Massachusetts Department of Environmental Protection

LES 01 EA
Instructions and Supporting Materials

Table of Contents

- introduction
- permit fact sheet
- completeness checklist

Introduction

MassDEP Laboratory Certification *Permit Applications*, as well as *Instructions & Support Materials*, are available for download from the MassDEP Web site at http://www.mass.gov/eea/agencies/massdep/service/approvals/laboratory-certification-forms.html in two file formats: Microsoft Word™ and Adobe Acrobat PDF™. Either format allows documents to be printed.

Instructions & Support Materials files in Microsoft Word™ format contain a series of documents that provide guidance on how to prepare a permit application. Although we recommend that you print out the entire package, you may choose to print specific documents by selecting the appropriate page numbers for printing.

Permit Applications in Microsoft Word™ format must be downloaded separately. Users with Microsoft Word™ 97 or later may complete these forms electronically.

Permitting packages in Adobe Acrobat PDF™ format combine *Permit Applications* and *Instructions & Support Materials* in a single document. Adobe Acrobat PDF™ files may only be viewed and printed without alteration. *Permit Applications* in this format may not be completed electronically.

Massachusetts Department of Environmental Protection

LES 01 EA
Permit Fact Sheet

1. What is the purpose of this permit?

Certification and operation of environmental analysis laboratories is authorized pursuant to MGL c. 21, s.27, c. 21A, s. 2(28), c. 21C, s. 4, c. 21E, s. 3, c. 111 § 142A-142E, 150A, 160 and 310 CMR 42.00.

These regulations establish a program for Department certification of laboratories to conduct analytical measurements for purposes of determining compliance with Department standards where the Department or a client requires that such measurements be conducted by a certified laboratory.

A program for the certification of laboratories conducting analytical measurements of drinking water is necessary for Massachusetts to meet the requirements of primary enforcement responsibility under the Safe Drinking Water Act and the National Primary Drinking Water Regulations. Massachusetts also certifies laboratories analyzing non-potable water. The Laboratory Certification Program identifies laboratories capable of consistently producing valid data (although certification does not guarantee the validity of the data).

2. Who must apply for this permit?

Any person (private corporation, individual, partnership or association, or other entity) who intends to conduct analytical measurements for the purposes of determining compliance with Department standards where the Department or the laboratory's client requires such measurements be conducted by a certified laboratory.

3. What other requirements should be considered when applying for this permit?

a. What prerequisites should be considered before applying for this permit?

None

b. What additional technical information must be provided to apply for this permit?

- Results of Proficiency Tests (PTs) performed by the laboratory must be submitted by the laboratory's PT Provider in accordance with the current Wall Experiment Station PT Policy.
- Laboratory Quality Assurance Plan.
- A laboratory located out-of-state seeking certification under 310 CMR 42.16 must submit a copy of the certificate and certified parameter list issued by its resident state or the USEPA and a copy of the on-site inspection report written by the certifying authority of the laboratory's resident state or the USEPA.

4. How should one apply for the permit?

To apply for any permit covered by 310 CMR 4.00, MassDEP's Timely Action and Fee Provisions, an applicant must complete, sign and submit:

- a MassDEP Transmittal Form for Permit Application and Payment http://www.mass.gov/eea/agencies/massdep/service/approvals/transmittal-form-for-payment.html, and
- a MassDEP application form for the appropriate permit category.

The Transmittal form is a unique numbered form which must be submitted with each application package. Transmittal Form must be submitted as follows:

- One copy accompanies the permit application sent to the MassDEP Primary Permitting Location indicated below.
- One copy accompanies payment to the MassDEP Post Office Box as indicated in Question 6 below.
- One copy for the applicant's records

All additional information, as defined in Question 3b above and identified in the Application Completeness checklist included in this application package, must be submitted with a copy of the transmittal form for the application to be processed properly.

PRIMARY PERMIT LOCATION

Director, Laboratory Certification Program
Massachusetts Department of Environmental Protection
Wall Experiment Station
37 Shattuck Street
Lawrence, MA 01843

5. What is the fee for this permit?

The fees for this permit are listed in the LES01 application. A complete list of fees for all laboratory certification categories may be found at:
http://www.mass.gov/eea/agencies/massdep/service/approvals/timely-action-fees-and-payments.html

6. How and when do I pay?

Payment should be made only by check payable to the: **Commonwealth of Massachusetts**. One copy of the transmittal form http://www.mass.gov/eea/agencies/massdep/service/approvals/transmittal-form-for-payment.html must accompany the check and be forwarded to the following address:

Massachusetts Department of Environmental Protection
P.O. Box 4062
Boston, MA 02211

Pursuant to 310 CMR 4.02 the following entities are exempt from these fees: any city, town, county, or district of the Commonwealth or any municipal housing authority. Applications for permits made by another state agency which cost $100 or less are exempt from payment.

