudulent" is grounds for denial of an application for a license pursuant to 935 CMR 500.400(1).

Applicant

I, Shankar P. Gautam, (*insert name*) certify as an authorized representative of G7 Lab LLC (*insert name of applicant*) that the applicant has executed a host community agreement with Town of Littleton, MA (*insert name of host community*) pursuant to G.L.c. 94G § 3(d) on Feburary 10th, 2020 (*insert date*).

Signature of ~~Authorized~~ Representative of Applicant

Host Community

I, Joseph Laydon, (*insert name*) certify that I am the contracting authority or have been duly authorized by the contracting authority for Town of Littleton (*insert name of host community*) to certify that the applicant and Town of Littleton (*insert name of host community*) has executed a host community agreement pursuant to G.L.c. 94G § 3(d) on February 10, 2020 (*insert date*).

Assistant Town Administrator
Signature of Contracting Authority or
Authorized Representative of Host Community

PLAN TO REMAIN COMPLIANT WITH LOCAL ZONING

G7 Lab, LLC, Independent Testing Laboratory, proposed location is 160 Ayer Road in the Town of Littleton and is located within the Town's Industrial B (IB) Zoning District and a special permit and site plan approval is required from the Littleton Planning Board pursuant to Article XXVIII of Chapter 173, the Town's Zoning Bylaw, enacted by Town Meetings in 2017 and 2018. There are no other provisions currently contained in the Littleton General Bylaws that apply to a Testing Facility.

Section 173-196 on Siting of such a Testing Laboratory specifically states the use is allowed by special permit and site plan review in the Industrial B Zone.

G7 Lab shall duly apply-for and comply-with the bylaw provisions and requirements set forth under subsections 194 through 202 of Zoning Section 173 and all applicable conditions that may be imposed by the Planning Board during the special permit and site plan approvals. Given the facility shall be completely enclosed within one of the four commercial units existing at the subject property with ample off-street parking few, if any, site plan conditions are anticipated.

The special permit criteria and requirements for approval by the planning board are detailed and comprehensive, fully incorporating by reference the regulations set forth in 935 CMR 500, et seq. established pursuant to MGL Chapter 94G. G7 Lab has entered into a real estate contract with the owner of the subject property and has control of the site to begin the permitting process. G7 Lab has determined that it can meet the Town's permitting requirements set forth in Section 173 of the Bylaw and that there are no known adverse conditions or matters that would adversely affect the permitting process and operation of the testing facility. G7 Lab shall comply with and maintain all applicable permits required for the testing laboratory.

Cannabis Control Commission
COMMONWEALTH OF MASSACHUSETTS

Community Outreach Meeting Attestation Form

Instructions

Community Outreach Meeting(s) are a requirement of the application to become a Marijuana Establishment (ME) and Medical Marijuana Treatment Center (MTC). 935 CMR 500.101(1), 500.101(2), 501.101(1), and 501.101(2). The applicant must complete each section of this form and attach all required documents as a single PDF document before uploading it into the application. If your application is for a license that will be located at more than one (1) location, and in different municipalities, applicants must complete two (2) attestation forms – one for each municipality. Failure to complete a section will result in the application not being deemed complete. Please note that submission of information that is "misleading, incorrect, false, or fraudulent" is grounds for denial of an application for a license pursuant to 935 CMR 500.400(2) and 501.400(2).

Attestation

I, the below indicated authorized representative of that the applicant, attest that the applicant has complied with the Community Outreach Meeting requirements of 935 CMR 500.101 and/or 935 CMR 501.101 as outlined below:

1. The Community Outreach Meeting was held on the following date(s): 12/10/19

2. At least one (1) meeting was held within the municipality where the ME is proposed to be located.

3. At least one (1) meeting was held after normal business hours (this requirement can be satisfied along with requirement #2 if the meeting was held within the municipality and after normal business hours).

4. A copy of the community outreach notice containing the time, place, and subject matter of the meeting, including the proposed address of the ME or MTC was published in a newspaper of general circulation in the municipality at least 14 calendar days prior to the meeting. A copy of this publication notice is labeled and attached as "Attachment A."

    a. Date of publication: 11/15/19

    b. Name of publication: Eagle-Independent

5. A copy of the community outreach notice containing the time, place, and subject matter of the meeting, including the proposed address of the ME or MTC was filed with clerk of the municipality. A copy of this filed notice is labeled and attached as "Attachment B."

    a. Date notice filed: 11/8/19

6. A copy of the community outreach notice containing the time, place, and subject matter of the meeting, including the proposed address of the ME or MTC was mailed at least seven (7) calendar days prior to the community outreach meeting to abutters of the proposed address, and residents within 300 feet of the property line of the applicant's proposed location as they appear on the most recent applicable tax list, notwithstanding that the land of the abutter or resident is located in another municipality. A copy of this mailed notice is labeled and attached as "Attachment C." Please redact the name of any abutter or resident in this notice.

    a. Date notice(s) mailed: 11/16/19

7. The applicant presented information at the Community Outreach Meeting, which at a minimum included the following:
    a. The type(s) of ME or MTC to be located at the proposed address;
    b. Information adequate to demonstrate that the location will be maintained securely;
    c. Steps to be taken by the ME or MTC to prevent diversion to minors;
    d. A plan by the ME or MTC to positively impact the community; and
    e. Information adequate to demonstrate that the location will not constitute a nuisance as defined by law.

8. Community members were permitted to ask questions and receive answers from representatives of the ME or MTC.

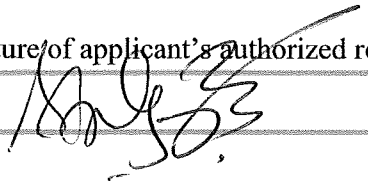
Name of applicant:

Shankar P. Gautam

Name of applicant's authorized representative:

Shankar P. Gautam

Signature of applicant's authorized representative:



ATTACHMENT A

he purchaser shall have no ecourse against the Mortgagor, lortgagee or the Mortgagee's ey. The description of the premis- ntained in said mortgage shall l in the event of an error in this ation. **TIME WILL BE OF THE NCE.**

terms, if any, to be announced at le.
.S. Bank National Association, as ee, on behalf of the holders of the Stearns Asset Backed Securities I Trust 2005-AC6, Asset-Backed Certificates, Series 2005-AC6

Present Holder of said Mortgage,
By Its Attorneys,
ORLANS PC
PO Box 540540
Waltham, MA 02454
Phone: (781) 790-7800
18-004265

3841572
nd 11/1, 11/8, 11/15/19

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rd, 10 Main Street
LEGAL NOTICE
COMMONWEALTH OF MASSACHUSETTS

SHERIFF'S SALE

MIDDLESEX, SS.

n execution and will be sold by auction on the 5th day of er, 2019 at 11:00 o'clock, am, heriffs Office at 271 Cambridge Cambridge, Massachusetts, in nty of Middlesex, all the right, d interest that said Corbett ment, Inc. of 1 Pleasant Street, 15, Westford, in the County of ex had (not exempt by law from execution or from attachment) 11th day of September, 2019, e time when the same was n execution, in and to the fol- escribed real estate, to wit: ***10 treet, Westford, MA 01886. 8243, Page #285***

d in Westford, Middlesex Massachusetts, with the build- improvements located there- ted at 10 Main Street in said , and being shown as Parcel lan of land entitled "Plan of - ANR 12 Main Street, Massachusetts", Scale: 1" = e 10, 2014, prepared by h Consultants ing/Design/Surveying/Permitti red for: Corbett Development, Box 4136, Westford, MA hich plan is recorded with the x North District Registry of t Plan Book 237, Plan 145. e to said plan is herein made e particular description of the mises.

ontaining 63,314 square feet more or less, according to Subject to and with the ben- following matters:

fit of the Servicemembers Civil Relief Act: 50 U.S.C. c. 50 § 3901 (et seq):

Citizens Bank, N.A f/k/a RBS Citizens N.A. s/b/m Citizens Bank of Massachusetts

claiming to have an interest in a Mortgage covering real property in Needham, numbered 51 Gilbert Road, given by Julene E. Schultz to Citizens Bank of Massachusetts, dated April 12, 2006, and filed in Norfolk County Registry District of the Land Court as Document No. 1101982 and noted on Certificate of Title No. 155104 has/have filed with this court a complaint for determination of Defendant's/Defendants' Servicemembers status.

If you now are, or recently have been, in the active military service of the United States of America, then you may be entitled to the benefits of the Servicemembers Civil Relief Act. If you object to a foreclosure of the above-mentioned property on that basis, then you or your attorney must file a written appearance and answer in this court at **Three Pemberton Square, Boston, MA 02108** on or before **December 9, 2019** or you may lose the opportunity to challenge the foreclosure on the grounds of noncompliance with the Act.

Witness, GORDON H. PIPER, Chief Justice of said Court on October 28, 2019.

Attest:

Deborah J. Patterson
Recorder

AD#13848224
Eagle-Independent 11/15/19

Westford, 2 Priscilla Lane, Ice House Easement

LEGAL NOTICE
COMMONWEALTH OF MASSACHUSETTS

SHERIFF'S SALE

MIDDLESEX, SS.

Taken on execution and will be sold by public auction on the 5th day of December, 2019 at 11:30 o'clock, am, at the Sheriffs Office at 271 Cambridge Street, Cambridge, Massachusetts, in the County of Middlesex, all the right, title and interest that said Corbett Development, Inc. of 1 Pleasant Street, Unit #6-15, Westford, in the County of Middlesex had (not exempt by law from levy on execution or from attachment) on the 11th day of September, 2019, being the time when the same was seized on execution, in and to the following described real estate, to wit: ***2 Priscilla***

7:00 PM, Tuesday,
December 03, 2019
Westford Town Hall Meeting Room
55 Main St Westford, MA 01886

COMMUNITY NEEDS FORUM

The Community Preservation Committee (CPC) invites all citizens and Town boards to participate in this open forum to discuss what their priorities are regarding Community Preservation Funds.

For additional information contact Jesse Beyer, CPC Administrator at (978) 399-2905 or jbeyer@westfordma.gov

AD#13849064
Eagle-Independent 11/15/19

Chelmsford, 23 Seventh Lane
LEGAL NOTICE

The Board of Appeals of the Town of Chelmsford will hold a public hearing on **Thursday, December 5, 2019, at 7:00pm,** in Room 204 of the Town Offices, 50 Billerica Road, to hear requests for Special Permits, Variances and other appeals.

Hearings for Special Permits & Variances Begin at 7:00 P.M.

23 Seventh Lane, Quality Green Homes, is seeking a variance under 195-9, conformity, for reduced lot area. The applicant requests relief from lot area to create 2 buildable lots, any other relief deemed necessary.

Files and plans are available for review in the Community Development Office, Room LL01 of the Town Offices, 50 Billerica Road, between 9:00 a.m. and 4:00 p.m., Monday through Friday.

Per Order,
Brian Reidy, Chairman

AD#13848537
Eagle-Independent 11/15, 11/22/19

Community Outreach Meeting Notice
LEGAL NOTICE

Notice is hereby given in accordance with M.G.L. ch. 94G and the Massachusetts Cannabis Control Commission's regulations at 935 CMR 500.000 et seq. that a Community Outreach Meeting for a proposed Marijuana Establishment is scheduled for December 10th, 2019 at 6:30 PM at Courtyard by Marriott 102 Constitution Ave, The Point, Littleton, MA 01460. The proposed Independent Testing Laboratory is anticipated to be located at 160 Ayer Rd, Unit #3, Littleton, MA 01460.

Interested members of the community are encouraged to ask questions and receive answers from G7 Labs LLC representatives about the proposed facility and operations.

AD#13848341
Eagle-Independent 11/15, 11/22/19

LEGAL

ATTACHMENT A

After a tetani

Legal Notices Legal Notices

Westford, 10 Main Street
LEGAL NOTICE
COMMONWEALTH OF MASSACHUSETTS

SHERIFF'S SALE

MIDDLESEX, SS.

Taken on execution and will be sold by public auction on the 5th day of December, 2019 at 11:00 o'clock, am, at the Sheriffs Office at 271 Cambridge Street, Cambridge, Massachusetts, in the County of Middlesex, all the right, title and interest that said Corbett Development, Inc. of 1 Pleasant Street, Unit #6-15, Westford, in the County of Middlesex had (not exempt by law from levy on execution or from attachment) on the 11th day of September, 2019, being the time when the same was seized on execution, in and to the following described real estate, to wit: ***10 Main Street, Westford, MA 01886. Book #28243, Page #285***

The land in Westford, Middlesex County, Massachusetts, with the buildings and improvements located thereon, situated at 10 Main Street in said Westford, and being shown as Parcel A on a plan of land entitled "Plan of Land — ANR 12 Main Street, Westford, Massachusetts", Scale: 1" = 40', June 10, 2014, prepared by Landtech Consultants Engineering/Design/Surveying/Permitting, prepared for: Corbett Development, Inc., PO Box 4136, Westford, MA 01886, which plan is recorded with the Middlesex North District Registry of Deeds at Plan Book 237, Plan 145. Reference to said plan is herein made for a more particular description of the within premises.

Parcel A containing 63,314 square feet (1.45 Ac.) more or less, according to said plan. Subject to and with the benefit of the following matters:
Matters set forth on Plan recorded with

Chelmsford, 57 Hunt Road
LEGAL NOTICE
COMMONWEALTH OF MASSACHUSETTS

LAND COURT
DEPARTMENT OF THE TRIAL COURT
19 SM 005106
ORDER OF NOTICE

TO:
Margaret J. Galanos as Personal Representative of the Estate of Katherine Psiras, Theo Giras, Valerie Beaubien, Sandra Jean, Donna Tucker and Gail Smith

and to all persons entitled to the benefit of the Servicemembers Civil Relief Act, 50 U.S.C. §§ 3901 et seq.:

Nationstar Mortgage LLC d/b/a Champion Mortgage Company

claiming to have an interest in a Mortgage covering real property in Chelmsford, numbered 57 Hunt Road, given by Katherine Psiras to Bank of America, N.A., dated September 15, 2008, and recorded in Middlesex County (Northern District) Registry of District Land Court in Document No. 00250128, and Noted on Certificate of Title No. 12124, and now held by Plaintiff by assignment, has/have filed with this court a complaint for determination of Defendant's/Defendants' Servicemembers status.

If you now are, or recently have been, in the active military service of the United States of America, then you may be entitled to the benefits of the Servicemembers Civil Relief Act. If you object to a foreclosure of the above-mentioned property on that basis, then you or your attorney must file a written appearance and answer in this court at **Three Pemberton Square, Boston, MA 02108** on or before December 16, 2019 or you may lose the opportunity to challenge the foreclosure on the

Chelmsford, 23 Seventh Lane
LEGAL NOTICE

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Brian Reidy, Chairman

AD#13848537
Eagle-Independent 11/15, 11/22/19

Community Outreach Meeting Notice
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AD#13848341
Eagle-Independent 11/15, 11/22/19

ATTACHMENT B:

ATTACHMENT B

Notice of Community Outreach Meeting

Notice is hereby given in accordance with M.G.L. ch. 94G and the Massachusetts Cannabis Control Commission's regulations at 935 CMR 500.000 et seq. that a Community Outreach Meeting for a proposed Marijuana Establishment is scheduled for December 10th, 2019 at 6:30 PM at Courtyard by Marriott 102 Constitution Ave, The Point, Littleton, MA 01460. The proposed Independent Testing Laboratory is anticipated to be located at 160 Ayer Rd, Unit #3, Littleton, MA, 01460.

Interested members of the community are encouraged to ask questions and receive answers from G7 Labs LLC representatives about the proposed facility and operations.

Sincerely,

G7 Labs LLC.
G7labsllc@gmail.com

ATTACHMENT B

Gmail **G7 LAB LLC <g7labllc@gmail.com>**

Notice of Community Outreach Meeting

6 messages

shankar gautam <g7labllc@gmail.com> Fri, Nov 8, 2019 at 10:57 AM
To: dcrory@littletonma.org, mtophill@littletonma.org

Dear Town Clerk,

I would like to request to file a notice of community outreach meeting with the town clerk , the planning board, the contracting authority and local licensing authority for the adult use of marijuana or any applicable board within the town of Littleton, MA. Please find the attached notice of community hearing.

A copy of this notice will be published in a local newspaper at least fourteen (14) calendar days prior to the meeting. this notice will be mailed at least fourteen (14) calendar days prior to the meeting to abutters of the purposed address of the Marijuana Establishemnt, owners of land directly opposite on any public or private street or way, and to the abutters within 300 feet of the property line of the petitioner as they appear on the most recent applicable tax list.

Thank you!

Shankar Gautam.

G7 Labs LLC.

Community outreach town publication .docx
13K

Mail Delivery Subsystem <mailer-daemon@googlemail.com> Fri, Nov 8, 2019 at 10:57 AM
To: g7labllc@gmail.com

Address not found

Your message wasn't delivered to **mtophill@littletonma.org** because the address couldn't be found, or is unable to receive mail.

LEARN MORE

This link will take you to a third-party site

The response from the remote server was:

ATTACHMENT B

550 Invalid Recipient - https://community.mimecast.com/docs/DOC-1369#550
[lQrFTyOcMZqmtKOkf0hA5Q.us121]

Final-Recipient: rfc822; mtophill@littletonma.org
Action: failed
Status: 5.0.0
Remote-MTA: dns; us-smtp-inbound-1.mimecast.com. (207.211.30.141, the server for the domain littletonma.org.)
Diagnostic-Code: smtp; 550 Invalid Recipient - https://community.mimecast.com/docs/DOC-1369#550 [lQrFTyOcMZqmtKOkf0hA5Q.us121]
Last-Attempt-Date: Fri, 08 Nov 2019 07:57:27 -0800 (PST)

---------- Forwarded message ----------
From: shankar gautam <g7labllc@gmail.com>
To: dcrory@littletonma.org, mtophill@littletonma.org
Cc:
Bcc:
Date: Fri, 8 Nov 2019 10:57:14 -0500
Subject: Notice of Community Outreach Meeting

Dear Town Clerk,

I would like to request to file a notice of community outreach meeting with the town clerk , the planning board, the contracting authority and local licensing authority for the adult use of marijuana or any applicable board within the town of Littleton, MA. Please find the attached notice of community hearing.

A copy of this notice will be published in a local newspaper at least fourteen (14) calendar days prior to the meeting. this notice will be mailed at least fourteen (14) calendar days prior to the meeting to abutters of the purposed address of the Marijuana Establishemnt, owners of land directly opposite on any public or private street or way, and to the abutters within 300 feet of the property line of the petitioner as they appear on the most recent applicable tax list.
Thank you!
Shankar Gautam.
G7 Labs LLC.

----- Message truncated -----

---

shankar gautam <g7labllc@gmail.com> Fri, Nov 8, 2019 at 11:00 AM
To: mtoohill@littletonma.org

--
[Quoted text hidden]

Community outreach town publication .docx
13K

Diane Crory <DCrory@littletonma.org> Fri, Nov 8, 2019 at 11:33 AM
To: shankar gautam <g7labllc@gmail.com>

ATTACHMENT B

I am in receipt of the posting and we will post it today. You would need to get your list of abutters from the Assessors for the 300' property lineand they are on the 2nd floor in the Assessor's Office, Room 206.

[Quoted text hidden]

G7 LAB LLC <g7labllc@gmail.com> Fri, Nov 8, 2019 at 11:47 AM
To: Diane Crory <DCrory@littletonma.org>

Thank you Diane,
I have the list of abutters.

Shankar
[Quoted text hidden]

Maren Toohill <MToohill@littletonma.org> Fri, Nov 8, 2019 at 12:01 PM
To: shankar gautam <g7labllc@gmail.com>
Cc: Diane Crory <DCrory@littletonma.org>

Thank you for providing notice to the Planning Board.

Maren

Maren A. Toohill, AICP

Town Planner

978/540-2425

MToohill@littletonma.org

Town of Littleton

[Quoted text hidden]

ATTACHMENT 'C'

ATTACHMENT C

Dear Abutter,

Notice is hereby given in accordance with M.G.L. ch. 94G and the Massachusetts Cannabis Control Commission's regulations at 935 CMR 500.000 et seq. that a Community Outreach Meeting for a proposed Marijuana Establishment is scheduled for December 10th, 2019 at 6:30 PM at Courtyard by Marriott 102 Constitution Ave, The Point, Littleton, MA 01460. The proposed Independent Testing Laboratory is anticipated to be located at 160 Ayer Rd, Unit #3, Littleton, MA, 01460.

Topics to be discussed at the meeting will include, but not be limited to:

1. The type of Adult-Use Marijuana Establishment to be located at the proposed address;

2. Plans for maintaining a secure facility;

3. Plans to prevent diversion to minors;

4. Plans to positively impact the community; and

5. Plans to ensure the establishment will not constitute a nuisance to the community.

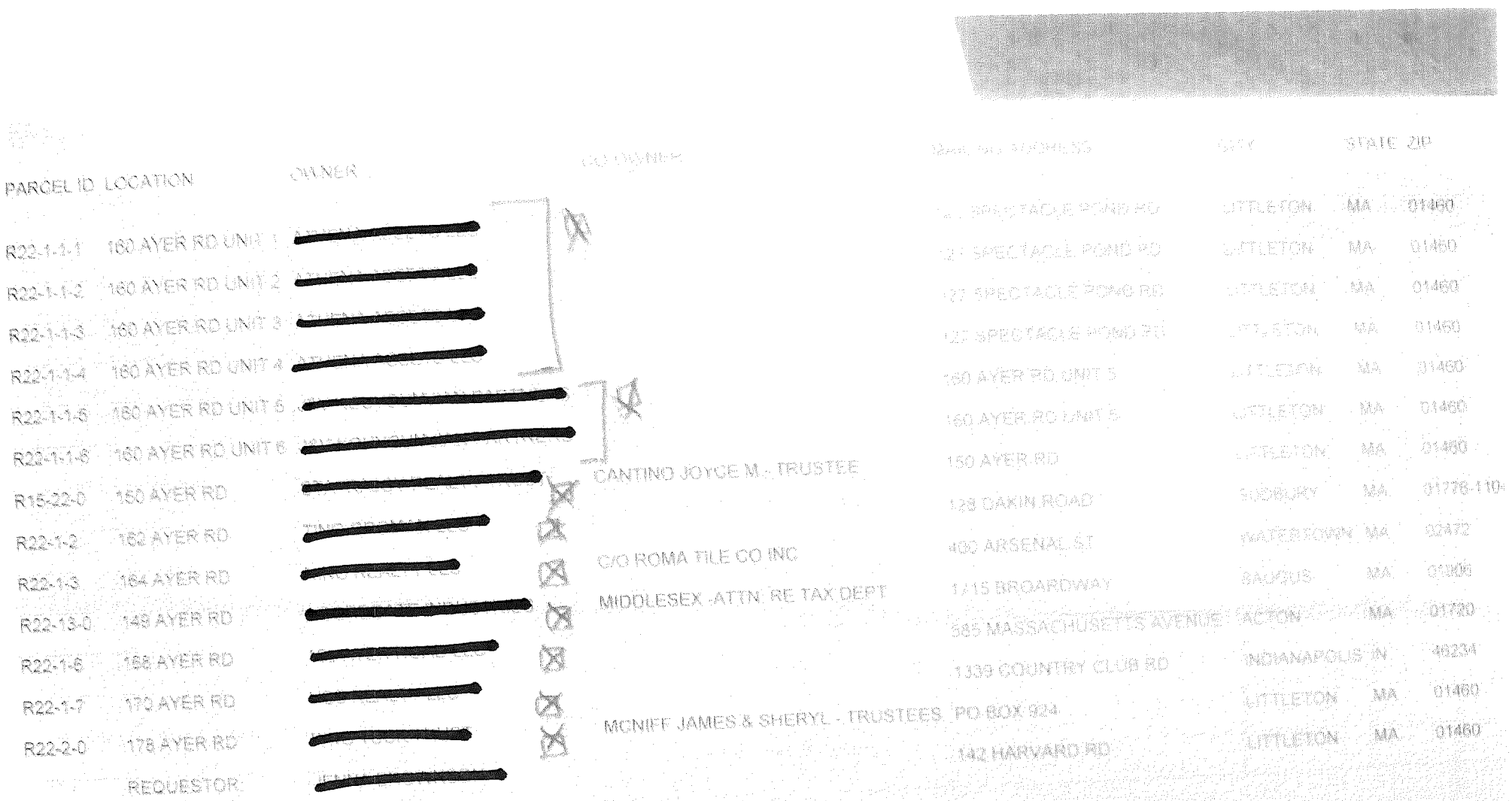
Interested members of the community are encouraged to ask questions and receive answers from G7 Labs LLC representatives about the proposed facility and operations.

A copy of this notice will be published in a local newspaper at least fourteen (14) calendar days prior to the meeting and filed with the appropriate Town entities. This notice was also mailed at least fourteen (14) calendar days prior to the meeting to abutters of the proposed address of the Marijuana Establishment, owners of land directly opposite on any public or private street or way, and to the abutters within 300 feet of the property line of the petitioner as they appear on the most recent applicable tax list.

There will be an opportunity for the public to ask questions.

Sincerely,

G7 Labs LLC.



PARCEL ID	LOCATION	OWNER	C/O OWNER	ADDRESS	CITY	STATE	ZIP
R22-1-1-1	160 AYER RD UNIT 1	[redacted]		23 SPECTACLE POND RD	LITTLETON	MA	01460
R22-1-1-2	160 AYER RD UNIT 2	[redacted]		23 SPECTACLE POND RD	LITTLETON	MA	01460
R22-1-1-3	160 AYER RD UNIT 3	[redacted]		27 SPECTACLE POND RD	LITTLETON	MA	01460
R22-1-1-4	160 AYER RD UNIT 4	[redacted]		23 SPECTACLE POND RD	LITTLETON	MA	01460
R22-1-1-5	160 AYER RD UNIT 5	[redacted]		160 AYER RD UNIT 5	LITTLETON	MA	01460
R22-1-1-6	160 AYER RD UNIT 6	[redacted]		160 AYER RD UNIT 6	LITTLETON	MA	01460
R15-22-0	150 AYER RD	[redacted]	CANTINO JOYCE M. - TRUSTEE	150 AYER RD	LITTLETON	MA	01460
R22-1-2	162 AYER RD	[redacted]		129 OAKIN ROAD	SHIRLEY	MA	01776-1104
R22-1-3	164 AYER RD	[redacted]	C/O ROMA TILE CO INC	400 ARSENAL ST	WATERTOWN	MA	02472
R22-13-0	149 AYER RD	[redacted]	MIDDLESEX -ATTN: RE TAX DEPT	1A15 BROADWAY	SAUGUS	MA	01906
R22-1-6	168 AYER RD	[redacted]		585 MASSACHUSETTS AVENUE	ACTON	MA	01720
R22-1-7	170 AYER RD	[redacted]		1339 COUNTRY CLUB RD	INDIANAPOLIS	IN	46234
R22-2-0	178 AYER RD	[redacted]	MCNIFF JAMES & SHERYL - TRUSTEES	PO BOX 924	LITTLETON	MA	01460
	REQUESTOR:	[redacted]		142 HARVARD RD	LITTLETON	MA	01460

mailed by USPS on 11/16/2019.

ATTACHMENT C

Courtyard by Marriott Boston Littleton

www.marriott.com/bosit
102 Constitution Ave
Littleton, MA 01460
Phone (978)506-5038
Fax (978)440-5039

Billing / Credit Card Authorization

FUNCTION/GROUP DATE: 12/10/2019

COMPANY NAME: G7 labs LLC

BILLING ADDRESS: 99 pond ave,Apt 408 Brookline , Ma 02445

ATTN: Shankar Gautam

IN ORDER TO ESTABLISH BILLING PRIVILEGES WITH A CREDIT CARD, PLEASE PROVIDE THE FOLLOWING INFORMATION:

CREDIT CARD NUMBER: [redacted]

EXPIRATION DATE: [redacted]

CARDHOLDER NAME: Shankar Gautam

CHARGE: ☑ ALL CHARGES ☐ ROOM & TAX ☐ INCIDENTALS ☐ GUARANTEE (CXL / ATTRITION)

All charges associated with the Cancellation and or Attrition clause will be applied to this credit card

GROUP NAME:

INDIVIDUAL RESERVATIONS/CONFIRMATION NUMBERS:

THE CARDHOLDER'S SIGNATURE MUST APPEAR BELOW IN ORDER TO ACKNOWLEDGE THIS AGREEMENT. I HEREBY AUTHORIZE THE LITTLETON COURTYARD BY MARRIOTT TO USE MY CREDIT CARD TO SETTLE MY ACCOUNT.

(CARDHOLDER'S SIGNATURE)

From: **G7 LAB LLC** g7labllc@gmail.com
Subject: Licensee renewal with CCC
Date: June 2, 2022 at 12:00 PM
To: aansaldi@littletonma.org

GL

Hi Tony,
I am renewing my License with CCC and They require me to communicate with the town requesting for any evidence or charges for community impact.
Thus, I would like to request any documentation if available for community impact and charges if any caused to the town by my business.

Thank you,
Shankar Gautam
Technical Manager
G7 Lab LLC
Independent Testing Laboratory
Certified Minority Owned Business
160 Ayer Rd, STE 3
Littleton, MA 01460

G7 Lab, LLC.
INDEPENDENT TESTING LABORATORY

G7 Lab LLC
160 Ayer Rd, STE3
Littleton, MA 01460

To
Cannabis Control Commission,
Union Station, 2 Washington Square
Worcester, MA 01604

Attestation form

Subject: No response from Town of Littleton, MA.

Signed under the pains and penalties of perjury, I, Shankar P. Gautam, an authorized representative of G7 Labs LLC certify that G7 Labs LLC did not receive a response from town of Littleton, MA when G7 Lab LLC requested a community impact cost and documentation of such cost.

Signature of Agent

6-28-2022
Date

Name: Shankar Gautam
Title: CEO/ Technical Manager
Entity: G7 Lab LLC

POSITIVE IMPACT PLAN

Goals: Provide financial support to Massachusetts Recreational Consumer Council because it is an entity that offers support, education and/or job training to Massachusetts residents disproportionately impacted by the War on Drugs. The amount of this donation will depend on the financial growth and profitability of the company. As sales and profits increase, G7 Lab LLC ("G7 Lab") will revisit its program donation goals to consider more generous donations as business allows.

