Department of Energy Consolidated Audit Program
Accreditation Program for Laboratories

Frequently Asked Questions

The following are a list of general questions posed to the Department of Energy (DOE) regarding the Department of Energy Consolidated Audit Program – Accreditation Program. Additional questions should be forwarded to the Analytical Service Manager at steve.clark@hq.doe.gov.

1. **Question:** Could you please provide a list of the Accreditation Bodies (ABs) that can perform Department of Energy Consolidated Audit Program Accreditation Program (DOECAP-AP) for Laboratories and their contact information.

   DOECAP Response: The ABs that have been recognized by the DOE to perform accreditations to the DOECAP-AP are:

   American Association for Laboratory Accreditation (A2LA)

   Address: 5202 Presidents Court, Suite 220
   City, State, Zip: Frederick MD 21703
   Contact: Chris Gunning
   Title: Accreditation Manager - Life Sciences
   Email: cgunning@A2LA.org
   Phone: 240.575.7481
   Fax: 301.662.2974
   Website: www.A2LA.org

   Perry Johnson Laboratory Accreditation, Inc. (PJLA)

   Address: 755 W. Big Beaver Rd., Suite 1325
   City, State, Zip: Troy, MI 48084
   Contact: Tracy Szerszen
   Title: President/Operations Manager
   Email: Tszerszen@PJLabs.com
   Phone: 877-369-5227 Ext. 4731
   Fax: 248-213-0737
   Website: www.pjlabs.com

   ANSI-ASQ National Accreditation Board (ANAB)

   Address: 11627 Coldwater Rd., Suite 101
   City, State, Zip: Fort Wayne, IN 46845
   Contact: Zaneta Popovska
   Title: Accreditation Manager
   Email: zpopovska@anab.org
   Direct Phone: 414-501-5341
   Main Phone: 414-501-5494
   Fax: 260-637-2791
   Website: www.anab.org

2. **Question:** What is the target deadline for analytical laboratories already participating in the DOE Consolidated Audit Program to become assessed for accreditation to QSM v5.1?

   DOECAP Response: All laboratory program participants are expected to transition to third-party accreditation no later than December 31, 2018, unless separate arrangements are made with the Office of Environment, Health, Safety and Security through the Analytical Services Program Manager.

3. **Question:** What if a laboratory does not wish to participate in the DOECAP-AP?

   DOECAP Response: While DOECAP-AP accreditation may not be a current requirement in your site-specific contract, all contract offices throughout the DOE Complex have been encouraged to standardize the terms and conditions of existing and proposed contracts to allow acceptance and participation in the DOECAP, to include the audit accreditation process. Commercial laboratories formerly audited by DOE Federal and contractor personnel will be expected to utilize the assessment process provided by one of three approved third-party accreditation bodies (ABs). ABs will conduct assessments using the requirements in the Department of Defense/ DOE Quality Systems Manual (QSM), which guides DOECAP audits currently. DOECAP accreditation assessments meet the requirement to conduct DOECAP audits.

4. **Question:** Will a laboratory be guaranteed a contract award if it is accredited by an AB to the DOECAP-AP?

   DOECAP Response: No. Lack of participation in the DOECAP-AP does not mean that an analytical laboratory cannot contract with a DOE Complex site, nor does accreditation guarantee a contract award. Discretion is placed on the DOE Complex or site contract holder to ensure the contracted laboratory meets their specific needs and requirements. However, accreditation is a requirement for participation in the DOECAP.

5. **Question:** If there are not enough assessors to allow interested laboratories to become accredited before December 31, 2018, will laboratories be permitted to continue operating under an existing contract approval?

   DOECAP Response: Laboratories can continue operating under existing contract approvals, within the scope of those approvals, until they expire or until a modification can be initiated to reflect the accreditation program for participation in the DOECAP-AP.

6. **Question:** My laboratory is an Industrial Hygiene (IH) laboratory not an analytical laboratory. How can I be accredited to DOECAP-AP?

   DOECAP Response: IH laboratories have been assessed to the QSM in the past and will still be assessed to it through the ABs. DOECAP-AP will be assessing to the latest version of the QSM.

7. **Question:** If our contract requires a specialized analysis to be performed that is outside the usual scope of analysis, and has been requested by the contracting DOE site, how would we be assessed and accredited by the AB?

