



Department of Energy Consolidated Audit Program-Accreditation Program (DOECAP-AP) Procedural Plan



Steve Clark
Manager, Analytical Services Program
Office of Sustainable Environmental
Stewardship (AU-21)
Office of Environment, Health, Safety and
Security
U.S. Department of Energy



Agenda



- **DOE Consolidated Audit Program – Accreditation Procedural Plan (DOECAP-AP) Development and Purpose**
- **Use**
- **Program Quality Assurance**
- **Implementing Procedures**
- **Appendices**
 - Appendix A: DOE CAP Implementing Procedures
 - Appendix B: Resources for Recognizing Accrediting Bodies
 - Appendix C: Frequently Asked Questions
 - Appendix D: Quality Systems Manual Issue Sheet and Instructions
 - Appendix E: Definitions
 - Appendix F: Acronyms
 - Appendix G: References
- **DOECAP SharePoint**



Document Development and Purpose: Administrative Procedure (AD-1)



- Last Edition signed in Fiscal Year 2016
- Audit Program Procedures
- Contract Support Tasks Outlined
- Updated Every 2 Years

United States Department of Energy



*Department of Energy Consolidated
Audit Program (DOECAP)
Policies and Practices*

**Administrative Procedure
(AD-1)
Revision 3.0**

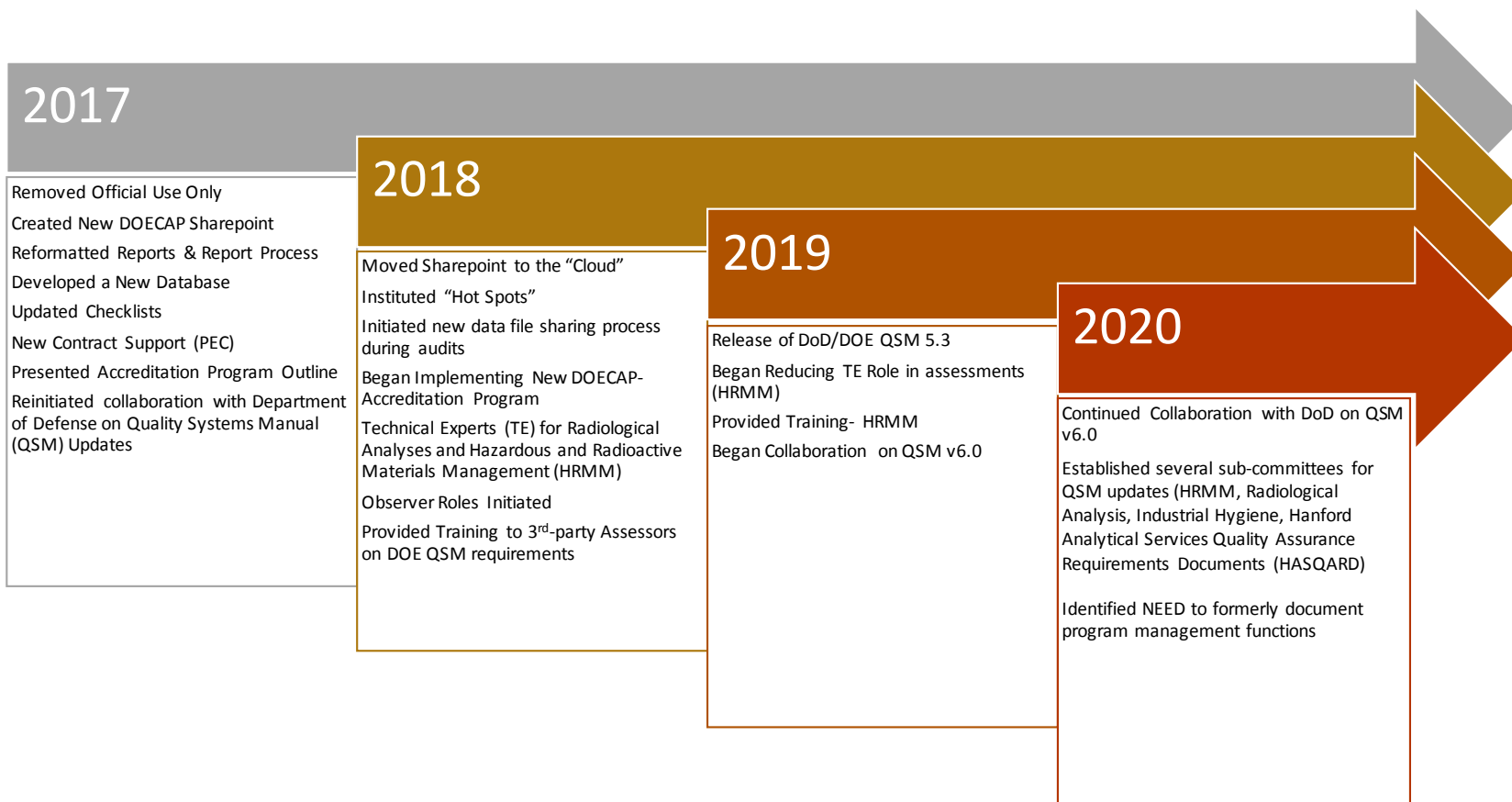
Approved:


