

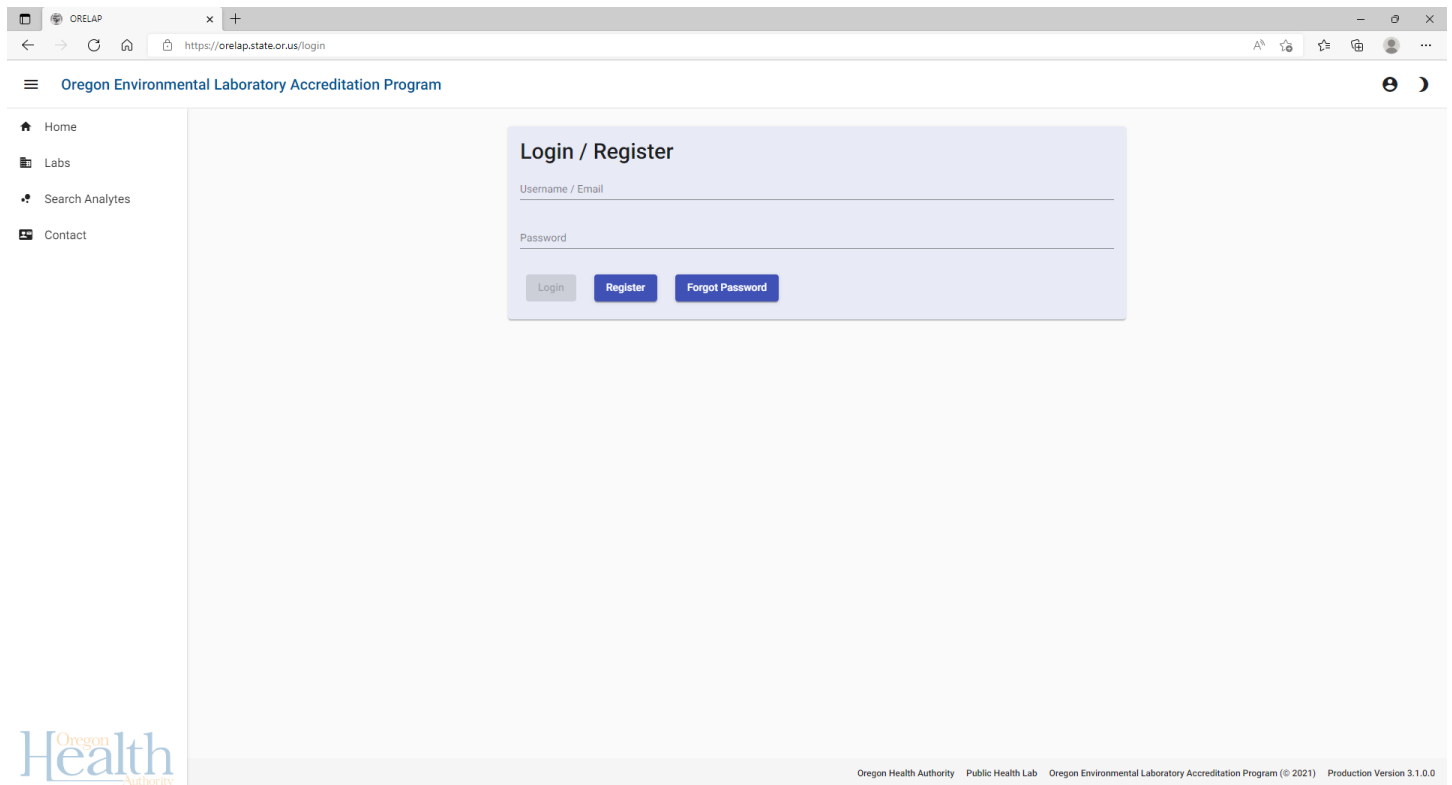
ORELAP Assessment:

How to respond to findings in ODIE

After your assessment, the inspection team will compile a list of findings, if any, and create an inspection report in the ORELAP Data Input and Edit (ODIE) application. This document is a step-by-step guide to responding to the inspection findings.

