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: <u>https://orelap.state.or.us/home</u>. You can also find a link on the ORELAP webpage here: <u>https://www.oregon.gov/oha/ph/laboratoryservices/environmentallaboratoryaccreditation/pages/index.aspx</u>. 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.

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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.

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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.

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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.

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| 🖭 Contact | Technology | Reference | Matrix | Action | Status | 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 | | | | |
| | Quality Control | V1M4 1.5.2.2.2 | | Corrective Action | CA_RESPONSE1 | 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 acting and deciment a technically velic daesor for the corrective action. Correctives | | | | |
| | Quality Control | V1M4 1.6.2.2 | | Corrective Action | CA_RESPONSE1 | contractive Became and declaring the technicity was related to the contract became became action 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 (ii) raising the soliton soliton and the quantitation limit if | | | | |
| | Random Sampling | V1M4 1.6.3.1 | Sol | Corrective Action | CA_RESPONSE1 | 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. | | | | |
| | Quality Control | V1M4 1.6.3.2 | | Corrective Action | CA_RESPONSE1 | Inspector Findings | | | | |
| | HPLC-FL | V1M4 1.7.1 | Bio Sol | Corrective Action | CA_RESPONSE1 | The laboratory did not take corrective action for this result. | | | | |
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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.

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| | abs | Random Sampling | V IWI4 1.0.3.1 | 301 | Conective Action | | 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. | 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. | | |
| | Search Analytes | HPLC-FL | V1M4 1.6.3.2 V1M4 1.7.1 | Bio Sol | Corrective Action | CA_RESPONSE1 | | Impeter Findings The laboratory did not take corrective action for this result. | | |
| 10 | Contact | | | ltems per pag | ge: <u>5</u> v 1 - 5 of 1 | 16 < < > > | ı. | | | L |
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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.

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| itact | Technology | Reference | Matrix | Action | Status | the same con which sampl a) Results of and shall me | ncentration as the initial LQQ verification on each instrument during each quarter in les are being analyzed for each quality system matrix, method, and analyte. f each LQQ verification sample analysis shall be evaluated at the time of the testing ext the qualitative identification criteria in the method and laboratory Standard |
| | Quality Control | V1M4 1.5.2.2.2 | | Corrective Action | CA_RESPONSE1 | Operating Pro the laborator b) If a contin | rocedure (SOP) and the quantitated result shall be greater than the DL and meet ry established accuracy criteria as established by Section 1.5.2.2.0). uing LOQ verification test does not meet this requirement, the laboratory shall take |
| | Quality Control | V1M4 1.6.2.2 | | Corrective Action | CA_RESPONSE1 | corrective ac action shall t repeating the | ction and document a technically valid reason for the corrective action. Corrective be one of the following: (i) correcting method or instrument performance and e verification test; (ii) evaluating the laboratory established control limits to ensure |
| | Random Sampling | V1M4 1.6.3.1 | Sol | Corrective Action | CA_RESPONSE1 | the spiking le calendar day | current performance, or (iii) raising the spinning level (and the quantization nime in evel is above if and repeating the initial vertication study within hitry (30) ys of the initial failure. Any samples analyzed in a batch associated with a failing tion shall be readarzed or greatered with qualifiers. |
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| | HPLC-FL | V1M4 1.7.1 | Bio Sol | Corrective Action | CA_RESPONSE1 | The laborato | ory did not take corrective action for this result. |
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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.

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| A Home ■ Labs ■ Council Accelutor | Findings and Observations for: | ٥ | Selected Corrective Action: V1M4 1.5.2.2.2 Quality Control Corrective Action - CA_RESPONSE1 Requirement The laboration chall propose and applying a minimum of one (1) LOD undification example mixed at |
| Search Analytes Contact | Technology Reference Quality Control V1M41.5.2.2 Quality Control V1M41.6.2.2 Random Sampling V1M41.6.3.1 Quality Control V1M41.6.3.2 HPLC-FL V1M41.7.1 | Matrix Action Status 2 Corrective Action COMPLETED Corrective Action CA_RESPONSE1 Sol Corrective Action CA_RESPONSE1 Corrective Action CA_RESPONSE1 Bio Sol Corrective Action CA_RESPONSE1 | The spontacky standards that are also static LCP in initiation to the (1) LCP remains during the sphere all which is supples are being supplet of research capity system matrix method, and analysis a) Results of each LOQ verification sample analysis shall be evaluated at the time of the testing and shall meet the qualitative identification certeria 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 1.5.2.2.0. 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 (1) correcting method or instrument performance and repeating the verification fault. (1) evaluating the laboratory stablished cortic burnets to the supplet the spiking level is above (1) and repeating the linking verification study within thirty (30) calender day of the initial faultar. Any samples analyzed in a batch associated with a failing LOQ verification shall be corrective action for this result. |
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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.

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| ♠ Home | Quality Control V1M4 1 | .5.2.2.2 Corrective Action | CA_RESPONSE2 | Uperating Procedure (SUP) and the quantitate result shall be greater than the UL and meet the laboratory established accuracy criteria as established by Section 15.2.2.4). b) If a continuing LOD verification test does not meet this requirement, the laboratory shall take meeting and deminant we be investigated in terms for this meret investigation for the context of the section o |
| 🖿 Labs | Quality Control V1M4 1 | .6.2.2 Corrective Action | CA_RESPONSE1 | contexture actions randocument a recommany same asson for the contrare actions contexture 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 spixing level (and the quantitation limit if |
| • Search Analytes | Random Sampling V1M4 1 | .6.3.1 Sol Corrective Action | CA_RESPONSE1 | 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. |
| Le Contact | Quality Control V1M4 1 | .6.3.2 Corrective Action | CA_RESPONSE1 | Inspector Findings |
| | HPLC-FL V1M41 | .7.1 Bio Sol Corrective Action | CA_RESPONSE1 | 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. |
| | | Items per page: 5 | $ \langle \rangle \rangle$ | |
| | Return Cancel Submit R | esponse Inspection Report | | Lab Response The lab has corrected this deficiency. |
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| | Filter | | | Inspector Response Need further documentation that this has been fixed. |
| | Document Name | | | |
| | Supporting Documentation.zip | | 0 | Lab Response 2 |
| | SOP and Training.zip | | 0 | Attached finalized SOP with training documents. |
| | | Items per page: 5 v 1 - 2 of 2 | < < > > | |
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| | | | | Nice work! |
| Health | | | | 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.