Goal: Donate a total of $5,000.00 annually[1] to the organization as more particularly described below.

Program: The donation to be made to the following organizations are intended to benefit its ability to develop skills for Economic Empowerment Priority Applicants and Social Equity Training Program participants through mentoring, educational and informational events with cannabis industry networking opportunities, and to provide financial support to allow them to continue educating adult- use cannabis consumers in Massachusetts:

> Massachusetts Recreational Consumer Council ($5,00.00 annual donation) to be paid 6 months after receiving final licensure and every year thereafter.

Measurement and Accountability: At the end of each year, G7 Lab will conduct an analysis and create a report on the amounts and percentages of donations and other financial support that the company has given to the programs outlined above. G7 Lab will continue to assess the viability and impact of financial donations made, and annually review donation goals amounts.

G7 Lab acknowledges and is aware, and will adhere to, the requirements set forth in 935 CMR 500.105(4) which provides the permitted and prohibited advertising, branding, marketing, and sponsorship practices of every Marijuana Establishment.

Any actions taken, or programs instituted by G7 Lab, will not violate the Commission's regulations with respect to limitations on ownership or control or other applicable state laws.

G7 Lab expressly understands that the progress or success of this plan will be required to be demonstrated upon each annual license renewal period in conformity with 935 CMR 500.101(1) and (2).

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[1] Upon renewal of licensure, with the renewal application to be submitted at least 60-days prior to the anniversary date of the grant of provisional licensure.

The Commonwealth of Massachusetts
Secretary of the Commonwealth
State House, Boston, Massachusetts 02133

William Francis Galvin
Secretary of the Commonwealth

March 16, 2020

TO WHOM IT MAY CONCERN:

I hereby certify that a certificate of organization of a Limited Liability Company was filed in this office by

G7 LAB LLC

in accordance with the provisions of Massachusetts General Laws Chapter 156C on **February 18, 2019.**

I further certify that said Limited Liability Company has filed all annual reports due and paid all fees with respect to such reports; that said Limited Liability Company has not filed a certificate of cancellation; that there are no proceedings presently pending under the Massachusetts General Laws Chapter 156C, § 70 for said Limited Liability Company's dissolution; and that said Limited Liability Company is in good standing with this office.

I also certify that the names of all managers listed in the most recent filing are: **SHANKAR GAUTAM**

I further certify, the names of all persons authorized to execute documents filed with this office and listed in the most recent filing are: **SHANKAR GAUTAM, PRATIMA BHATTARAI**

The names of all persons authorized to act with respect to real property listed in the most recent filing are: **SHANKAR PRASAD GAUTAM**

In testimony of which,
I have hereunto affixed the
Great Seal of the Commonwealth
on the date first above written.

William Francis Galvin

Secretary of the Commonwealth

Processed By:KMT

Commonwealth of Massachusetts
Department of Revenue
Kevin W. Brown, Acting Commissioner

mass.gov/dor

Letter ID: L0546159680
Notice Date: March 19, 2020
Case ID: 0-000-878-799

CERTIFICATE OF GOOD STANDING AND/OR TAX COMPLIANCE

SHANKAR GAUTAM
G7 LAB LLC
160 AYER RD UNIT 3
LITTLETON MA 01460-1103

Why did I receive this notice?

The Commissioner of Revenue certifies that, as of the date of this certificate, G7 LAB LLC is in compliance with its tax obligations under Chapter 62C of the Massachusetts General Laws.

This certificate doesn't certify that the taxpayer is compliant in taxes such as unemployment insurance administered by agencies other than the Department of Revenue, or taxes under any other provisions of law.

This is not a waiver of lien issued under Chapter 62C, section 52 of the Massachusetts General Laws.

What if I have questions?

If you have questions, call us at (617) 887-6400 or toll-free in Massachusetts at (800) 392-6089, Monday through Friday, 8:30 a.m. to 4:30 p.m..

Visit us online!

Visit mass.gov/dor to learn more about Massachusetts tax laws and DOR policies and procedures, including your Taxpayer Bill of Rights, and MassTaxConnect for easy access to your account:

- Review or update your account
- Contact us using e-message
- Sign up for e-billing to save paper
- Make payments or set up autopay

Edward W. Coyle, Jr., Chief
Collections Bureau

AMENDED AND RESTATED OPERATING AGREEMENT

OF

G7 LAB LLC

(a Member-Managed Massachusetts Limited Liability Company)

Effective as of April 1, 2020

THE UNITS REPRESENTED BY THIS OPERATING AGREEMENT HAVE NOT BEEN REGISTERED UNDER THE UNITED STATES SECURITIES ACT OF 1933, AS AMENDED, OR UNDER ANY OTHER APPLICABLE SECURITIES LAWS. SUCH UNITS MAY NOT BE SOLD, ASSIGNED, PLEDGED OR OTHERWISE DISPOSED OF AT ANY TIME WITHOUT EFFECTIVE REGISTRATION UNDER SUCH ACT AND LAWS OR EXEMPTION THEREFROM, AND COMPLIANCE WITH THE OTHER SUBSTANTIAL RESTRICTIONS ON TRANSFERABILITY SET FORTH HEREIN.

AMENDED AND RESTATED OPERATING AGREEMENT

OF

G7 LAB LLC

(a Massachusetts Limited Liability Company)

This AMENDED AND RESTATED OPERATING AGREEMENT (this "***Agreement***") of G7 LAB LLC, a limited liability company organized under the laws of the Commonwealth of Massachusetts (the "***Company***"), is entered into and made effective as of April 1, 2020 by and among the Company, Shankar P. Gautam, a domiciliary of the Commonwealth of Massachusetts, Pratima Bhattarai, a domiciliary of the Commonwealth of Massachusetts, and all other persons or entities who shall execute and deliver this Agreement or authorized counterparts or facsimiles of the same pursuant to the provisions hereof.

This Agreement supersedes and replaces all prior agreements, written or oral, between each of its signatories, on any subject matter provided for in this Agreement or on any subject related to the governance of the Company or the rights, duties, powers and obligations of the Members of the Company to each other. Without limiting the generality of the foregoing, this Agreement supersedes and replaces, in its entirety, that certain Operating Agreement of the Company having an execution date of May 7th, 2019.

WHEREAS, the Company was formed by the filing of the Certificate of Organization of the Company with the Secretary of the Commonwealth of Massachusetts on February 18, 2019;

WHEREAS, the Members and the Company intend that this Agreement shall set forth the understanding amongst them with respect to the terms and conditions of their respective interests, rights and obligations with respect to the Company, its management and operation, and the economic arrangement between the Members with respect to the Company; and

NOW, THEREFORE, the parties hereto, intending to be legally bound hereby, agree as follows:

GENERAL

Definitions. Certain capitalized terms used in this Agreement shall have the respective meanings set forth on **Schedule B** attached hereto and made a part hereof, unless otherwise expressly provided herein or unless the context otherwise requires. Certain capitalized terms not defined herein may be defined in the provisions of the Massachusetts Limited Liability Company Act.

Overview. This Agreement sets forth, among other things, the manner in which the Company will be operated and the manner in which the profits and losses of the Company will be shared by the Members.

Name. The name of the Company shall be G7 LAB LLC.

Principal Office. The principal office of the Company shall be at 160 Ayer Rd, Unit 3, Littleton, MA 01460 or at such other place or places as the Members may determine from time to time.

Registered Office. The registered office of the Company shall be the office of the initial registered agent named in the Certificate of Organization or such other office (which need not be a place of business of the Company) as the Members may designate from time to time in the manner provided by the Act and applicable law.

The registered agent for service of process on the Company in the Commonwealth of Massachusetts shall be the initial registered agent named in the Certificate of Organization or such other Person or Persons as the Members may designate from time to time in the manner provided by the Act and applicable law.

Term. The Company commenced on February 18, 2019, the date that the Certificate of Organization of the Company was filed with the Massachusetts Secretary of the Commonwealth and shall continue in existence in perpetuity or until earlier dissolved in accordance with the provisions of this Agreement and the Act.

Purpose. Within the meaning of 935 CMR 500.1 *et. seq.*, and the other rules and regulations set forth by the Cannabis Control Commission or any other law or rule of the Commonwealth of Massachusetts related to the conduct of a lawful cannabis-related business, the principal purpose of the Company is to conduct a lawful cannabis-related business, specifically, a lawful cannabis testing facility. The Company is authorized to perform any act necessary and incidental to further its principal purpose. No term or provision of this Agreement inconsistent with such purpose is enforceable.

Title to Property. All Company Property shall be owned by the Company as an entity and no Member shall have any ownership interest in such property in his, her or its individual name or right solely by reason of being a Member, and except as otherwise provided in this Agreement, each Member's interest in the Company shall be personal property for all purposes. The Company shall hold all Company Property in the name of the Company and not in the name of any Member.

Operating Agreement and the Act. This Agreement shall constitute the "operating agreement" (as that term is used in the Act) of the Company. The rights, powers, duties, obligations and liabilities of the Members shall be determined pursuant to the Act and this Agreement. To the extent that the rights, powers, duties, obligations and liabilities of any Member are different by reason of any provision of this Agreement than they would be under the Act in the absence of such provision, this Agreement shall, to the extent permitted by the Act, control.

Special Provisions Relating to the Operation of a Cannabis-Related Business in Massachusetts. To the extent required under the laws of the Commonwealth of Massachusetts including, without limitation, the applicable rules and regulations of the Cannabis Control Commission, the Company shall have the stated and specific purpose of operating a lawful cannabis-related business. Other provisions of this Agreement notwithstanding, the Company shall have no power, nor any of its Members or Managers have the power, to cause the

Company to do anything, or be organized in any fashion, with such applicable laws. No person may be a Member whose status as a Member or holder of any Units of the Company would cause the Company to be ineligible to receive a license to conduct a cannabis-related business in the Commonwealth of Massachusetts. The commission of any act by any Member tending to render the Company ineligible for a license to conduct a cannabis-related business in Massachusetts shall constitute sufficient independent grounds for the expulsion of that Member, without recourse and without the need for notice, from the Company. No person who is a license-holder or partial holder or owner of a license to conduct any cannabis-related business other than a licensed Massachusetts cannabis testing facility may be a Member or hold any actual or *de facto* interest in, or control over, the Company. Any Member's acquiring or attempting to acquire such an interest shall terminate, by operation of law and without notice, that Member's interest in the Company.

MEMBERS

Meetings of Members. The Members shall meet at least once each Fiscal Year at the principal office of the Company or at such other place within or outside of the Commonwealth of Massachusetts as the Members may agree, on such date and at such time as may be fixed by the Members for the transaction of such lawful business as may come before the meeting. Special meetings of the Members may be called by any Member upon written notice to the other Members or by telephone or facsimile, which notice must be given no fewer than two (2) business days and no more than sixty (60) days prior to the date of the meeting. No business shall be acted upon at a special meeting that is not stated in the notice of the meeting. Meetings of Members may be held by telephone or any other communications equipment, by means of which all participating Members can simultaneously hear each other during the meeting. Special meetings shall be held at the principal office of the Company or at such other place within or outside of the Commonwealth of Massachusetts as the Members may agree. All meetings of the Members shall be called to order and presided over by such Person or Persons who may be designated by the Members.

Quorum. Unless a quorum consisting of at least a Majority of the Management Interests of the Members is present in person or by proxy, no action may be taken at a meeting of Members.

Action by Written Consent. Any action that may be taken at a meeting of the Members may be taken without a meeting, if a consent or consents in writing, setting forth the action so taken, shall be signed by Members whose percentage of Units would be sufficient to approve the action at a meeting of the Members. All Members who do not participate in taking the action by written consent shall be given written notice thereof by the Company promptly after such action has been taken.

Voting Rights; Required Vote. Each Member shall be entitled to vote his, her or its Units to the extent such Units bear Management Interests with respect to any action required or permitted to be taken by the Members under this Agreement. All such actions that require the vote, consent or approval of the Members shall require the affirmative vote, consent or approval of a Majority of the Management Interests, as represented by Units, of the Members, unless the question or matter is one upon which, by express provision of applicable law or of the

Certificate of Organization or this Agreement, a different vote is required, and in which case, such express provision shall govern and control the decision of such question or matter.

Deadlock. In the event that a proposed action of the Members does not receive the vote, consent or approval of a Majority of the Management Interest of the Members pursuant to this Agreement and results in a deadlock of the Members (a "***Deadlock***"), the Deadlock shall be resolved as follows:

1. The Members shall mutually agree upon an independent third-party of relevant experience and competence to decide the matter by mediation.
2. If after 30 days of mediation the matter still has not been decided, the Company shall be dissolved.

Proxies. Every Member entitled to a vote may vote either in person or by proxy. Every proxy shall be executed in writing by the Member or by his, her or its duly authorized attorney-in-fact and filed with the corporate records of the Company. A proxy, unless coupled with an interest, shall be revocable at will by the Member authorizing the proxy, notwithstanding any other agreement or any provision in the proxy to the contrary, but the revocation of a proxy shall not be effective until written notice thereof has been received by the Company.

Issuance of Additional Units. The Company may not sell or issue additional Units or other equity interests in the Company ("***New Units***") without the affirmative vote, consent, or approval of a Majority of the Management Interest of the Members. Until there are more than two Members, such a decision shall require the unanimous consent of the Members. Dilution, whether or not *pro rata*, shall be determined at the time of issuance of such Units by a majority vote of the Management Interest of the Members.

Preemptive Rights of Members. Any sale and issuance of New Units shall be subject to the following preemptive rights of the Members (the "***Preemptive Rights***"):

The Company must first offer each Member the opportunity to purchase up to a percentage of the New Units equal to such Member's Percentage Interest of Units at the time of the proposed offering, so that, after the issuance of all such proposed New Units, such Member's Percentage Interest of Units will be the same as the Percentage Interest of Units maintained by such Member immediately prior to the issuance of any such New Units.

Activities of Members. To the extent permitted under the Act, the following provisions shall apply:

Nothing in this Agreement shall preclude any Member, or any Affiliates of any Member, from engaging in other transactions and possessing interests and making investments in and loans to other business ventures of any nature or description (except, without limitation, businesses that compete directly with the Company), independently or with others, whether existing as of the date hereof or hereafter coming into existence, and neither the Company nor any other Member shall have any rights in or to any such other transactions, investments or ventures or the income or profits derived therefrom, except to the extent that no Member may have any such interests, investments, or loans owed from any lawful cannabis business that is not a Massachusetts cannabis testing facility.

Subject to the other express provisions of this Agreement, each Member and agent of the Company at any time and from time to time may engage in and possess interests in other business ventures of any and every type and description, other than a lawful cannabis business that is not a Massachusetts cannabis testing facility, independently or with others, ventures not in direct competition with the Company, with no obligation to offer to the Company or any other Member or agent the right to participate therein.

Liability of the Members. Except as otherwise provided by the Act or as contemplated by this Agreement, the debts, obligations and liabilities of the Company, whether arising in contract, tort or otherwise, shall be solely the debts, obligations and liabilities of the Company. No Member shall be obligated personally or have any liability for the debts, obligations or liabilities of the Company or for the acts or omissions of any other Member, officer, agent or employee of the Company, except to the extent provided in the Act or as specifically and expressly agreed to by such Member in writing.

No Withdrawal. A Member shall not cease to be a Member as a result of a Bankruptcy of such Member or as a result of any other events specified in the Act. So long as a Member continues to hold any Units, such Member shall not have the ability to withdraw or resign as a Member prior to the dissolution and winding up of the Company and any such withdrawal or resignation or attempted withdrawal or resignation by a Member prior to the dissolution or winding up of the Company shall be null and void absent the unanimous consent of the remaining Members. As soon as any Person who is a Member ceases to hold any Units, such Person shall no longer be a Member.

Compensation; Expenses. Members shall not be entitled to receive any salary, fee or draw for services rendered to or on behalf of the Company or otherwise in its capacity as a Member, unless otherwise approved by the Members; *provided, however*, that Members shall be entitled to be reimbursed for reasonable and necessary out-of-pocket costs and expenses incurred in the course of their services hereunder. Members who are also *bona fide* employees of the Company may receive salaries from the Company in their capacity as employees.

Priority and Return of Capital. No Member shall have priority over any other Member, either as to the return of Capital Contributions or as to Profits, Losses or distributions; *provided, however*, that this Section shall not apply to loans that a Member has made to the Company as authorized herein, or the terms of any New Units authorized in accordance with the terms of this Agreement.

No Company Certificates. The Units of the Members in the Company shall not be certificated.

Names and Capital Contributions of Members. The names of the Members, along with the number of Units owned by such Members and their respective Capital Contributions and Percentage Interests, are as set forth on **Schedule A**, attached hereto and made a part hereof. The Members shall cause **Schedule A** to be updated as necessary from time to time.

Confidentiality. Each Member acknowledges that in their capacity as a member or principal of a Member, employee or officer of the Company they may from time to time be entrusted with various types of Confidential Information (e.g., customer lists, financial

information, marketing strategies, production techniques, software etc.) and other information of a privileged and confidential nature which, upon disclosure, would be highly prejudicial to the interests of the Company (collectively the "Confidential Information").

Any matters, financial or otherwise, with respect to the Company, its subsidiaries or Affiliates, including without limitation the terms of this Agreement, which are not divulged by the Company to the public in the ordinary course of its Business shall be deemed to be Confidential Information and any Member who wishes to divulge such Confidential Information to any third party (other than a purchaser as permitted under this Agreement who is subject to obligations of confidentiality in favor of the Company) shall, as a condition to such divulging, obtain the prior approval of a Member. Each Member acknowledges and agrees that the right to possess and maintain confidentially all such Confidential Information constitutes a proprietary right of the Company which the Company is entitled to protect.

Each Member agrees that it will not at any time, whether then a Member of the Company or not, directly or indirectly disclose Confidential Information to any Person (other than as required in the performance of a Member's duties or to a Member's own professional advisors on a need-to-know basis or to a purchaser as permitted under this Agreement who is subject to obligations of confidentiality in favor of the Company) not authorized by the Company to receive such information except as required by law or court order.

Each Member shall return to the Company all property, written information and documents of the Corporation and all Confidential Information and all copies of the same, whether in written, electronic or other form and certify as to such information's return or destruction forthwith upon his or her cessation as a Member. For greater certainty, nothing in this Agreement imposes liability upon any Member for making disclosures of Confidential Information where such disclosure (a) is required by law or court order; or (b) is otherwise disclosed not as a result of a breach by the Member of his, her or its obligations hereunder.

Exceptions to Confidentiality Related to the Business of the Company. In the event that the Company enters into any line of business that is or may become subject of regulation that requires the public or private disclosure to any regulator or other entity of information that would otherwise constitute Confidential Information, including without limitation a requirement by the Massachusetts Department of Agriculture or the Cannabis Control Commission to disclose the material terms of otherwise-Confidential Information such as the material terms of this Agreement, such information shall not constitute Confidential Information to the limited extent of permitting the Members to disclose the minimum amount of otherwise-Confidential Information required under any such law or regulation.

Non-Solicitation. None of the Officers nor any Members or their respective Affiliates shall, directly or indirectly, (i) solicit, entice away or in any other manner persuade or attempt

to persuade any employees, contractors or vendors of the Company to alter his, her or its relationship with the Company or its business or (ii) engage or employ any former employees, contractors, vendors of the Company for a period of three (3) years after such persons or entities have severed their relationship with the Company (except (*y*) if such employee is terminated by the Company or (*z*) if such employee is responding to a newspaper advertisement, job posting or other general solicitation not targeted at such employee). For purposes of clarification, the parties agree that the limitations contained in clause (ii) of the preceding sentence shall not apply to any regional, national, or international firms engaged by the Company.

MANAGEMENT AND OFFICERS

Management. The business and affairs of the Company will be managed by the Members. The Members shall conduct the business of the Company consistent with its purposes as set forth in herein in a prudent and businesslike manner. The Members shall have full and complete authority, power and discretion to manage and control the business, affairs and properties of the Company, to make all decisions regarding those matters and to perform any and all other acts or activities customary or incident to the management of the Company's business, except for decisions expressly requiring a vote of the Members as provided herein.

The initial Members of the Company shall be Shankar P. Gautam, a domiciliary of the Commonwealth of Massachusetts, and Pratima Bhattarai, a domiciliary of the Commonwealth of Massachusetts. A Member may be removed only for cause. The Members may style themselves or hold themselves out to the general public as a "Member" or other customary and usual terms denoting the authority to act on behalf of the Company.

Where the Members designate one or several of themselves as Managers, such designation shall be by their unanimous consent, and shall confer only those powers permitted by the Act, which the Members may limit or expand at their discretion.

Specific Rights and Powers of the Board. The Company shall have a Board of Directors initially comprised of the initial Members of the Company. The Board my make any decisions on behalf of the Company, or delegate such powers to those Members comprising the Board at their discretion. Decisions among Members of the Board, where the Board has an even number of Members, shall be subject to the deadlock provisions regarding mediation and other resolution provided as to ordinary decisions of the Members. Any decision that the Manager makes shall be deemed made by the Board except where the Board expressly prohibits or overrides an action of the Manager.

Without limiting the generality of this Section, the Board shall have the power and authority on behalf of the Company to do the following, except where such act would constitute an act requiring a vote as provided elsewhere herein:

Execute any and all documents or instruments of any kind that the Member deems necessary or appropriate to achieve the purposes of the Company, including, without limitation, contracts, agreements, leases, subleases, easements, deeds, notes, mortgages and

other documents or instruments of any kind or character or amendments of any such documents or instruments;

Borrow money from individuals, banks and other lending institutions on the general credit of the Company for use in the Company business, all upon such terms and containing such features as the Member may determine to be necessary or desirable in its absolute discretion, except that any such debt in excess of $1,000 shall require the unanimous consent of the initial Members;

Confess judgment against the Company and to execute any document granting to any Person the right to confess judgment against the Company in the event of the Company's default in the performance of its obligations under any loan agreement, note, or other agreement or instrument;

Incur, secure, renew, replace, refinance, modify, extend, repay or otherwise discharge any indebtedness of the Company;

Sell, exchange, lease, mortgage, pledge, assign, or otherwise transfer, dispose of or encumber all or a portion of the Company Property or any interest therein;

Procure and maintain, at the expense of the Company and with responsible companies, such insurance as may be available in such amounts and covering such risks as the Member shall deem necessary or desirable in the Member's absolute discretion, including insurance policies insuring the Member against liability arising as a result of any action he or she may take or fail to take in his capacity as Member of the Company;

Employ and dismiss from employment any and all Company employees, agents, independent contractors, attorneys and accountants;

Supervise the preparation and filing of all Company tax returns;

Open, maintain and close bank and investment accounts and arrangements, draw checks and other orders for the payment of money, and designate individuals with authority to sign or give instructions with respect to those accounts and arrangements;

Engage in correspondence with any regulatory or governmental body, including the Internal Revenue Service and the Securities and Exchange Commission;

Delegate any or all of the administrative and managerial powers conferred upon a general manager or to Officers, employees or agents of the Company;

Bring, defend or settle actions at law or equity; and

Retain and compensate on behalf of the Company such accountants, attorneys, realtors, tax specialists, management companies, consultants or other professionals as the Member shall deem necessary or desirable in the Member's absolute discretion in order to carry out the purposes and business of the Company.

Determining the Board; Procedures for Board Elections. The Board may expand or reduce its number at any time by the unanimous decision of the Board Members (except,

where being reduced, the assent of a Board Member being removed by such a reduction is not required unless that Board Member is one of the initial Members of the Company, in which case the Initial Members shall act in unanimity). The Board may create additional Board Member seats without the specific appointment of such a Board Member. The addition or removal of a Board Member shall not affect a Members' status *qua* a Member, I.e., the removal of a Board Member from the Board shall not constitute the expulsion of that Member from the Company.

Actions Requiring a Vote. Any elective purchase by the Company, or the creation of new indebtedness, in excess of $10,000 in a single transaction or series of related transactions shall require the Manager to deliver written notice of such transaction to the Members, who may vote upon such transaction at their discretion.

Authority of Attorneys-In-Fact, Employees, Agents and Members. Unless authorized to do so by this Agreement or by the Members, no attorney-in-fact, employee or other agent of the Company shall have any power or authority to bind the Company in any way, to pledge its credit, or to render it liable for any purpose.

Records, Audits and Reports. Proper and complete records and books of account shall be kept by the Company. The books and records shall at all times be maintained at the principal office of the Company and shall be open to the reasonable inspection and examination of the Members or their duly authorized representatives for any proper purpose relating to the Company during normal business hours.

Returns and Other Elections. The Members shall cause the preparation and timely filing of all tax returns required to be filed by the Company pursuant to the Code and all other tax returns deemed necessary and required in each jurisdiction in which the Company does business. Copies of such returns or pertinent information therefrom, will be furnished to the Members within a reasonable time after the end of the Company's Fiscal Year as required by law or upon a Member's written request. All elections permitted to be made by the Company under federal or state laws will be made by the Members by their unanimous decision. Each of the Members acknowledges and agrees that in no event shall another Member or the Company be liable or otherwise responsible for the tax treatment or tax-related aspects of any investment or other activity of the Members or the Company, it being understood that each Member should consult his or her own tax advisers regarding such matters.

Tax Matters Partner. The Members shall designate a "***Tax Matters Partner***" (as defined in Code Section 6231) who shall be authorized and required to represent the Company (at the Company's expense) in connection with all examinations of the Company's affairs by tax authorities, including, without limitation, administrative and judicial proceedings, and to expend Company funds for professional services and costs associated therewith. The Members agree to cooperate with each other and to do, or refrain from doing, any and all things reasonably required to conduct such proceedings. The initial Tax Matters Partner shall be Shankar Gautam.

Officers. The Members may from time to time elect or appoint one or more officers of the Company, and such officers shall have such titles, powers, duties and tenure as the Members shall from time to time determine. Vacancies may be filled or new offices created and filled by resolution of the Members. Any officer or agent elected or appointed by the Members may be

removed by the Members whenever in their judgment the best interests of the Company would be served; *provided, however*, that such removal shall be without prejudice to the contract rights, if any, of the person so removed. An officer is not required to be a Member. No officer shall be delegated the authority to take any action requiring the approval of the Members without the prior consent of such Members as are required to approve such actions. The Company shall have a Manager who is also a Member, who shall have all the powers of a Manager under the Act and as provided for in this Agreement. The initial Manager of the Company shall be Member Shankar Gautam, who may not be removed without his consent.

Checks, Notes, Etc. The Members shall from time to time designate the officers or agents of the Company who shall have power, in its name, to sign and endorse checks and other negotiable instruments and to borrow money for the Company, and in its name, to make notes or other evidences of indebtedness.

CONTRIBUTIONS TO THE COMPANY AND CAPITAL ACCOUNTS

Capital Contributions. The Members have contributed to the capital of the Company, as their "Initial Capital Contributions," the sums (whether in cash, by contribution of property, or a combination thereof) set forth on **Schedule A** to this Agreement. No allocation of Units in the Company shall be based in part or in whole upon Initial Capital Contributions. Nothing in this Agreement shall prevent any Member from claiming their Initial Capital Contributions as business-related expenses for tax purposes. No Member shall have any obligation to contribute any additional amount to the capital of the Company. Loans made to the Company by a Member pursuant to the below subsection shall not be deemed to be Capital Contributions.

Loans by Members. Any one or more Members may, but shall not be obligated to, loan to the Company additional amounts from time to time to enable the Company to meet operating expenses and other cash needs; *provided, however*, that each such loan shall be approved by the Members. Each such loan shall be at such rate of interest and be subject to such terms and conditions that are fair and reasonable to the Company and comparable to the terms otherwise generally available at the time from commercial lenders. Each such loan shall be evidenced by a written note executed by the Company and delivered to the Member making the loan.

Limitation on Return of Capital. None of the Members shall be entitled to a return of capital at any fixed time or upon demand, to receive interest on capital or to receive any distribution from the Company. In furtherance of and not in limitation of the foregoing sentence, the Members shall not have any right of any return of their Capital Contributions. A Member is not required to contribute or lend any cash or property to the Company to enable the Company to return any Member's Capital Contributions.

Capital Accounts.

The Company shall maintain a separate Capital Account for each Member. Capital Accounts shall not govern distributions by the Company to the Members, it being understood that Capital Accounts shall be maintained solely to assist the Company in allocating Tax Items.

The Capital Account of each Member shall be increased by an amount equal to such Member's Capital Contribution as and when paid and by such Member's share of Profits, and reduced by such Member's share of Losses and the amount of any distributions to such Member. Each Member's Capital Account will be maintained and adjusted in accordance with the Code and the Treasury Regulations thereunder, including the adjustments to capital accounts permitted by Section 704(b) of the Code and the Treasury Regulations thereunder in the case of a Member who receives the benefit or detriment of any basis adjustment under Sections 734, 743 and 754 of the Code. It is intended that appropriate adjustments will thereby be made to Capital Accounts to give effect to any Tax Item that is allocated pursuant to this Agreement and any adjustments to the allocation of any such item subsequently made upon audit by the Internal Revenue Service or otherwise. Each Member's Capital Account will include the Capital Account, as so adjusted, of any predecessor holders of the interest of such Member in the Company.

Capital Deficits. None of the Members shall be obligated to repay to the Company, any other Member or any creditor any deficit in such Member's Capital Account arising at any time during the term of the Company or upon dissolution and liquidation of the Company. The Members shall not be liable for the return of the capital of the Members and it is expressly understood that any such return shall be made solely from the Company's assets.

ALLOCATION OF PROFITS AND LOSSES

Allocation of Profits and Losses. Except as otherwise expressly provided in this Agreement, all Profits or Losses of the Company (including each item of income, gain, loss, deduction or credit entering into the computation thereof) for each Fiscal Year shall be allocated among the Members in accordance with their respective Economic Interests; *provided, however*, that (a) if one or more Members shall have positive balances in their Capital Accounts and one or more Members shall have deficit balances in their Capital Accounts, Profits shall first be allocated to those Members having deficit balances in their Capital Accounts to the extent of and in proportion to such deficit balances, and (b) if one or more Members shall have deficit balances in their Capital Accounts and one or more Members shall have positive balances in their Capital Accounts, Losses shall first be allocated to those Members having positive balances in their Capital Accounts to the extent of and in proportion to such positive balances. Capital Accounts will not govern distributions by the Company to the Members, it being understood that Capital Accounts will be maintained solely to assist the Company in allocating Tax Items of the Company.