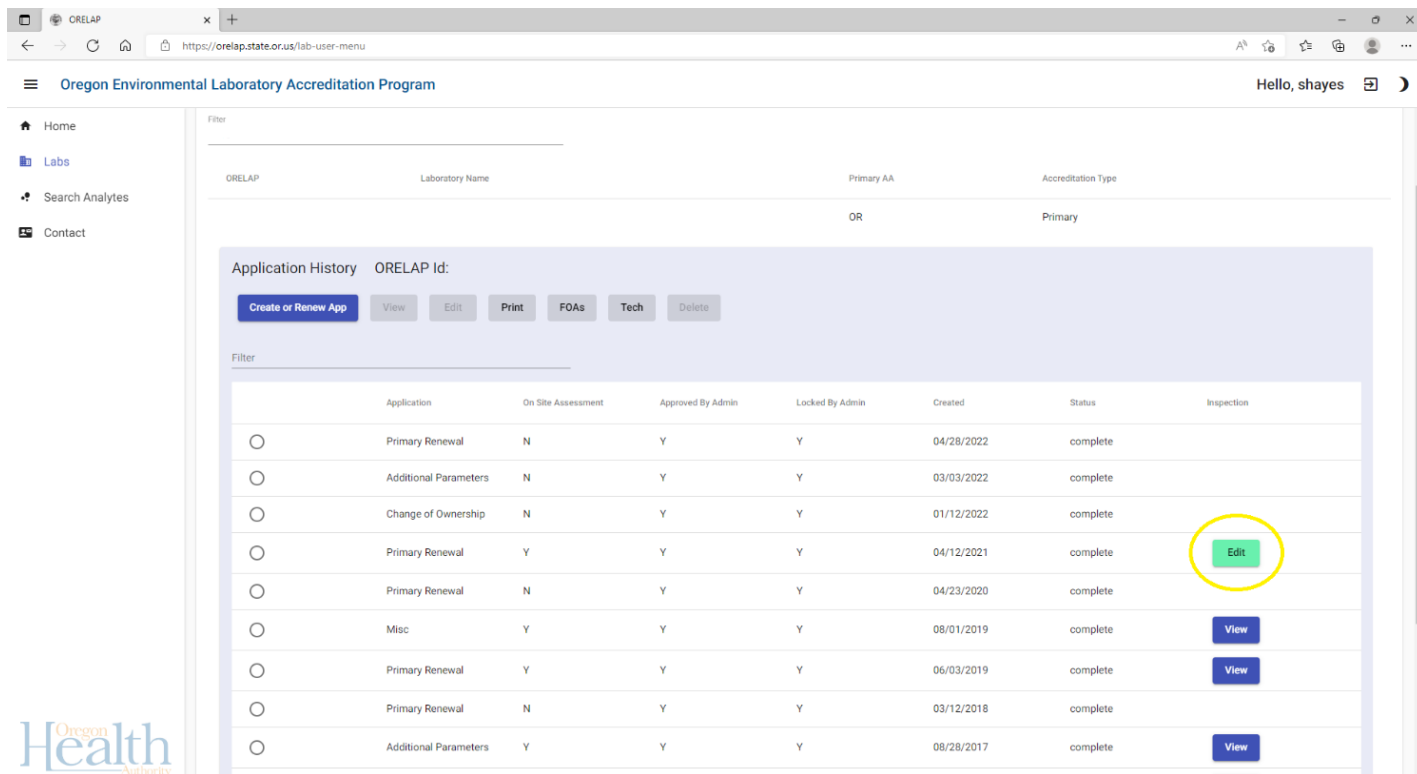
The laboratory's registered user(s) will receive an automated email when the inspection report is ready to view. You have thirty (30) calendar days to submit your responses after you receive this email.