   DOECAP Response: If such an analysis is requested by a laboratory to be added to its scope, ABs would apply the requirements of ISO/IEC 17025:2005/TNI 2009/QSM section 5.4 (Environmental Methods and Method Validation), section 5.6 (Measurement Traceability), and the applicable technical module. Where available, Performance Test (PT) samples will be included in the validation of specialized analyses. Validation can be per the specification of the customer and/or selected by the laboratory but must be appropriate and demonstrated if it is not a well-recognized, widely used method.

   In most cases, ABs will accredit laboratories to their own documented procedures, and verify that the procedures have been properly validated. This includes meeting the requirements of ISO/IEC 17025:2005/TNI 2009/QSM and/or the program or have been accepted and specified or approved "by the customer".

8. **Question:** How many assessors will there be during a typical onsite assessment?

   DOECAP Response: ABs will determine the number of assessors assigned to each laboratory assessment team. This will depend on factors such as the requested scope of accreditation, whether this is an initial or follow-up accreditation, findings in previous assessment reports, etc. However, a minimum of two (2) former DOECAP auditors are expected to accompany the AB assessment teams as Observers only. DOECAP will also be supplying technical experts assisting the assessors in the areas of hazardous and radioactive waste management and data quality for radiochemistry analyses.

9. **Question:** What will happen if a site requires certification for a specific test (e.g., TPH) and no DOECAP-AP accredited laboratories possess that certification?

   DOECAP Response: DOECAP-AP accreditation is expected for laboratories performing testing in support of DOE Complex sites. If no laboratory is accredited under the DOECAP-AP to perform the required testing, project teams should contact the Analytical Services Manager (ASP) for assistance. Discretion is placed on the DOE Complex or site contract holder to ensure the contracted laboratory meets their specific needs and requirements to support their mission.

10. **Question:** Will laboratories be required to have National Environmental Laboratory Accreditation Program (NELAP) accreditation in addition to DOECAP-AP accreditation?

    DOECAP Response: No.

11. **Question:** How much will accreditation cost?

    DOECAP Response: ABs will determine the costs for accreditation. Costs are often associated with the level of scope being sought. An additional cost may be required for those laboratories contracted by sites operating under the Hanford Analytical Quality Assurance Requirements Documents (HASQARD). Laboratories are encouraged to contact the ABs for more information.

12. **Question:** How much information will be provided on the list of DOECAP-AP accredited laboratories (will this indicate specific analytes for which the laboratory is accredited?)

    DOECAP Response: At a minimum, the DOECAP-AP list of accredited laboratories will be published on the Department of Defense's Denix website (http://www.denix.osd.mil/edqw/home/) and available on the DOECAP SharePoint site. The information provided will include scopes of accreditation and methods. Detailed scopes of accreditation including specific analytes will be available on the AB's websites as well.

13. **Question:** Will DOE Complex contract holders and contractors searching for accredited laboratories be able to see the ABs assessment reports?

    DOECAP Response: ABs will not provide assessment reports to DOE Complex prime contractors directly; however, the ASP Manager will provide the contracted sites and requested DOE Complex participant's copies, upon request. Copies will be posted in the assessed sites individual DOECAP folders for reference. Any additional requests for report copies will be reviewed and addressed by the ASP Manager.

14. **Question:** Will laboratory applications for accreditation be available online?

    DOECAP Response: Consult the ABs for applications.

15. **Question:** Will variances be allowed as part of DOECAP-AP accreditation requirements?

    DOECAP Response: No. However, if there are irresolvable questions between the laboratory and AB regarding QSM interpretation and application, they should be forwarded to the ASP Manager at Steve.Clark@hq.doe.gov. The questions and answers (FAQs) will be posted on the Denix site under the FAQ's and the DOECAP SharePoint.

16. **Question:** Is there a backlog of laboratory applicants?

    DOECAP Response: Consult the ABs.

17. **Question:** Can laboratories write a Request for Proposal for the purpose of selecting an AB?

    DOECAP Response: Yes.

18. **Question:** Will each location of a laboratory require a separate accreditation?

    DOECAP Response: Laboratories will be accredited based on the processes and procedures of the AB. Consult the AB for information on their accreditation process and requirements.

19. **Question:** Do you plan on setting up a forum for laboratories seeking clarification of DOECAP-AP requirements?

    DOECAP Response: Laboratories having questions can submit them to the ASP Manager at Steve.Clark@hq.doe.gov. The questions and answers will be reviewed by the DOE Data Quality Workgroup before being referred to the QSM Environmental Data Quality Workgroup for consideration and clarification. Answers to questions and clarifications (e.g., FAQs) will eventually be posted on the DOECAP SharePoint.

    Laboratories having questions related to a finding written by an AB must go through the AB for resolution.