7. When will I get the permit?

If your application is administratively complete when first submitted, and if the information you provide is technically sufficient, MassDEP must provide a decision on the permit by the end of the timelines for the administrative review, the technical review, the inspection review and any public comment review that may be required. MassDEP must refund the fee if it cannot issue its decision within the required time period.

It is in the best interest of the applicant to submit a complete, thorough and accurate application. If the application has administrative deficiencies or technical deficiencies, a second review period will be required

for each, thereby extending the timeframe for a final decision on the permit application. Further information on timelines is presented in questions 8, 9 and 10.

8. When does the timeline begin?

The timeline begins on the day following the receipt of the application and payment. The schedule for timely action will be suspended if there is a failure of payment for any reason following the recording date. MassDEP will inform you of the timelines and the name and telephone number of the individual handling the application.

9. What are the timelines for permit review?

Schedules for timely action vary for each permit, but all will include some combination of the following review periods:

Administrative Completeness Review (AC) - to determine whether all required elements of the application have been provided by the applicant. The Department may request additional information during the review.

An initial administrative completeness review will result in:

- a determination of administrative completeness, or
- a statement of administrative deficiencies

If necessary, a second administrative completeness review will be conducted. After the applicant responds to the statement of deficiencies, the second AC review period will be the same number of days allowed in the first AC review period. The result of the second review will be:

- a determination of administrative completeness, or
- a denial of the permit application

Technical Review (T1) - to review the merits of the permit application and supporting materials. More information may be requested without stopping the clock during a technical review. The result of an initial technical review is:

- a decision to grant or deny the permit, or
- a statement identifying technical or other substantive deficiencies in the application process.
- a decision to conduct an on-site inspection of the laboratory

An applicant may decline to provide additional information in response to a statement of technical deficiency and obtain a decision by MassDEP based on the record at the time. If this option is chosen, there will be no supplemental technical review.

Note: A failure to respond to a statement of technical deficiency within the time allowed by the Department will result in a permit denial with no refund.

Supplemental Technical Review (T2) - to review the merits of the permit application and supporting materials as supplemented, modified, or amended as a result of a deficiency in T1. A supplemental technical

review may be required if MassDEP would otherwise deny or substantially modify or restrict the certificate based on the available information. Additional information may be requested during the review, but the clock will not stop. A supplemental technical review will result in:

- a decision to grant or deny the permit, or
- an on-site inspection

On-Site Inspection and Post Inspection Review - to conduct an on-site inspection of the facilities to determine whether the laboratory satisfies the Department's standards for certification. An on-site laboratory inspection and post inspection review will result in:

- a statement identifying deficiencies, if any, identified during the on-site or post inspection review, and
- a decision to grant or deny the permit

Supplemental Inspection Review - to review the merits of the on-site inspection and supporting materials as supplemented, modified, or amended. Additional information may be requested during the review, but the clock will not stop. A supplemental inspection review will result in:

- a decision to grant or deny the permit

NOTE: A decision to grant or deny a permit following the inspection review period is subject to appeal.

The timelines for this permit are available on the MassDEP Website:
http://www.mass.gov/eea/agencies/massdep/service/approvals/timely-action-fees-and-payments.html

10. What if MassDEP does not complete its work before the expiration of the timeline?

Generally, if the review of the application package is not completed according to the scheduled timelines, MassDEP will refund the fee to the party who paid the original fee. This does not determine that a permit will be denied or approved. Approval does not depend on adherence to the timelines by MassDEP, nor is a permit considered to be granted if the timelines are not met. This refund system is intended to demonstrate the good faith efforts of MassDEP to increase efficiency while continuing to protect the environment.

Be advised that the timelines may be affected by provisions in the regulations including but not limited to failure of payment, other agency actions and judicial and enforcement proceedings. Please refer to the regulations for more detail.

11. What if my application is withdrawn?

If an applicant withdraws an application before the beginning of the technical review, 50% of the fee will be refunded. If the applicant withdraws at any time after the technical review begins, none of the fee will be refunded.

12. What is the purpose of the annual compliance/assurance fee for this permit?

Compliance assurance fees are designed to provide adequate resources for enforcement, inspection and monitoring programs. These resources are essential to the improvement and effective maintenance of these

programs. Without assured compliance, some members of the regulated community will continue to violate environmental laws and regulations, while honest members will be placed at a competitive disadvantage.

Generally, no annual compliance/assurance fee shall be assessed for a permit in the fiscal year in which the permit is issued. Please consult 310 CMR 4.03 of the fees regulations for further information.

13 . How much will I pay for the annual compliance/assurance fee?