§280E Profits and Losses. In the event that the Company ends its fiscal year with a net cash balance lower than the net cash balance with which it began the year, the Company shall be deemed to have had a "Loss" to that extent regardless of the tax deductibility of certain of the Company's expenses owing to the provisions of §280E of the Code. The Company may not pass along any gains to any Member where, but for §280E of the Code, the Company would have taken a Loss as set forth on its tax return for that year. Any such gains (or "Profits"), where there are gains on the basis of the §280 non-deductibility of certain otherwise-deductible expenses, shall be deemed retained earnings by the Company.

Compliance with the Code. The allocation provisions in this Section are intended to comply with applicable provisions of the Code, including regulations promulgated under

Section 704 of the Code, and successor statutes and regulations thereof, and shall be interpreted and applied in a manner consistent with such statutory and regulatory provisions.

Allocation of Profits and Losses upon Transfer or Change in Units. It is agreed that if all or a portion of a Member's Units are transferred or adjusted as permitted herein, Profits and Losses for the transfer's Fiscal Year shall be allocated between the transferor and the transferee based upon the number of days in said Fiscal Year that each owned such Units, without regard to the dates upon which income was received or expenses were incurred during said Fiscal Year, except as otherwise required by the provisions of Code Section 706 and Treasury Regulations thereunder or as the transferor and transferee may agree with the Board's consent.

Contributed Property. Notwithstanding anything contained herein to the contrary, if a Member contributes property to the Company having a fair market value that differs from its adjusted basis at the time of contribution, then items of income, gain, loss and deduction with respect to such property shall be shared among the Members so as to take account of the variation between the adjusted tax basis of the property to the Company and its fair market value at the time of contribution, in the manner prescribed in Code Section 704(c) and the Treasury Regulations thereunder. Any applicable tax elections will be made by the Board and shall be binding on all Members.

DISTRIBUTIONS

Tax Distributions.

The Company shall make distributions pursuant to this Section to each Member in an amount no less than the federal, state and local income tax liability of such Member as a result of the allocations of Tax Items to such Member. Any distribution made by reason of this Section is referred to as a "***Tax Distribution***."

Each Tax Distribution shall be made not less than five (5) business days before the next occurring due date for federal estimated income tax payments. In determining the amount of any Tax Distribution, it shall be assumed that the Tax Items were the only items entering into the computation of tax liability of the Members.

Notwithstanding anything in this Section, the Company shall not be obligated, and the Members shall not be obligated to cause the Company, to borrow funds or obtain additional Capital Contributions to fund Tax Distributions.

Limitation upon Distributions. No distributions of any nature shall be permitted under this Section if, after any such distribution, either (i) the net assets of the Company would be less than zero, (ii) the Company would be insolvent or (iii) the Company would not have sufficient cash available to meet the reasonably anticipated needs of the Company, as such needs are determined in the reasonable discretion of the Members. Notwithstanding any provision to the contrary contained in this Agreement, the Company shall not make any distribution to Members if such distribution would otherwise violate the Act or other applicable law.

TRANSFER OF UNITS

Restrictions on Sale or Other Disposition. Except as otherwise provided for in this Agreement, each Member agrees not to sell, assign, transfer, give, donate, bequeath, pledge, deposit or in any way alienate, encumber, hypothecate, or dispose of (collectively, "***Transfer***") all or any portion of such Member's Units now owned or hereafter acquired by such Member. Any purported Transfer or other disposition of Units or assets of the Company in violation hereof shall be void and ineffectual and shall not operate to transfer any interest or title to the purported transferee.

Members' Right of First Refusal.

If a Member desires to Transfer any of his, her or its Units to any transferee other than those expressly permitted in this Section or any Units owned by any Member shall be subject to sale or other Transfer by reason of (i) bankruptcy or insolvency proceedings, whether voluntary or involuntary, (ii) distribution of marital property following divorce, or (iii) distraint, levy, execution or other involuntary Transfer, then such selling Member, or Member otherwise affected by such Transfer (in either case, a "***Selling Member***"), shall, as soon as reasonably practical (but in the case of a proposed Transfer pursuant to subsection (i), at least sixty (60) days prior to the effective date of such proposed Transfer), submit in writing to the other Member the proposed terms and conditions of the proposed Transfer (the "***Terms***"). Such Terms shall include, without limitation, the price to be received by the transferee (or in the case of a proposed Transfer pursuant to subsection (ii), the price, value or consideration, if readily determinable, on the basis of which such Units are proposed to be transferred to such transferee), the number of Units to be transferred (the "***For Sale Units***") and the proposed transferee. After receipt of the Terms of the proposed Transfer, the other Member will have thirty (30) days (the "***Notice Period***") to exercise its right of first refusal hereunder to redeem the For Sale Units at the lesser of (xi) the price or value as may be set forth in the Terms or (xii) the Agreed Value, with the terms of such consideration to be paid for the Units to be in the manner as stated herein, by notifying the Selling Member in writing of its intention to exercise its first refusal right.

Notwithstanding anything herein to the contrary, in the event of the purchase by a Member of another Member's Units pursuant to this Section due to the death of a Member, if at the time of such death the Company has in place a key man life insurance policy on such Member, then the proceeds from such life insurance policy shall be applied to the purchase price for such deceased Member's Units and, if applicable, the Closing Date shall be delayed to allow for the administration and receipt of such life insurance proceeds from the insurer.

Restrictions Applicable to All Transfers. Except as may be otherwise set forth herein, all Transfers of Units will be subject to the following conditions:

Prior to any Transfer, the Transferor will cause the prospective transferee, if not already a Member, to execute and deliver to the Company and the other Members a joinder to this Agreement; and

The Units have not been registered under the Securities Act of 1933 or any applicable state securities laws, and may not be transferred in the absence of an effective

registration statement under such laws or pursuant to an exemption from such laws. If Units are being transferred pursuant to such an exemption, then the transferor will give prior written notice of such exemption to the Company and the Company may request an opinion of the transferor's counsel as to the availability of such exemption, which opinion and counsel must be reasonably satisfactory to the Company.

Exception for Estate Planning. A Transfer to an Affiliate of a Member or the Family of such Member of the right to receive distributions with respect to such Member's Units, shall be permitted and shall not constitute a Transfer subject to the right of first refusal provisions of herein. Further, the assignee of financial rights with respect to Units shall not become a Member or be treated as a holder of such Units, and the Company shall continue to treat the Member making such assignment as a Member and holder of such Units for all purposes under this Agreement.

DISSOLUTION AND TERMINATION

Dissolution. The Company shall be dissolved upon the occurrence of any of the following events:

unanimous written consent of the Members;

the entry of a decree of judicial dissolution of the Company under the Act; or

a Deadlock of the Members is not resolved within 30 days of the Deadlock's commencement.

The Company shall not be dissolved upon the death, incompetency, retirement, resignation, expulsion, dissolution or bankruptcy of a Member, unless such an event occurs at a time when the Company has only one other Member and, within ninety (90) days after such event, the remaining Member determines that it does not want to continue the business of the Company. If a Member who is an individual dies or a court of competent jurisdiction adjudges him to be incompetent to manage his or her person or his or her property, then such Member's executor, administrator, guardian, conservator, or other legal representative may exercise all of the Member's rights for the purpose of settling his or her estate or administering his or her property, subject to the terms and conditions of this Agreement.

Winding Up, Liquidation and Distribution of Assets

Upon dissolution, an accounting shall be made by the Company's independent accountants of the accounts of the Company and of the Company's assets, liabilities and operations, from the date of the last previous accounting until the date of dissolution. The Members shall then promptly proceed to wind up the affairs of the Company.

If the Company is dissolved and its affairs are to be wound up, the Members are directed to:

sell or otherwise liquidate such of the Company's assets as may be required to discharge all liabilities of the Company, including liabilities to Members who are creditors, to the extent otherwise permitted by law, other than liabilities to Members for distributions, and establish such reserves as may be reasonably necessary to provide for contingent liabilities of the Company (for purposes of determining the Capital Accounts of the Members, the amounts of such reserves shall be deemed to be an expense of the Company);

distribute the remaining assets to the Members on a pro-rata basis, in accordance with their respective Units, such distributions to be made either in cash or in kind, as determined by the Members, with any assets distributed in kind being valued for this purpose at their fair market value as determined by the Members; and

allocate any Profit or Loss resulting from such sales to the Capital Accounts.

Notwithstanding anything to the contrary in this Agreement, upon a liquidation within the meaning of Treasury Regulation §1.704-1(b)(2)(ii)(g), if any Member has a deficit Capital Account (after giving effect to all contributions, distributions, allocations and other Capital Account adjustments for all taxable years, including the year during which such liquidation occurs), such Member shall have no obligation to make any Capital Contribution, and the negative balance of such Member's Capital Account shall not be considered a debt owed by such Member to the Company or to any other Person for any purpose whatsoever.

The Members shall comply with all requirements of applicable law pertaining to the winding up of the affairs of the Company and the final distribution of its assets, including filing a Certificate of Cancellation upon the completion of the winding up process.

Return of Contribution Nonrecourse to Other Members. Except as provided by law or as expressly provided in this Agreement, upon dissolution, each Member shall look solely to the assets of the Company for the return of such Member's Capital Contribution. If the Company Property remaining after the payment or discharge of the debts and liabilities of the Company is insufficient to return the Capital Contribution of one or more Members in accordance with this Agreement, such Member or Members shall have no recourse against any other Member.

EXCULPATION AND INDEMNIFICATION

Exculpation of Covered Persons.

Covered Persons. As used herein, the term "***Covered Person***" shall mean (i) each Member, and (ii) each Officer, employee, agent or representative of the Company.

Standard of Care. No Covered Person shall be liable to the Company or any other Covered Person for any loss, damage or claim incurred by reason of any action taken or omitted to be taken by such Covered Person in good faith and with the belief that such action or omission is in, or not opposed to, the best interest of the Company, so long as such action or omission does not constitute fraud, gross negligence or willful misconduct by such Covered Person.

Good Faith Reliance. A Covered Person shall be fully protected in relying in good faith upon the records of the Company and upon such information, opinions, reports or statements (including financial statements and information, opinions, reports or statements as to the value or amount of the assets, liabilities, Profits or Losses of the Company or any facts pertinent to the existence and amount of assets from which distributions might properly be paid) of the following Persons or groups: (i) another Member; (ii) one or more Officers or employees of the Company; (iii) any attorney, independent accountant, appraiser or other expert or professional employed or engaged by or on behalf of the Company; or (iv) any other Person selected in good faith by or on behalf of the Company, in each case as to matters that such relying Person reasonably believes to be within such other Person's professional or expert competence. The preceding sentence shall in no way limit any Person's right to rely on information to the extent provided in the Act.

MISCELLANEOUS PROVISIONS

Notices. All notices and communications required or permitted to be given hereunder (a) shall be in writing; (b) shall be sent by messenger, certified or registered U.S. mail, a reliable express delivery service, or electronic mail, charges prepaid as applicable, to the appropriate address(es) or number(s) set forth on **Schedule A** to this Agreement (or such other address as such party may designate by notice to all other parties hereto); and (c) shall be deemed to have been given on the date of receipt by the addressee (or, if the date of receipt is not a business day, on the first business day after the date of receipt), as evidenced by (A) a receipt executed by the addressee (or a responsible person in his or her office or member of his or her household) or a notice to the effect that such addressee refused to accept such communication, if sent by messenger, U.S. mail or express delivery service, (B) confirmation of a facsimile transmission (either orally or by written confirmation) or (C) a receipt of such e-mail confirmed by reply message or read receipt. All parties shall act in good faith to promptly confirm receipt of communications where confirmation of receipt is required to effect notice pursuant to this subsection and is requested by the notifying party.

Waiver of Action for Partition. No Member or permitted assignee shall have the right to require a partition of all or a portion of the Company Property, and by signing this Agreement or a joinder hereto or counterpart hereof, each Member or permitted assignee irrevocably waives any right to maintain an action for partition of the Company Property.

Further Assurances. Each of the Members shall hereafter execute and deliver such further instruments and do such further acts and things consistent with the provisions of this Agreement as may be required or useful to carry out the full intent and purpose of this Agreement or as may be necessary to comply with any laws, rules or regulations.

Waivers. No party's undertakings or agreements contained in this Agreement shall be deemed to have been waived unless such waiver is made by an instrument in writing signed by an authorized representative of such Member. Failure of a party to insist on strict compliance with the provisions of this Agreement shall not constitute waiver of that party's right to demand later compliance with the same or other provisions of this Agreement. A waiver of a breach of this Agreement will not constitute a waiver of the provision itself or of any subsequent breach,

or of any other provision of this Agreement.

Rights and Remedies Cumulative; Creditors. The rights and remedies provided by this Agreement are cumulative, and the use of any one right or remedy by any party shall not preclude or waive the right to use any other remedy. Said rights and remedies are given in addition to any other legal rights the parties may have. None of the provisions of this Agreement shall be for the benefit of or enforceable by any creditors of the Company or of the Members.

Construction. The headings in this Agreement are inserted solely for convenience of reference and are in no way intended to describe, interpret, define, or limit the scope, extent or intent of this Agreement or any provision hereof. When the context in which words are used in this Agreement indicates that such is the intent, singular words shall include the plural and vice versa and masculine words shall include the feminine and the neuter genders and vice versa.

Amendment. This Agreement may be altered or amended only by the unanimous consent of the Members.

Severability. If any provision of this Agreement or the application thereof to any Person or circumstance shall be invalid, illegal or unenforceable to any extent, the remainder of this Agreement and the application thereof shall not be affected and shall be enforceable to the fullest extent permitted by law.

Heirs, Successors and Assigns. Each and all of the covenants, terms, provisions and agreements herein contained shall be binding upon and inure to the benefit of the parties hereto and, to the extent permitted by this Agreement, their respective heirs, legal representatives, successors and assigns.

Governing Law. This Agreement is made under and shall be governed by and construed in accordance with the laws of the Commonwealth of Massachusetts, without regard to its rules on conflicts of laws, and specifically the Act.

No Prior Operating Agreements. This Agreement shall expressly supersede and replace any and all prior operating agreements. The signatures of the Members to this Agreement shall constitute an action by unanimous written consent authorizing the repeal and replacement of any prior operating agreements to the extent that such an action is required pursuant to any such agreements' own terms.

Dispute Resolution. The parties hereto agree that any suit or proceeding arising out of this Agreement shall be brought only in the courts of the Commonwealth of Massachusetts; *provided, however*, that no party waives its right to request removal of such action or proceeding from the state court to a federal court. Each party hereto consents to the personal jurisdiction of such courts and agrees that service of process in any such suit or proceeding will be sufficiently accomplished if accomplished in accordance with the notice provisions set forth in the Agreement.

Code and Treasury Regulation References. Any reference to a section of the Code or a Treasury Regulation in this Agreement shall be deemed to refer to corresponding provisions of subsequent superseding federal revenue laws and regulations in the event that the section of the Code or Treasury Regulation so referenced has been so superseded.

Counterparts. This Agreement may be executed in any number of counterparts and may be executed and delivered by facsimile or other electronic transmission. Each such counterpart shall be deemed to be an original instrument, but all such counterparts together shall constitute one agreement.

[Signature Page Follows]

IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the date first set forth above.

COMPANY:

G7 LABS LLC

By:_____

Shankar P. Gautam

Member and Manager

By:_____

Pratima Bhattarai

Member

SCHEDULE A

OPERATING AGREEMENT

OF

G7 LABS LLC

CAPITALIZATION TABLE

Name	Capital Contribution	Units	% Management Interest	% Economic Interest
Shankar P. Gautam	$61,510.00	600,000	60	60
Pratima Bhattarai	$41,006.00	400,000	40	40

SCHEDULE B

OPERATING AGREEMENT

OF

G7 LAB LLC

DEFINITIONS

The following terms shall have the following meanings when used in this Agreement:

"***Act***" means the applicable law of the Commonwealth of Massachusetts governing limited liability companies organized in Massachusetts, the Massachusetts Limited Liability Company Act, *et seq*, and any successor statute, as it may be amended from time to time.

"***Affiliate***" shall mean any other Person that directly or indirectly Controls or is Controlled by or is under common Control with such Person, or any Person that is an employee of or an officer of or partner in or serves in a similar capacity or relationship with respect to a Person.

"***Agreed Value***" means the fair market value of any Units at issue, as mutually agreed to by the parties selling and purchasing Units, or in the absence of such mutual agreement, determined in the following manner:

Each party will obtain its own appraiser to conduct an appraisal, the cost of which will be borne by such party. If the two appraisals are within 10% of each other, the average of those appraisals will be the fair market value. If the two appraisals are more than 10% apart, then the two appraisers will hire a third appraiser, the cost of which will be split equally between the two parties, to obtain a third appraisal and the average of the two appraisals that are closest in amount will be the fair market value. Any appraisal will be based upon the value of the entire Company sold to a single buyer in a single transaction for cash and shall include discounts for illiquidity or lack of control but shall not include any premium for control.

"***Available Cash***" means the cash held by or immediately available to, the Company less such reserves for capital expenditures or other liabilities or other purposes as the Members, in their sole discretion, may determine.

"***Bankruptcy***" means, with respect to a Member, the occurrence of any of the following: (a) the filing of an application by such Member for, or a consent to, the appointment of a trustee of such Member's assets, (b) the filing by such Member of a voluntary petition in bankruptcy or the filing of a pleading in any court of record admitting in writing such Member's inability to pay its debts as they come due, (c) the making by such Member of a general assignment for the benefit of such Member's creditors, (d) the filing by such Member of an answer admitting the material allegations of, or such Member's consenting to, or defaulting in answering a bankruptcy petition filed against such Member in any bankruptcy proceeding or (e) the expiration of sixty (60) days following the entry of an order, judgment or decree by any court of competent jurisdiction adjudicating such Member a bankrupt or appointing a trustee of such

Member's assets.

"***Capital Account***" as of any given date shall mean the amount set forth on **Schedule A** as adjusted.

"***Capital Contribution***" shall mean any contribution to the capital of the Company in cash or property by a Member or predecessor thereof whenever made.

"***Certificate of Organization***" shall mean the Certificate of Organization of the Company as filed with the Massachusetts Secretary of the Commonwealth on August 27, 2019, as amended from time to time.

"***Code***" shall mean the Internal Revenue Code of 1986, as amended from time to time, or corresponding provisions of subsequent superseding federal revenue laws.

"***Company Property***" means real and personal property owed, acquired by, or contributed to the Company and any improvements thereto, and shall include both tangible and intangible property.

"***Control***" means the possession, directly or indirectly, of the power to direct the management and policies of a Person, whether through the ownership of voting securities, contract or otherwise.

"***Decedent***" shall mean an individual Member who has died.

"***Entity***" shall mean any general partnership, limited partnership, limited liability partnership, limited liability company, corporation, joint venture, trust, business trust, cooperative, association, foreign trust, foreign business organization or other business entity.

"***Family***", as applied to any individual, shall mean (a) the children of such individual (by birth or adoption), (b) the parents, spouse and siblings of such individual, (c) the children of the siblings of such individual, (d) any trust solely for the benefit of, or any partnership, limited liability company or other entity owned solely by, any one or more of such aforementioned individuals (so long as such individuals have the exclusive right to Control such trust or other entity) and (e) the estate of such individual.

"***Fiscal Year***" shall mean the period terminating on December 31 of each year during the term hereof or on such earlier date in any year in which the Company shall be dissolved as provided herein.

"***Losses***" shall mean the net losses of the Company for federal income tax purposes, as determined separately, and not cumulatively, for each Fiscal Year of the Company or other relevant period, after appropriate adjustment for items otherwise allocated, if any, pursuant to this Agreement.

"***Majority in Interest***" of Members shall mean one or more Members whose combined Percentage Interests of a given class of Units exceed fifty percent (50%) of all Percentage Interests of Units owned by all Members of the same class of Units. The Company shall initially have one class of Units, with additional classes created or removed only in accordance with the

procedures provided herein for the issuance of new Units.

"***Member***" shall mean each of the parties who executes a counterpart of this Agreement as a Member, and each of the parties who may hereafter become a Member pursuant to the terms and conditions of this Agreement.

"***Percentage Interest***" of Units or of Members shall mean the number of Units of a given class held at a particular time by such Member, divided by the total number of all Units of the same class then held by all Members, expressed as a percentage.

"***Person***" shall mean any individual or Entity, and the heirs, executors, administrators, legal representatives, successors and assigns of such Person, where the context so permits.

"***Profits***" shall mean the net profits of the Company for federal income tax purposes, as determined separately, and not cumulatively, for each Fiscal Year of the Company or other relevant period, after appropriate adjustment for items otherwise allocated, if any, pursuant to this Agreement.

"***Tax Items***" means Profits and Losses and items of income, gain, loss, deduction and credit of the Company as determined for federal, state and local income tax purposes.

"***Treasury Regulations***" shall include proposed, temporary and final regulations promulgated under the Code.

"***Unit***" shall mean those interests in the Company that shall have (a) economic value and rights in or to the profits, gains, losses, distributions and other economic interests of the Company and/or (b) voting membership rights in the Company.

The Commonwealth of Massachusetts
William Francis Galvin

Minimum Fee: $500.00

Secretary of the Commonwealth, Corporations Division
One Ashburton Place, 17th floor
Boston, MA 02108-1512
Telephone: (617) 727-9640

Certificate of Organization
(General Laws, Chapter)

Identification Number: 001369282

1. The exact name of the limited liability company is: G7 LAB LLC

2a. Location of its principal office:
No. and Street: 410 GREAT ROAD
SUITE 225
City or Town: LITTLETON State: MA Zip: 01460 Country: USA

2b. Street address of the office in the Commonwealth at which the records will be maintained:
No. and Street: 410 GREAT ROAD
SUITE 225
City or Town: LITTLETON State: MA Zip: 01460 Country: USA

3. The general character of business, and if the limited liability company is organized to render professional service, the service to be rendered:
G7 LAB LLC IS A FULL SERVICE LABORATORY WHICH INTENDS TO PERFORM TESTING ON MEDICINAL AND RECREATIONAL/ADULT USE CANNABIS AS MANDATED BY CANNABIS COMMISSION OF STATE OF MA, AFTER OBTAINING ALL REQUIRED PERMITS FROM LOCAL AND STATE AUTHORITIES. THE SERVICE PROVIDED WILL BE TESTING SERVICES FOR GROWERS, RMDS, OR ANY OTHER APPLICABLE VENDORS WANTING TO TEST CANNBIS AS PER CANNABIS COMMISSIONS GUIDELINE AND REGULATIONS.

4. The latest date of dissolution, if specified:

5. Name and address of the Resident Agent:
Name: SHANKAR P. GAUTAM
No. and Street: 99 POND AVE
408 D
City or Town: BROOKLINE State: MA Zip: 02445 Country: USA

I, SHANKAR P. GAUTAM resident agent of the above limited liability company, consent to my appointment as the resident agent of the above limited liability company pursuant to G. L. Chapter 156C Section 12.

6. The name and business address of each manager, if any:

Title	Individual Name First, Middle, Last, Suffix	Address (no PO Box) Address, City or Town, State, Zip Code
MANAGER	SHANKAR P. GAUTAM	410 GREAT ROAD SUITE 225 LITTLETON, MA 01460 USA

7. The name and business address of the person(s) in addition to the manager(s), authorized to execute documents to be filed with the Corporations Division, and at least one person shall be named if there are no managers.

Title	Individual Name First, Middle, Last, Suffix	Address (no PO Box) Address, City or Town, State, Zip Code
SOC SIGNATORY	PRATIMA BHATTARAI	410 GREAT ROAD SUITE 225 LITTLETON, MA 01460 USA

8. The name and business address of the person(s) authorized to execute, acknowledge, deliver and record any recordable instrument purporting to affect an interest in real property:

Title	Individual Name First, Middle, Last, Suffix	Address (no PO Box) Address, City or Town, State, Zip Code
REAL PROPERTY	SHANKAR PRASAD GAUTAM	410 GREAT ROAD SUITE 225 LITTLETON, MA 01460 USA

9. Additional matters:

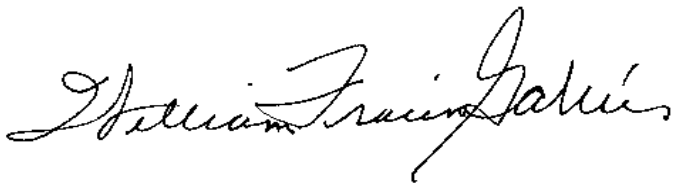
SIGNED UNDER THE PENALTIES OF PERJURY, this 18 Day of February, 2019,
SHANKAR P. GAUTAM

(The certificate must be signed by the person forming the LLC.)

THE COMMONWEALTH OF MASSACHUSETTS

I hereby certify that, upon examination of this document, duly submitted to me, it appears that the provisions of the General Laws relative to corporations have been complied with, and I hereby approve said articles; and the filing fee having been paid, said articles are deemed to have been filed with me on:

February 18, 2019 01:24 PM



WILLIAM FRANCIS GALVIN

Secretary of the Commonwealth

Certificate of Good Standing or Compliance from the Massachusetts Department of Unemployment Assistance Attestation Form

Signed under the pains and penalties of perjury, I, Shankar P. Gautam, an authorized representative of G7 Labs LLC certify that G7 Labs LLC does not currently have employees and is therefore unable to register with the Massachusetts Department of Unemployment Assistance to obtain a Certificate of Good Standing or Compliance.

Signature of Agent

04-21-2020
Date

Name: Shankar P. Gautam

Title: CEO/Technical Manager.

Entity: G7 Lab LLC

The Commonwealth of Massachusetts
William Francis Galvin

Minimum Fee: $100.00

Secretary of the Commonwealth, Corporations Division
One Ashburton Place, 17th floor
Boston, MA 02108-1512
Telephone: (617) 727-9640

Certificate of Amendment
(General Laws, Chapter)

Identification Number: 001369282

The date of filing of the original certificate of organization: 2/18/2019

1.a. Exact name of the limited liability company: G7 LAB LLC

1.b. The exact name of the limited liability company *as amended*, is: G7 LAB LLC

2a. Location of its principal office:
No. and Street: 160 AYER RD
UNIT 3
City or Town: LITTLETON State: MA Zip: 01460 Country: USA

3. *As amended,* the general character of business, and if the limited liability company is organized to render professional service, the service to be rendered:

4. The latest date of dissolution, if specified:

5. Name and address of the Resident Agent:
Name: SHANKAR P. GAUTAM
No. and Street: 99 POND AVE
408 D
City or Town: BROOKLINE State: MA Zip: 02445 Country: USA

6. The name and business address of each manager, if any:

Title	Individual Name First, Middle, Last, Suffix	Address (no PO Box) Address, City or Town, State, Zip Code
MANAGER	SHANKAR GAUTAM	160 AYER RD LITTLETON, MA 01460 USA

7. The name and business address of the person(s) in addition to the manager(s), authorized to execute documents to be filed with the Corporations Division, and at least one person shall be named if there are no managers.

Title	Individual Name First, Middle, Last, Suffix	Address (no PO Box) Address, City or Town, State, Zip Code
SOC SIGNATORY	PRATIMA BHATTARAI	160 AYER RD LITTLETON, MA 01460 USA

8. The name and business address of the person(s) authorized to execute, acknowledge, deliver and record

any recordable instrument purporting to affect an interest in real property:

Title	Individual Name First, Middle, Last, Suffix	Address (no PO Box) Address, City or Town, State, Zip Code
REAL PROPERTY	SHANKAR PRASAD GAUTAM	410 GREAT ROAD SUITE 225 LITTLETON, MA 01460 USA

9. Additional matters:

10. State the amendments to the certificate:
ADDRESS CHANGE OF PRIMARY BUSINESS AND LAB LOCATION

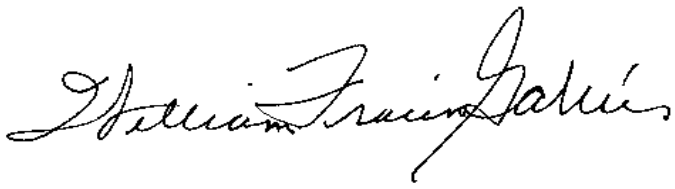
11. The amendment certificate shall be effective when filed unless a later effective date is specified:
1/28/2020

SIGNED UNDER THE PENALTIES OF PERJURY, this 27 Day of January, 2020,
SHANKAR GAUTAM **, Signature of Authorized Signatory.**

THE COMMONWEALTH OF MASSACHUSETTS

I hereby certify that, upon examination of this document, duly submitted to me, it appears that the provisions of the General Laws relative to corporations have been complied with, and I hereby approve said articles; and the filing fee having been paid, said articles are deemed to have been filed with me on:

January 27, 2020 01:04 PM



WILLIAM FRANCIS GALVIN

Secretary of the Commonwealth

Business Plan

Executive Summary

G7 Lab LLC ("G7 Lab LLC") is a start-up company committed to providing the most convenient testing service to the cannabis industry. G7 Lab is registered in Massachusetts by Shankar Gautam. G7 Lab will quickly gain market share serving the Massachusetts cannabis community after receiving a final license from the Cannabis Control Commission ("the CCC").

Objectives

G7 Lab has established three significant objectives to pursue. The first is securing a final License for Adult- and Medical-use cannabis testing from the CCC. The second objective is to develop 100% of their revenue from the cannabis community of growers and manufacturers in Massachusetts. The third objective is the desire to reach profitability within 24 to 36 months. This is especially important since G7 Lab will be using debt and would like to see a positive return on investment ("ROI") within 24 to 36 months.

Market

G7 Lab has identified two market segments they will serve. First is the large number of growers associated with marijuana microbusiness. This customer segment has more than 100 potential customers with a growth rate of about 20%. The second group is corporate growers having growing sites in multiple locations. There are multiple potential customers in this segment.