Login to the ODIE application at: <https://orelap.state.or.us/home>. You can also find a link on the ORELAP webpage here: <https://www.oregon.gov/oha/ph/laboratoryservices/environmentallaboratoryaccreditation/pages/index.aspx>. Do not use a search engine to find the ODIE application, as the top result will often be the administrative website for ODIE, which you cannot access. Once at the ODIE homepage, click "Labs" to bring up the login screen.

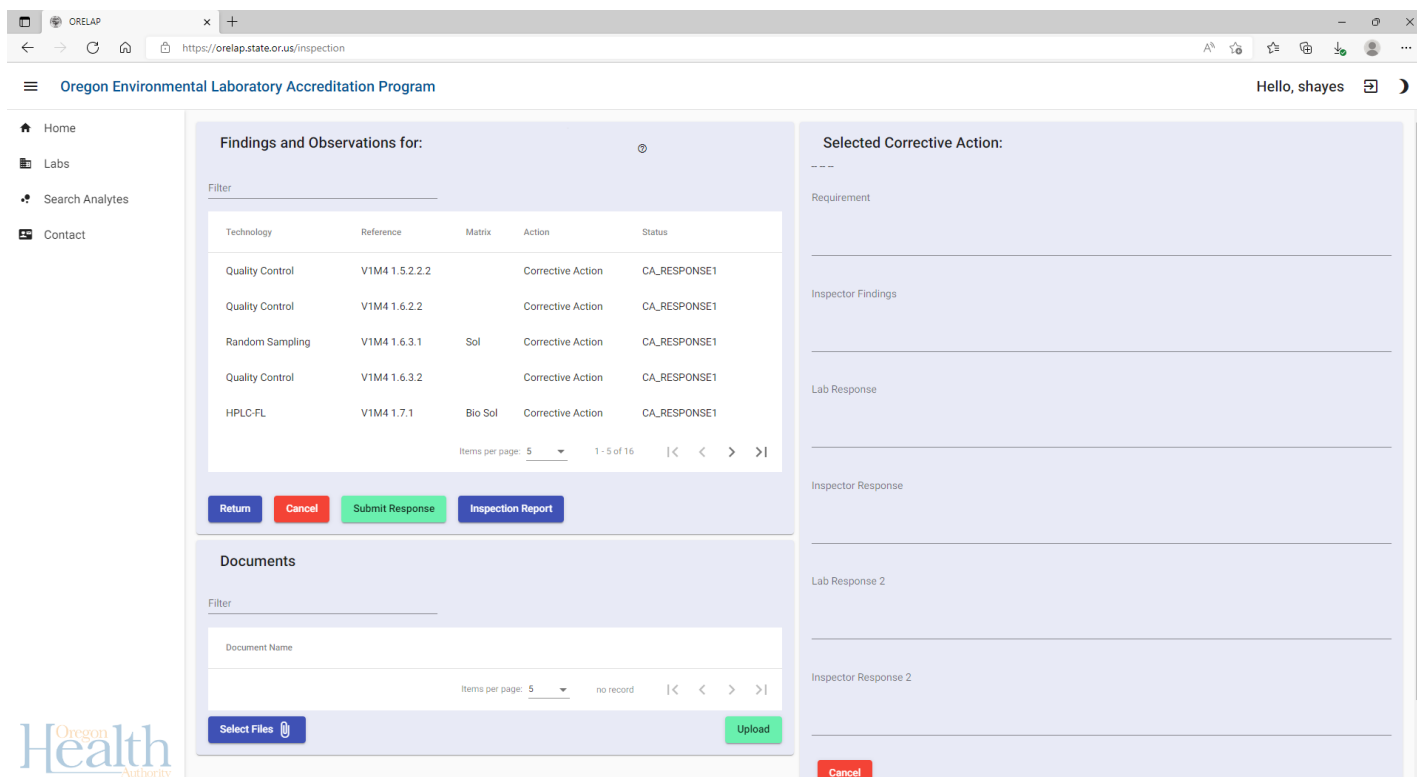


The screenshot shows a web browser window with the URL <https://orelap.state.or.us/login>. The page title is "Oregon Environmental Laboratory Accreditation Program". On the left, there is a navigation menu with links for Home, Labs, Search Analytes, and Contact. The main content area features a "Login / Register" form with two input fields: "Username / Email" and "Password". Below the fields are three buttons: "Login", "Register", and "Forgot Password". The footer contains the Oregon Health Authority logo and the text: "Oregon Health Authority Public Health Lab Oregon Environmental Laboratory Accreditation Program (© 2021) Production Version 3.1.0.0".

