

**United States Department of Agriculture, Food Safety and Inspection Service
Office of Public Health Science, Laboratory QA Division**

SOP No: PEPRL 0004.08		Page 1 of 4
Title: PEPRLab Program Entry/Out of Program Guidelines		
Revision: 08	Replaces: PEPRL 0004.07	Effective: 1/23/2008

1. Purpose:

This document establishes the procedures and guidelines that must be followed when a laboratory seeks entry into or is removed from the **Pasteurized Egg Products Recognized Laboratory (PEPRLab)** Program.

2. Scope:

This Standard Operating Procedure (SOP) applies to a laboratory seeking entry into the PEPRLab Program. It also applies to a recognized laboratory that is removed from the PEPRLab Program.

3. Definitions:

3.1 Applicant – Any laboratory seeking entry into the PEPRLab Program.

3.2 Client-letter – A signed letter from the applicant’s potential client(s), addressed to the applicant, on the client’s company letterhead. This client-letter must state that the client is a USDA, FSIS inspected egg-breaking or egg product plant and will be using the applicant to analyze the plant’s egg product surveillance samples for *Salmonella*. The **USDA, FSIS establishment number of the client (plant) must also be included** in the letter.

3.3 Inactivity on the part of the applicant – Allowing a period of 3 months to pass during the application period without contacting the Program Office or allowing a period of 6 months to pass from the time of receipt of the Program application materials without concluding the application process.

3.4 Out of Program (OOP): A laboratory is removed from the PEPRLab Program either at its request or for failure to adhere to the requirements of the program.

4. Procedure for entering into the PEPRLab Program

4.1 Any laboratory applying for entry into the PEPRLab Program must send a letter, on their company letterhead, (or an e-mail containing a letterhead attachment) addressed to the PEPRLab Program Manager, with a copy to the Microbiology QA Branch Chief, stating their desire to join the Program.

**United States Department of Agriculture, Food Safety and Inspection Service
Office of Public Health Science, Laboratory QA Division**

SOP No: PEPRL 0004.08		Page 2 of 4
Title: PEPRLab Program Entry/Out of Program Guidelines		
Revision: 08	Replaces: PEPRL 0004.07	Effective: 1/23/2008

The application process may be terminated at the discretion of the Program Manager due to inactivity on the part of the applicant, as defined in section 3 “Definitions” (above).

- 4.2** Upon receipt of this letter of inquiry, the Program Manager shall:
- Enter the applicant into the PEPRLab database.
 - Start a folder for the applicant in the PEPRLab files.
 - Send to the applicant the following packet of material containing information on the PEPRLab Program, as well as three forms to be completed and returned to the Program Manager:
 - An Application for the USDA, FSIS PEPRLab Program (PEPRL F-0004)
 - A PEPRLab Program Information Update Request (PEPRL F-0003)
 - A copy of SOP No. PEPRL 0004, Program Entry/Exit Guidelines
 - A copy of SOP No. PEPRL 0007, Program Requirements for Recognized Laboratories
 - A copy of Form No. PEPRL F-0008, Self Assessment Checklist
 - A copy of Sections I and VII of the AMS/Science Division’s “Laboratory Methods for Egg Products”
 - A cover letter containing the Internet addresses for the FDA BAM Online and the FSIS MLG Online and a requirement that the applicant provide a **copy** of a client-letter containing the information specified in section 3 “Definitions” (above)
- 4.3** Upon receipt of the client-letter, the three completed forms (PEPRLab F-0004, PEPRL F-0003, and PEPRL F-0008) from the applicant, the Program Manager will review them and note any discrepancies, problems, or concerns that need to be clarified and/or addressed by the applicant.
- 4.4** Upon completion of the review process, the Program Manager may contact the applicant and schedule a teleconference to discuss/clarify discrepancies or problems found during the review process. The applicant may initiate contact at any time to discuss questions that they may have concerning the PEPRLab Program.
- 4.5** Upon completion of the teleconference, **the applicant will** take the necessary steps needed to correct any and all non-compliance issues raised during the teleconference, and will send written confirmation that these specific concerns have been adequately addressed.

