# LABORATORY OBSERVER ROLE

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**December 6, 2022** 

Observer: A subject matter expert authorized by the ASPM to observe an Accreditation Assessment of an analytical laboratory by an AB Team.

From the Department of Energy Consolidated Audit Program-Accreditation Program Procedural Plan (2020)

# DEFINITION OF AN OBSERVER

General Scope

Do not actively participate in, or interfere with, ongoing audit activities;

Coordinate with the ASPM prior to the audit;

Are subject to AB Team Lead's direction while on-site at the audited facility; and

Document activities and record feed back on the Observer Report Form (ensure that reports are detailed and complete).

#### DOECAP-AP ASSESSMENT OBSERVERS

#### **OBSERVER QUALIFICATIONS**



COMPLETE AND
MAINTAIN
DOECAP-AP
ASSESSMENT
OBSERVER
TRAINING;



SIGN A
CONFIDENTIALITY
AGREEMENT TO
NOT DISCLOSE
ANY
INFORMATION
FROM THE
ASSESSMENT;



AGREE TO FOLLOW THE DOECAP CODE OF CONDUCT;



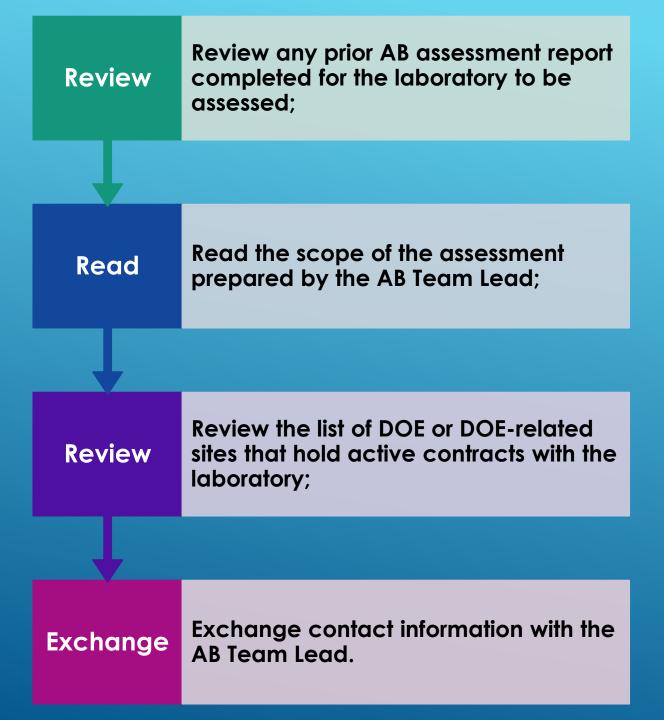
BE AUTHORIZED BY
THE ASP
MANAGER.

Once the AB is notified, the observer will be included on communications between the Laboratory and the AB's Assessors.

An observer may wish to get copies of documents sent by the Laboratory to the AB in advance of the audit.

The AB will provide a Scope for the Audit

**Pre-Audit** 



Pre-Audit (Continued)



Does not actively participate in (i.e., perform auditor functions) or interfere with ongoing audit activities



Is subject to the lead auditor's (or Lead AB Assessor) direction while on site at the audited facility

Rules of Engagement



An observer may not engage in any part of the audit unless requested.

## During the Audit

- Stay with the subject area counterpart from the beginning to the end of the audit;
- Observe the AB team member and evaluate their preparedness for the audit;
- Refer to the Observer Report Form throughout the audit. Take notes and later link observations to the pertinent sections of the form. This will aid in developing the evaluation;

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Do not give any opinions or observations at any time. Doing so is grounds for the AB Team Lead to eject the observer from the assessment;

#### Do give

Do give opinions or referrals only if solicited by the AB Team Lead;

### Do not initiate

Do not initiate any conversation with the assessed laboratory employees regarding the assessment, assessment process, the AB, or the assessors; and

#### Attend

Attend the entire assessment including the opening and closing meetings with the laboratory.

# During the Audit (continued)

Confirmation that adequate preparation, observation, and review of findings by DOECAP-AP to evaluate the AB assessment team's ability to identify non-conformances.

Confirmation that the AB assessment team is assessing according to the QSM.

### Performance Objectives



#### Issues

- Any issues of concern should still be routed directly from the observer to the ASP Manager after the audit using the Observer Report Form. Serious issues require immediate notification.
- It is at the discretion of the ASP Manager on how to handle the feedback from an observer.



Order

In order to document activities and record feedback, the DOECAP-AP Observer Form is used and sent to the ASP Manager after the audit.

Use

Use compiled notes to fill in the applicable parts of the Observer Report Form in the evening, after assessment hours and away from any AB assessor; and

Submit

Submit the completed Observer Report Form directly to the ASPM within 2 days of the assessment out brief.

## Observer Reports



### **QUESTIONS**





**THANK YOU**