The open inspection can be viewed by clicking on “Edit” in the inspection column. Previous closed assessments may be read by clicking the “View” button. If you cannot see the “Edit” button, the inspection was likely assigned to an older renewal application where it was originally paid, so expand your application list.



This will take you to the Findings and Observations page. Findings are sorted by their technology and reference. Findings can be classified as Immediate, Corrective Action, or Recommendation. Recommendations do not require a response. Immediate Actions are for repeat or severe findings and require more in-depth corrective actions. Click on the “Inspection Report” button to generate the official inspection report in a PDF format.



Clicking on a finding will bring up more information in the righthand column. The Requirement field includes the rule or regulation cited for the finding, and the Inspector Findings field includes the actual finding written by the inspection team.

The screenshot shows the ORELAP interface with a table of findings and observations. The table has columns for Technology, Reference, Matrix, Action, and Status. The findings listed are:

Technology	Reference	Matrix	Action	Status
Quality Control	V1M4 1.5.2.2.2		Corrective Action	CA_RESPONSE1
Quality Control	V1M4 1.6.2.2		Corrective Action	CA_RESPONSE1
Random Sampling	V1M4 1.6.3.1	Sol	Corrective Action	CA_RESPONSE1
Quality Control	V1M4 1.6.3.2		Corrective Action	CA_RESPONSE1
HPLC-FL	V1M4 1.7.1	Bio Sol	Corrective Action	CA_RESPONSE1

Below the table are buttons for Return, Cancel, Submit Response, and Inspection Report. There is also a Documents section with a filter and an Upload button.

For findings that are Immediate or Corrective Action, the laboratory must enter its response in the Lab Response field and upload any supporting files/documents (file size limit is 20 Mb). Please make sure to click the “Save” button after each update.

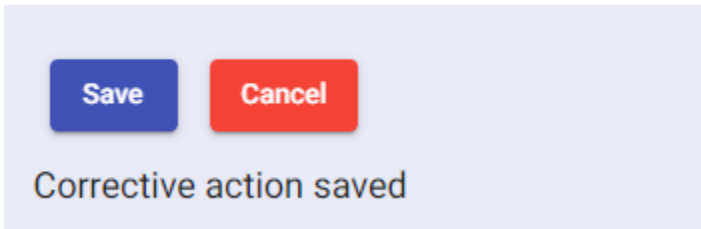
This screenshot shows the details of a finding and the response process. The finding is: "The laboratory shall prepare and analyze a minimum of one (1) LOQ verification sample spiked at the same concentration as the initial LOQ verification on each instrument during each quarter in which samples are being analyzed for each quality system matrix, method, and analyte." The Inspector Findings field contains: "The laboratory did not take corrective action for this result."

The Lab Response field contains: "The lab has corrected this deficiency" (indicated by a red arrow).

