



# LES 04 EA

## Instructions and Supporting Materials

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### Introduction

Links to MassDEP Laboratory Certification *Permit Instructions & Support Materials*, are available on the web at <https://www.mass.gov/lists/laboratory-certification-forms>

*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* must be completed using the EEA ePLACE Portal at <https://eplace.eea.mass.gov/citizenaccess/Default.aspx>



# LES 04 EA Permit Fact Sheet

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## 1. What is the purpose of this permit?

Application to certify additional testing category(s) at microbiological analysis laboratories as 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 MassDEP certification of laboratories to conduct analytical measurements for purposes of determining compliance with Department standards where the MassDEP 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?

- Current MassDEP Laboratory Authorization Number and ePlace account
- 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.
- Standard Operating Procedures
- 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, and submit a MassDEP application for the appropriate permit category using the EEA ePLACE Portal. Use the "amendment" link beside the laboratory's authorization to access the LES04 EA application.



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All additional information, as defined in Question 3b above and identified in the Application Completeness checklist included in these instructions, must be uploaded with the application for it to be processed properly.

## 5. What is the fee for this permit?

The fees for this permit are calculated during the application process. A complete list of fees for all laboratory certification categories may be found at: <https://www.mass.gov/lists/laboratory-certification-forms>

## 6. How and when do I pay?

On-line when the application is completed, or:

Payment may be made by check payable to the:

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

Ensure checks include the application number provided when the on-line application is submitted.

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, 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.

## 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.



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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



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**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 regulations governing timelines associated with the permit may be found at:

<https://www.mass.gov/regulations/310-CMR-400-timely-action-schedule-and-fee-provisions>

### 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 [310 CMR 4.00: Timely Action Schedule and Fee Provisions | Mass.gov](#)

### 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.



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### 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 and standard operating procedures.
- Make sure the proper, approved methods are listed and performed by the laboratory for the matrix in which certification is requested, e.g., drinking water methods for certification in the potable water category.
- 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>



## LES 04 EA

# Application Completeness Checklist

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- A MassDEP application form for the modification of microbiology laboratory permit category (LES04EA) is properly completed.
- 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.
- Copies of Standard Operating Procedures are submitted
- Laboratory Personnel Information forms are submitted for each individual added to the laboratory's personnel table, and individuals meet both the education and experience requirements at 310 CMR 42.08(1) for the position held
- For laboratories located out-of-state, a copy of the certificate and certified parameter list issued by its resident state or the USEPA is 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 is submitted.

To submit the application package:

- Checklist items above must be completed.
- Make fee payment (\$220.00 plus an amount for each certified testing category) pay on-line or send checks to the lockbox below (ensure checks include the application number provided when the on-line application is submitted):

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