Current annual compliance fees can be found on the MassDEP Website at http://www.mass.gov/eea/agencies/massdep/service/approvals/timely-action-fees-and-payments.html

14. How long is the permit in effect?

According to 310 CMR 42.09 (2), certificates shall be valid for one year unless earlier revoked in accordance with 310 CMR 42.12.

15. What can I do to avoid the most common mistakes made in applying for this permit?

- Make sure the application form is completed with all requested information especially with regard to personnel qualifications.
- Submit all requested materials including the laboratory quality assurance plan
- Keep all application materials up to date by notifying the MassDEP of any change in the application including any changes in personnel. Submit new Proficiency Test Study results as they become available. Laboratories located outside Massachusetts should provide copies of updated certificates and certified parameter lists issued by the laboratory's resident state or the USEPA.

16. Where can I get copies of the regulations that apply to this permit?

These regulations include, but are not limited to:

- The Certification and Operation of Environmental Analysis Laboratories contained in 310 CMR 42.00.
- The Timely Action and Fee Provisions, 310 CMR 4.00.
- The Administrative Penalty Regulations, 310 CMR 5.00.

They may be purchased at:

State House Bookstore
Room 116
Boston, MA 02133
617-727-2834

State House West Bookstore
436 Dwight Street
Springfield, MA 01103
413-784-1376

Southeastern Office of the
Secretary of the Commonwealth
218 South Main St., Suite 206
Fall River, MA 02721
508-646-1374

Or, go to http://www.sec.state.ma.us/spr/sprcat/catidx.htm

Massachusetts Department of Environmental Protection

LES 01 EA
Application Completeness Checklist

- ☐ A MassDEP Transmittal Form for Permit Application and Payment is completed and attached: http://www.mass.gov/eea/agencies/massdep/service/approvals/transmittal-form-for-payment.html

- ☐ A MassDEP application form for the microbiology laboratory permit category (LES01EA) is properly filled out.

- ☐ Results of Proficiency Test studies must be submitted by the laboratory's PT Provider at the same time that study results are released to the laboratory. (See the current WES PT Policy).

- ☐ A copy of the Laboratory Quality Assurance Plan is submitted.

- ☐ For laboratories located out-of-state, a copy of the certificate and certified parameter list issued by its resident state or the USEPA must be submitted.

- ☐ For laboratories located out-of-state, a copy of the on-site inspection report written by the certifying authority of the laboratory's resident state or the USEPA must be submitted.

To submit the application package:

- ☐ Checklist items above must be completed.

- ☐ Send a copy of the application package along with one copy of the MassDEP Transmittal Form to:

  Director, Laboratory Certification Program
  Massachusetts Department of Environmental Protection
  Wall Experiment Station
  37 Shattuck Street
  Lawrence, MA 01843

- ☐ Send one copy of the MassDEP Transmittal Form along with the fee payment ($280.00 plus an amount for each certified testing category) to:

  Massachusetts Department of Environmental Protection
  P.O. Box 4062
  Boston, MA 02211

Massachusetts Department of Environmental Protection

LES 01 EA

Application for Initial Certification of Laboratory for Environmental Analysis - Microbiology

Transmittal Number

Laboratory ID (if known)

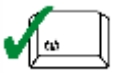
Tax ID Number (FEIN)

A. Laboratory Information

Please type or print in ink. Each question must be answered completely and truthfully.
Please return application forms to:

Director, Laboratory Certification Program
Massachusetts Department of Environmental Protection
Wall Experiment Station
37 Shattuck St.
Lawrence, MA 01843

Important: When filling out forms on the computer, use only the tab key to move your cursor - do not use the return key.



Laboratory Name

Street Address

City/Town | State | Zip Code

Mailing address (if different from above)

City/Town | State | Zip Code

Telephone Number | FAX Number

E-Mail Address | Web Address

Type of Laboratory

☐ Government
☐ Federal ☐ Local ☐ Water District ☐ State ☐ County
☐ Private

☐ Academic

Name(s) of laboratory owner(s) - Please list all owners including private individuals, corporations or government entities.

