Oregon
Environmental Laboratory Accreditation Program

Department of Agriculture, Laboratory Division
Department of Environmental Quality, Laboratory Program
Oregon Health Authority, Public Health Division

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RE: ORELAP Remote Assessment Policy

To Whom it May Concern:

Permanent amendments to Oregon Administrative Rules (OAR), chapter 333, division 64 became effective on January 1, 2021. As part of those amendments, the definition of on-site assessment was changed to allow remote assessments during periods when the Governor has declared a state of emergency. ORELAP may conduct remote assessments as allowed by OAR 333-064-0025 (20).

Remote assessments will conform to the requirements for assessment described in the ORELAP Policy Manual and the TNI Standard, except with the deviations described in this document.

Remote assessments may take place when the following conditions have been met:

- The Governor has declared a state of emergency;

- Travel to a laboratory or specific location is not advisable;

- ORELAP has determined the laboratory has the resources to participate in a remote assessment; and

- Public health will not be jeopardized by using a remote assessment in place of an on-site assessment. (ORELAP must evaluate risk to public health in deciding when an on-site assessment, remote assessment, or hybrid assessment will be used.)

Pre-Assessment Procedures

The lead assessor will call or email the laboratory primary contact to discuss the laboratory's resources to determine if a remote assessment is practicable. The availability of video conferencing, teleconferencing, printers/scanners, screen-sharing, phone reception, internet, cameras, and other technological capabilities will factor into the decision. The lead assessor will also take account of staff schedules and health and safety considerations. If video conferences from areas of the facility will not be allowed due to security concerns, ORELAP should determine if the laboratory is a good candidate for remote assessment. Assessors shall be informed in writing of any information, including analytical data that is controlled for national security reasons and cannot be released to the public.

The lead assessor will work with the laboratory to determine a date for the remote assessment. Conferences and interviews shall occur during established working hours at the laboratory's location and time zone unless special arrangements are made with the laboratory. The lead assessor may request a list of laboratory job or work orders over the past year to assist with selecting representative samples for data package deliverables. The lead assessor may also schedule a time to test conferencing tools prior to the remote assessment.

The lead assessor will create a schedule confirmation letter with the following information:

- Tentative times of the opening and closing conferences.

- Tentative times for staff interviews, including the method/technology to be assessed.

- Document and record requests for electronic delivery to ORELAP prior to the assessment with a due date, to include:

    o Data packages for samples, with a description of what constitutes a data package

    o The current quality manual

    o Current Standard Operation Procedures (SOPs)

    o Previous internal audits

    o Previous management reviews

    o Recently closed and currently open corrective actions plans

    o Technical Director credentials

    o Demonstrations of Capability

    o Data Integrity Training records

    o Master List of SOPs, Forms, Logbooks

- Explanation of Confidential Business Information (CBI) and how in cases of test reports the client information may be redacted by the laboratory.

The random selection of sample data packages for review is especially critical to the outcome of a remote assessment and should be representative of all laboratory functions in order to

determine compliance. Data packages for selected samples will be sent to the assessment team prior to the remote assessment and will include all associated documentation from sample receipt through analysis and final reporting. These will be similar to what are called "CLP Level IV" data packages. The lead assessor must understand it may require significant time for the laboratory to assemble these records, and plan accordingly. The assessment team should request as few data packages as necessary. If the scope of accreditation is small or if records are readily available by screen sharing, data packages may not be required.

Data package components will include records of:

- Sample receiving logs and chain-of-custody documents

- Preservation checks and sample storage

- Sample processing records, including digestions, extractions, filtering, etc.

- Calibration records and relevant pages from logbooks for support equipment, such as:

    o   Thermometers used for hot blocks, water baths, incubators, storage refrigerators

    o   Balances and weight sets including calibrations and daily checks

    o   Pipettes and bottle top dispensers

    o   Autoclave temperature and pressure calibration records

- Calibration records for analytical instrumentation

- Analytical records for the sample batch, including all daily QC, all printouts, all worksheets, and electronic records

- Sample reporting records and final sample report

- Data review checklists

- Certificates of analysis for relevant standards and reference materials

- Standard and reagent preparation records

- Method Validation records, including detection limit and quantitation limit studies and verifications

- Demonstrations of capability for relevant staff

Prior to the assessment, ORELAP will review the documents and records submitted by the laboratory in preparation for the assessment. If any of the staff interviews need to be rescheduled, ORELAP will work with the laboratory to set-up an alternative timeslot prior to the assessment. Participation in the remote assessment is not optional, and the same level of cooperation is expected as for on-site assessments.