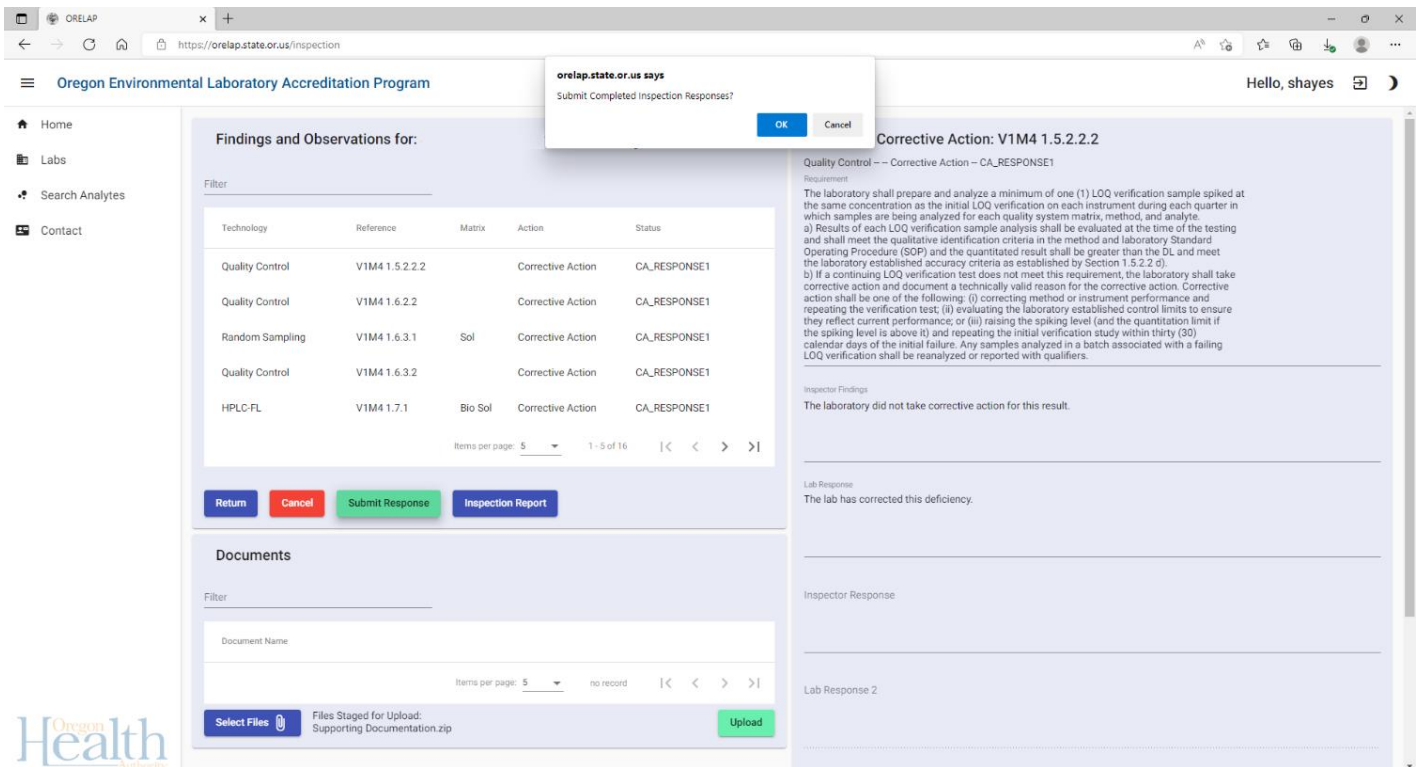
The Documents section shows a file named "Supporting Documentation.zip" (indicated by a red arrow) that has been staged for upload. The "Upload" button is also circled in red.

At the bottom of the interface, the "Save" button is circled in red.

This message will appear after clicking the “Save” button to let you know your progress has been saved. ODIE has an internal timer that will automatically logout if you are idle too long. Save frequently to prevent losing your progress! One suggestion is to write out your responses in a word processing application, and then copy & paste them into ODIE.



When you are finished responding to all the findings, click on the “Submit Response” button. Doing so will lock in all your responses and send an automatic email notification to the inspectors. Once submitted, the response fields will be locked and the laboratory will no longer be able to upload documents.



The laboratory’s registered user(s) will receive an automated email when the corrective actions have been reviewed. You have thirty (30) calendar days to submit any needed responses after you receive this email. Login as before and navigate to the open inspection report.

The inspectors will record their review of each corrective action in the Inspector Response field. If the inspector has determined the corrective action is acceptable, their review will state their acceptance or approval, and the Status field for the corrective action in the lefthand column will show up as COMPLETED.