Services

G7 Lab offers comprehensive cannabis tests for cannabis growers and manufacturers to make sure their products are sold in compliance with the regulations promulgated by the CCC and Massachusetts Department of Public Health ("MDPH"). All testing required by the CCC will be performed in house as follows as per MDPH testing protocols:

A. Potency:
   - Testing Protocol: High Pressure Liquid Chromatography (HPLC)
     1. Delta 9-THC,
     2. THCa,
     3. CBD
     4. CBDa

B. Heavy Metal Analysis
   - Testing Protocol-Ion Coupled Plasma Mass Spectrometry (ICP-MS)
     1. Arsenic (inorganic)(As)
     2. Cadmium (Cd)
     3. Lead (Pb)
     4. Total mercury (Hg)

C. Microbiological Contaminants
- Testing Protocol: Quantitative Polymerase Chain Reaction (qPCR)
    1. AC =Total Viable Aerobic Bacteria
    2. YM =Total Yeast & Mold
    3. CC =Total Coliforms
    4. EB =Total Bile-Tolerant Gram-Negative Bacteria

D. Pathogenic bacteria Screen
- Testing Protocol: Quantitative Polymerase chain reaction (qPCR)
    1. (ECPT) E. coli (O157)
    2. (SPT) Salmonella

E. Mycotoxin Test: >20 ppb Sum of:
- Testing Protocol: LCMS/MS
    1. aflatoxin B1 (AFB_1)
    2. aflatoxin B2 (AFB_2)
    3. aflatoxin G1 (AFG_1)
    4. aflatoxin G2 (AFG_2)
    5. Ochratoxin A.

F. Pesticide screening:
- Testing Protocol: Liquid Chromatography Tandem Mass Spectrometry(LCMS/MS), Gas Chromatography Tandem Mass spectrometry (GC-MS/MS)

1. Bifenazate Acaricide LC; LC-MS/MS
2. Bifenthrin (synthetic pyrethroid) Insecticide GC-MS/MS
3. Cyfluthrin (synthetic pyrethroid) Insecticide LC-MS/MS
4. Etoxazole Acaricide GC-MS(/MS)
5. Imazalil Fungicide LC-MS/MS
6. Imidacloprid Insecticide LC-MS/MS
7. Myclobutanil Fungicide LC-MS/MS
8. Spiromesifen Insecticide LC-MS/MS
9. Trifloxystrobin Fungicide LC-MS/MS

G. Residual Solvents:
- Testing Protocol: Head-space Gas Chromatography-Mass Spectrometer, (HS-GC-MS)

Solvent	Concentration Limit (mg/kg)
n-Butane	1
Propane	1
Ethanol	1
Iso-Butane	1

Hexane	1

H. Terpene profile
- Testing Protocol: Headspace Gas Chromatography-Flame Ionization Detector, (HS-GC-FID)

alpha-Bisabolol	Camphene
delta-3-Carene	beta-Caryophyllene
Caryophyllene-Oxide	para-Cymene
Eucalyptol	Geraniol
Guaiol	alpha-Humulene
Isopulegol	D-Limonene
Linalool	beta-Myrcene
cis-Nerolidol	trans-Nerolidol
Ocimene	beta-Ocimene
alpha-Pinene	beta-Pinene
alpha-Terpinene	gamma-Terpinene
Terpinolene	

I. Vitamin E Acetate:
- Testing Protocol: HPLC

The following types of samples will be tested:

Production Stage Classification for Medical Marijuana Products as per MDPH

Production Stage	*Product Class*
Finished Plant Material	Flower
Cannabis Resin & Concentrates	Oil Resin Shatter Wax
Marijuana-Infused Product (MIP) Edible	(Food, Drink, Capsule) Suppository Tincture Topical Other

Management

G7 Lab was founded and is led by Shankar Gautam and Pratima Bhattarai. Shankar has an undergraduate degree in Cell and Molecular Biology with a Minor in Biochemistry. After

graduation Shankar worked for various clinical and reference laboratories as a Chemist and Medical Technologist. Pratima has an MBA and is focused on the business and marketing prospect of the business.

Surveying the business environment after legalization of cannabis in Massachusetts with the thought of opening their own laboratory, they recognized the great need for a lab close to western Massachusetts and developed a plan and secured financing for the venture.

Objectives

- To gain 30-40% of the cannabis testing industry in Massachusetts
- Reach profitability within 24-36 months.

Mission

It is G7 Lab's mission to serve the cannabis industry of Massachusetts with fast and accurate testing services. G7 Lab exists to exceed all their customer's expectations.

Keys to Success

1. Follow all local and state laws applicable to independent testing laboratory within the State
2. Create safe and secure working environment for employees
3. Set up a strong contract with cannabis growers and RMD's within Massachusetts
4. Follow a strict regime of accounting controls to help ensure profitability

Company Summary

G7 Lab has been formed as an L.L.C., registered in Massachusetts. G7 Lab is a multiple member entity owned by Shankar Gautam and Pratima Bhattarai.

Company Ownership

The owners of G7 Lab LLC are Shankar Gautam and Pratima Bhattarai. Shankar and Pratima have received private financing and will have a long-term loan to pay off.

Services

Test
1. Potency 2. Potency -edibles 3. Potency- wax and oils
3. Heavy Metal Analysis-
4. Microbiological Contaminants
5. Mycotoxins
6. Pesticide screening
7. Residual Solvents
8. Terpene profile

9. Vitamin E acetate

G7 Lab will have a courier service available for pickup for all its customers.
This service will be free of cost for high volume customers and there will be a minimal charge for low volume and occasional customers.

The samples reaching the lab by 3:00 p.m. will be tested the same day of collection as per protocols of the CCC and MDPH. The results of testing will be reported via G7 Lab's website customer portal and or e-mail.

Marketing Strategy

G7 Lab will undertake a marketing strategy that is compliant with the marketing regulations promulgated by the CCC and MDPH.

Financials

Capital Cost

Capital Cost	Cost ($)
Application fee	3000.0
License application Medicinal & Recreational 10,000X2	20000.0
Surveillance System (5000), door security X3($400), labor (13800)	20000.0
Equipment Set up and initial supplies 3000X5	15000.0
UPS+backup generator +install 1000	5129.0
Air Purifier with carbon filter, Smell mitigation	1400.0
Exhaust install ICPMS w/ pumps at 350 cfu each 500 X2	1000.0
Plumbing Sink x2 purchase and water purifier, eye shower install	1000.0
Biological safety Hood Install	500.0
Lab Isolation wall w/door Front and back	2000.0
Bighorn 30.94 cu. ft. Executive Vault, 120 Minute Fire Rating 2799+500 install	3299.0
Transport all lab equipment from Storage to Lab	1300.0
Total	73628.0

All equipment and furniture required for the laboratory has been acquired through private contract during liquidation of a biopharmaceutical company or via auction. Please see Appendix A for the list of equipment and furniture acquired by the laboratory.

The above costs have been thoroughly researched and are based on actual quotes. Due to multiple Non-Disclosure Agreements (NDA) the parties agreeing to the quotes cannot be disclosed.

Assumptions

Running Cost until Provisional License (Per month)

The month to month running cost of the laboratory prior to provisional license by the CCC.

Item	Amount ($)
Rent (option agreement)	2000
utility	100
Total	2100

All work shall only start after provisional licensure from the CCC.

Additional cost after provisional Licensure (Per Month)

Cost Category	Amount (	UI+taxes	Total($)
Technologist 1 @ 20 Volunteer	0	0	0
Technologist 2 $18@20 hour/week	1560	210.6	1770.6
Electricity 2132 KWH for all electric components	700		
Website, software, LIS , Document control, my sq	224.5		
Instrument specific supplies Columns, Vials etc	600		
gases for Instruments N2, Argon,Hydrogen	280		
Hazardous waste management 55 gallon /3 month	66		
lab supplies Gloves , lab coat, pipet tips etc.	150		
Total			3791.1

Total Per month post provisional and before final License= 3791+3000 (rent+ condo fee) =6791/month

Total running cost after full license (Per month)

Personal Cost	Cost/week	Ui +taxes	Total($)
Employee Cost	**Cost/week**	**Ui +taxes**	**Total($)**
Technologist 1 @ 20 hrs per week Volunteer	0	0	$0
Technologist 2 $18@20 hrs per week	1560	210.6	$1,771
Courier 1 @ $16/hr (PER DIEM)	2733.33	369	$3,102
Courier 2 @ 16/hr(PER DIEM)	2733.33	369	$3,102
Courer car fuel 100 gal @$3 per gallon			$300
Courier car insurance			$100
Professional Liability Insurance			$742
Electricity 2132 KWH for all electric components	700		$700
Website, software, LIS , Document control, my sql	224.5		$225
Instrument specific supplies Columns, Vials etc	600		$600
gases for Instruments N2, Argon,Hydrogen	280		$280
Hazardous waste management 55 gallon /3 month	66		$66
lab supplies Gloves , lab coat, pipet tips etc.	150		$150
Rent +Condo Fee+cam			$3,000
Total per month			$14,137

Running cost post license without revenue

1. **Total Cost – 2 Courier + courier Fuel =$14137-6504=$7633/month.**

Total Running Cost Post licensure (Year 2 to 5)					
Cost	**Cost/month**	**Total ($) Year 2**	**Year 3**	**Year 4**	**Year 5**
Cost of supplies x5 increase due to volume	4602.83	276169.8	284454.9	292988.5	301778.2
4 FTE Technologist	3343.7	173836	165312.5	170271.9	175380.1
2 FTE Couriers	3102.3	74880	77126.4	79440.192	81823.39776
Quality/Operation Manager	6066	96000	98880	101846.4	104901.8
Technical Supervisor/Security	7500	96000	98880	101846.4	104901.8
Positive Impact Littleton scholarship	241	13342	16000	16000	16000
Service contract	3,333	40000	50000	55000	60000
Profit Sharing (3%net profit)	1,803	20014	29447	42145	40949
Health Insurance	11,666	140000	147000	154350	162067.5
Unforeseen expenses	2,000	24000	24720	25461.6	26225.4
Total	$43,658	$954,242	$991,821	$1,039,350	$1,074,027
Total revnue		$1,456,000	$1,794,000	$2,247,700	$2,236,000
Total profit		$501,758	$802,179	$1,208,350	$1,161,973

3% Inflation adjustment and raise for employees is projected, however Taxes paid by owners is not part of the calculation

Revenue projection

Billed services	**Rate ($)**	**Unit /week**	**Sales ($)**
Potency	75	20	1500
Potency -edibles	100	2	200
Potency- wax and oils	100	1	100
Heavy Metal Analysis-	135	5	675
Microbiological Contaminates Testing	85	10	850
Pathogenic bacteria Screen	135	10	1350
Mycotoxin test	90	10	900
Pesticide screening	200	5	1000
Residual Solvents	85	5	425
Terpene profile	85	5	425
Total		**73**	**7425**

- *Total first year revenue projection =$386,100.00.*
- *Net revenue without salary to owners = $386,100- $169,644= $216,456.0*
- *Revenue projections will be adjusted based on reported test monthly volumes month after month.*

Testing Services projection

	Year 1	YEAR 2	YEAR 3	YEAR 4	YEAR 5
Charges ($)					
	1500	3750	5625	7500	7500
	200	1500	2000	3500	3500
	100	1000	1500	3000	3000
	675	2550	2975	3400	3400
	850	2550	2975	3400	3400
	1350	2550	2975	3400	3400
	900	2700	3150	3600	3600
	1000	6000	7000	8000	8000
	425	1500	1750	2000	2000
	425	2550	2975	3400	3400
Total per week	**7425**	28000	34500	43225	43000
Total Revenue per year	**$386,100**	**$1,456,000**	**$1,794,000**	**$2,247,700**	**$2,236,000**

Running Cost prior licensure = $2100.0/month (Option Agreement)
Running Cost after provisional-licensure = $6791/month
Running Cost after post-licensure without any revenue = $7633.00

Total Funds

Personal Funds = $110,000.00
Loan = $150,000.00-$175,000.00 (Pre-approved)
Plan to raise capital after provisional for 10% equity = $200,000.00
Total Funds = $460,000-$485,000.00
Please see attached proof of funds and pre-approval letter from Loan.

Initial Setup cost = $73,628.00
Total Funds-Initial Setup ($460.00-$73,628.00) = $386,832.00

Running cost covered without any revenue for a period of $386,832.00/$7366 = 50.6 months.
Running cost covered without raising capital $186,832/$7366 = 25 months.

Plan for applicant's solvency.
If the laboratory is unable to attain a final license from the CCC, all the equipment and furniture will be liquidated and the LLC will be dissolved. Total loss will be the running cost up to pre-licensure which is just an option to lease agreement rent plus electric cost.

Appendix A. Acquired Instrument List

	Instrument	Quantity
1	Agilent 1100 HPLC	1
2	Agilent 1100 LCMSD	1
3	Leica ATC 2000 Microscope	1
4	Cannon Rebel Ti DSLR with tripod +Focus Light	1
5	Mettler Toledo Ab104 S & calibrating weights	2
6	Millipore Milli Q A10 Water purifier	1
7	Perkin Elmer Elan 6000 ICPMS & accessories	1
8	Perking Elmer Elan 6100 ICPMS & accessories	1
9	Agilent 6890 GCMS with headspace	2
10	Waters Micromass Quattro LC/MS/MS	1
11	Agilent 6890 GCMS	1
12	Thermo TSQ vantage With Agilent 1100 LCMS/MS	1
13	Agilent Aria MS G8830 A Option 010 qPCR	1
14	Bio safety hood	1
15	various lab benches	8
16	Eagle manufacturing flammable liquid storage cabinet 36 gallon	1
17	Explosion proof VWR freezer	1
18	Thermo refrigerator	1
19	Manual Pipets	10
20	Lab Glassware	30
21	Trace metal grade glassware	20
22	Mass spec benches	2
22	Hettich Rotina 380 centrifuge	1
22	Hettich 280S centrifuge	1

G7LABLL-01 SMILLER1

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY) 6/15/2022

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER	CONTACT NAME:	
VANTREO Insurance Brokerage 100 Stony Point Rd, Suite 160 Santa Rosa, CA 95401	PHONE (A/C, No, Ext): (707) 546-2300	FAX (A/C, No): (707) 546-2915
	E-MAIL ADDRESS:	
	INSURER(S) AFFORDING COVERAGE	NAIC #
	INSURER A : James River Insurance Company	12203
INSURED	INSURER B :	
G7 LAB, LLC 160 AYER ROAD UNIT 3 Littleton, MA 01460	INSURER C :	
	INSURER D :	
	INSURER E :	
	INSURER F :	

COVERAGES **CERTIFICATE NUMBER:** **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY						EACH OCCURRENCE	$ 1,000,000
	X CLAIMS-MADE ☐ OCCUR			00131925-0	7/1/2022	7/1/2023	DAMAGE TO RENTED PREMISES (Ea occurrence)	$ 50,000
							MED EXP (Any one person)	$
							PERSONAL & ADV INJURY	$ 1,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$ 2,000,000
	X POLICY ☐ PRO-JECT ☐ LOC						PRODUCTS - COMP/OP AGG	$ 2,000,000
	☐ OTHER:							$
	AUTOMOBILE LIABILITY						COMBINED SINGLE LIMIT (Ea accident)	$
	☐ ANY AUTO						BODILY INJURY (Per person)	$
	☐ OWNED AUTOS ONLY ☐ SCHEDULED AUTOS						BODILY INJURY (Per accident)	$
	☐ HIRED AUTOS ONLY ☐ NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	$
								$
	☐ UMBRELLA LIAB ☐ OCCUR						EACH OCCURRENCE	$
	☐ EXCESS LIAB ☐ CLAIMS-MADE						AGGREGATE	$
	☐ DED ☐ RETENTION $							$
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y / N						☐ PER STATUTE ☐ OTH-ER	
	ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? ☐ (Mandatory in NH)	N / A					E.L. EACH ACCIDENT	$
	If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE - EA EMPLOYEE	$
							E.L. DISEASE - POLICY LIMIT	$
A	Professional Liabili			00131925-0	7/1/2022	7/1/2023	Per Claim/Aggregate	1,000,000
A	Cyber Liability			00131925-0	7/1/2022	7/1/2023	Per Claim	100,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

CERTIFICATE HOLDER

State of MA

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

Cindy Bruce

MAINTAINING OF FINANCIAL RECORDS

G7 Lab LLC ("G7 Lab") policy is to maintain financial records in accordance with 935 CMR 500.105(9)(e). The records will include manual or computerized records of assets and liabilities, monetary transactions; books of accounts, which shall include journals, ledgers, and supporting documents, agreements, checks, invoices and vouchers; sales records including the quantity, form, and cost of marijuana products; and salary and wages paid to each employee, stipends paid to each board member, and any executive compensation, bonus, benefit, or item of value paid to any individual affiliated with a Marijuana Establishment, including members of the non-profit corporation.

Following the closure of G7 Lab, all records will be kept for at least two years, at G7 Lab's sole expense, and in a form and location acceptable to the Commission, in accordance with 935 CMR 500.105(9)(g). G7 Lab shall keep financial records for a minimum of three years from the date of the filed tax return, in accordance with 830 CMR 62C.25.1(7) and 935 CMR 500.140(6)(e).

RESTRICTING ACCESS TO AGE 21 OR OLDER

G7 Lab LLC ("G7 Lab" or "the Company") is a marijuana establishment as defined by 935 CMR 500.002. The Company sets forth the following policies and procedures for restricting access to marijuana and marijuana infused products to individuals over the age of twenty-one (21) pursuant to the Cannabis Control Commission's (the "Commission") regulations at 935 CMR 500.105(1)(o). This regulation states that written operating procedures for the Company shall include "[p]olicies and procedures to prevent the diversion of marijuana to individuals younger than 21 years old."

A. COMPLIANCE WITH 935 CMR 500.105(1)(o)

The Company incorporates and adopts herein by reference, all of the provisions for the prevention of diversion outlined in the Company's Standard Operating Procedure for the Prevention of Diversion. The provisions detailed in the Company's Standard Operating Procedure for the Prevention of Diversion apply to the prevention of diversion of marijuana and marijuana infused products to all minors and all individuals under the age of twenty-one (21).

B. SPECIFIC PROVISIONS FOR RESTRICTING ACCESS TO AGE 21 AND OLDER

As stated above, the Company incorporates herein, all provisions for the prevention of diversion of marijuana and marijuana infused product to individuals under the age of twenty-one (21) as detailed in the Company's Standard Operating Procedure for the Prevention of Diversion. Specific provisions regarding restricting access to individuals age twenty-one (21) and older include the following:

1. The Company will only employ marijuana establishment agents, as defined by the Commission's definitions at 935 CMR 500.002, who are at least twenty-one (21) years old.

2. The Company will only allow visitors, age twenty-one (21) or older, at the Company's facilities. The Company defines visitors in accordance with the Commission's definitions at 935 CMR 500.002. The Company will designate an authorized agent to check the identification of all visitors entering the Company's facilities and entry shall only be granted to those aged twenty-one (21) or older. Acceptable forms of currently valid identification include:
    a. A motor vehicle license;
    b. A liquor purchase identification card;
    c. A government-issued identification card;
    d. A government-issued passport; and
    e. A United States-issued military identification card.

RECORD KEEPING PROCEDURES

G7 Lab LLC ("G7 Lab") records shall be available to the Cannabis Control Commission ("CCC') upon request pursuant to 935 CMR 500.105(9). G7 Lab shall maintain records in accordance with generally accepted accounting principles. All written records required by any section of 935 CMR 500.000 are subject to inspection, in addition to written operating procedures as required by 935 CMR 500.105(1), inventory records as required by 935 CMR 500.105(8) and seed-to-sale tracking records for all marijuana products are required by 935 CMR 500.105(8)(e).

Personnel records shall also be maintained, in accordance with 935 CMR 500.105(9)(d), including but not limited to job descriptions and/or employment contracts each employee, organizational charts, staffing plans, periodic performance evaluations, verification of references, employment contracts, documentation of all required training, including training regarding privacy and confidentiality agreements and the signed statement confirming the date, time and place that training was received, record of disciplinary action, notice of completed responsible vendor training and eight-hour duty training, personnel policies and procedures, and background checks obtained in accordance with 935 CMR 500.030. Personnel records will be maintained pursuant to 935 CMR 105(9)(d). Additionally, business records will be maintained in accordance with 935 CMR 500.105(9)(e), specifically the following business records shall be maintained: assets and liabilities; monetary transactions; books of accounts; sales records; and salary and wages paid to each employee. Waste disposal records will be maintained pursuant to 935 CMR 500.105(12), which specifically requires waste records be kept for at least three years.

VISITOR LOG

G7 Lab will maintain a visitor log that documents all authorized visitors to the facility, including outside vendors, contractors, and visitors, in accordance with 935 CMR 500.110(4)(e). All visitors must show proper valid identification demonstrating that they are at least twenty-one (21) years of age and they shall be logged in and out; that log shall be available for inspection by the Commission at all times.

REAL-TIME INVENTORY RECORDS

G7 Lab will maintain real-time inventory records, including at minimum, an inventory of all marijuana and marijuana products received from wholesalers, ready for sale to wholesale customers, and all damaged, defective, expired, or contaminated marijuana and marijuana products awaiting disposal, in accordance with 935 CMR 500.105(8). Real-time inventory records shall be accessible via METRC, the Commonwealth's seed-to-sale tracking software of record, or a third-party software platform capable of direct and secure integration with METRC. G7 Lab will continuously maintain hard copy documentation of all inventory records. The record of each inventory shall include, at a minimum, the date of inventory, a summary of inventory findings, and the names, signatures, and titles of the individual Licensed Marijuana Establishment Agent(s) who conducted the inventory.

MANIFESTS

G7 Lab will maintain records of all manifests for no less than one year and make them available to the Commission upon request, in accordance with 935 CMR 500.105(f). Manifests will include, at a minimum, the originating Licensed Marijuana Establishment Agent's (Agent) name, address, and registration number; the names and registration number of the Agent who transported the marijuana

products; the names and registration number of the marijuana establishment agent who prepared the manifest; the destination Licensed Marijuana Establishment's (LME) name, address, and registration number; a description of marijuana products being transported, including the weight and form or type of product; the mileage of the transporting vehicle at departure from origination LME and the mileage upon arrival at the destination LME, as well as the mileage upon returning to the originating LME; the date and time of departure from the originating LME and arrival at destination LME; a signature line for the marijuana establishment agent who receives the marijuana; the weight and inventory before departure and upon receipt; the date and time that the transported products were re-weighted and re-inventoried; and the vehicle make, model, and license plate number. G7 Lab will maintain records of all manifests for a minimum of one year in accordance with 935 CMR 500.105(13)(f)(5).

INCIDENT REPORTS

G7 Lab will maintain incident reporting records notifying appropriate law enforcement authorities and the Commission about any breach of security immediately, and in no instance, more than 24 hours following the discovery of the breach, in accordance with 935 CMR 500.110(7). Incident reporting notification shall occur, but not be limited to, during the following occasions: discovery of discrepancies identified during inventory; diversion, theft, or loss of any marijuana product; any criminal action involving or occurring on or in the Marijuana Establishment premises; and suspicious act involving the sale, cultivation, distribution, processing or production of marijuana by any person; unauthorized destruction of marijuana; any loss or unauthorized alteration of records relating to marijuana; an alarm activation or other event that requires response by public safety personnel or security personnel privately engaged by the Marijuana Establishment; the failure of any security alarm due to a loss of electrical power or mechanical malfunction that is expected to last more than eight hours; or any other breach of security.

G7 Lab shall, within ten calendar days, provide notice to the Commission of any incident described in 935 CMR 500.110(7)(a) by submitting an incident report in the form and manner determined by the Commission which details the circumstances of the event, any corrective action taken, and confirmation that the appropriate law enforcement authorities were notified. G7 Lab shall maintain all documentation relating to an incident for not less than one year or the duration of an open investigation, whichever is longer, and make said documentation available to the Commission and law enforcement authorities upon request.

TRANSPORTATION LOGS

In the event that G7 Lab operates its own vehicle to transport marijuana products, it will maintain a transportation log of all destinations traveled, trip dates and times, starting and ending mileage of each trip, and any emergency stops, including the reason for the stop, duration, location, and any activities of personnel existing the vehicle, as required by 935 CMR 500.115(13). G7 Lab shall retain all transportation logs for no less than a year and make them available to the Commission upon request.

SECURITY AUDITS

G7 Lab will, on an annual basis, obtain at its own expense, a security system audit by a vendor approved by the Commission, in accordance with 935 CMR 500.110(8). A report of the audit will be submitted, in a form and manner determined by the Commission, no later than 30 calendar days after the audit is conducted. If the audit identifies concerns related to G7 Lab's security system, G7 Lab will also submit a plan to the Commission to mitigate those concerns within ten business days of submitting the audit.

CONFIDENTIAL RECORDS

G7 Lab will ensure that all confidential information, including but not limited to employee personnel records, financial reports, inventory records and manifests, business plans, and other documents are kept safeguarded and private, in accordance with 935 CMR 500.105(1)(k). All confidential hard copy records will be stored in lockable filing cabinets within the Director of Compliance's Office, which shall be maintained as a Limited Access Area that shall only be accessible to the minimum number of duly-authorized Licensed Marijuana Establishment Agents required to operate. No keys or passwords will be left in locks, doors, in unrestricted access areas, unattended, or otherwise left accessible to anyone other than the responsible authorized personnel. All confidential electronic files will be safeguarded by a protected network and password protections, as appropriate and required by the Commission. All hard copy confidential records will be shredded when no longer needed.

Following the closure of the Marijuana Establishment, all records will be kept for at least two years at G7 Lab's sole expense and in a form and location acceptable to the Commission, pursuant to 935 CMR 500.105(9)(g).

PERSONNEL POLICIES INCLUDING BACKGROUND CHECKS

G7 Lab LLC ("G7 Lab") has drafted and instituted these personnel policies to provide equal opportunity in all areas of employment, including hiring, recruitment, training and development, promotions, transfers, layoff, termination, compensation, benefits, social and recreational programs, and all other conditions and privileges of employment, in accordance with applicable federal, state, and local laws. G7 Lab shall make reasonable accommodations for qualified individuals with demonstrated physical or cognitive disabilities, in accordance with all applicable laws. In accordance with 935 CMR 500.101(1)(b), G7 Lab is providing these personnel policies, including background check policies, for its Independent Testing Laboratory.

Management is primarily responsible for seeing that equal employment opportunity policies are implemented, but all members of the staff share the responsibility for ensuring that, by their personal actions, the policies are effective and apply uniformly to everyone. Any employee, including managers, that G7 Lab determines to be involved in discriminatory practices are subject to disciplinary action and may be terminated. G7 Lab strives to maintain a work environment that is free from discrimination, intimidation, hostility, or other offenses that might interfere with work performance. In keeping with this desire, we will not tolerate any unlawful harassment of employees by anyone, including any manager, co-worker, vendor or clients.

In accordance with 935 CMR 500.105(1), General Operational Requirements for Marijuana Establishments, Written Operating Procedures, as a Marijuana Establishment, G7 Lab has and follows a set of detailed written operating procedures. G7 Lab has developed and will follow a set of such operating procedures at its facility. G7 Lab's operating procedures shall include, but are not necessarily limited to the following:

(a) Security measures in compliance with 935 CMR 500.110;
(b) Employee security policies, including personal safety and crime prevention techniques;
(c) A description of the Marijuana Establishment's hours of operation and after-hours contact information, which shall be provided to the Commission, made available to law enforcement officials upon request, and updated pursuant to 935 CMR 500.000.
(d) Storage of marijuana in compliance with 935 CMR 500.105(11);
(e) Procedures to ensure accurate record-keeping, including inventory protocols in compliance with 935 CMR 500.105(8) and (9);
(g) A staffing plan and staffing records in compliance with 935 CMR 500.105(9);
(h) Emergency procedures, including a disaster plan with procedures to be followed in case of fire or other emergencies;
(i) Alcohol, smoke, and drug-free workplace policies;
(j) A plan describing how confidential information will be maintained;
(k) A policy for the immediate dismissal of any marijuana establishment agent who has:

1. Diverted marijuana, which shall be reported to law enforcement officials and to the Commission;
2. Engaged in unsafe practices with regard to operation of the Marijuana Establishment, which shall be reported to the Commission; or
3. Been convicted or entered a guilty plea, plea of nolo contendere, or admission to sufficient facts of a felony drug offense involving distribution to a minor in the Commonwealth, or a like violation of the laws of another state, the United States

or a foreign jurisdiction, or a military, territorial, or Native American tribal authority.

(l) A list of all board members and executives of a Marijuana Establishment, and members, if any, of the licensee must be made available upon request by any individual. 935 CMR 500.105(1) (m) requirement may be fulfilled by placing this information on the Marijuana Establishment's website.

(m) Policies and procedures for the handling of cash on Marijuana Establishment premises including but not limited to storage, collection frequency, and transport to financial institution(s).

(n) Policies and procedures to prevent the diversion of marijuana to individuals younger than 21 years old.

(o) Policies and procedures for energy efficiency and conservation that shall include:

1. Identification of potential energy use reduction opportunities (including but not limited to natural lighting, heat recovery ventilation and energy efficiency measures), and a plan for implementation of such opportunities;
2. Consideration of opportunities for renewable energy generation, including, where applicable, submission of building plans showing where energy generators could be placed on the site, and an explanation of why the identified opportunities were not pursued, if applicable;
3. Strategies to reduce electric demand (such as lighting schedules, active load management and energy storage); and
4. Engagement with energy efficiency programs offered pursuant to M.G.L. c. 25, § 21, or through municipal lighting plants.

(p) Policies and procedures to promote workplace safety consistent with applicable standards set by the Occupational Safety and Health administration including plans to identify and address any biological, chemical or physical hazards. Such policies and procedures shall include, at a minimum, a hazard communication plan, personal protective equipment assessment, a fire protection plan, and an emergency action plan.