**United States Department of Agriculture, Food Safety and Inspection Service
Office of Public Health Science, Laboratory QA Division**

SOP No: PEPRL 0004.08		Page 3 of 4
Title: PEPRLab Program Entry/Out of Program Guidelines		
Revision: 08	Replaces: PEPRL 0004.07	Effective: 1/23/2008

- 4.6** After receipt of any required written confirmation of corrective actions (CAs) taken by the applicant as a result of the teleconference, the Program Manager will meet with the Program Coordinator and/or Branch Chief to establish a tentative on-site audit schedule. The PEPRLab Program Auditor conducting the on-site review will notify the applicant of the audit schedule.

Upon completion of the on-site review by the PEPRLab Program Auditor, a report will be written and filed, following the audit guidelines set out in SOP No. PEPRL 0005. Following review and approval of the audit report by the PEPRLab Program Manager, it will be sent to the Lab Director/Manager of the applying laboratory, with a copy filed in the Program Office.

The applicant must respond to **all** non-conformances listed in the audit report **within 30 calendar days of receipt of the audit report**, by sending a corrective action response to the Program Manager. This corrective action response **must** include objective evidence documentation that needed corrective actions have been implemented. Examples of this objective evidence would be a training record, an updated approved procedure, or a new/revised form complete with entered data showing that it is properly used. Information on tardy CAs can be found in section 4.8 of SOP No. PEPRL 0005.

Upon successful completion of the pre-entry audit, a letter will be sent to the applicant. The letter will inform them of their **interim** acceptance (Note: If the laboratory has also correctly identified an initial double set of egg Proficiency Test samples, the laboratory is eligible for full acceptance into the PEPRLAB PROGRAM.) A laboratory with interim acceptance is eligible to perform the *Salmonella* analysis of surveillance samples. An official **PEPRLab number** will be assigned to the laboratory and **it is to be used on all correspondence involving the PEPRLab Program.**

- 4.7** Successful analysis (correctly identifying at least 90%) of an initial double set of egg Proficiency Test (PT) samples is required before the applicant can be fully accepted into the program. The PT samples will be sent when the next round of testing is scheduled for the PEPRLab Program.

If the applicant fails to correctly identify each of the initial PT samples they must review their laboratory practices and submit a corrective action response to the PEPRLab Program Manager, defining their evaluation of the cause(s) of the failure and the corrective action(s) instituted to assure that any problems have been corrected.

**United States Department of Agriculture, Food Safety and Inspection Service
Office of Public Health Science, Laboratory QA Division**

SOP No: PEPRL 0004.08		Page 4 of 4
Title: PEPRLab Program Entry/Out of Program Guidelines		
Revision: 08	Replaces: PEPRL 0004.07	Effective: 1/23/2008

After receiving the corrective action response and consulting with the Branch Chief, the Program Manager will decide a course of action to be taken in connection with the applicant's proficiency testing difficulty.

- 4.8** The PEPRLab Program manager may decide to include an applicant laboratory in a PT event prior to completion of the entry audit and subsequent acceptance of their corrective actions. However, the applicant laboratory shall not be granted interim acceptance into the program until their initial entry audit is closed. When the requirements of both pre-entry audit and initial PT samples analysis have been successfully fulfilled by the applicant, the Program Manager shall:
- Send a letter to the applicant, formally accepting them into the PEPRLab Program.
 - Notify the USDA, FSIS Field Operations, Policy Development Division, egg products contacts and the relevant Field Operations District Manager of the addition of a new laboratory in the PEPRLab Program.
 - Update the PEPRLab database to include the needed information regarding the new laboratory.

5. Procedure for removal from the PEPRLab Program (OOP)

Once a recognized laboratory has been removed from the PEPRLab Program the Program Manager (or designee) shall notify the following:

- The laboratory that is being removed from the program
- The appropriate District Office(s)- The district where the client(s) of the PEPRLab are located.
- The egg products contact person(s) in Policy Development Division
- The LQAD Director and MQAB Chief

The Program Manager (or designee) shall perform the following steps:

- Change the status in the laboratory's records in the PEPRLab database from active to out of program (OOP).
- Move the laboratory's folder(s) from the active section to the inactive section of the PEPRLab files.
- Remove the laboratory from the audit schedule.