Findings and Observations for:

Technology	Reference	Matrix	Action	Status
Quality Control	V1M4 1.5.2.2.2		Corrective Action	COMPLETED
Quality Control	V1M4 1.6.2.2		Corrective Action	CA_RESPONSE1
Random Sampling	V1M4 1.6.3.1	Sol	Corrective Action	CA_RESPONSE1
Quality Control	V1M4 1.6.3.2		Corrective Action	CA_RESPONSE1
HPLC-FL	V1M4 1.7.1	Bio Sol	Corrective Action	CA_RESPONSE1

Selected Corrective Action: V1M4 1.5.2.2.2

Requirement
 The laboratory shall prepare and analyze a minimum of one (1) LOQ verification sample spiked at the same concentration as the initial LOQ verification on each instrument during each quarter in which samples are being analyzed for each quality system matrix, method, and analyte.
 a) Results of each LOQ verification sample analysis shall be evaluated at the time of the testing and shall meet the qualitative identification criteria in the method and Laboratory Standard Operating Procedure (SOP) and the quantitated result shall be greater than the DL and meet the laboratory established accuracy criteria as established by Section 1.5.2.2 d).
 b) If a continuing LOQ verification test does not meet this requirement, the laboratory shall take corrective action and document a technically valid reason for the corrective action. Corrective action shall be one of the following: (i) correcting method or instrument performance and repeating the verification test; (ii) evaluating the laboratory established control limits to ensure they reflect current performance; or (iii) raising the spiking level (and the quantitation limit if the spiking level is above it) and repeating the initial verification study within thirty (30) calendar days of the initial failure. Any samples analyzed in a batch associated with a failing LOQ verification shall be reanalyzed or reported with qualifiers.

Inspector Findings
 The laboratory did not take corrective action for this result.

Lab Response
 The lab has corrected this deficiency.

Inspector Response
 Acceptable, finding closed.

Lab Response 2

For remaining findings, read the inspector’s review and respond accordingly by recording your response in the Lab Response 2 field and submit any additional documents as before. Use the “Save” button as before.

Findings and Observations for:

Quality Control	V1M4 1.5.2.2.2		Corrective Action	CA_RESPONSE2
Quality Control	V1M4 1.6.2.2		Corrective Action	CA_RESPONSE1
Random Sampling	V1M4 1.6.3.1	Sol	Corrective Action	CA_RESPONSE1
Quality Control	V1M4 1.6.3.2		Corrective Action	CA_RESPONSE1
HPLC-FL	V1M4 1.7.1	Bio Sol	Corrective Action	CA_RESPONSE1

Requirement
 Operating Procedure (SOP) and the quantitated result shall be greater than the UL and meet the laboratory established accuracy criteria as established by Section 1.5.2.2 d).
 b) If a continuing LOQ verification test does not meet this requirement, the laboratory shall take corrective action and document a technically valid reason for the corrective action. Corrective action shall be one of the following: (i) correcting method or instrument performance and repeating the verification test; (ii) evaluating the laboratory established control limits to ensure they reflect current performance; or (iii) raising the spiking level (and the quantitation limit if the spiking level is above it) and repeating the initial verification study within thirty (30) calendar days of the initial failure. Any samples analyzed in a batch associated with a failing LOQ verification shall be reanalyzed or reported with qualifiers.

Inspector Findings
 The quarterly limit of quantitation (LOQ) verification for potency method (UNODC 5.4.8) had a result that did not meet the laboratory's requirements for THC-A (see sequence ID S220487). The laboratory did not take corrective action for this result. MJ 11/18/2022. Reviewed by RP 11/22/2022.

Lab Response
 The lab has corrected this deficiency.

Inspector Response
 Need further documentation that this has been fixed.

Lab Response 2
 Attached finalized SOP with training documents.

Inspector Response 2
 Acceptable, finding closed.
 Nice work!

Save **Cancel**

When you have responded to all open findings, click on the “Submit Response” button, as before. Inspectors will receive an automatic email. When the inspection has been closed, you will receive a final automated email.