Pursuant to 935 CMR 500.029(2), an application for registration of a Laboratory Agent submitted to the Commission by an Independent Testing Laboratory shall include:

a. The full name, date of birth and address of the individual;
b. All aliases used previously or currently in use by the individual including maiden name, if any;
c. Written acknowledgment by the individual of the limitations on his or her authorization to possess, transport, and Process Marijuana for testing purposes in the Commonwealth;
d. A copy of the applicant's driver's license, government-issued identification card, liquor purchase identification card issued pursuant to M.G.L. c. 138 § 34B, or other verifiable identity document acceptable to the Commission;
e. An attestation signed by the applicant that the applicant will not engage in the diversion of Marijuana and Marijuana Products;
f. Written acknowledgement signed by the applicant of any limitations on his or her authorization to possess, test or transport marijuana products in the Commonwealth;
g. Authorization to obtain a full set of fingerprints, in accordance with M.G.L. c 94G § 21, submitted in a form and manner as determined by the Commision; and
h. Background information including, as applicable:
    1. a description and the relevant dates of any criminal action under the laws of the Commonwealth, or an Other Jurisdiction, whether for a felony or misdemeanor and which resulted in conviction, or guilty plea, or plea of *nolo contendere*, or admission of sufficient facts;

2. a description and the relevant dates of any civil or administrative action under the laws of the Commonwealth or an Other Jurisdiction, relating to any professional or occupational or fraudulent practices;
3. a description and relevant dates of any past or pending denial, suspension, or revocation of a license or registration, or the denial of a renewal of a license or registration, for any type of business or profession, by Other Jurisdictions;
4. a description and relevant dates of any past discipline by, or a pending disciplinary action or unresolved complaint by, the Commonwealth, or a like action or complaint by an Other Jurisdiction, with regard to any professional license or registration held by the applicant;
5. a nonrefundable application fee paid by the Independent Testing Laboratory with which the Independent Testing Laboratory Agent will be associated; and
6. any other information required by the Commission.

An Independent Testing Laboratory Person Having Direct Control registered with the Massachusetts DCJIS pursuant to 803 CMR 2.04: *iCORI Registration* shall submit to the Commission a CORI report and any other background check information required by the Commission for each individual for whom the Independent Testing Laboratory seeks a Laboratory Agent registration, obtained within 30 calendar days prior to submission. 935 CMR 500.029(4)

An Independent Testing Laboratory shall notify the Commission no more than one business day after a Laboratory Agent ceases to be associated with the Independent Testing Laboratory. The Laboratory Agent's registration shall be immediately void when the agent is no longer associated with the Independent Testing Laboratory. 935 CMR 500.029(5)

After obtaining a Registration Card for a Laboratory Agent, an Independent Testing Laboratory is responsible for notifying the Commission, in a form and manner determined by the Commission, as soon as possible, but in any event, within 5 business days of any changes to the information that the Independent Testing Laboratory was previously required to submit to the Commission or after discovery that a Registration Card has been lost or stolen. 935 CMR 500.029(7)

A Laboratory Agent shall always carry the Registration Card associated with the appropriate Independent Testing Laboratory while in possession of Marijuana Products, including at all times while at an Independent Testing Laboratory, or while transporting Marijuana or Marijuana Products. 935 CMR 500.029(8)

A Laboratory Agent affiliated with multiple Independent Testing Laboratories shall be registered as a Laboratory Agent by each Independent Testing Laboratory and shall be issued a Registration Card for each lab. 935 CMR 500.029(9)

Laboratory Agents are strictly prohibited from receiving direct or indirect financial compensation from any Marijuana Establishment for which the Laboratory Agent is conducting testing, other than reasonable contract fees paid for conducting the testing in the due course of work. 935 CMR 500.029(10)

Laboratory Agents shall not be employed by other types of Marijuana Establishments while employed as a Laboratory Agent at one or more Independent Testing Laboratories. 935 CMR 500.029(11)

An Independent Testing Laboratory or any associated Person or Entity Having Direct or Indirect Control, may not have a License in any other class. 935 CMR 500.050(1)(b)(2)

G7 Lab LLC

In accordance with 935 CMR 500.105 (9), General Operational Requirements for Marijuana Establishments, Record Keeping, G7 Lab's personnel records will be available for inspection by the Commission, upon request. G7 Lab's records shall be maintained in accordance with generally accepted accounting principles. Written records that are required and are subject to inspection include, but are not necessarily limited to, all records required in any section of 935 CMR 500.000, in addition to the following:

The following G7 Lab personnel records:

1. Job descriptions for each employee and volunteer position, as well as organizational charts consistent with the job descriptions;
2. A personnel record for each of G7 Lab's marijuana establishment agents. Such records shall be maintained for at least 12 months after termination of the individual's affiliation with G7 Lab and shall include, at a minimum, the following:
    a. all materials submitted to the Commission pursuant to 935 CMR 500.030(2);
    b. documentation of verification of references;
    c. the job description or employment contract that includes duties, authority, responsibilities, qualifications, and supervision
    d. documentation of all required training, including training regarding privacy and confidentiality requirements, and the signed statement of the individual indicating the date, time, and place he or she received said training and the topics discussed, including the name and title of presenters;
    e. documentation of periodic performance evaluations;
    f. a record of any disciplinary action taken; and
    g. notice of completed responsible vendor and eight-hour related duty training.
3. A staffing plan that will demonstrate accessible business hours and safe conditions;
4. Personnel policies and procedures; and
5. All background check reports obtained in accordance with 935 CMR 500.030.

Following closure of a Marijuana Establishment, all records must be kept for at least two years at the expense of the Marijuana Establishment and in a form and location acceptable to the Commission. G7 Lab understands that in the event that G7 Lab were to close, all records will be kept for at least two years at the expense of G7 Lab.

QUALIFICATIONS AND TRAINING

G7 Lab LLC ("G7 Lab") shall, pursuant to 935 CMR 500.105(2), ensure that all marijuana establishment agents complete training prior to performing job functions. Training will be tailored to the role and responsibilities of the job function. At a minimum, staff shall receive eight hours of on-going training annually. New marijuana establishment agents will receive employee orientation prior to beginning work with G7 Lab. Each department manager will provide orientation for laboratory agents assigned to their department. Orientation will include a summary overview of all the training modules.

All G7 Lab employees will be duly registered as marijuana establishment agents and must complete a background check in accordance with 935 CMR 500.029(1). All registered agents of G7 Lab shall meet suitability standards of 935 CMR 500.803.

Pursuant to 935 CMR 500.029, the Commission shall issue a Laboratory Agent Registration Card to each individual associated as an employee or volunteer with an Independent Testing Laboratory who is licensed pursuant to 935 CMR 500.050(7) or 935 CMR 501.029: *Registration of Independent Testing Laboratory Agents*, who is determined to be suitable for registration. All such individuals shall:

a. be 21 years of age or older;
b. have not been convicted of any felony drug offense in the Commonwealth or a like violation of the laws of an Other Jurisdiction;
c. have not been convicted of any offense involving the distribution of controlled substances to a minor or a like violation of the laws of an Other Jurisdiction; and
d. be determined to be suitable for registration consistent with the provisions of 935 CMR 500.800, 935 CMR 500.801 or 935 CMR 500.803.

An Independent Testing Laboratory shall be accredited to the most current International Organization for Standardization (ISO) 17025 by a third-party accrediting body that is a signatory to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement or certified, registered or accredited by an organization approved by the Commission. 935 CMR 500.50(7)

1. Purpose

The purpose of this procedure is to establish qualification criteria and define an internal training program and to ensure the competency of laboratory personnel. Training and training verification are key factors for successful laboratory operations.

2. Scope

This training procedure is used to ensure that training has taken place with each employee for procedures and methods that the employee performs. The procedure applies to on-the-job training, in-house training and new-hire training. The training is verified and recorded. The training procedure is applicable to new employees, for the introduction of new procedures and methods, for retraining of employees, and for reverification of employee performance.

3. Responsibility

A. Laboratory Management

1. Ensures implementation of training procedure.
2. Responsible for the evaluation, training and growth of the technical and quality related skills of employees by establishing training schedule and rotation for all new employees and by ensuring personnel receive training and demonstrate competence.
3. Maintains employee training records electronically in media lab compass module.
4. Ensures proper supervision of trainees until training completed.
5. Ensures training records are complete.
6. Monitors employee performance to identify the need for retraining or additional continuing education.
7. Identifies training needs resulting from new or revised procedures and processes.
8. Authorizes personnel to perform specific laboratory activities.
9. Ensures and records continued competency of employees.
10. Has relevant knowledge of the technology, methods and procedures used, purpose of each test, and an understanding of the significance of deviations found with regard to the normal use of the items, materials, products, etc. concerned within their area of responsibility.
11. Ensures training is conducted and recorded for quality management system policies and procedures.

B. Staff

- Completes required training within specified timeframe.
- Becomes and stays knowledgeable in procedures and methods performed, NOTE: Employees are responsible for self-training, through reading current literature and technical papers.
- Ensures all mandated training, is completed and certificate submitted to Management or Technical Manager.

- Reads and complies with standards, regulations, policies, procedures, and work instructions.

4. Background

None

5. Qualification

The required qualification for laboratory staff is as follows:

5.1.1 Technical Manager/ Quality Manager

Associate Degree in Natural Science (Biology, Chemistry, Physics) or 5-year experience in an analytical testing Laboratory certified by EPA, ISO or international Agency recognized in USA.

5.1.2 All other Laboratory Staff

High School Diploma

6. Procedure

6.1. Training and Competency Requirements

Before starting any work-related duties, the employee will be familiar with work related documents. These documents include procedures, work instructions, applicable manuals and regulations. Employees undergoing training are supervised until training is completed and competency demonstrated.

A. Training requirements are outlined and documented on the basis of the position description of duties and responsibilities.
B. Training and competency are determined by the employee's educational qualifications, experience, complexity of the test method, and knowledge of the test method performed.
C. The employee will not perform any procedure, inspection, or method until all applicable training has been completed and competency demonstrated.
D. Employees may request training related to their duties. Included in these services are online courses, borrowing books from the laboratory and web-based courses.
E. Employees submit records to supervisor and/or Technical manager for filing upon completion of training.
F. Training and competency records shall be maintained electronically using media lab compass module.
G. The effectiveness of training is evaluated by but not limited to reviews performed by management and performance evaluations.

6.2. Training Technique

A. The training process for technical procedures such as laboratory analysis consists of the following steps:

1. Trainee reads the laboratory procedures, work instructions, or other applicable documents.
2. Trainee observes demonstration of the procedure by a trainer.
3. Trainee performs the procedure under observation by a trainer.
4. Trainee successfully completes the procedure independently.

B. The training process for non-technical procedures includes, but is not limited to:
1. Reading laboratory procedures,
2. Instructions,
3. Demonstrations,
4. Lectures and discussions,
5. Self-study,
6. Computer-based training,
7. Viewing videos, and
8. Manufacturer's training or demonstration.

C. An employee's performance is verified by measurement against a defined performance standard. The measures used to verify an employee's performance are assessment tools.

6.3 Assessment tools

A. Administration of a Written Evaluation: Written evaluations can be used in areas where verification of a participant's knowledge is desired. Knowledge of theory or principles, problem-solving ability, logical sequence used, and independent or group decision making may be ascertained.
B. Observation of Procedure, Process, or Outcome: Observation by a trainer of an employee performing or demonstrating a procedure.
C. Verification of Response to Situational Problems or Calculations Related to the Procedure: Example circumstances include resolution of a posed and procedure-related situational problem or recommendation of procedure-related course of action that is consistent with policies and regulations.
D. Response to Oral Queries Related to a Step or Procedure: Answers provided by the employee to questions asked by trainer.
E. Testing Blind QC Samples: Employees are unaware when blind test samples are assigned. They appear identical to other samples, are in routinely used containers, and are from a similar source. The intent is to provide simulated samples to measure realistic analytic conditions. This tool assesses all phases of laboratory performance.

F. Testing of Known Samples: Participants know and often plan for known testing events, such as external proficiency surveys and commercially prepared quality control samples. Samples for quality assurance or quality control purposes are identified immediately upon receipt in the laboratory. It is considered a waste of time and resources to conduct more careful handling and analysis on these samples or perform duplicate testing. This tool assesses the analytical phase only.
G. Testing Previously Analyzed Samples: Duplicate or replicate testing provides accessible internal comparisons and contributes to the validation of the analytic phase. These sources may be previously tested samples, samples of known constituents, and already reported proficiency testing samples. This tool assesses the analytical phase only.

6.4. Demonstration of Competency

A. Competency assessment is one method to verify that analysts are competent to perform testing and report accurate and timely results.
B. To be competent, an analyst must know how to perform a test, have the ability to perform the test, be able to perform the test properly without supervision, and know when there is a problem with the test that must be solved before reporting results.
C. The major technologies (at minimum the items on accreditation scope) require demonstration of initial and ongoing competency by any of the following tools:
    1. Direct observation of test performance and instrument maintenance and function checks
    2. Monitoring the recording and reporting of results
    3. Review of intermediate checks, QC results, proficiency test results
    4. Assessment of test performance through external/internal PT's
    5. Samples analyzed; Method validations; Accuracy/Precision on lab control samples
D. Records of at least four separately prepared, separately analyzed, nonconsecutive laboratory control samples with acceptable levels of precision and accuracy. This is required for all initial demonstrations of capability.
E. After initial demonstration of capability, acceptable analysis of a proficiency test sample or four passing laboratory control sample (LCS) samples from routine analyses are valid as an ongoing demonstration of capability

6.5. Authorization of Personnel

A. Laboratory management authorizes personnel to perform specific laboratory activities as defined in local policies and procedures.
B. When personnel are authorized for a portion of a method, the training records must indicate which parts of the method the employee has received training.

6.6. Training and Competency Records

A. Training and competency records are maintained electronically on media lab competency module.
B. Training records should include a description of the training, the trainee name, the trainer, dates of training, and indication of successful completion. Training records are archived for exiting employees. Examples of training records:

1. Completed training checklist prepared internally for procedure.
2. Completed blind quality control (QC) samples, proficiency surveys, acceptable preparation and analysis of QC samples.
3. Completed written evaluations.
4. Signed acknowledgment of reading assigned procedural documents.
5. Attendance sign-in sheets for in-house training.
6. A certificate from manufacturer's training courses, computer-based classes, and committees served
7. Submission of technical papers and handouts of presentations given.
8. College transcripts for courses taken, licenses, memberships held, and special conferences attended.
9. Completed paperwork on safety briefing, orientation modules, and in- or out-processing steps for new hires or those leaving the organizational unit.

6.7. Retraining and Reverification

6.7.1. Retraining:

A. Employees will be retrained whenever significant changes occur in policies, values, goals, procedures, processes, and methods or instruments.
B. Employees will be retrained when the level of performance is unsatisfactory.

6.7.2. Reverification:

A. Reverification occurs when employees attend required courses, continuing education, presentations, workshops, conferences, and scheduled training either in house or manufacturer's training.
B. Performance reverification occurs when proficiency surveys, blind QC samples, or duplicate testing are submitted.

6.8. Required Training

All employees and laboratory staff members are to undergo training in a number of procedures, policies and practices upon entry of employment and during their career. What

follows are types of required training and they may vary from employee to employee based on duties.

6.8.1. Facility Orientation

A. New employees completing required administrative forms as part of initial processing; and
B. Introduction to co-workers, personnel policies, working conditions, daily routine, issuance of manuals, quality assurance system and any miscellaneous matters.

6.8.2. Safety Training (may include the following topics):

A. Hazard communication standard (Right to Know),
B. Universal precautions,
C. Exposure control plan,
D. Medical surveillance program,
E. Personal protective equipment,
F. Security briefing,
G. Safety briefing,
H. Radiation protection training,
I. Fire extinguisher training,
J. Emergency evacuation,
K. Safety practices in the laboratory,
L. Chemical Hygiene, and
M. Hazardous Waste Management that includes annual training on handling, storage, and disposal of hazardous materials

6.8.5. Quality Management System training

Examples include:

A. MediaLab Training
B. Introduction to the Quality Management System
C. Root Cause and Corrective Action procedures

6.8.7. Other Training

Often laboratory staff has an opportunity to attend auxiliary training when available and resources permitting. This type of training includes:

A. Attendance at presentations, courses, conferences; and
B. Computer courses such as in-house training, instructional, and manufacturer's training on software in use such as Microsoft Word and Excel, ChemStation, and Outlook.

7. Glossary/Definitions

A. FV/PM – Function Verification/Preventive Maintenance.

B. Procedure – This is a description of the sequence of steps leading to a defined outcome or product. A procedure can be technical or administrative.

C. Retraining – Retraining is required when assessments show less than satisfactory performance or whenever significant changes occur in procedures or processes.

D. Reverification – This is a process that ensures employees remain at an acceptable level of performance.

E. Trainer – Trainers are persons that are knowledgeable in and regularly perform the procedures in which they instruct others. Necessary attributes include good verbal skills, demonstrated attention to detail, and objectivity.

F. Training Methods - The process of training and criteria for success are defined.

G. Training checklist – The training checklist is prepared from the procedure by defining all steps to perform a procedure for the verification of employee's competency.

H. Training Verification – This is a systematic approach to demonstrate that the training outcome is successful.

8. Records

Training and competency management files and records are recorded and managed electronically in media lab compass module.

9. Appendix

None

10. References

A. Quality Assurance Program Plan for Analytical Testing Laboratories Performing Analyses of Finished Medical Marijuana Products and Marijuana-Infused Products in Massachusetts, Massachusetts Department of Public Health, Version 5.0 May 15,2018

B. FDA staff manual. Guide 3120.1 Personnel – Staff Development and Training

C. ISO/IEC 17025:2017, General requirements for the competence of testing and calibration laboratories, Section 6.2.

D. AOAC International Guidelines for Laboratories Performing

E. Microbiological and Chemical Analysis of Food, Dietary Supplements, and Pharmaceuticals – An Aid to Interpretation of ISO/IEC 17025:2017; August 2018.

QUALITY CONTROL AND TESTING

G7 Lab LLC ("G7 Lab") will not sell or market any marijuana product that has not been tested by licensed Independent Testing Laboratories ("ITL"). Testing of marijuana products shall be performed by an Independent Testing Laboratory in compliance with protocol(s) established in accordance with M.G.L. c.94G § 15 and in a form and manner determined by the Commission including, but not limited to, the Protocol for Sampling and Analysis of Finished Medical Marijuana Products and Marijuana-infused Products). Testing of environmental media (e.g., soils, solid growing media, and water) shall be performed in compliance with the Protocol for Sampling and Analysis of Environmental Media for Massachusetts Registered Medical Marijuana Dispensaries published by the Commission. 935 CMR 500.160(1).

Marijuana shall be tested for the Cannabinoid Profile and for contaminants as specified by the Commission including, but not limited to, mold, mildew, heavy metals, plant growth regulators, and the presence of Pesticides. The Commission may require additional testing. 935 CMR 500.160(2)

An Independent Testing Laboratory shall report any results indicating contamination to the Commission within 72 hours of identification. 935 CMR 500.160(3); M.G.L. c.94G § 15(a)(3).

An ITL shall apply for a certificate of registration from the Commission prior to testing, processing or transporting marijuana. M.G.L. c.94G § 15(b)(1).

A Marijuana Establishment shall maintain the results of all testing for no less than one year. Testing results shall be valid for a period of one year. 935 CMR 500.160(4).

All transportation of Marijuana to and from Independent Testing Laboratories providing Marijuana testing services shall comply with 935 CMR 500.105(13).

All storage of Marijuana at a laboratory providing Marijuana testing services shall comply with 935 CMR.105(11).

All excess Marijuana must be disposed of in compliance with 935 CMR 500.105(12), either by the Independent Testing Laboratory returning excess Marijuana to the source Marijuana Establishment for disposal or by the Independent Testing Laboratory disposing of it directly.

Marijuana and Marijuana Products submitted for retesting prior to remediation must be submitted to an Independent Testing Laboratory other than the laboratory which provided the initial failed result. Marijuana submitted for retesting after documented remediation may be submitted to the same Independent Testing Laboratory that produced the initial failed testing result prior to remediation.

G7 Lab's policies for handling of marijuana shall be in compliance with 935 CMR 500.105(3). G7 Lab will comply with the following sanitary requirements, that include, but are not limited to: hand washing stations; sufficient space for storage of materials; removal of waste; clean floors, walls and ceilings; sanitary building fixtures; sufficient water supply and plumbing; and storage facilities that prevent contamination. All G7 Lab staff will be trained and shall ensure that marijuana and marijuana products are handled with appropriate food handling and sanitation standards specified in 105 CMR 300.000. G7 Lab will ensure that if furnishes the facility with the proper equipment and storage materials, including

adequate and convenient hand washing facilities; food-grade stainless steel tables; and temperature- and humidity- control storage units, refrigerators, and freezers.

All G7 Lab staff will immediately notify the Director of Compliance of any actual or potential quality control issues, including facility cleanliness/sterility, tool equipment functionality, and storage conditions. All issues with the facility will be investigated and immediately rectified by the Director of Compliance.

All G7 Lab staff will receive relevant quality assurance training. All staff will wear gloves when handling marijuana and marijuana products, and exercise frequent hand washing and personal cleanliness, as specified in 935 CMR 500.105(3). Marijuana products will be processed in a secure access area of G7 Lab.

Any spoiled, contaminated, dirty, spilled, or returned marijuana products are considered marijuana waste and will follow G7 Lab procedures for marijuana waste disposal, in accordance with 935 CMR 500.105(12). Marijuana waste will be regularly collected and stored in the secure-access, locked inventory vault.

Pursuant to 935 CMR 500.105(11)(a)-(e), G7 Lab shall provide adequate lighting, ventilation, temperature, humidity, space and equipment, in accordance with applicable provisions of 935 CMR 500.105 and 500.110. G7 Lab will have a separate area for storage of marijuana that is outdated, damaged, deteriorated, mislabeled, or contaminated, or whose containers or packaging have been opened or breached, unless such products are destroyed. G7 Lab storage areas will be kept in a clean and orderly condition, free from infestations by insects, rodents, birds, and any other type of pest. The G7 Lab storage areas will be maintained in accordance with the security requirements of 935 CMR 500.110 and its Security Plan.

Sections in This Document

1. Introduction

This Laboratory Manual of Quality Policies has been prepared to meet the requirements for laboratory accreditation of the International Organization for Standardization/International Electrotechnical Commission (ISO/IEC 17025:2017) and Cannabis Control Commission of MA (CCC) requirement for Certification and or registration of G7 Lab LLC(G7) as an Independent Testing Laboratory for Testing Cannabis plant flower, Cannabis infused products or any cannabis related testing.

This manual is directly based on FDA manual of Quality Policies for ORA regulatory Laboratories.

2. Controlled Distribution of the Quality Manual

The management of G7 is responsible for maintaining the official master copy of the Laboratory Manual which contains the Laboratory Quality Assurance Manual. This Manual consists of Laboratory Manual of Management Requirements and, ISO 17025:2017 Laboratory Procedures. Biennial review is coordinated by the management. All the laboratory procedures, Standard Operating Procedure (SOP), manuals, policies will be maintained via document control module of Media Lab INC.

3. Quality Policy Statement

G7 is committed to providing testing that meets both the needs of the customers, CCC and the requirements of ISO/IEC 17025:2017 and to continually improve the effectiveness of the management system. Testing results are reported within stated limits of accuracy, precision, and detection limits as described in the methods used for analysis.

3.1. Management System Objectives

A. The primary objective of the management system established by G7 is to assure the accuracy and precision of laboratory results so that they will be reliable, interpretable, repeatable, and defensible. Data quality objectives are described in the terms of:

1. Accuracy
2. Precision
3. detection and quantitation limits,
4. timeliness, and
5. comparability.

B. Second, strive to meet or exceed the CCC, ISO/IEC 17025:2017 requirements, local regulations if applicable and customer's needs and expectations.

C. Third, maintain G7s' reputation for quality by fostering continuous process improvement and problem prevention.

These objectives are considered as part of the reviews performed by management.

3.2. Management System Awareness and Implementation

The management system documents and test methods are included as training elements in the laboratory's training program addressed in the laboratory training procedure. This ensures that staff is familiar with quality documentation and implement the quality policies and procedures in their work. See G7 Gen 3.0 Personnel Training and Competency Management.

4. General Requirements

4.1. Impartiality

4.1.1. To avoid conflicts of interest, pressures, and influences, G7. employees will be familiar with and observe the standards Set by G7, the requirements of CCC, and ISO 17025:2017.

4.1.2. Risks to impartiality are continuously reviewed and eliminated or minimized to ensure there is no compromise to the objectivity of staff engaged in laboratory activities.

Two core concepts are embodied in these principles: (a) Employees shall not use laboratory for private gain, (b) and employees shall act impartially and not give preferential treatment to any private organization or individual.

4.1.3. Risks to impartiality may be identified during required routine disclosures by employees or during audits. When laboratory employees or processes pose a risk to impartiality, an assessment is made of the nature of the risk and appropriate corrective actions are taken by the laboratory management.

4.2. Confidentiality

4.2.1. All G7 staff certify their agreement to abide by G7's confidential information Policy. Contract employees are required to sign this form as well. This form certifies their agreement to abide with G7's confidentiality requirements which are also included in purchasing agreements, as needed, with vendors performing work in areas where laboratory work is performed.

4.2.2. G7 does not release confidential information to external parties. Information is released only to CCC, the customer or designated representative and local or State law enforcement if required or relevant.

4.2.3. Reports of information and data are transmitted and filed in accordance with official policies. Most reports are only transmitted internally within the laboratory, except as required by law or regulation. Information is released only to CCC, the customer or designated representative.

4.2.4. G7 is a controlled-access building to further ensure protection of data. Visitors to G7 are escorted by Lab Agents beyond reception area and allowed only in areas approved by security protocols in place to ensure no customer information is compromised. Additionally, employees are committed to properly keep and use confidential information obtained or witnessed during their duties.

5. Structural Requirements

5.1. Laboratory as a legal Entity

G7 is a Limited liability company registered in The Commonwealth of Massachusetts with the secretary of the Commonwealth. The Laboratory is required to follow the CCC regulations in 935 CMR as applicable to Independent Testing Laboratory, ISO/IEC 17025:2017 and all applicable local regulation.

5.2. Management Responsible for Laboratory

The Technical Manager (TM) is responsible for establishing the organization's commitment to the management system, implementing it, and delegating responsibility for its accomplishment.

The Technical manager is also responsible for issuing policy and procedures and monitoring their implementation.

Laboratory management, Technical manager and laboratory staff are responsible for ensuring that analytical activities meet the requirements of the CCC, ISO17025:2017, regulations in 935 CMR 500 and local regulations. In addition, each person involved in the generation of data is part of the management system.

5.3. Scope of Accredited Laboratory Activities

Laboratory activities encompass all processes from the review of vendG7 for external products and services to sample, equipment, supply, and data handling and reporting within the laboratory. G7 will have documented training, proficiency, and method validation and verification programs in place. To ensure consistency in these processes controlled, approved documents are maintained to provide guidance in all processes and records retained to recreate processes, if needed. These also provide the basis to evaluate risks and improvements where gaps are identified through nonconformances, complaints, and annual management review of the inputs and outputs of operations.

5.4. Laboratory Requirements

The intent of G7 is to operate testing laboratory per the following requirements:

A. 935 CMR 500

B. ISO/IEC 17025:2017,

C. Massachusetts Department of Public Health (MDPH)

D. G7's compliance programs and assignments,

E. State and local laws and regulations, and

F. Accreditation requirements.

5.5. Laboratory Organizational Structure and Procedures

5.5.1. G7 being a small laboratory The TM and Quality Manager's (QM) responsibility is carried out by the TM as allowed by the QAPP manual of MDPH. The organization and the relationship among the laboratory staff are reflected in the laboratory's organizational chart maintained by the laboratory. These charts provide relationships between management, technical operations, and support personnel. The chart is presented as follows:

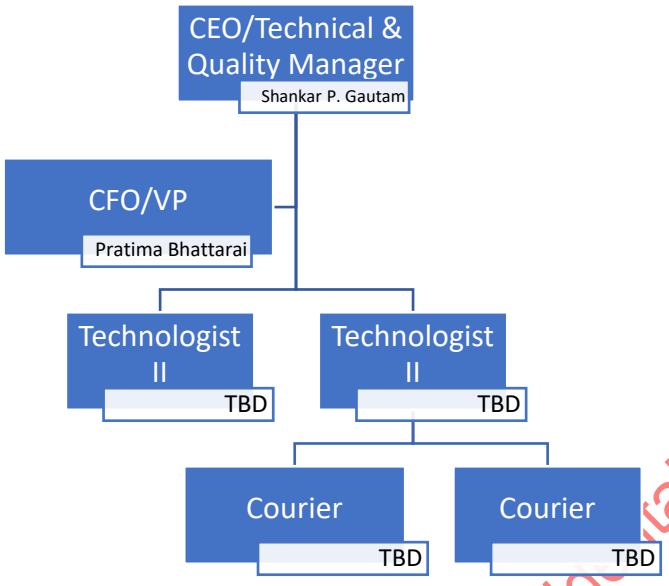


Figure 1. organizational Chart, TBD=To be Dependent

5.5.2. The laboratory has managerial staff with the authority to discharge their duties as reflected in the prepared job descriptions by the laboratory. This authority includes the implementation, maintenance, and improvement of the management system.

Job responsibilities and position description for laboratory employees are documented in the document control management system. All documents are controlled and managed in media lab document control system.

5.5.3. The laboratory management system is outlined in the following documents:

A. Quality Assurance Manual,

B. Written procedures,

C. Work Instructions,

D. References, and

E. Forms and records.

This management system is established to address the requirements in ISO/IEC 17025:2017 and CCC 935 CMR 500. G7 establishes and maintains documents per the procedure for document control. The documents listed above are accessible to all laboratory personnel and are included in the laboratory's training program.

5.6. Personnel Responsibilities and Authority

Laboratory personnel are aware of their roles and contributions in the management system and of its objectives through regularly scheduled training provided by the management. Laboratory personnel irrespective of other responsibilities have the authority and resources to carry out their duties.

5.6.1. General roles and responsibilities for laboratory personnel are summarized as follows:

F. Technical Manager

1. Ensures that the management system is established, implemented, and maintained in conformance with the requirements of ISO/IEC 17025:2017, CCC and local regulations.
2. Advocates and coordinates quality improvements to the management system.
3. Oversee technical functions.
4. Ensure compliance with the requirements of ISO/IEC 17025:2017.
5. Ensure management system procedures, applicable standards, specifications, and regulations are followed.
6. Ensure that qualified, skilled, and trained personnel and other resources are available.
7. Ensure that products and services satisfy customer requirements.