Jorge Ferrer, DOECAP Manager

1/13/14
Date



Document Development and Purpose: Evolution of DOECAP into DOECAP-AP



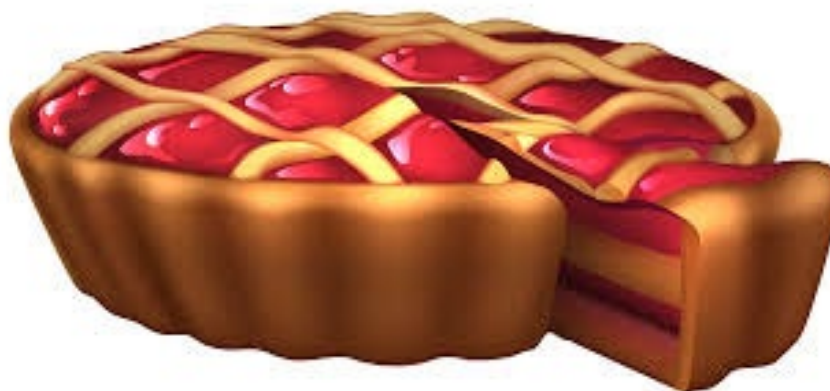


Document Development and Purpose: Intent of the Plan: Identify PIE



Need to Document:

- Program Procedures
- Implementation Strategies and Requirements
- Expectations



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Department of Energy Consolidated Audit Program-Accreditation Program Procedural Plan



Department of Energy Consolidated Audit Program-Accreditation Program Procedural Plan



August 2020

Includes:

- Program Details
- Stakeholder Roles and Responsibilities
- Program Procedures
- Observer Requirements
- Conditions and Criteria for Accrediting Bodies
- DOECAP Sharepoint Access
- And more....

NOTE: This document does not establish new requirements, and any existing conditions referenced are from DOE Orders, best management industry practices, or federal, state, or contractual obligations



Question: Who Will Use This Document?
Answer: DOECAP Stakeholders



DOECAP Stakeholder Roles and Responsibilities for:

- Analytical Services Program Manager
- Accrediting Bodies (ABs)
- Commercial Analytical Laboratories
- Observers
- DOE Complex Contract Holders
- DOE Complex Site Federal and Contractor POCs



Roles and Responsibilities: Example



Analytical Services Program Manager

- Interfaces with DOE Headquarters on funding issues to ensure DOECAP is supported;
- Manages the DOECAP annual budget;
- Provides management oversight of DOECAP's implementation, including the performance of an annual program review and periodic observation of DOECAP audits;
- Develops and maintains the DOECAP program plan and reference guide, and is the custodian of all program-related procedural and quality documents;
- Approves all DOECAP schedules, documents, reports, and correspondence;
- Reviews AB applications for completeness and compliance with requirements of the DOECAP-AP with the DQW;
- Responsible for granting and, when necessary, revoking AB recognition, following consultation with, and recommendation by, the DQW; and
- Maintains a list of DOECAP-approved ABs for use by commercial laboratories.



Program Quality Assurance



- Management Self Assessments
- Annual Program Review - Trends Analysis
 - Quantity and quality of findings and observations;
 - Relative risks posed to DOE by findings; and
 - Performance of audited facilities over time, to determine improvement or degradation of service to DOE.
- Review of Assessment Report Summaries
- Ongoing Review of the QSM
- Routine AB Meetings



Appendices: Appendix A DOECAP-AP Implementing Procedures



- A1.** DOECAP-AP Requirements for Accreditation Bodies: Achieving, Maintaining, and Revoking Recognition
- A2.** Data Quality Workgroup (DQW) Management of the Quality Systems Manual and Oversight of Assessments
- A3.** Conduct of the DOECAP Assessments
- A4.** Requirements for DOECAP-AP Assessment Observers
- A5.** Handling Complaints
- A6.** Conducting Project-Specific DOECAP Audits for Non-Accredited Laboratories
- A7.** DOECAP Code of Conduct
- A8.** DOECAP Confidentiality Agreement
- A9.** Accessing the DOECAP Sharepoint