20. Question: How will you handle the accreditation of non-standard methods?

DOECAP Response: These will be handled like performance-based methods, where methods will be assessed to Measurement Performance Criteria (MPCs).

21. Question: How will the ASP Manager resolve differences between state certification requirements and DOE QSM requirements?

DOECAP Response: Laboratories are required to meet any state or local regulations. DOECAP-AP accreditation does not affect state or local requirements. When performing analyses for a specific project, the laboratory must meet relevant requirements for that project.

22. Question: Will the DOECAP-AP accreditation include radiological analyses?

DOECAP Response: Yes. All scopes of accreditation will be in accordance with the latest version of the QSM.

23. Question: Will ABs accredit to method or analyte?

DOECAP Response: Analyte.

24. Question: Will laboratories be accredited to specific versions of methods?

DOECAP Response: Yes.

25. Question: What requirements apply to the AB's use of subcontractors as assessors?

DOECAP Response: The ABs are required to notify the ASP Manager regarding the use of subcontractors. Subcontractors must be trained according to requirements contained in the AB's training plan. The ABs are responsible for the conduct of their subcontractors.

26. Question: In the event the ABs are not able to accredit all applicants by December 2018, what other options are available for using a specific laboratory?

DOECAP Response: If no laboratories are DOECAP-AP accredited for the testing required, or for other reasons, the ASP Manager should be contacted for assistance.

27. Question: If a laboratory has the necessary State certification for a specific method, does it still need DOECAP-AP accreditation?

DOECAP Response: Yes. Laboratories must meet all state and local requirements; however, the laboratory also must have DOECAP-AP accreditation if performing work for DOE Complex contractors and sites.

28. Question: How will DOE want assessors and ABs to evaluate PT results?
For example, how many analytes can fail for a method before the method itself is considered a failure? Has DOE selected acceptable PT providers and given this information to the ABs?

DOECAP Response: ABs and assessors should follow the latest version of the QSM for details. However, for all radiological analyses, MAPEP is the required PT program.

29. **Question:** Is the AB required to review each Standard Operating Procedure (SOP) and Limit of Detection (LOD)/Limit of Quantitation (LOQ) verification for each method, matrix, and analyte in the scope? If so, do ALL SOPs need to be reviewed during an on-site assessment or only areas (technologies)? For example, HPLC, GC, ICP, etc.

    DOECAP Response: DOECAP-AP accreditations will be performed by ABs using their assessment and accreditation procedures. However, all methods that are part of the laboratory's scope of accreditation must be reviewed either on-site or prior to the on-site. This review should include the applicable SOPs and associated performance data such as PT studies, LOD and LOQ, and in-house control limits.

    At a minimum, on-site assessments must include a representative sampling of the methods to ensure that all technologies are assessed.

30. **Question:** What does an assessor do if method requirements conflict with project or Table F requirements?

    DOECAP Response: The QSM states, "If there is a contradiction between the method and the following tables, the requirements specified in the tables shall be followed unless project-specific or regulatory approval is required."

31. **Question:** NELAC 5.10.2.m requires reporting results that meet all requirements of NELAC, specifically with regard to NELAC markings/logos. Do these requirements apply to DOECAP-AP accreditation?

    DOECAP Response: No. Laboratories accredited under the DOECAP-AP must meet the requirements of the DoD/DOE QSM. NELAC markings/logos are not required.

32. **Question:** Are assessors required to be United States (US) citizens?

    DOECAP Response: No. The DOECAP-AP does not require assessors to be US citizens. However, the AB shall contact the laboratory prior to the assessment to ensure that the use of a non-US citizen as an assessor does not violate any security or classification restrictions on the work that the laboratory is performing. If the laboratory has no objection to the use of the non-US citizen assessor, then the ASP Manager is consulted for final approval.

33. **Question:** If a laboratory requests accreditation for methods they have just started bringing online and no customer samples have been analyzed, can these methods be accredited?

    DOECAP Response: A laboratory does not need to have analyzed customer samples prior to accreditation for specific methods. However, they must have the supporting documentation to allow proper evaluation by the AB. Please contact the AB for more information and refer to the most recent version of the QSM for initial PT specific requirements.

34. **Question:** I was recently assessed for my DoD-ELAP accreditation by an AB last year as part of our 2-yr assessment cycle. I am not due for another onsite assessment until 2019. Will I have to arrange and fund a full onsite assessment to begin my DOECAP-AP cycle? Will I be able to get both the DoD-ELAP and the DOECAP-AP on the same cycle to save money and time?