G. Laboratory staff

1. Ensure the quality of their work.
2. Operate in conformance with the requirements of the management system.

5.6.2. All laboratory employees have the authority and are encouraged to identify and report deviations from the management system or procedures for laboratory activities.

5.6.3. All laboratory employees contribute toward initiation of actions to minimize such deviations or provide input toward improvement to the system. These actions are monitored and reviewed by laboratory management.

5.6.4. The laboratory Technical Manager is responsible for monitoring the laboratory's management system and reporting its performance and any need for improvement to laboratory management.

Laboratory Management is responsible for the technical operations of the laboratory. Resources for training, laboratory methods, measurement traceability, and purchasing. Qualified laboratory personnel are assigned to serve in the absence of key managerial personnel, such as Laboratory Technical Manager to maintain unbroken continuation of operations. In addition, the laboratory has an active and executable contingency plan for the Continuity of Operations (COOP) in place with effectiveness drills enacted at least once each year.

5.7. Communication and Integrity of the Management System

5.7.1. Effective communication from management occurs through, but is not limited to, huddles, memos, newsletters, electronic presentations, emails, or verbally to laboratory personnel regarding the effectiveness of the management system and the importance of meeting statutory, and regulatory requirements.

5.7.2. The management system process and procedures as defined in this manual maintain the integrity of the management system when changes such as a change in the structure of the organization or management, or a change is a policy or procedure are made.

6. Resource Requirements

6.1. General

Personnel, facilities, equipment, systems and support services necessary for the management and performance of laboratory activities are evaluated and put in place to ensure defensible data and conformity to the requirements of ISO/IEC 17025:2017 General requirements for the competence of testing and calibration laboratories.

The sections following below address the facts affecting the correctness and reliability of the tests performed by a laboratory. These facts include contributions from:

A. Personnel (G7 Lab Gen 02, Personnel Training and Competency Management),

B. Facilities and environmental conditions (G7GEN06 Facilities and Environmental Conditions),

C. Equipment G7GEN08 Equipment

D. Metrological traceability (G7GEN09 Methods, Method Verification and Validation

E. Externally provided products and services

F. The procedures listed in each section address these facts.

6.2. Personnel

6.2.1. **Personnel**

All laboratory personnel that could influence laboratory activities act impartially, are competent, and perform their work according to the laboratory's management system. These positions include, but are not limited to: supervisors and managers, laboratory support staff, sample custodians, and administrative management staff.

6.2.2. **Competence Requirements**

Competence is based on education, experience, demonstrated skills, and training. Staff records contain the documentation of personnel education, qualification, experience, technical knowledge, skills, and training for the position held.

Skills of personnel are based upon demonstration of competence. Competency requirements for each function influencing the results of laboratory activities are documented in the laboratory's training documents. This demonstration is to be completed successfully before laboratory personnel generate data independently. The effectiveness of personnel training is documented in, but not limited to management reviews, internal audits, external assessments, proficiency testing, and performance evaluations.

6.2.3. **Personnel Competence**

Laboratory management ensures that laboratory personnel have the competence to perform their duties and to evaluate the significance of deviations.

Trainees undergo a training program in accordance with the laboratory's training documents. Trainees perform procedures when training and competency has been demonstrated. The documented demonstration of competence is an exercise that the trainee performs independent of supervision. The trainee is considered competent after the specified criteria have been successfully met. Please refer to *G7 GEN03* Personnel Training and Competency Management Procedure for further details on training and competency management.

6.2.4. **Communication of Duties, Responsibilities and Authorities**

Job duties, responsibilities and authorities for laboratory employees are documented in the management system procedures and operating instructions.

Position descriptions are maintained by G7 in media lab document control module electronically. The laboratory maintains active job descriptions for managerial, technical, and key support personnel involved in laboratory activities. Job descriptions are established based on current duties and technologies utilized.

The laboratory employees involved in laboratory activities have access to consensus standards, instrument manufacturers' manuals, and laboratory procedures for reference.

Effective communication from management occurs through, but not limited to, memos, newsletters, electronic presentations, emails, or verbally to laboratory personnel regarding the effectiveness of the management system.

6.2.5. **Personnel Procedures**

A. The procedure for determining competence requirements are defined in the laboratory's documents and G7 GEN03Personnel Training and Competency Management.

B. G7 maintains the hiring procedures for the Laboratory. G7GEN11 Hiring Procedure describes the selection procedures.

C. The individual and management are jointly responsible for the setting, the pursuit, and achievement of educational goals for professional advancement. The annual performance evaluation process can be used by the individual to discuss career advancement and training possibilities. By using this process, individuals can identify areas of study and request training oriented towards the attainment of their goals.

D. Training needs are identified in accordance with the analyst's background (e.g. Chemist, Microbiologist). In-house training is conducted per laboratory's training procedure. Present and anticipated tasks of the laboratory are addressed in the planning of special training modules.

The management system documents and test methods are included as training elements in the laboratory's training program addressed in the laboratory training procedure. This ensures that staff is familiar with quality documentation and implement the quality policies and procedures in their work.

E. The laboratory utilizes the skills and talent of both full-time employees and contract personnel. The requirements of the management system are administered equally to both categories. No differentiation is made between the two categories of workers. Supervision, training, and competence are documented for all technical and key support personnel.

Trainees do not perform regulatory work until competent as per the laboratory training program.

F. Personnel are authorized to perform specific laboratory activities according to section 6.2.6 and local documents.

G. Personnel competency is monitored through onsite reviews, reporting and worksheet write-ups, demonstration through documentation of the required instrument maintenance and function checks, results obtained on proficiency test samples, number of samples analyzed satisfactorily and QC samples within established criteria.

6.2.6. **Personnel Authorization**

The Laboratory Management authorizes personnel to perform specific laboratory activities, including but not limited to:

A. Development, modification, verification and validation of methods;

B. Analysis of results, including statements of conformity or opinions and interpretations;

C. Report, review and authorization of results;

Records of authorizations, demonstration of competence, education, training, and experience are maintained by the laboratory electronically in media lab competency module and dated. Training files are maintained and include these records.

Related Procedures/References

- G7 Lab Gen 02 Personnel Training and Competency Management

6.3. Facilities and Environmental Conditions

6.3.1. **Suitability of Facilities and Environmental Conditions**

The laboratory environmental conditions facilitate the correct performance of analytical testing. Examples of environmental influences are energy sources, lighting, biological sterility, dust, humidity, and temperature. The laboratory monitG7 critical environmental conditions to ensure that results and the quality of the measurement are not adversely affected or invalidated.

6.3.2. **Documentation of Requirements for Facilities and Environmental Conditions**

Test methods and environmental monitoring procedures used by the laboratory include instructions addressing applicable environmental conditions.

6.3.3. **Monitoring, Controlling and Recording Environmental Conditions**

Environmental conditions requiring monitoring include, but are not limited to:

A. room temperature and humidity,

B. biosafety hoods and laminar flow hoods,

C. metal contamination on benches and hoods in laboratories performing metal analysis,

D. microbiological contamination on bench surfaces and hoods in microbiology benches

Where environmental controls are needed, the environmental conditions are recorded.

Testing activities are stopped when the environmental conditions invalidate the test results or adversely affect quality control. Monitoring activities are conducted as part of the laboratory test or calibration methods.

6.3.4. **Measures to Control Facilities**

The following measures to control facilities are implemented, monitored and periodically reviewed:

A. Access and use of areas affecting laboratory activities

Laboratories are limited access areas. Access and use are controlled by, but is not limited to:

1. issuance of keycards for entrance,
2. escorting visitG7,
3. issuance of identification badges, and

B. Housekeeping

Laboratory areas are maintained clean and orderly to prevent contamination of samples and to facilitate the efficiency of laboratory operations.
The laboratory's Chemical Hygiene Plan(G7GEN06) and Hazardous Waste Management Plan (G7GEN13) include measures taken to ensure good housekeeping in the laboratory.

C. Cross-contamination

Separate areas are maintained for incompatible activities. Measures taken to prevent cross-contamination include, but are not limited to:

1. chemistry laboratories are separated from microbiology laboratories,
2. sample receiving, and storage are conducted in designated areas,
3. separate storage for standards and reference materials, and
4. media preparation and sterilization are separated from work areas.

Related Procedures/References

- G7GEN 10 Facilities and Environmental Conditions.
- G7GEN06 Chemical Hygiene Plan.
- G7GEN13 Hazardous Waste Management Plan.

6.3.5. **Work Performed Outside the Laboratory's Permanent Control**

The laboratory staff are not authorized to perform laboratory activities at sites outside of the laboratory's control, facility.

6.4. Equipment

6.4.1. Access to Laboratory Equipment

The laboratory has sample preparation, measurement and test equipment for the correct performance of the tests and calibrations. The laboratory also has ancillary equipment for processing samples and for processing data. Also see section 6.5 Metrological Traceability.
The laboratory purchases the equipment. Maintenance contracts are established as needed. In those cases where the laboratory leases equipment it has direct control concerning its use. Leased equipment is managed in the same manner as purchased equipment according to the management system requirements.

G7 maintains an equipment inventory of all laboratory equipment used to perform regulatory testing.

6.4.2. Equipment Outside the Laboratory's Permanent Control

If for any reason equipment leaves the direct control of the laboratory the laboratory ensures the equipment requirements are met before using the equipment.

6.4.3. Procedure for Handling, Transport, Storage, Use and Planned Maintenance of Equipment

The laboratory has procedures G7GEN08 Equipment for the safe handling, transport, storage, use and planned maintenance of equipment to ensure proper functioning and to prevent contamination or deterioration.

6.4.4. Verification of Equipment Prior to Being Placed or Returned into Service

The equipment performance is verified, and verification records are maintained. Equipment is to meet the laboratory's testing parameters and conform to standard specifications before being placed or returned into service.

Procedures for equipment verification are provided in G7GEN08 Equipment.

6.4.5. Equipment Accuracy/Uncertainty

Equipment and its software used for testing are to achieve the accuracy expected, measurement uncertainty required, and comply with specifications of the testing concerned.

The uncertainty contributions are addressed in G7GEN 20 Estimation of Uncertainty of Measurement.

6.4.6. Equipment Calibration

Measuring equipment is calibrated when the measurement accuracy or uncertainty affect the reported results and/or calibration of the equipment is required to establish metrological traceability of the reported result.

Procedures for equipment calibration are provided in procedure G7GEN08 Equipment

6.4.7. **Calibration Program**

The equipment calibration program is defined in G7GEN15 Measurement Traceability. These procedures are reviewed and revised according TO G7GEN 24 Document Control and Management.

6.4.8. **Calibration Status**

Equipment under the control of the laboratory and requiring calibration, or having a defined period of validity, is labeled or coded to indicate the calibration status or period of validity. Alternatively, equipment calibration status may be identified in an associated record to indicate the status of calibration.

6.4.9. **Out of Service**

Equipment that has been subjected to overloading or mishandling, gives suspect results, or has been shown to be defective or outside specified limits, is taken out of service. It is isolated to prevent its use or clearly labeled or marked as being “Out of Service” to prevent its use until it has been repaired and shown by calibration or test to perform correctly.

6.4.10. **Calibration Confirmation**

Intermediate calibration confirmation checks are performed to maintain confidence in the calibration status of the equipment.

Metrological confirmation for reference standards and reference materials included in the calibration program is conducted according to a schedule addressed in the procedure in G7GEN08 Equipment. The confirmation is conducted to maintain confidence in the calibration status of reference standards and reference materials.

6.4.11. **Correction Factor**

Where calibrations give rise to a set of correction factor, these factors are updated and implemented to meet specified requirements.

6.4.12. **Safeguards**

Test and calibration equipment, including both hardware and software, are safeguarded from adjustments that would invalidate the test or calibration results. Safeguards are provided using access control to the laboratory.

6.4.13. Equipment Records

Records are maintained of each item of equipment and its software that can influence laboratory activities.

The records include at least the following items, where applicable:

A. identity of equipment, including its software and firmware version.

B. manufacturer's name, type identification, and serial number or other unique identification;

C. evidence of verification that equipment conforms with specified requirements;

D. current location of the equipment;

E. calibration dates, results and copies of reports and certificates of calibrations, adjustments, acceptance criteria, and the due date of next calibration or the calibration interval;

F. documentation of references materials, results, acceptance criteria, relevant dates and the period of validity;

G. maintenance plan and maintenance carried out to date, where relevant to the performance of the equipment; and

H. details of any damage, malfunction, modification or repair to the equipment.

6.5. Metrological Traceability

6.5.1. Establishing and maintaining metrological traceability

The program for calibration of equipment demands that calibrations and measurements made by the laboratory are traceable to the International System of Units.

Calibration laboratories providing calibration standards to G7 are to provide evidence of measurement traceability of its own measurement standards and measuring instrument to the SI. This is done by means of an unbroken chain of calibration or comparisons linking them to primary standards of the SI units of measurement. Such primary standards are those used by national measurement standards.

Calibration certificates issued by calibration laboratories are to include the measurement results, including the measurement uncertainty and a statement of conformance with an identified metrological specification.

6.5.2. Ensuring measurement results are traceable

A. Calibration laboratories providing services or calibration material to G7 are to provide documentation demonstrating measurement capability and competence to perform the calibration material requested.

B. A reference material is a homogenous and well characterized substance used for standardization of equipment used in the testing process. Reference materials are traceable to national or international standard reference materials (SRMs), such as National Institute of Standards and Technology (NIST), or certified reference materials (CRMs) from competent suppliers of reference materials.

   The measurement integrity of internal reference materials generated by the laboratory is evaluated against either standard reference materials or certified reference materials from an independent source when it is technically and economically possible.

C. The measurement traceability to SI units may be achieved by measurements related to national measurement standards. National measurement standards may be used as primary standards that are primary realizations of the SI units or agreed representations of SI units. National measurement standards based on fundamental physical constants, or standards calibrated by another national metrological institute may be use as primary standards.

6.5.3. **Non-traceability of reference standards to SI units**

Calibrations that cannot provide strict measurement traceability to SI units are conducted such that the calibration results can provide confidence in the measurements made in the course of the analysis.

6.6. Externally Provided Products and Services

6.6.1. **Suitability of Externally Provided Products and Services**

The laboratory ensures that only suitable externally provided products and services that affect laboratory activities are used when they are intended for incorporation into the laboratory's activities and/or used to support the operation of the laboratory.

G7 labs do not subcontract routine analyses within their scope of accreditation.

Collaborative activities conducted with external laboratories, such as universities, are research in nature and do not involve the routine analysis of samples.

Subcontracting Laboratories

Based on workload fluctuations and resource needs, G7 may request samples assigned to other CCC licensed laboratories for analysis. Samples are administratively transferred after arrangements are made to ensure that the receiving laboratory has the capacity and capability to complete it in a timely manner.

Notification of Customer

The performing laboratory on the certificate of analysis serves as a notice of the transfer.

Laboratory Responsibility

The laboratory to which the sample has been transferred assumes responsibility to the collector for the work.

Related Procedures/References

- G7GEN16 Chain of Custody – Sample Handling

6.6.2. **Purchasing services and supplies**

A. G7GEN17 Purchasing and Receipt provides policies and instructions for procurement of supplies, materials, equipment, and services that affect the quality of tests. It documents the procedures for purchase, reception, and storage of supplies, materials, and equipment relevant to tests.

B. Purchasing documents for items affecting the quality of laboratory output describe the services or supplies ordered. These purchasing documents are reviewed and approved for technical content prior to submission.

Records of supplier evaluations are maintained by purchasers of laboratories equipment, services, and supplies.

C. Records of unsatisfactory materials and supplies and their disposition are maintained. These records establish trends in vendor performance and ensure that continuing quality material is accepted. A vendor is considered unacceptable and is not used when the quality of product or service does not meet expectations or specifications.

6.6.3. **Communicating requirements to external providers**

Critical specifications and requirements are clearly described on the purchasing requests and are communicated to external providers by the Purchasing Agent. These criteria include:

A. The products and services to be provided;

B. The acceptance criteria; and

C. Competence, including any required qualification of personnel

G7 does not subcontract routine analyses within their scope of accreditation.

7.0 Process Requirements

7.1. Review of Requests, Tenders, and Contracts

7.1.1. **Procedure**

G7 develops and issues the Annual Fiscal Year (FY) Workplan for the lab. The workplan is based on several factors such as the budget, the number of analysts and amount of resources, the compliance program accomplishment goals.

Requests not covered by compliance programs or assignments are reviewed prior to receipt of samples by the laboratory's management when possible.

The results of this process are discussed and documented as part of the laboratory's annual management review.

Subcontracting Laboratories

The customer requesting collaborative testing by laboratories outside of G7 is responsible for the work done by such labs. G7 is responsible for such work under these circumstances.

Based on workload fluctuations and resource needs, G7 may send samples to other CCC Licensed laboratories within MA for analysis. Samples are administratively transferred after arrangements are made to ensure that the receiving laboratory has the capacity and capability to complete it in a timely manner.

The samples will be transferred after notifying the customer and CCC and the results will be reviewed in detail for conformance and data quality. The result will be reproduced in whole.

7.1.3. **Statements of Conformity**

When the customer requests a statement of conformity to a specification or standard for the test, the specification or standard and the decision rule are clearly defined in the compliance programs or standard. Otherwise, the laboratory communicates the decision rule selected to the customer and obtains their agreement.

7.1.4. **Differences and Deviations**

The lab reviews the annual workplan to ensure that laboratory has the capability and resources to provide the requested services. Any differences between the workplan and the laboratory capability are resolved prior to commencing work.

7.1.5. **Communicating with the customer**

Requests for deviations from work assignments or compliance programs are recorded. The lab interacts with the customer to determine whether the requested changes are acceptable by CCC regulations.; local regulations and do not impact the integrity of the laboratory or the validity of the results. Records of contract changes are maintained.

7.1.6. **Amendments to Contracts**

If a contract needs to be amended after work has commenced, the same contract review process is repeated, and any amendments are communicated to all affected personnel named in the contract.

7.1.7. **Customer Service**

The laboratory maintains communications regarding deviations from contract work.

The opportunity for the customer to witness laboratory activity is given upon request on a case by case basis after management review, providing the laboratory can maintain confidentiality to other customers during such cases.

7.1.8. **Records of Review**

G7 maintains a record of workplan reviews, changes, and change requests. Records are also maintained of discussions regarding ad hoc assignments.

7.2. Selection, Verification and Validation of Methods

7.2.1. **Selection and Verification of Methods**

Specific requirements for the Verification and Validation of methods process are outlined in G7GEN09 Method Validation and Verification.

7.2.1.1. The scope of test technologies and associated method source routinely used are identified in the laboratory's accreditation program documentation.

7.2.1.2. Laboratory methods and supporting documents are controlled according to Section 8.3 Control of Management System Documents and are readily available.

7.2.1.3. Laboratory methods are selected to meet the CCC, MDPH requirement, ISO\IEC 17025:2017 compliance and Laboratory's interest. Only the Standard methods Listed Appendix A Table 01 on Quality Assurance Program Plan for Analytical Testing laboratories Performing analysis of Finished Marijuana products and marijuana infused products in Massachusetts (QAPP) will be used.

Standard methods are those published by international, regional or national standards-writing bodies; by reputable technical organizations; in legal references; and FDA published methods. These methods include those in the United States Pharmacopeia, National Formulary, Homeopathic Pharmacopeia of the United States, Official Methods of Analysis of AOAC INTERNATIONAL or any supplement of any of them, American Public Health Association (APHA) Compendium of Methods for the Microbiological

Examination of Foods, FDA compliance programs, the Pesticide Analytical Manual (PAM), the Food Additives Analytical Manual, the Food Chemicals Codex, FDA
Bacteriological Analytical Manual (BAM), FDA Macroanalytical Procedures Manual (MPM), and ORA Laboratory Information Bulletins (LIBs) that are included in compliance programs and special assignments. Standard methods are preferred for use and are verified for use in the laboratory. A standard method may be supplemented with additional details in the form of a laboratory procedure to ensure consistent application. Those methods specified by the manufacturer of the equipment are considered as standard methods. Standard methods are verified according to the procedure, using QAPP 9.0 Validation of methods.

7.2.1.4 Any standard method not listed on Appendix A Table 01, Method Reference Table of QAPP will be validated using QAPP 9.0 Validation of methods. Records of the verification are retained by the lab. If the method is revised by the issuing body, verifications are repeated to the extent necessary.

7.2.1.6. Non-standard methods are those methods not taken from authoritative, validated sources. A nonstandard method has not undergone validation, such as a collaborative study or process to evaluate the method's performance capabilities.

Non-standard methods are not used and out of the scope for this manual.

7.2.1.7. Deviations from test methods are not authorized and allowed.

7.2.2. **Validation of Methods**

7.2.2.1. The laboratory validates standard methods, laboratory developed methods, and modified standard methods including use outside the intended scope or otherwise modified. Validation is conducted to confirm that the methods are fit for the intended use, relevant to the needs, and consistent with specified requirements. The validation is as extensive as is necessary to meet the needs of the given application or field of application.

7.2.2.2. When changes are made to a validated method, the influence of such changes shall be determined and where they are found to affect the original validation, a new method validation shall be performed as per QAPP method validation guideline.

7.2.2.3. The validation process addresses the needs of the given application or field of application. The laboratory analyst records the results obtained according to

the procedure, G7GEN09 Method Verification and Validation. The validation results include a statement as to whether the method is fit for the intended use. The intended use of the method. The attributes and data quality objectives include but are not limited to:

- accuracy,
- precision,
- specificity,
- detection limit,
- limit of quantitation,
- linearity,
- range, and
- ruggedness or robustness.

If all the data quality objectives are met as indicated by the data collected, the method is considered as validated.

7.2.2.4. The following records are maintained for each validation:

- Validation Plan
- the validation procedure used;
- specification of the requirements
- determination of the performance characteristics of the method;
- results obtained;
- a statement on the validity of the method, detailing its fitness for the intended use.

7.3 Sampling

7.3.1 Sample receipt and sample custody

A. Laboratory custody of samples begins when samples are received by the laboratory.

B. The Laboratory agent shall sign and record the date and time of sample receipt on the Chain of custody (COC). The COC is to be maintained electronically if possible. The validated time of sample receipt (VTSR) is the time the samples are received at the laboratory from the RMD personnel or representative, or private courier; it is not the time the samples are opened or logged in at the laboratory.

C. For receipt of samples outside normal hours of operation the laboratory is to be notified at least 2 days in advance to arrange for the receipt of the sample during non-standard hours.

D. Sample receipt temperature is be recorded in COC electronically while receiving sample. A record of samples will be maintained for samples receipt outside of acceptance criteria.
E. Sample storage refrigerator are maintained at ≤ 6.0°C and sample storage freezers at < -10°C.

7.3.2 Communicating sample receipt issues

A. Loss of sample volume, samples with temperatures > 6.0°C; improper chemical preservation of samples; or documentation discrepancies, shall be communicated to the customer or its designated consultant was soon as practical (via phone log or e-mail based on project personnel requirements) so that proper corrective action can be taken; documentation of this communication is to be preserved with the project records.
B. If the sample receipt criteria are not met, the samples are rejected and the customer will be informed immediately of the need to resample.

C. All samples placed “on hold” because of sample receipt issues is stored in accordance with sample temperature preservation requirements (e.g., in sample refrigeratG7 or freezers) until the issues have been resolved.

D. When an issue requiring notification is discovered after normal business hours (i.e., between 0800 and 1700 Eastern Standard Time, Monday through Friday), the laboratory will provide prompt verbal, text, or e-mail notification to the customer or its designee. The laboratory will maintain documentation detailing any sample receipt issues and the resolution directed by the customer or its designee in the project files.

7.3.3 Sample Homogenization

Samples received by the laboratory are to be homogenized in full before subsampling for analysis or subcontracting takes place. To demonstrate the effectiveness of homogenization and subsampling homogenization duplicate and a homogenization blank are to be assigned separately for flower and extract sample batches at defined intervals. The homogenization blank shall be randomly placed in the batch as to check all the homogenization equipment for possible carryover rather than using a dedicated homogenization apparatus for the blank each time it is requested.

7.3.3 Holding Times

A. Samples with holding times of < 48 hours are to have documentation of the time they were set up for the short hold-time analysis. For all sample shipments, the primary laboratory contact, for the dispensary shipping the samples, is to notify all applicable laboratory personnel of the expected sample delivery so that laboratory personnel can prepare to receive the sample.

B. The laboratory is to adhere to the required holding times for the initial sample preparation/analyses. If samples are received with a significant portion of the holding time expired and the laboratory is concerned about meeting holding time requirements, RMD, or its designee is to be notified immediately upon sample receipt. If subsequent analysis/extraction becomes necessary due to method or technical requirements or failing QC, the laboratory is to make every effort to analyze these dilutions/re-extractions /reanalyses within the method holding time specified in QAPP Appendix A.

7.4. Handling of Test or Calibration Items

The laboratory procedure G7GEN16 Chain of Custody /Sample handling describes the receipt, processing, protection, storage, retention, and disposal of samples. This procedure also provides the details for handling and protecting test items from deterioration, loss or damage during storage and processing. The laboratory has arrangements for storage and security that protect the condition and integrity of samples. Sample security arrangements apply both in the laboratory and in the custodial areas.

7.4.1. The laboratory has a system for uniquely identifying samples. The sample number is used to track its progress from the time the sample is collected until the analysis is completed and the sample is disposed. The sample number is also used to provide traceability between the sample and the data. The numbering system also provides traceability during transfer of samples within the laboratory. This sample number is unique and different from customer assigned Batch ID or sample ID.

7.4.2. When samples received do not meet established acceptance criteria, and chain of custody criteria, these deviations are recorded. The customer is consulted prior to commencement of analysis for further instructions.

Sample abnormalities or departures are also noted on the analytical worksheet.

7.4.3. When samples and calibration items have specific environmental conditions, those conditions are maintained, monitored and recorded. Monitoring records are collected according to established procedures. These activities are conducted according to the policies stated in Section 6.3 Facilities and Environmental Conditions.

7.5. Technical Records

7.5.1. Technical records for all activities that contribute to data reporting, depending on the type of analysis, include the original observations, derived data, calculations,

standard preparation, instrument printouts, and results. These records contain the date each activity is completed and the identity of all persons who perform each activity throughout the process, including those who review the data and results.

Observations, data, and calculations are recorded at the time they are made and are identifiable to the activity performed.

The records of each test contain sufficient information to repeat the test under conditions as close as possible to the original. This information includes environmental conditions that affect the test and factG7 that affect the measurement results and its associated measurement uncertainty.

Staff records, equipment calibration, and verification reports are retained in accordance with the laboratory's control of records procedure. These records contain sufficient information to establish an audit trail. The requirements for an audit trail in laboratory records are outlined in G7GEN19 Record and Data Management.

Data is reported electronically and/or scanned and uploaded into laboratory network drive or media lab which is a web-based programs.

The collection report identifies the personnel responsible for sampling. Also, includes the identity of the personnel responsible for performance of each test and for checking the results.

7.5.2. G7 ensure changes to technical records can be tracked to the previous version or to original observations. Both the original and amended data and files are retained, including the date the record was changed, an indication of what was changed and the person responsible for the alteration.

7.6. Evaluation of Measurement Uncertainty

7.6.1. Uncertainty Components

When estimating the uncertainty of measurement, all important uncertainty components are recorded in the uncertainty records for each determination and test technology.

7.6.2. Procedure for Calibration Activities

G7 does not perform calibration activities. At such time that calibration activities are performed, the laboratory is to address the requirements of ISO/IEC 17025:2017, QAPP AND CCC.

7.6.3. Procedure for Testing Activities

The laboratory has a procedure G7GEN20 Estimation of Uncertainty of Measurement, to estimate the uncertainty of measurement for testing activities.

The application of details in cases where the nature of the test method may preclude rigorous, metrologically and statistically valid, calculation of uncertainty of measurement is addressed in the procedure.

An attempt is made to identify all the components of uncertainty and make a reasonable estimation of the measurement uncertainty. This estimation is based on knowledge, experience, and validation data of the performance of the method and on the measurement scope. If needed as a part of the laboratory data, the uncertainty estimation is reported according to the procedure.

7.7. Ensuring the Validity of Results

7.7.1. Quality Control Procedures

The laboratory has quality control procedures to validate the results of tests undertaken. The monitoring data is recorded in such a way that trends may be detected, for example, statistical process control charts. Monitoring activities are planned and evaluated. Monitoring techniques may include, but are not limited to, the following:

A. Scheduled use of certified reference materials or quality control materials

B. Levey Jennings chart of Quality control (QC) data to recognize a trend or pattern.

C. Use of alternative instrumentation that has been calibrated to provide traceable results;

D. Functional check(s) of measuring and testing equipment;

E. Use of check or working standards with control charts;

F. Intermediate checks on measuring equipment;

G. Replicate tests using the same or different methods;

H. Retesting of reference materials and retained customer samples;

I. Correlation of results from tests conducted for different characteristics of a sample;

J. Review of reported results;

K. Scheduled participation in interlaboratory comparison or proficiency testing and calibration programs

L. Testing of blind samples.

7.7.2. G7 will participate in proficiency testing programs as required by ISO/IEC17025:2017, QAPP, CCC and MDPH.

A. One successful PT for each method and matrix included in Massachusetts regulation, if available, prior to reporting samples for compliance and one additional PT for each method and matrix combination annually.

B. PT samples are to be treated as and analyzed with typical samples in the normal production process where possible, including the same sample log-in procedures analysts, maintenance triggers, preparation, calibration, QC and acceptance criteria, sequence of analytical steps, number of replicates, data analysis, manual integrations, identification, and confirmation procedures.

C. Whenever possible, the PT sample is to be prepared and analyzed with other samples to avoid having a QC set unique to the PT. The PT cannot be chosen for spiking or duplication within a batch consistently, but if there are no other samples in-house for the analysis, the required QC for a batch is to be performed.