Appendices: Appendix B Resources for Accrediting Bodies Seeking Recognition



B1: Instructions for Completing an Application for Recognition

B2: Conditions and Criteria for the Recognition of Accreditation Bodies

B3: Application Packet Checklist

B4: Example Accreditation Body Recognition Letter

 Application for Recognition Instructions for Completing an Application for Recognition	
ISSUING AUTHORITY	DOCUMENT AUTHOR
DOE AU 21	Steve Clark

Appendix B: Resources for Recognizing Accrediting Bodies

Appendix B1: Instructions for Completing an Application for Recognition

- (1) Thoroughly read all documents furnished in this application package in order to understand the Department of Energy Consolidated Audit Program Accreditation Program (DOECAP-AP) recognition requirements.
- (2) Complete the attached application. Print or type all requested information. Where more space is needed for responses, attach additional pages to the application and identify the question(s) being answered.
- (3) The Accreditation Body's (ABs) Authorized Representative must sign the Conditions and Criteria for DOECAP Accreditation Program Recognition of AB of the application to signify agreement with the DOECAP-AP Conditions for Recognition.
- (4) Send the application and all related documents (retain a photocopy for your records) to:

By Email:

Mr. Steve Clark at Steve.Clark@hq.doe.gov

Or

By U.S. Mail:
 DOE Analytical Services Program Manager (ASPM)
 U.S. Department of Energy
 Office of Environment, Health, Safety and Security
 Office of Sustainable Environmental Stewardship (AU-21)
 19901 Germantown Road
 Germantown, MD

For questions or assistance with the application process, please contact Steve Clark, ASPM, at 301-903-1488, or via email at steve.clark@hq.doe.gov.

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Appendices: Appendix C

Department of Energy Consolidated Audit Program Accreditation Program for Laboratories Frequently Asked Questions (FAQs)



A 7-page listing of general questions posed to DOE regarding DOECAP-AP

Appendix C: Department of Energy Consolidated Audit Program Accreditation Program for Laboratories Frequently Asked Questions (FAQs)

The following are a list of general questions posed to the Department of Energy (DOE) regarding the DOE Consolidated Audit Program-Accreditation Program (DOECAP-AP).

Additional questions should be forwarded to the Analytical Services Program Manager (ASPM) at steve.clark@hq.doe.gov.

1. Question: Could you please provide a list of the Accreditation Bodies (AB) and their contact information that can perform audits for the DOECAP-AP for laboratories.

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: 5
202 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.pjllabs.com

ANSI-ASQ National Accreditation Board (ANAB) Address: 11627 Coldwater Rd., Suite 101 City,
State, Zip: Fort Wayne, IN 46845 Contact: Zaneta Popovska, Accreditation Manager
ANSI-ASQ National Accreditation Board (ANAB)

Fort Wayne, IN
Direct: 414-501-5341
Main: 414-501-5494
Fax: 260-637-2791
zpopovska@anab.org

2. Question: What is the target deadline for analytical laboratories already participating in DOECAP 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 the Associate Under Secretary for Environment, Health, Safety and Security through the ASPM.

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Appendices: Appendix D Department of Energy Analytical Services Program Quality Systems Manual Issue Sheet and Instructions

- D1. Quality Systems Manual Issue Sheet
- D2. Instructions on How to Submit
Quality Systems Manual Issue Sheet

ASP
ANALYTICAL SERVICES PROGRAM

DOECAP
DEPARTMENT OF ENERGY
CONSOLIDATED AUDIT PROGRAM

**Department of Energy
Analytical Services Program
Quality Systems Manual Issue Sheet**

Originator:

Position Title:

Date Submitted:

Issue of Concern:

Reference For: Change Clarification Deletion
 QSM TNI 2016 ISO 17025

Location of Issue: *(Please include version of document referenced; i.e., TNI 2016, QSM 3.1.1, etc)*

Discussion:

Recommended Change or Need for Clarification/Deletion:

Send all completed forms to steve.clark@hq.doe.gov for review and consideration. Thank you for your time.



Appendices: Appendix E Definitions



Appendix E: Definitions

Accreditation: Third-party attestation related to a **conformity assessment body** (e.g. analytical laboratory performing work for DOE) conveying formal demonstration of its competence to carry out specific conformity assessment tasks.

Accreditation Body: An authoritative body that performs accreditation.

Assessment: Process undertaken by an **accreditation body** to determine the competence of a **conformity assessment body** (e.g. analytical Laboratory performing work for DOE), based on standard(s) and/or other normative documents and for a defined scope of accreditation.

Conformity Assessment Body: A body that performs conformity assessment activities (e.g. analytical lab that performs analysis) and that can be the object of accreditation.

Data Quality Workgroup: DOEAP subcommittee consisting of DOE DOEAP participants. Membership consults with the Analytical Services Program Manager (ASPM) on a series of issues to include: QSM updates and questions, data validation procedures, and data trends.