    DOECAP Response: DOE is aware of this issue and is in support of laboratories transitioning towards a more cost effective and efficient approach in aligning the two separate accreditation program onsite assessment visits and overall accreditation schedules. During this initial year of transition, the 2018 calendar year, if a laboratory has already been assessed to the DoD/DOE QSM v5.1 by one of the 3 approved ABs and is found to have maintained their scopes of accreditation, then the initial DoD-ELAP audit from 2017 can be used as a reference to satisfy those joint DoD/DOE portions of the QSM being assessed. The remaining DOE Only portions of a full DOECAP-AP assessment, to include Radiological Analyses and Hazardous and Radioactive Material Management will require an onsite assessment. This gap analysis, or additional surveillance assessment, will complement the prior DoD-ELAP assessment therefore providing a complete review of the laboratory. Beginning January 1, 2019, all DOECAP-AP accrediting assessments will require a complete onsite assessment at least once every two years.

35. **Question:** I am trying to verify the audit dates that DOE scheduled with us last July. We typically receive an official letter and a request for pre-audit materials from DOECAP a few months ahead of the audit and an agenda, but we have not heard anything to confirm. I believe this was set up before DOECAP officially announced that they would be going the third-party auditor route, so our question is whether or not this DOECAP audit is still scheduled or not. We will be using one of the ABs as our DOE AB and the audit with the AB is to be scheduled for this fall.

    DOECAP Response: All DOECAP laboratories can disregard any earlier dates pre-scheduled with DOECAP for the 2018 calendar year. The intent of the DOECAP-AP program is for all audits to be conducted by the AB's. We are supporting and making arrangements directly with your selected AB in still performing the Radioactive Analyses and the Hazardous and Radioactive portions of the assessment, as applicable to your scope. Please proceed to make arrangements with the AB and we will coordinate their schedule with them. Labs merely need to schedule one assessment with the AB of their choice to acquire include DOECAP accreditation. Please coordinate with your chosen AB.

36. **Question:** What information, forms, standard operating procedures, licenses, permits, etc. do we provide ahead of my upcoming assessment, and where do I send them?

    DOECAP Response: In the past, DOECAP has provided a listing of requested information and checklists to be completed at least 30 days prior to an audit. Now that the ABs are leading the assessments, they will be requesting this information and for their own checklists to be completed prior to the scheduled date, usually 30 days or further out. In addition, for those sites that have Rad and HRMM on their assessment schedules, the DOECAP generated checklists are to be provided in advance of the assessment dates per the ABs instructions. This information is to be provided to the AB unless otherwise instructed by the AB. Information is routinely provided via SharePoint, email, or other means as provided by the AB. Please contact your AB directly for specifics.

37. **Question:** In reference to EPA 1633 4th Draft, dilution section; is the non-extracted internal standard (NIS) unimportant in determining efficiency of the prep process and can it be ignored? How do we handle dilutions and the resulting recoveries associated with this new NIS process? Our LIMS calculations will require changes to the way ISs are reported for 1633.

    DOECAP Response: The NIS is unimportant to determining efficiency of the prep process, that is function of the extracted internal standard (EIS). QAOS agrees with the approach "to multiply the NIS recovery by the dilution factor or multiply the NIS area by the dilution factor to get the true NIS area recovery."

38. **Question:** In reference to EPA 1633, are we supposed to multiply the EIS by the dilution factor and get a recovery and compare to tables 6 and 8 in addition to the > 5% recovery criteria or is the > 5% the only Criteria applied to diluted samples?

    DOECAP Response: The EIS percent recovery is calculated using the equation in Section 14.5.2 of EPA Method 1633. EIS percent recoveries for both an undiluted and diluted extract are compared to Tables 6 or 8. Since the EIS percent recovery acceptance criteria is established for all matrices, the 5% acceptance criteria will be removed from Section 15.3. EPA will be issuing an Errata Sheet to clarify this and other items in the method. The new text will indicate the following:

    If the response for an EIS in the diluted extract meet the S/N and retention time requirements in Sections 15.1.1 and 15.1.2, and the EIS percent recovery from the analysis of the diluted extract meet the applicable acceptance criteria listed in Table 6 or 8, then the compounds associated with the EIS compound may be quantified using the EIS response.

    If the diluted extract has an EIS percent recovery less than the acceptance criteria listed in Table 6 or 8 for the analyte that required the dilution, then the laboratory must prepare and analyze a smaller aliquot of the aqueous sample diluted to 500 mL or a smaller aliquot of a solid sample.