D. Prior to the closing date of a study, G7 personnel are not to:
   I. Subcontract analysis of a PT sample to another laboratory that is to be reported for accreditation purposes.
   II. Knowingly receive and analyze a PT for another laboratory that is to be reported.
   III. Communicate with an individual from another laboratory concerning the analysis of the PT sample.
   IV. Attempt to find out the assigned value of a PT from the PT Provider.
   V. Perform maintenance or calibration on an instrument when the data quality samples or instrument performance data would not normally necessitate such actions.
   VI. Provide additional verification, validation, or review.
   VII. Analyze the sample in multiple batches, on multiple instruments, or by multiple analysts.

7.7.3. The laboratory has defined the criteria for quality control data and performs analysis by such means as control charting. When data is found to be outside the established criteria, Corrective action is taken in accordance with laboratory G7GEN04 Quality Control policy

7.8. Reporting Results

7.8.1. **General Requirements**

Results are reported on analytical worksheets and in appropriate Laboratory information management system (LIMS).

7.8.1.1. Laboratory results are reviewed and authorized for release by TM, or designee. Reports are reviewed for accuracy, clarity and objectivity.

7.8.1.2. Laboratory reports, depending on the type of analysis, include the original observations, derived data, calculations, standard preparation, instrument printouts, and results. These reports are retained until closed in and/or LIS and final review is performed. An electronic test report is in and/or LIS. Staff records, equipment calibration, and verification reports are retained in accordance with the laboratory's control of records procedure.

The records contain sufficient information to establish an audit trail.

The collection report identifies the personnel responsible for sampling. This also includes the identity of the personnel responsible for performance of each test and for checking the results.

7.8.1.3. Test reporting is addressed in the procedure found in G7GEN22 Reporting Laboratory Data. This procedure gives the details for reporting data using consistent reporting formats for laboratory worksheets.

7.8.2. **Common Requirements for Reports (test, calibration or sampling)**

7.8.2.1. **Format**

The format for laboratory worksheets is designed to accommodate the type of test conducted to minimize the possibility of misunderstanding or misuse. The worksheet format is described in G7GEN 22 Reporting Laboratory Data.

Subcontracting laboratory is to report the results in compliance with the requirements of CCC, ISO 17025 and relevant state and local regulation.

7.8.2.2. **Data Provided by Customer**

Analysts describe the sample as received, including any information provided by the customer, on the sample worksheet. When information supplied by the customer can affect the validity of the results, a disclaimer statement is included on the worksheet.

7.8.3. Specific Requirements for Test Reports

7.8.3.1. Test Report Requirements

The following information is included in test reports for the interpretation of the test results:

A. Information on test conditions, such as environmental conditions;

B. Where relevant, a statement of conformance or non-conformance with specifications;

C. The measurement uncertainty presented in the same unit as the measurand, or in a term relative to the measurand when:

D. It is relevant to the validity of the test results;

E. A customer requires it, or;

F. The measurement uncertainty affects conformity to a specification limit;

G. Additional information that may be requested by methods, customers or groups of customers provided the information requested are within scope of the laboratory and allowed by CCC and ISO 17025:2017

7.8.4. Specific Requirements for Calibration Certificates

G7 do not issue calibration certificates. In-house calibrations are documented by a report, or sticker, or other suitable method.

7.8.5. Reporting Sampling – specific requirements

In addition to the instructions listed in Sections 7.8.1 General Requirements and 7.8.3. Specific Requirements, sampling information and conditions are posted to the laboratory for review on sample collection record.

7.8.6. Reporting Statements of Conformity

7.8.6.1. Decision Rules

Statements of conformity to a specification or standard require the use of a decision rule to take into account the uncertainty associated with method. Most decision rules used by G7 are documented in the compliance programs or standard methods. When the decision rule is not provided, the laboratory must document the decision rule and account for the level of risk associated with the decision rule used.

7.8.6.2. Reporting Statements of Conformity

Statements of conformity reported on worksheets clearly identify:

A. The results the statement applies to;

B. Which specifications or standards were met, or not met;

C. The decision rule applied (unless it is defined in the specification or standard.)

7.8.7. Reporting Opinions and Interpretations

Laboratory management expresses its opinion and interpretation of the compliance or non-compliance of the results through the laboratory classification assigned to each sample. This laboratory classification is recorded in LIMS and may be recorded in Media Lab.

Records are maintained of conversations expressing opinions and interpretations about a sample with the customer.

7.8.8. Amendments to Reports

Material amendments to analytical findings after issue are made only in the form of an additional document. They are flagged "Additional Analyses" in accordance with procedure G7GEN22 Reporting Laboratory Data. Amendments are to meet the same reporting criteria. Any changed information is clearly identified and where appropriate, the reason for the change is included in the report.

Related Procedures/References

- G7GEN 22 Reporting Laboratory Results.

7.9. Complaints

7.9.1. G7 has a complaint process describing the handling of complaints received from any party. See G7GEN02 Complaints and Feedback. In addition to the resolution of these complaints, improvement in the area of concern is addressed and implemented in most cases.

7.9.2. The process for handling complaints is documented in G7GEN02 complaint feedback. The laboratory confirms whether the complaint relates to laboratory activities that it is responsible for and, if so, then addresses it.

7.9.3. The process for handling complaints includes the following:

A. Description of the process for receiving, validating, investigating the complaint, and deciding appropriate actions to respond to it;

B. Tracking and recording complaints, including actions taken to resolve them;

C. Ensuring appropriate action is taken.

7.9.4. The laboratory receiving the complaint will gather all information required to investigate, validate, address, and review the complaint and its outcome.

7.9.5. When possible, the laboratory will acknowledge receipt of the complaint, provide progress reports with the outcome of resolution, and formal notice of completion to the complainant.

7.9.6. Communications to the complainant is addressed in procedure G7GEN02 complaint feedback.

7.10. Nonconforming Work

7.10.1. The G7 laboratories have a control of non-conforming work procedure that is implemented when any aspect of their activities, or the results of this work, does not conform to requirements of the management system, testing methods, or the requests of the customer. This procedure addresses the following elements:

A. responsibilities and authorities for the management of identified nonconforming work to include taking actions such as the halting of work and/or the withholding of test reports based upon risk levels established by the laboratory

B. actions are based upon the risk levels established by the laboratory;

C. an evaluation of the significance of non-conforming work including an impact analysis on previous results and, if necessary, recall of work with notification to the customer

D. remedial action taken, together with any decision about the acceptability of the non-conforming work

1. The customer is notified if investigations show that nonconformances have affected work performed for or data reported to the customer. This notification is documented.

E. responsibility for authorizing the resumption of work.

7.10.2. Records of nonconforming work and actions taken are maintained in QMiS.

7.10.3. If the non-conforming work could recur, or there are other significant problems identified, the corrective action procedures in G7GEN07 Corrective Action are promptly followed.

Related Procedures/References

- G7GEN05 Control of Nonconformance

7.11. Control of Data and Information Management

G7 Labs have access to the data and information needed to perform laboratory activities through various electronic records management systems including Media lab, LIMS, QA, and records maintained according to G7GEN19 Record and Data Management.

7.11.1. G7 information management system applications used for the acquisition, processing, recording, reporting, storage or retrieval of data are validated prior to introduction by G7.

If computer software is developed by the user, its development is authorized, documented in detail and algorithms are validated prior to implementation.

Changes to laboratory software configuration or modifications to commercial off-the-shelf software are also authorized, documented and validated prior to use.

7.11.2. G7 laboratories have processes for the protection of data to include, but not limited to data integrity, data confidentiality during entry, collection, storage, transmission and processing. The processes also ensure safeguards are in place to prevent unauthorized access to or amendment of records.

Information management system failures are recorded, and appropriate immediate and corrective actions are taken.

7.11.3. Laboratory information systems managed and maintained off site meet all applicable requirements of ISO 17025:2017.

7.11.4. Instructions, manuals and reference data relevant to the laboratory information systems are readily available to personnel through the document control process (see section 8.3).

7.11.5. Calculations and data transfers are reviewed before the data is reported. All changes are identified and verified where they occur. This process is detailed in the procedure for laboratory quality control identified in Volume I, Section 7.7 Ensuring the Validity of Results.

8.0 Management System Requirements

8.1. Options

8.1.1. General

G7 laboratories have established, documented, implemented, and maintained a management system capable of supporting and demonstrating the consistent achievement of the requirements of ISO/IEC 17025:2017 to assure the quality of laboratory results. In addition to meeting the requirements outlined in sections 4 to 7 of this document the Standard requires laboratories implement a management system in accordance one of the two following options.

8.1.2. Option A

G7 follows the requirements for option A, outlined in the following sections 8.2 to 8.9.

8.1.3. Option B

Option B of ISO/IEC 17025:2017 addresses minimal requirements for laboratories with a separate management system either certified to or at least structured to the requirements of ISO 9001. G7 does not fall within this category.

8.2. Management System Documentation (Option A)

8.2.1. Management System Policy

A. Good Professional Practice and the Quality of Testing

The laboratory management and personnel are committed to performing quality activities to assure integrity, accuracy, precision, reliability and timeliness of the data.

B. Standard of Service

The laboratory's standard of service for the testing program is defined by the ISO/IEC 17025:2017 requirements, CCC regulatory needs included as part of the laboratory methods, and the following:

1. Established and maintained documented procedures for laboratory operation based upon reference methods for testing provided by MDPH on Appendix A of QAPP or validated as per QAPP section 9. In some cases, testing and procedures as established by the instrument manufacturer are used.
2. Sample handling and management procedures to maintain integrity of both the samples and the documentation to support the analytical data.

3. Maintenance of records in such manner that facilitates retrieving them later. Records are maintained in the analyst worksheet packet or web application by sample number. Records may be archived on- or off-site or in a web application. Archival retention periods are stated in the laboratory's record management procedure and are in accordance with CCC's established record retention schedule.
4. Employment of qualified and trained personnel to perform the tasks to support the laboratory objectives. Competency demonstrations by technical personnel conducting laboratory methods are conducted and documented.
5. Routine maintenance of quality control data to support testing results by demonstrating that measurement processes are maintained in statistical control. Accuracy and precision control charts are used to monitor performance.
6. Maintenance of an instrument calibration program that provides measurement traceability to International System of Units (SI) units. This is accomplished with the use of national, international, or industry accepted standards of measurement.

G7 laboratory personnel follow the policies included in this Volume, the processes described in their local operating procedures, and the processes described in laboratory methods referenced in this Volume.

The sections in this Volume describe elements and reference procedures that outline the management system established to accomplish the mission of the laboratory.

8.2.2. The management system process and procedures as defined in this manual maintain the integrity of the management system for consistent operations when changes such as a change in the structure of the organization or management, or a change in a policy or procedure are made.

Primary consideration in all policies, procedures, and objectives is given toward retaining personnel competence and impartiality.

8.2.3. The policies for operation of the laboratory management system are established to address the requirements of ISO/IEC 17025:2017. G7 lab is committed to laboratory accreditation per the requirements of ISO/IEC 17025:2017.

The implementation of the quality policies is evidenced by the way work activities are conducted. Implementation of the management system procedures is evidenced by the generation of required records. The audit and management review activities are the mechanisms that are used to monitor the implementation effort of the laboratory management system.

Evidence of management's commitment to the management system and its continual improvement in effectiveness is demonstrated by but not limited to participation of all laboratory and management staff in the management reviews, performance of internal audits, proficiency testing, and the analysis of quality control samples.

8.2.4. Management system procedures supporting quality policies are cited in the Related Procedures/References at the end of each section of this Volume.

Where needed, the laboratory shall have procedures to implement the quality policies and include these procedures in the document control system. All documentation, processes, systems, records, related to the fulfillment of the requirements of ISO/IEC 17025:2017 shall be included in, referenced from, or linked to the management system.

8.2.5. All laboratory employees involved in laboratory activities have access to approved and controlled consensus standards, instrument manufacturers' manuals, and procedures for reference ensuring consistent application and validity of activities that contribute toward results reported.

8.3. Control of Management System Documents (Option A)

8.3.1. Changes to management system documents are made per the laboratory document control procedure and involve periodic revisions of this Volume.

The operational procedures for G7 laboratories are controlled as described in G7GEN24 *Document Control and Management.*

The document control and management procedure describe the process for controlling quality documents that form part of the laboratory management system. The quality documents include those required for the generation of laboratory data. Documents of external origin include regulations, standards, test methods, instructions and manuals.

Control of electronic management system documents and data is addressed in section 7.11.

8.3.2. Document control requirements:

A. Documents issued to personnel in the laboratory as part of the management system are reviewed for adequacy and approved by authorized personnel prior to issue in accordance with *G7GEN24 Document Control and Management procedure.*

B. Documents are reviewed per an established schedule and revised as necessary to ensure continuing suitability and conformance with the

management system and ISO/IEC 17025:2017 requirements. These reviews should include an assessment of reference documents and pertinent background information.

C. Altered or new text is identified either in the document, document change history section, on a cover page, redline file, or in attachments. Changes can be described in general terms since the details can be demonstrated in the archived document. Document revision is recorded on each document and tracked within Media Lab document Control module.

D. Authorized management system documents and external documents are available at locations where operations essential to the effective functioning of the laboratory are performed. Distribution and locale of these documents is controlled.

E. A document control header as described in the document control and management procedure uniquely identifies management system documents generated by the laboratory. Such identification includes the revision status, identification number and inclusive pagination.

F. The unintended use of obsolete documents is prevented, and suitable identification is applied to them if they are retained for any purpose.

8.4. Control of Records

8.4.1. G7 laboratories maintain records according to *G7GEN19 Record and Data Management* to sustain objective evidence showing fulfilment of the requirements of the quality system. These records are required to be legible and readily identifiable for retrieval.

8.4.2. Retention time, archival, and disposal of G7 Laboratory records are in accordance with Records Management Policy and existing record retention schedules.

Quality record storage and protection are maintained in Media lab or recorded within individual records file plan.

Internal access to records is controlled through various methods, such as, but not inclusive of, password protected storage, both electronic and physical, provided to authorized personnel to maintain confidentiality. Access from entities outside of CCC or accreditation bodies is not allowed and will be assessed on a case by case basis if requested.

8.5. Actions to Address Risks and Opportunities

8.5.1. Management G7 Laboratory meet regularly to assess risks and opportunities associated with all laboratory activities to:

A. Assure the management system achieves its intended results;

B. Enhance opportunities to achieve the purpose and objectives of the laboratory;

C. Prevent, or reduce negative impacts and potential failures in laboratory activities;

D. Achieve improvement

Examples of areas evaluated consist of the following, although the list is not all inclusive:

1. Turnaround times for data reporting
2. Training and competency
3. Structure to ensure impartiality of personnel
4. Equipment issues
5. Facilities/Environment
6. Effectiveness of corrective and preventive actions
7. Outcomes of internal audits
8. Complaints
9. Processes to ensure confidentiality

8.5.2. Plans, final evaluation, actions and implementation of actions, improvement, and assurance of intended actions are outlined in section 8.9 Management Reviews.

8.5.3. Actions taken to address risks and opportunities are proportional to the potential impact on the validity of laboratory results.

8.6. Improvement

8.6.1. The effectiveness of the laboratory's management system is improved by using the following activities: internal audits; management reviews; analysis of quality control data; corrective actions; preventive actions.

8.6.2. The laboratory seeks customer feedback on their services and general performance. Records of the comments, both positive and negative, are maintained and are considered for identifying management system improvements during reviews performed by laboratory management.

8.7. Corrective Actions

G7 laboratory designates the authorities for implementing corrective action when one of the following is identified:

A. non-conforming work,

B. departures from the policies and activities outlined within the management system, and

C. departures from required technical operations.

8.7.1. When a non-conformance is identified, the corrective action chosen addresses the magnitude of the non-conformance and the risk attributed to the non-conformance.

A. Immediate action is implemented to correct a nonconformity and address the consequences.

B. An evaluation is performed to determine the cause(s), a history of similar issue(s), potential for recurrence, and the need for action to eliminate the problem to prevent recurrence.

C. Corrective actions are determined and implemented based upon this evaluation.

D. A review of the effectiveness of corrective actions is performed.

E. If necessary, updates for risks and opportunities are determined during planning.

F. Essential changes discovered during the corrective action investigation are implemented within the management system, where necessary.

8.7.2. Corrective actions are appropriate to the effects of the nonconformities encountered.

8.7.3. Corrective actions are recorded, to include the nature of the nonconformities, cause(s) and subsequent actions taken, including the results of any corrective action. Related Procedures/References

- *G7GEN07 Corrective Action*

8.8. Internal Audits

8.8.1. **General**

Internal audits are conducted according to a schedule included in the laboratory's audit procedure. Internal audits are conducted of activities to verify that operations continue to conform to the requirements of the management system and ISO/IEC 17025:2017.

An internal audit process is used to evaluate the effectiveness of the management system established for laboratory operations.

8.8.2. **Audit Program**

A. The program takes into consideration the importance of the laboratory activities concerned, changes affecting the laboratory, and the results of previous audits.

B. The management defines the audit criteria and scope for each audit in an audit plan.

C. Results of the audits are reported to laboratory management.

D. When audit findings cast doubt on the effectiveness of operations or the correctness or validity of the laboratory's test or calibration results, the laboratory implements appropriate correction and corrective actions in a timely manner according *to G7GEN07 Corrective Action*.

E. The area of activity audited, the audit findings, and corrective action that arise from them are recorded according the laboratory's audit procedure.

Related Procedures/References

- *G7GEN26 Audits.*
- *G7GEN07 Corrective Action*.

8.9. Management Reviews

A management review is conducted by the laboratory's management at least once each fiscal Year; however, can be conducted more often according to planned intervals determined by laboratory management.

This review is conducted to ensure continuing suitability, adequacy, and effectiveness based upon information related to the inputs and outputs of laboratory activities and operations and stated policies and objectives.

Related Procedures/References

- G7GEN27 Management Review

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9. Document History

Revision #	Status* (D, I, R)	Date	Author Name and Title	Approving Official Name and Title

* - D: Draft, I: Initial, R: Revision, C: Cancel

10. Change History

Revision #	Change

11.0 References

US FDA. "Field Science Laboratory Manual. Available at: https://www.fda.gov/science-research/field-science-and-laboratories/field-science-laboratory-manual

MDPH 2018. "Quality Assurance Program Plan for Analytical Testing Laboratories Performing Analyses of Finished Medical Marijuana Products and Marijuana-Infused Products in Massachusetts." The Commonwealth of Massachusetts Executive Office of Health and Human Services Department of Public Health Bureau of Health Care Safety and Quality Medical Use of Marijuana Program, Massachusetts Department of Public Health, May15, 2018

ISO/IEC 17025. 2017. General Requirements for the Competence of Testing and Calibration Laboratories. International Organization for Standardization/International Electrotechnical Commission

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1. Purpose

This procedure describes the monitoring activities in a laboratory quality control (QC) program to ensure the quality of test results.

2. Scope

This procedure is applicable to G7 Lab LLC (G7) performing regulatory testing.

3. Responsibility

A. Laboratory Management

1. Establish a laboratory quality control program.
2. Ensure that quality control is performed and review quality control data for acceptability and trends.

B. Laboratory staff

1. Conduct quality control analyses in accordance with the laboratory quality control program.

C. Technical Manager OR Quality manager

1. Monitor quality control data for non-conformances and trends.

4. Background

None

5. Procedure

5.1. Laboratory Quality Control Program

Laboratory quality control (QC) is an essential aspect of ensuring that data released is fit for the purpose determined by the quality objectives (i.e. accuracy and precision). The dual foundations of the laboratory quality control program are its internal quality control, composed of day-to-day monitoring of analytical performance, and its external QC, based on the laboratory's performance in proficiency testing programs.

When properly executed, quality control samples monitor the various aspects of data quality on a routine basis. In instances where QC falls outside acceptable limits, the sample data produced may be questionable and, after investigation, a determination is made as to its validity. With professional experience and a common-sense approach quality control is the principal recourse available for ensuring that only defensible data is released.

All quality control data and corrective action will be recorded, charted and managed via LIS or third party software electronically.

5.1.1. Quality Control Materials

A quality control material may include, but is not limited to, Certified Reference Materials (CRMs), Reference Materials (RMs), replicate analysis, positive/negative control samples, laboratory control samples (LCS), blanks, and matrix spikes.

In the absence of any CRM or RM, the laboratory shall do its best to obtain a material with some limited consensus of accuracy (e.g. by subjecting material to multiple methods or analyses in-house, sharing material with another laboratory to determine an average result, etc.)

The suitability of the quality control material used shall be justified by the laboratory.

For enumeration assays, a quantified quality control material shall be used.

When testing for pathogens or select agents, a quality control material that contains a surrogate analyte may be used.

5.1.2. Internal Quality Control

QC is used to measure accuracy, precision, contamination, and matrix effects. QC material shall be used with each batch of samples analyzed. Generally, QCs are run per batch or set of samples at a frequency of 5% or one every twenty samples. If the laboratory is not able to meet this guideline, the batch must be defined and justified in the laboratory's documents. The batch shall begin and end with QC material.

The laboratory determines, where feasible, the accuracy and precision of all analyses performed.

Internal QC is run with each analytical batch to verify continuous system suitability specifications established are met, as well as demonstrates accuracy and precision or other parameters determined for the method type.

Method precision is periodically evaluated by the laboratory using the QC schemes described below.

5.1.2.1. Chemistry QC schemes

A. QC schemes required for chemistry consist of:

1. Meet system suitability requirements: system suitability is intended to determine whether the 'system' including instruments, analysts, etc. is capable of performing a particular process, test, or assay.
2. Blanks, either matrix or reagent, to determine and measure contamination and interferences - The results of blanks should be compared with the sample analyzed per analysis to determine whether the source of any analyte present is due to sample or laboratory contamination, interferences, the sample matrix, or the actual analyte in the samples. Blanks should be below the method detection limit where possible. Blank results are evaluated and corrected where possible. If blank results are consistently above the method detection level (MDL) established, the MDL should be reestablished. High blank results may also indicate contamination either from the solvent, laboratory equipment or laboratory environment.
3. Matrix spikes and/or reagent spike- Matrix spikes measure the effects the sample matrix may have on the analytical method, usually the analyte recovery. Method accuracy is recorded and controlled based on the percent recovery of matrix spikes for quantitative analysis and the positive response of the analyte for qualitative analysis.
4. Duplicate samples or matrix spike duplicates - Duplicate sample or matrix spike duplicates measure precision of the analytical process. Duplicate analysis usually involves a replicate sample, sub-sampled in the laboratory, but for some methods it is in the form of a matrix spike duplicate. Method precision is recorded and controlled based on the relative percent difference (RPD) or the positive response for qualitative analysis.
5. Quality control samples - Quality control samples (QCS) measure method performance. The matrix of the QCS should match the matrix of the samples being analyzed and should pass through the entire sample preparation process. The QCS, therefore, measures both the sample preparation process and the analytical process.

6. Standards - Calibration check standards referred to as initial calibration verification (ICV) and continuing calibration verification (CCV) are used to determine whether an analytical procedure is in control and stays within control. They are used to detect analytical method errors from procedural or operator errors or contamination from laboratory sources.
7. Accuracy and precision control charts
    B. The lab shall define the acceptance criteria for each test method for the following items (when included in the test method): system suitability, calibration curves, calibration checks, ICV, CCV, QCS, blanks, matrix spikes, and duplicates.
    C. The accuracy expressed as percent recovery should be 80% to 120% unless otherwise specified, i.e. by in-house statistical analysis.
    D. The precision expressed as relative percent difference (RPD) should be < 20% unless otherwise specified, i.e. in-house statistical analysis. In procedures where multiple determinations or subs are analyzed, one can be chosen as the duplicate quality control sample.
    E. Analyze calibration check standards/samples. Each Initial Calibration Verification (ICV) and Continuing Calibration Verification (CCV) should have a percent recovery of 70% to 130% as per MDPH QAPP unless otherwise specified, i.e. by in-house statistical analysis.
    F. The lab shall have a procedure or policy that provides guidance and/or criteria for the reprocessing and/or reintegrating of analytical data.

5.1.2.2. Microbiology QC Schemes

A. QC schemes required for microbiology include running QC controls concurrently with each sample batch or set. They are:
    1. Positive and negative culture controls - positive and negative controls give correct response,
    2. System controls
    3. Collector controls,

4. Applicable kit controls (positive and negative),
5. Media quality - the culture controls additionally verify the acceptability of the media,
6. Un-inoculated media – un-inoculated media control reveals no visible growth, and
7. Accuracy and precision control charts.

B. Sample Duplicates or Spiked Samples– For quantitative methods, sample duplicates (for samples with expected values > 25 cfu/g) or spiked samples will be run for each batch of samples.

C. Media lot testing for suitability and acceptance for use must occur prior to sample testing (i.e. no concurrent studies).

5.1.3. External Quality Control Program

A. Participation in proficiency testing is an important means of quality control and assessing laboratory performance. Accrediting agencies require laboratories to participate in programs relevant to the laboratory's scope of testing.

B. G7 maintains a documented proficiency testing (PT) plan that includes:

1. How the laboratory will cover its entire scopes annually.

   Proficiency testing for all Chemical scope methods may not be necessary if the laboratory can provide evidence, showing similarity of tests on the Chemical scope.

2. The scheduled PT for next years.

C. When no PT or interlaboratory comparison is available, the laboratory shall develop and justify an alternative plan for monitoring data.

D. Proficiency testing and interlaboratory comparisons are used as a tool to assist in the identification of laboratory problems that may exist and that have eluded the internal quality control program. They are not intended to represent individuals in the laboratory, unless this represents the normal mode of operation in which only one person is involved in the analysis. It is essential that proficiency testing samples are treated as routine samples to the extent possible.

E. Analyses of proficiency samples should not be repeated, unless it is necessary to repeat the entire procedure or the data on those specific samples exceed the method's linearity.

F. Proficiency testing is quality control for method analytical data. It is not necessary to perform a check sample where normally done as a Program requirement.

G. Samples should be run in duplicate only in those procedures where samples are normally analyzed in duplicate.

H. Proficiency testing shall be rotated among qualified analysts

I. Management review all PT data and ensures proficiency and/or interlaboratory comparison data are submitted to the issuing authority by the date(s) defined when issued. Copies of all proficiency studies are retained in the laboratory. The final reports from the issuing authority are reviewed by the testing area management upon receipt. All unacceptable results are investigated in accordance with G7GEN05 Control of Nonconforming Work.

J. Most external PT providers issue acceptability limits and criteria; when issued, the laboratory shall use that criteria. If the PT provider does not issue acceptability criteria or the laboratory is performing proficiency testing by alternative means, then they shall have procedures that define the acceptability of the results.

5.1.4. Other Quality Control Monitoring Activities

Other QC procedures that may be used include:

A. Replicate testing - Replicate testing may be performed on samples which are found to be violative. The original sample results are verified by using an alternative method or by rechecking results by the same method. A violative chemistry result may be verified by a second instrument, another method, a second analyst or repeated by the same analyst. A violative microbiology result by a rapid screening method is verified by a culture method.

B. Retesting of retained items - Retained samples can be re-introduced into the workload as regular samples in order to assess laboratory performance.

C. Correlation - Checking for correlation means evaluating the interrelated characteristics of the sample. By comparing results from different analyses on the same test item, one checks for reasonableness (i.e. Does the data make sense or correspond as anticipated?). Certain characteristics within the sample will maintain an analogous relationship to one another with regard to the type of test being performed. If one

characteristic is dependent on or at all indicative of another characteristic, they should be compared for consistency. The designated reviewer should be able to anticipate and recognize an analogous relationship with different characteristics of the same sample. Any deviation such as the absence of expected primary characteristics or the sudden appearance of previously unobserved characteristics of the sample, signals the probability of error.

5.1.5. Evaluation of Quality Control Data

All worksheets are submitted to the technical manager, alternate staff or designee for review. The QC range of each quality control data is evaluated for acceptability. Data that fall inside established control limits are judged to be acceptable, while data lying outside of the control interval are considered suspect. Control limits established by the laboratory are not to be exceeded except as resolved under a recorded corrective action process. This planned action includes the checking of results for calculation or transcription errors, preparation or use of new standards, recalibration of instrument, reanalysis of all samples with new controls or reagents, use of alternate system, and repeating analysis.

5.1.6. Quality Control Charts

The control chart is a graphical presentation of QC efficiency. If the procedure is in-control, the results will almost always be within established control limits.

Accuracy and precision control charts are used to determine if the measurement system process is in control and whether the results generated by the measurement system are acceptable. The control chart provides the tool for distinguishing the pattern of indeterminate (random) variation from the determinate (assignable cause) variation. This technique displays the test data from a process or method in a form which graphically compares the variability of all test results with the average or expected variability of small groups of data, in effect, a graphical analysis of variance.

The average or mean value is calculated and the spread (dispersion or range) is established. Common practice sets the warning limits at ± 2 standard deviations while control limits are set at ± 3 standard deviations on each side of the mean. Since the distribution of averages exhibits a normal form, the probability of results exceeding the control limits is readily calculated.

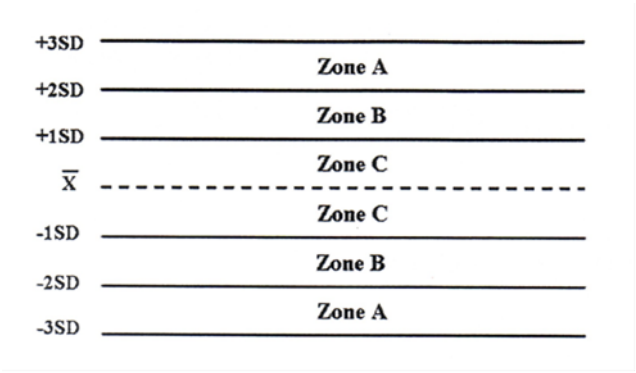

Figure 1: Example of a Control Chart

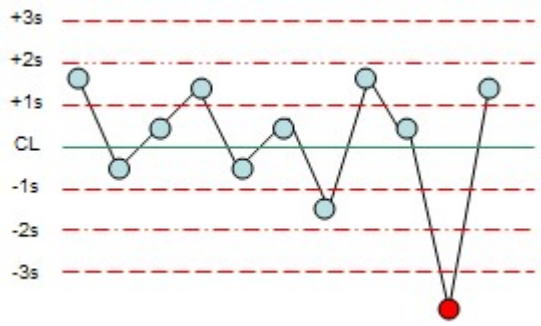

Figure 2: A Control Chart showing a 3SD outlier

Further, the chart will disclose trends and shifts from assignable causes which can be corrected. A trend will show a tendency or movement in a particular direction. If a series of consecutive data points move steadily either upward or downward, a trend is indicated. If a series of consecutive data points fall either above or below the center line, a shift is indicated. When a trend or shift is detected, it is annotated as such on the chart and reviewed to the extent possible to identify if a significant concern is indicated. If the review indicates a significant concern, follow the nonconforming work procedure.