Hours of Operation:

	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
From:							
To:							

Massachusetts Department of Environmental Protection

LES 01 EA

Application for Initial Certification of Laboratory for Environmental Analysis - Microbiology

Transmittal Number

Laboratory ID (if known)

Tax ID Number (FEIN)

B. Personnel Information (This form may be duplicated before completion)

Name

Title

- ☐ Laboratory Director
- ☐ Laboratory Supervisor
- ☐ Laboratory Analyst
- ☐ Other: _____ If Other, Please Specify

Education

Academic Institution	Major	Total Semester Credit Hrs.		Degree, Diploma or Certificate
		Chemistry	Microbiology	
		Chemistry	Microbiology	
		Chemistry	Microbiology	

Environmental Analysis Experience (begin with current position):

Name & Address of Lab or Institution	Employed from (Mo/Yr)	to (Mo/Yr)	Position Held	Microbiology Methods/# Months Experience

Other certificates, specialized training, etc.:

Transmittal Number

Laboratory ID (if known)

Tax ID Number (FEIN)

C. Laboratory Equipment

Equipment	Manufacturer	Model
pH Meter (accuracy to 0 ± 0.05 units)		
Balances (Top loader or Pan-provided with weights of good quality)		
Thermometers (Checked against certified thermometer)		
Incubators (Air, Waterbaths or Aluminum Block)		
Description:		
Autoclave		
Hot Air Oven (Must maintain stable sterilization temp. 170°C for 2 hrs.)		
Refrigerator		
Optical/Counting/Lighting		
binocular microscope		
colony counter		
Inoculation Equipment (Nichrome 3 mm loop, application sticks, pre-sterilized plastic or metal loops)		
Membrane Filtration Equipment (Units may be glass, stainless steel or plastic)		
Membrane Filters and Pads (47 mm diameter 0.45 μm pore size. Must be sterile)		
Laboratory glass, plasticware and metal		

Transmittal Number

Laboratory ID (if known)

Tax ID Number (FEIN)

C. Laboratory Equipment (cont.)

Equipment	Manufacturer	Model
Ultraviolet Lamps		
254 nm		
366 nm		
Culture Dishes (Pyrex glass or disposable)		
MF Plates		
HPC		
Culture Tubes (Borosilicate glass Caps must be autoclavable plastic or metal)		
Measuring Equipment [1 mL, 5 mL, 10 mL pipets pyrex disposable glass or plastic. Graduates – 10 mL, 25 mL, 100 mL, pyrex or plastic (autoclavable)]		
Laboratory Reagent Water (must be available)		
Rinse and Dilution Water (must be prepared according to *Standard Methods*)		
Other		

D. Certification

I certify the above information is true and accurate to the best of my knowledge.

Print Name

Authorized Signature

Date

Position/Title

Massachusetts Department of Environmental Protection

Supplemental Form to LES 01 EA

Areas for Certification and Certification Application Fees

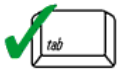
Transmittal Number

Facility ID# (if known)

Tax ID Number (FEIN)

A. Instructions

Important: When filling out forms on the computer, use only the tab key to move your cursor - do not use the return key.



The Initial certification fee is $280 plus an amount for each certified testing category as indicted below. Please check the categories within each discipline and matrix for which you are requesting certification and indicate the method(s) to be employed.
Note: There are no additional fees for certification in the water treatment and distribution analytes; they are included in the $280.00 initial certification fee.

B. Potable Water

	Method No. and Reference	Fee
Water Treatment and Distribution		
☐ Total Coliform	_____	included
☐ *Escherichia coli*	_____	included
Source Water		
☐ Total Coliform	_____	$45
☐ Fecal Coliform	_____	$43 (1)
☐ *Escherichia coli*	_____	$45 (2)
☐ Enterococci	_____	$43 (3)
☐ Heterotrophic Plate Count	_____	included

C. Non-Potable Water

	Method No. and Reference	Fee
Ambient Water		
☐ *Escherichia coli*	_____	$45 (2)
☐ Enterococci	_____	$43 (3)
Wastewater		
☐ Fecal Coliform	_____	$43 (1)
☐ *Escherichia coli*	_____	$45 (2)
☐ Enterococci	_____	$43 (3)

Transmittal Number

Facility ID# (if known)

Tax ID Number (FEIN)

SUBTOTAL Fees: Non-Potable Water	
SUBTOTAL Fees: Potable Water	
Initial Certification Fee	**$280**
TOTAL FEES	

(1) Only one fee is paid if a lab is seeking certification for fecal coliform using the same or similar method(s) in source water and/or wastewater. For example, if a lab is seeking certification for fecal coliform using the same or similar method(s) in source water and wastewater, the fee for fecal coliform is $43 not $86.

(2) Only one fee is paid if lab is seeking certification for *E. coli* using the same or similar method(s) in source water, ambient water, and/or wastewater. For example, if a lab is seeking certification for *E. coli* in source water and wastewater using the same or similar method(s), the fee for *E. coli* is $45 not $90.

(3) Only one fee is paid if lab is seeking certification for enterococci using the same or similar method(s) in source water, ambient water, and/or wastewater. For example, if a lab is seeking certification for enterococci using the same or similar method(s) in source water and wastewater, the fee for enterococci is $43 not $86.

D. Certification

I certify the above information is true and accurate to the best of my knowledge.

Print Name

Authorized Signature

Date

Position/Title