Prior to the opening conference, ORELAP will send electronic documents to the laboratory, to include:

- CBI notice and claim form

- Opening and Closing conference attendance sheets

- ORELAP appraisal forms

- "How to respond in ODIE" guide document

Opening Conference

The assessors will meet with the facility's administrator or laboratory director (however named) and management staff via video or teleconferencing tools. At the start of the opening conference, the lead assessor will introduce themselves and any team members. The purpose of the assessment and assessment process will be briefly explained. Plans for an exit interview shall be made known.

During the opening conference the lead assessor will utilize the opening conference checklist to discuss the following topics:

- Explain the assessment objectives and which version of the TNI Standard will be used.

- Direct the laboratory to fill out the opening conference attendance roster, scan it, and email it back to the lead assessor.

- Review which tests will be examined, the timeslots for interviews, and the relevant staff for interview. This will usually be the final opportunity for the laboratory to request a time change for staff interviews.

- Address CBI concerns and instruct the laboratory director to complete the NELAP Assessment Confidentiality Notice form, scan it, and email it back to the lead assessor.

- Review special requirements that the laboratory may have (e.g., requirements related to information security).

- Allow the laboratory director (however named) to ask any questions necessary to understand the remote assessment process and events that will follow the assessment.

- Ask the laboratory to complete the appraisal form and return it to ORELAP by mail following the end of the assessment.

Initial Tour

If possible and deemed necessary by ORELAP staff, a video tour may be requested of the laboratory. During the virtual walk-through, assessors should observe spacing of processes, ventilation, types of equipment, storage, glassware washing, media and solution preparation and disposal of waste, handling/labeling/storage of specimens, and personnel performing tests. Note any problems or concerns for further evaluation during the assessment process.

Staff Interviews

Staff interviews will occur by teleconference or video conference in accordance with the preset schedule finalized during the opening conference. The interview will be informed by the review of relevant data packages and documents reviewed by the assessor prior to the interview. The assessor may create a list of additional record requests during the laboratory staff interview. If additional records are needed, ORELAP shall make a clear request for the records. Once the information is requested, the laboratory will be allowed reasonable time to produce the records. If the assessor has follow-up questions for the staff member, these may be communicated by email or during a follow up interview. The assessor may request photographs, video, screen captures of computer screens, or other electronic media to help determine laboratory compliance.

Potential deficiencies will be communicated during interviews so technical staff may clarify any misunderstandings or produce additional records. When disagreements occur between the laboratory staff and the assessor(s), additional reference materials or documents may be submitted to support the laboratory's position. The assessors may also discuss potential deficiencies with other ORELAP staff. Assessors will be mindful of the increased likelihood for miscommunication during remote assessments.

After reviewing the records sent to ORELAP along with supporting evidence observed during the analyst interviews, if no potential findings are identified, no further review is required.

Handling Confidential Business Information (CBI)

Remote assessment will require delivery of electronic records to ORELAP assessors for review. The laboratory may claim any of this information as CBI and ORELAP will hold this information in a secure manner. ORELAP will follow its current procedures for handling of CBI in the event of a public request or legal proceeding. ORELAP will remain mindful of laboratory concerns for privacy when requesting electronic delivery of records. To reduce the number of electronic deliverables, the laboratory may use screen sharing or live video to show assessors records without having to send them by email.

The laboratory may also redact information that identifies their clients on test reports.

Closing Conference

At the conclusion of the assessment, the team members may meet offline to discuss and organize findings and recommendations. Findings will communicated either in writing or orally during the closing conference.

It should be made clear that all findings presented at the closing conference are subject to review and change prior to the issuance of the final assessment report approved by ORELAP.

Due to the increased likelihood of miscommunications inherent in a remote assessment, ORELAP and the laboratory should approach the closing conference as an opportunity to clarify any findings. The lead assessor shall provide the laboratory opportunity to ask questions about

the basis of findings. If the laboratory disagrees with the findings of the assessment team, the lead assessor will determine the best course of action.

If additional information comes to light during the closing conference, the deficiency may be further evaluated by ORELAP after conclusion of the remote assessment. This may be communicated by email.

During the closing conference the lead assessor will utilize the closing conference checklist to discuss the following topics:

- Direct the laboratory to fill out the closing conference attendance roster, scan it, and email it to the lead assessor.

- Discuss positive aspects of the assessment.

- Remind the laboratory of actions ORELAP may make as a result of the assessment.

- Request the laboratory to fill out the CBI claim form, if necessary, scan it, and email it to the lead assessor.

- Review the list of preliminary findings and recommendations.

- Allow the laboratory director (however named) to ask any questions necessary to understand next steps.

- Ask the laboratory to complete the appraisal form on their own time and return by mail to ORELAP after the assessment is closed.

- Provide written instructions on responding to the assessment findings in ODIE.

Sincerely,

Travis Bartholomew, ORELAP Manager
Public Health Division
Oregon Health Authority