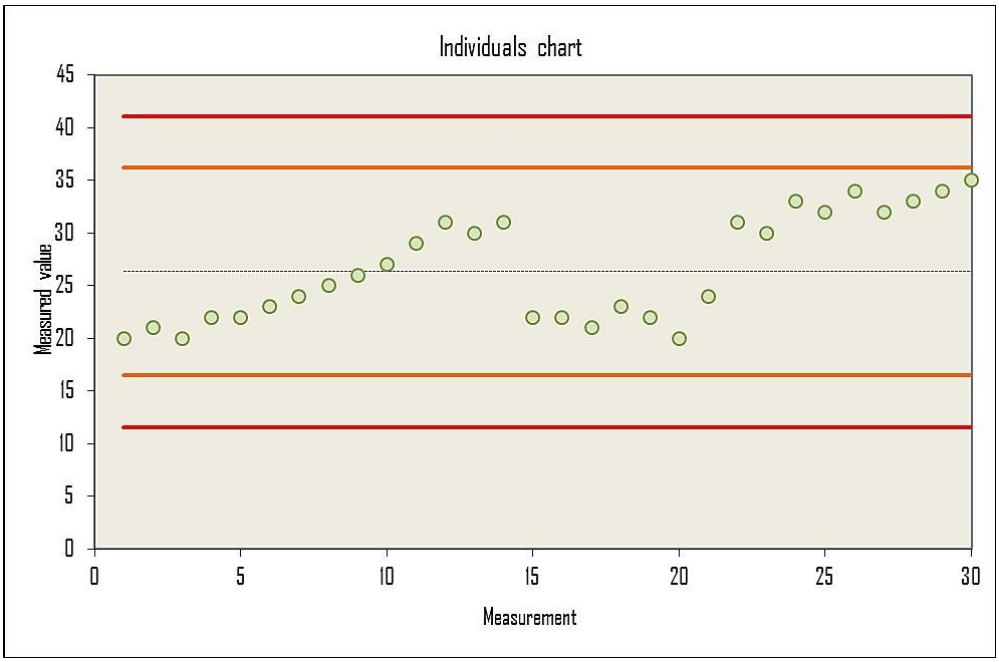

Figure 3: Control Chart showing a trend

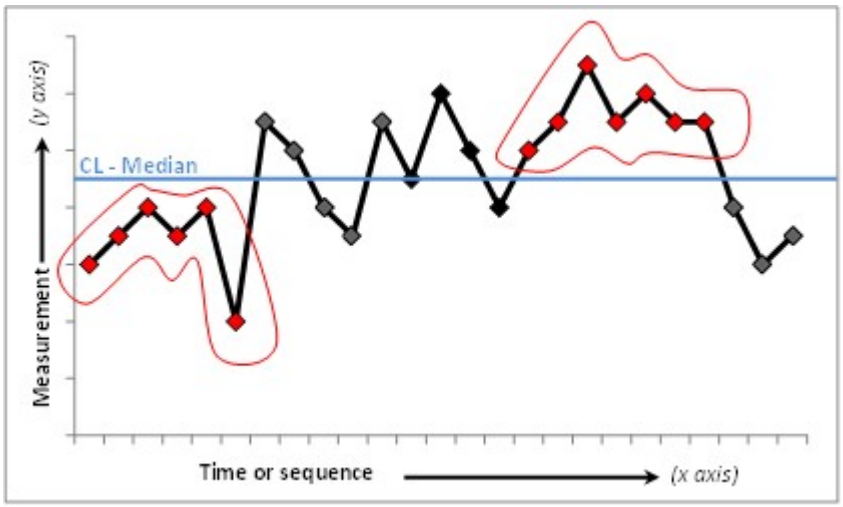

Figure 4: Control Chart showing a Shift

It is emphasized that there is absolutely no substitute for sound judgment based on an appreciation of the analytical system, the technique, the quality control materials utilized, and the analytical interpretation of the data generated by the procedure.

Levey-Jennings or Shewhart Control Chart - The data from a series of analytical tests are plotted with the vertical scale in units such as percent

(percent recovery), and the horizontal scale in units of batch number or time. The mean and standard deviation is calculated on the data. Upper and lower control limits are established at the mean ± 3X the calculated standard deviation. Upper and lower warning limits are established at the mean ± 2X the calculated standard deviation.

Precision charts (other names are Range Chart or R-chart) – The data from duplicates are plotted with the vertical scale in units such as percent (RPD), and the horizontal scale in units of batch number or time. The mean and standard deviation is calculated on the data. The upper control limit is established at the mean X 3.27 and the upper warning limit is established at the mean X 2.51. Precision control charts do not have a lower warning and control limit.

6.1.7. Statistical Process Control

A. Statistical limits are determined at the 99% confidence interval. The evaluation of control limits is made after no less 20 QC points are accumulated from different batches i.e. separate runs/batches, different days, different analysts, etc.

B. Accuracy is expressed as percent recovery of spiked samples.

C. Percent recovery is calculated as follows for spikes in solvent or standard spikes:

$$\% \text{ Recovery} = 100 \times \frac{X}{K}$$

where:

X = observed value

K = known value

D. Accuracy is calculated for spikes into natural matrices as follows:

$$\text{Recovery} = 100 \times \frac{X_s - X_u}{K}$$

where:

X_s = measured value for spiked sample

X_u = measured value for unspiked sample

K = known value of the spike in the sample E. For accuracy, this interval is computed as: Accuracy Interval = Mean Recovery ± 3 X S where: S = Standard deviation for individual values

$$S = \sqrt{\frac{\sum (X_i - X)^2}{N-1}}$$

where:

X_i = value of individual measurement

X = arithmetic mean of the measurements

N = number of the measurements

F. For qualitative analysis, accuracy is expressed as positive (presence) or negative (absence).

G. Precision is expressed as relative standard deviation (RSD) or relative percent difference (RPD) of duplicate samples.

H. RSD is calculated from standard deviation and mean recovery, when the standard deviation is derived from multiple recovery results as follows:

$$RSD = CV = 100 \times \frac{\sigma}{X}$$

where:

RSD = relative standard deviation

CV = coefficient of variation σ = standard deviation

X = arithmetic mean of the measurements

I. RPD is calculated when only two sample results are available as follows:

$$RPD = \frac{|R_1 - R_2|}{R} \times 100$$

where:

| R1 - R2 | = Absolute difference between the determinations

R = arithmetic mean of the two values

J. For precision based on RPD of duplicate samples this limit is computed as:

Upper Control Limit = 3.27 X RPD where: RPD

= mean relative percent difference

K. For qualitative analysis, precision is expressed as true and false positive rates; and true and false negative rates.

$$\% \text{ false positive} = \frac{\#\ falsepositives}{total\#knownnegatives} \times 100$$

$$\% \text{ false negative} = \frac{\#\ falsenegatives}{total\#knownpositives} \times 100$$

6.1.8. Treatment of Outliers and Trends

A. An outlier is a datum that is different from the main data pattern, and/or is not representative of the data set. Outliers are extreme cases of one variable, or a combination of variables, which have a strong influence on the calculation or statistics. The principal safeguards against obtaining or using an outlier are vigilance during all operations and visual inspection of data before performing statistical analyses. Each suspected outlier is evaluated and rejected if found to be unrepresentative, or to have a high probability of being unrepresentative. Rejection for a reason is referred to as rejection for assignable cause.

B. A plot outside of the control limits may be an indication of an assignable cause. If a quality control result falls above or below the control limits (3 SD) of the control chart, the value is investigated. The investigation is a planned action to correct the problem and to prevent the reporting of incorrect results. Sometimes the investigation will reveal a recording or computational mistake that can be revised to obtain the correct value. If the investigation reveals an assignable cause, i.e. deterioration of reagents, improperly prepared reagents, inadequate storage of reagents or standards, the analysis is repeated. When outliers are found, all

analytical results for that analytical batch are inspected to ensure that erroneous results are not reported.

C. Quality control data outside of the control limits (3SD) rejected due to assignable cause remain in the permanent records of the laboratory, for example, on QC charts. However, a datum so determined to be an outlier will be flagged as such and is excluded from the data set before statistical calculations are made. Control limits calculated from data sets containing outliers are not valid.

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7. Glossary/ Definitions

A. Accuracy – Accuracy is the nearness of a measurement or the mean of a set of measurements to the true value. Accuracy is assessed in terms of percent recovery for quality control check samples and matrix spikes.

B. Analytical solution – An analytical solution is the sample in the form as introduced to an instrument. The analytical solution is the end result of the sample preparation, extraction, and digestion procedures.

C. Analytical spike – An analytical spike is a sample made by spiking an analytical solution after the sample preparation or digestion process.

D. Batch - A batch is the basic unit of measure by which the number of quality control samples needed is determined. The analytical batch is those samples, sample extracts, or sample digestates that are analyzed together with the same method sequence, the same lots of reagents, and manipulations common to each sample within the same time period or in continuous sequential time periods. The extraction batch is those samples extracted or digested using the same techniques. Samples in each analytical or extraction batch should be of similar composition.

E. Calibration blank – A calibration blank is usually an organic or aqueous solution that is as free of analyte as possible and prepared with the same volume of chemical reagents used in the preparation of the calibration standards and diluted to the same volume with the same solvent (water or organic) used in the preparation of the calibration standard. The calibration blank is used to give the null reading for the calibration curve. For methods in which the calibration solutions receive the full sample preparation treatment, the calibration blank is identical to, and becomes referred to as, the method blank.

F. Continuing Calibration Verification (CCV) – A CCV is a standard solution used to verify freedom of excessive instrument drift. The CCV is a periodic check of the calibration.

G. Control charts – This is a chart consisting of an expected value (typically the mean) and an acceptable range of occurrences expressed as control limits. The values obtained from measurements versus the time sequence of entries are plotted to produce control charts.

H. Duplicate samples – Duplicate samples are two separate samples taken from the same source (i.e. samples in separate containers and analyzed independently).

I. Initial Calibration Verification (ICV) – This is an independent standard solution used to verify the calibration standard level. An independent standard solution is defined as a standard solution composed of the analyte of interest from a separate (different) source, a different lot or a separately prepared set of two primary standards may be used.

J. Laboratory Control Sample (LCS) – A well characterized sample of known analytes and concentration, or a stable artifact, that is measured over time to monitor the stability of the measurement process.

K. Matrix spike sample – A matrix spike sample is prepared by adding a predetermined quantity of stock solution of representative analytes to an actual sample matrix (as opposed to an ideal matrix, e.g. reagent water, or site blanks, etc.) prior to sample extraction/digestion and analysis. The matrix spike is used to measure accuracy of the method in the sample matrix.

L. Matrix spike duplicate analysis - Equal and predetermined quantities of stock solutions of certain analytes are added to each of two aliquots of a sample prior to extraction or digestion and analysis. Matrix spike duplicates can be used to measure precision.

M. Method detection limit (MDL) – The MDL is the minimum concentration of a substance that can be measured and reported with 99% confidence that the analyte concentration is greater than zero. It is determined from the analysis of replicates of a sample containing the analyte at very low concentration.

N. Monitor – To monitor is to observe and record activity to measure compliance with a specific standard of performance; routine and ongoing collection of data about the indicator.

O. Precision – Precision is the agreement between a set of replicate measurements without assumption or knowledge of the true value. Analytical precision is assessed by means of laboratory duplicate or replicate or duplicate matrix spike analysis. The most commonly used estimates of precision are the relative standard deviation (RSD) or the coefficient of variation (CV).

P. Quality Assurance – Quality assurance is an integrated system of management activities involving planning, implementation, assessment, reporting, and quality improvement to ensure that a process, item, or service is the type and quality needed and expected by the client.

8. Records

A. Control charts for accuracy and precision

B. Proficiency test results

C. Nonconforming work and corrective action records

9. Supporting Documents

A. G7 GEN 05 Control of Nonconforming Work

B. G7GEN Corrective Action

10.0 References

A. Quality Assurance Program Plan for Analytical Testing Laboratories Performing Analyses of Finished Medical Marijuana Products and Marijuana-Infused Products in Massachusetts, Volume 5.0, MDPH

B. FOOD AND DRUG ADMINISTRATION OFFICE OF REGULATORY AFFAIRS ORA Laboratory Manual Volume II, Ensuring the Quality of Test Results, ORA-LAB 5.9

C. Taylor, J. K. (1993). Handbook for SRM users. Gaithersburg, MD: National Institute of Standards and Technology

D. ISO/IEC 17025:2017, General requirements for the competence of testing and calibration laboratories, Section 7.7

E. AOAC International Guidelines for Laboratories Performing Microbiological and Chemical Analysis of Food, Dietary Supplements, and Pharmaceuticals. An Aid to Interpretation of ISO/IEC 17025:2017; August 2018.

10. Document History

Revision #	Status* (D, I, R)	Date	Author Name and Title	Approving Official Name and Title

* - D: Draft, I: Initial, R: Revision

11. Change History

Revision #	Change

12. Attachments None

1. Purpose

To provide guidelines when any aspect of testing, or the results of this work, do not conform with laboratory procedures or specified requirements.

2. Scope

This procedure applies to G7 lab LLC. This procedure directly concerns the laboratory's quality assurance program.

3. Responsibility

The G7 laboratory designates the responsibilities and authorities for the management of nonconforming work within laboratory's quality documents with actions (including halting of work and withholding of test reports, as necessary) defined and taken when nonconforming work is identified. These actions are based upon the risk levels established by the laboratory.

The laboratory quality documents will include designation of authority for resumption of work if halted.

4. Background

If properly executed, quality control parameters can monitor the various aspects of data quality on a routine basis. In instances where performance falls outside acceptable limits, the data produced can be questioned and, after investigation, a determination made as to its validity. The laboratory's internal quality assurance program is the principal recourse available for ensuring that only a quality product is released. Quality control parameters and quality assurance elements are defined in the laboratory's quality management program. These identified quality control parameters are the critical elements that would cause a nonconforming product if not met.

5. Procedure

Identification of nonconforming work or problems with the management system or with testing activities can occur at various places within the management

system and technical operations. Examples are customer complaints, quality control (QC), instrument calibration, checking of consumable materials, staff observations or supervision, test report checking, management reviews, and internal or external audits.

A. Identified nonconformances with any procedure, process, quality control parameter or customer requirement are recorded in Medialab (G7 Lab LLC's Quality Management information System). This process involves documenting the nonconformance, evaluation of the significance or impact the nonconforming work has on the quality system, technical operations, and data reported, and any remedial actions taken.

B. When the evaluation (based upon the significance of the nonconforming work) indicates that it could reoccur or that there is doubt about the compliance of the laboratory's operations with its own policies and procedures, the corrective action procedures outlined in *G7Gen07* Corrective action shall be promptly followed.

C. Corrections will be performed immediately, together with any decisions about the acceptability of the nonconforming work.

D. Dispositions or actions taken on a nonconforming work product are based upon an impact analysis on previous results and include one of the following:

   1. Rework – action taken on nonconforming product so that it will fulfill the specified requirements;
   2. Redone – action taken to re-collect sample or reanalyze (redo) sample to bring the product into conformance;
   3. Use as is – approving the use of nonconforming product without rework or redoing, a disclaimer is made that the product was accepted and the quality requirements that the product did not meet are specified; and
   4. Unable to use – action taken if unable to resolve the problem. The receiver is notified that the data cannot be reported.

E. Data, reports, and actions are not released until the problem is resolved and verified by management. The sample may need to be reanalyzed or re-collected or the inspection redone. If unable to resolve the problem, the receiver is notified that the laboratory data cannot be reported or accepted; with disclaimers made that the product did not meet quality standards.

F. When a non-conformance has been identified and the validity of previously-reported data is in question, a corrective action with investigation will be opened, the customer is notified, and if possible, the product brought into limits by rework or reanalysis to confirm the validity of what was reported.

G. If in error, a corrected report will then be sent to the customer. The corrected report must be identified as an amended or corrected report.

H. A customer supplied product (sample) which is lost, damaged or otherwise unsuitable will be annotated in the web application, such as Field Accomplishment and Compliance Tracking System (FACTS) or Laboratory Information Management System (LIMS), and reported to the customer verbally or electronically.

6. Glossary/Definitions

Nonconformance – This is a departure of a quality characteristic from its intended level or state that occurs with enough severity to cause an associated product or service to not meet a specification or requirement.

7. Records

A. Nonconformance or Corrective Action records.

B. Records of communications with the customer

8. Supporting Documents

A. G7Gen07 Corrective Action

9. References

A. Quality Assurance Program Plan for Analytical Testing Laboratories Performing Analyses of Finished Medical Marijuana Products and Marijuana-Infused Products in Massachusetts, Volume 5.0, MDPH

B. ISO/IEC 17025:2017, General requirements for the competence of testing and calibration laboratories, Section 7.10

C. AOAC International Guidelines for Laboratories Performing Microbiological and Chemical Analysis of Food, Dietary Supplements, and Pharmaceuticals: An Aid to Interpretation of ISO/IEC 17025:2017; August 2018.

10. Document History

Revision #	Status* (D, I, R)	Date	Author Name and Title	Approving Official Name and Title
* - D: Draft, I: Initial, R: Revision				

11. Change History

Revision #	Change

12. Attachments

None

1. Purpose

To provide guidance in the process of identifying, evaluating, recording, investigating, correcting the causes of, and determining the disposition of nonconforming processes, services, and work products (hereafter referred to as nonconformances). The cornerstone of corrective actions is written, and retrievable records of actions taken and follow-up monitoring to determine that corrective actions have been performed, documented, and found to be effective.

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2. Scope

This procedure applies to G7 laboratories and laboratory work products and processes. This procedure directly concerns the laboratory's quality assurance program.

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3. Responsibility

- Technical Manager:
  1. Take action to control and correct nonconformances when they occur.
  2. Ensure that corrective actions are performed, implemented, and communicated.
  3. Review corrective actions that have been taken and approve or recommend if further corrective actions are needed.
  4. Complete appropriate sections of nonconformance and corrective action records in the Quality Management System (Media Lab).
- Employees:
  1. Initiate and/or participate in the completion of corrective actions.
  2. Complete appropriate sections of the nonconformance and corrective action records in QMiS.
- The Quality Manager (QM):

1. Monitors the quality system for systematic problems.
2. Facilitates the corrective action process.
3. Initiates corrective actions in Media Lab when needed, i.e. as a result of complaints/feedback, nonconformances, audit results, management review, or other findings.
4. Monitors corrections and corrective actions for trends, effectiveness, and timely completion.
5. Maintains all records generated during corrections, corrective actions and their investigation(s), including objective evidence of actions taken, in Medialab.

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4. Background

Nonconformances can occur at various places within the quality system and technical operations. Examples include customer complaints, unacceptable quality control samples, instrument and sample problems, environmental problems that affect results, purchased materials for laboratory use, staff observations, management reviews and audits. Processes, services, and/or products considered to be nonconforming may be identified in the following ways:

- Incoming product from suppliers
- Services provided by external sources (i.e. service contractors)
- Processes producing unacceptable results or products.
- Internal or External Quality Audits.

A. AOAC International Guidelines for Laboratories Performing Microbiological and Chemical Analysis of Food, Dietary Supplements, and Pharmaceuticals – An Aid to Interpretation of ISO/IEC 17025:2017; August 2018.

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5. Procedure

5.1. Review of Nonconformity

A. When a nonconformity occurs, the laboratory must take action to control and correct it with actions appropriate to the effects of the nonconformities encountered.

B. A review of the consequences of the nonconformity is performed to determine if a Correction or Corrective Action is warranted.

5.2. Correction

A. If a minor nonconformance is detected where a product was not affected but absolute compliance to a statement of intent or clause of a standard was not met on basis of objective evidence, it can be recorded as a correction only with rectification actions recorded and closed.

B. An obvious trend in a repeated minor nonconformance can escalate it to a corrective action.

5.3. Root Cause & Corrective Action

A. Once a nonconformance that impacts a lab's product, processes, or service is detected an evaluation of the need for action to eliminate the cause(s) will be performed.

B. The laboratory determines if similar nonconformities exist or could potentially occur.

C. An investigation to determine the root cause(s) of the problem will be initiated in order to determine an effective corrective action.

D. Often the root cause is not obvious, therefore careful analysis of all potential causes of the problem is required. Areas to investigate can include:

1. The samples or sample specifications
2. Methods and/or procedures
3. Staff skills and training
4. Consumables and/or vendors used
5. Equipment and its calibration

E. Once the root cause has been determined potential corrective actions shall be identified.

1. Decide what can be done to prevent the problem from recurring.

2. Determine how the solution will be implemented.
3. Define who will be responsible for implementation.
4. Evaluate the risks of implementing the solution.

F. The corrective action(s) most likely to eliminate the problem and to prevent a recurrence shall be selected for implementation.

G. Changes required as a result of the investigation shall be recorded and implemented (i.e. procedure revisions, training, resumption of work where it was stopped due to the nonconformance, etc.).

H. The Technical manager ™ closes the corrective action when there is objective evidence that the actions are completed and effective.

5.4. Monitoring for Effectiveness

A. Corrective actions that are implemented must be monitored to determine if they are and/or continue to be effective.

B. The TM can keep a completed action report open for a specified time to monitor effectiveness, and then close the issue once it has been determined to be effective.

C. Once an action report has been closed its effectiveness can still be determined with an audit in the area affected by the original nonconformance.

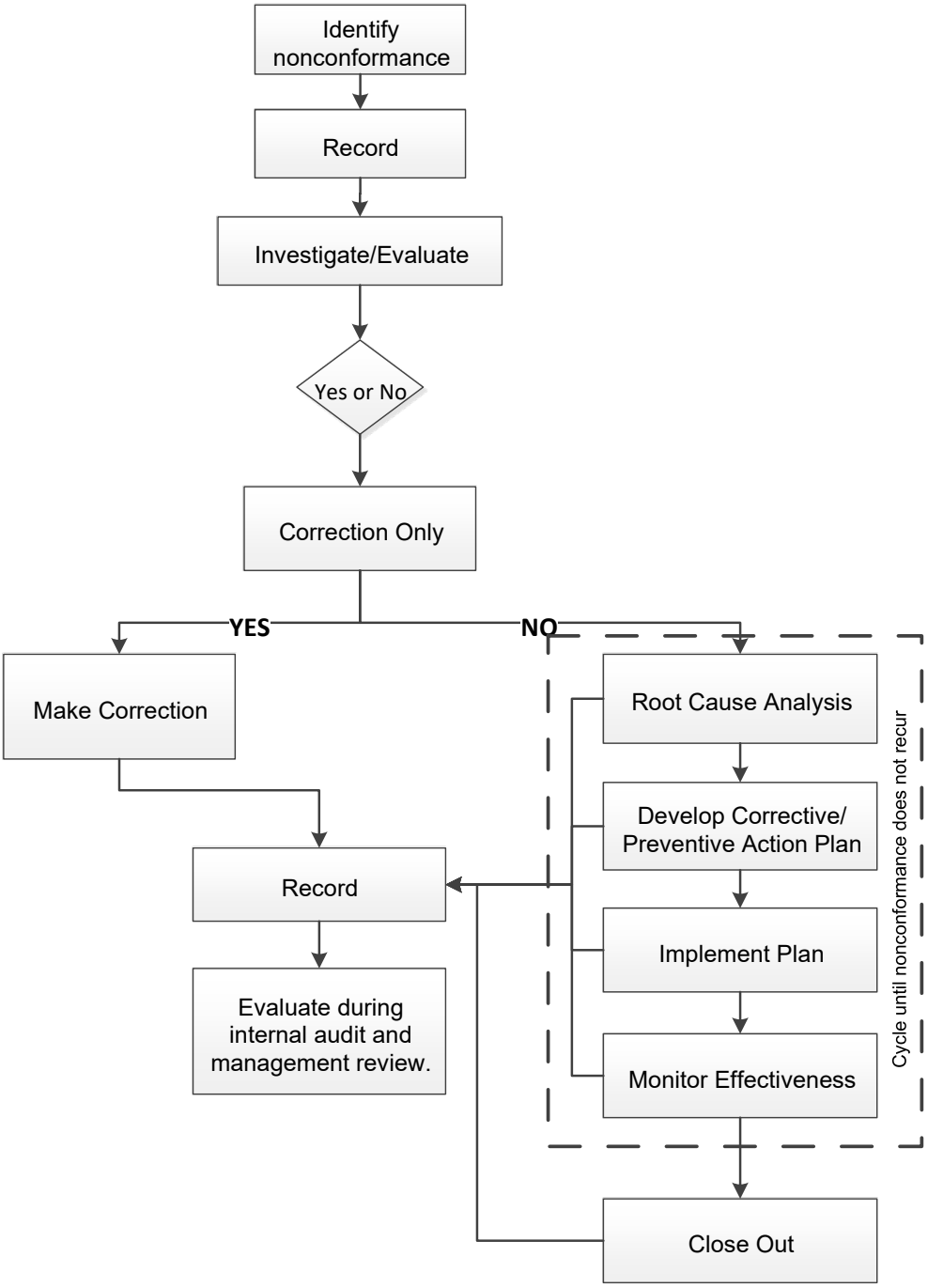
D. In the event a corrective action is found to be ineffective a new nonconformance report will be initiated with a different root cause investigation to determine why the first corrective action was not effective, if the true root cause was determined, and to evaluate and identify the best corrective action to implement and record.

E. This additional corrective action must also under go monitoring to determine its effectiveness

5.5. Recording Correction(s) and Corrective Action(s)

Record nonconformance, investigation, correction, corrective action information in Media lab and according to local laboratory procedures.

1. Process Map



7. Glossary/Definitions

A. Correction - action taken to render the work product acceptable for use by eliminating the detected nonconformity.

B. Corrective Action - The steps taken to eliminate the root cause(s) identified by a root cause analysis.

C. Deficiency – an alternate term used to describe a non-conformance.

D. Nonconformance – A non-fulfillment of a specified or implied requirement of the quality management system or of a quality work product.

E. Observation – a perceived or detected abnormality or anomaly that is not out of conformance to a specified or implied requirement; yet could possibly become a non-conformance if not acted upon or can be improved upon.

F. Preventive Action: Steps to mitigate or remove the underlying cause of a nonconformance.

G. Media Lab – G7 lab LLC's Quality Management information System software. This is where corrective actions are recorded

H. Root Cause(s) – The underlying reason (i.e. cause) that results in a nonconformance.

I. Root Cause Analysis – A systematic method of problem solving that identifies the root cause(s) of non-conformances.

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8. Records

A. Correction and Corrective Action Reports

B. Notes created during Root Cause investigation(s)

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9. Supporting Documents

A. Media Lab Help Files, User Manual

B. G7 Gen05 Control of Nonconforming Work

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10. References

A. Quality Assurance Program Plan for Analytical Testing Laboratories Performing Analyses of Finished Medical Marijuana Products and Marijuana-Infused Products in Massachusetts, Volume 5.0, May15. 2018

B. ISO/IEC 17025:2017, General requirements for the competence of testing and calibration laboratories, Section 8.7.

11. Document History

Revision #	Status* (D, I, R)	Date	Author Name and Title	Approving Official Name and Title
* - D: Draft, I: Initial, R: Revision				

12. Change History

Revision #	Change

13. Attachments

None

DIVERSITY PLAN

G7 Lab ("G7 Lab" or the "Company") is committed to actively promoting diversity, inclusion, and cultural competency, by implementing programmatic and operational procedures and policies that will help to make G7 Lab a leader and champion of diversity, both in the Town of Littleton and throughout the broader Massachusetts cannabis industry.

G7 Lab's commitment to diversity is reflected in the following Goal, which shall be pursued through the Programs outlined herein, and the progress of which shall be judged by the Measurements/Metrics as stated below, and adjusted as needed if necessary:

Goal: Achieve at least 10% of our staffing needs from women (5%) and minorities (5%).

Programs to Achieve Diversity Goal:

- Provide on-site interactive workshops, annually (at minimum), covering such topics as the prevention of sexual harassment, racial and cultural diversity, and methods of fostering an inclusive work atmosphere.
- Increase diversity of the make-up of our staff by actively seeking out minorities, women, veterans, people with disabilities, and/or members of the LGBTQ+community, both through in-house hiring initiatives and participation in online diversity job boards including but not limited to https://diversityjobs.com/ and https://www.pdnrecruits.com/ and in-person job fairs at least annually and as staffing needs merit.
- Establish clearly written policies regarding diversity and a zero-tolerance policy for discrimination and/or sexual harassment, which shall be incorporated into our employee handbook.

Measurements:

- *Qualitative Metrics*: Perform annual evaluation of inclusion/diversity initiatives to ensure diversity is one of G7 Lab's strengths and remains a primary focus. This may include anonymous employee surveys or other private submission opportunities so that we can attempt to avoid any sort of reluctance for our employees to inform management how we are truly doing in pursuit of our diversity plan goals. The results of the surveys shall be compared to prior years' results to allow G7 Lab to adjust our programs in the event that our goal is not being achieved.
- *Quantitative Metrics*: We will strive to achieve at least 10% of our staffing needs from women and minorities. The personnel files shall be evaluated on a semi-annual basis to determine how many employees are women and minorities that occupy positions within the company and that number shall be divided by G7 Lab's total staffing at its Littleton facility to determine the percentage achieved.

G7 Lab acknowledges that it shall show progress or success of our plan at least annually as an express condition of renewal of its licensure, with the submission of a renewal application to be submitted no later than 60 days prior to the date of the anniversary of the issuance of provisional licensure, and every year thereafter.

G7 Lab LLC

G7 Lab will adhere to the requirements set forth in 935 CMR 500.105(4) which provides the permitted and prohibited advertising, branding, marketing, and sponsorship practices of Marijuana Establishments.

G7 Lab acknowledges that any actions taken, or programs instituted will not violate the Commission's regulations with respect to limitations on ownership or control or other applicable state laws.