Department of Energy: The acronym *DOE* as used in this procedure refers to both DOE and the National Nuclear Security Administration (NNSA). For example, a DOE point of contact (POC) might be employed by either DOE or NNSA and the term *DOE field managers* refers to both DOE and NNSA Field Element Managers.

DOECAP Approved Accrediting Body: An organized body of assessors who provide accreditation services to commercial laboratories. Accreditation Bodies (AB) must be U.S.-based signatories to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA). The ABs must continue to meet program requirements, including submission of a documented management system conforming to ISO/IEC 17011, acceptance of specific Conditions and Criteria for Recognition, and completion of assessor training as required. Contact information for DOECAP approved ABs is available from the ASPM on the DOECAP SharePoint site and on the DoD Defense Information Exchange (DENIX) website. Laboratories may select any of the MRA-listed approved ABs for services.

DOECAP A-P Assessment Audit: An assessment conducted by a DOECAP-approved AB.

ISO/IEC 17011: 2004, Conformity assessment-Requirements for Accreditation Bodies accrediting conformity assessment bodies: This ISO standard sets the requirements for competence and consistent operation and impartiality of the ABs that are performing the conformity assessments of the conformity assessment body (e.g. the analytical laboratory performing DOE work).

Non-conformance: A failure to adequately establish or document requirements consistent

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with applicable regulations, industry standards, or contract(s) or a deviation from established requirements including internal standard operating procedures. DOECAP documents identify deficiencies in the form of findings.

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

Point of Contact (POC): A specified federal employee (DOE or DOD, for the DOECAP-AP), a specified employee at analytical laboratory, or a contractor employee designated by a federal employee, that is responsible for working directly with DOECAP to facilitate Program implementation at a particular DOE site or within a particular DOE program.

Quality Assurance Program: "The overall program or management system established to assign responsibilities and authorities, define policies and requirements, and provide for the performance and assessment of work." (See DOE Order 414.1, current version).

Quality Systems Manual (QSM) for Analytical Services: The QSM provides the baseline requirements for establishing and managing quality systems for laboratories performing analytical testing services for the Department of Defense and DOE.

ILAC MRA: ILAC is the international organization for accreditation bodies. ILAC is involved in the accreditation of conformity assessment bodies, including calibration laboratories and testing laboratories and inspection bodies. The ILAC Mutual Recognition Arrangement (ILAC MRA) provides significant technical underpinning to the calibration, testing, medical testing and inspection results of the accredited conformity assessment bodies and in turn delivers confidence in the acceptance of results.

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Appendices: Appendix F and Appendix G (excerpts)



Appendix F: Acronyms

AB- Accrediting Body

AIT-Auditor in Training

ASP- Analytical Services Program

ASPM- Analytical Services Program Manager

CAP- Corrective Action Plan

DoD- Department of Defense

DOE- Department of Energy

DOECAP- Department of Energy Consolidated Audit Program

DOECAP-AP- Department of Energy Consolidated Audit Program-Accreditation Program

DQW- Data Quality Workgroup

EDQW- Environmental Data Quality Workgroup

ELAP- DoD Environmental Laboratory Accreditation Program

FAQ- Frequently Asked Questions

HASQARD- Hanford Analytical Quality Assurance Requirements Documents

HRMM- Hazardous Radioactive Material Management

IEC- International Electrotechnical Commission

ILAC- International Laboratory Accreditation Cooperation

ISO- International Organization of Standardization

MRA- Mutual Recognition Arrangement

O- Order

Appendix G: References

Reference	Description
ISO/IEC 17011:2017 Conformity assessment — Requirements for accreditation bodies accrediting conformity assessment bodies	Specifies general requirements for accreditation bodies assessing and accrediting conformity assessment bodies. It is also appropriate as a requirements document for the peer evaluation process for mutual recognition arrangements between accreditation bodies
Department of Defense (DoD)/Department of Energy (DOE) Quality System Manual, current version	Provides baseline requirements for the establishment and management of quality systems for laboratories performing analytical testing services for the DoD and DOE.
DOE O 414.1D, current version	Defines roles and responsibilities for providing quality assurance for DOE products and services.
Hanford Analytical Quality Assurance Requirements Documents (HASQARD) Revision 4 Volume 1 (Programmatic) or current revision.	Volume 1 describes the administrative requirements applicable to each of the other three volumes and is intended to be used in conjunction with the other three technical volumes. As noted in Volume 1, Section 1.1, the HASQARD identifies the quality principles, practices, and processes for sampling and for the analytical service provider's quality assurance (QA) documents covering regulatory analysis (e.g., Tri-Party Agreement, permits, process chemistry, and research and development efforts related to the Hanford Site clean-up activities).

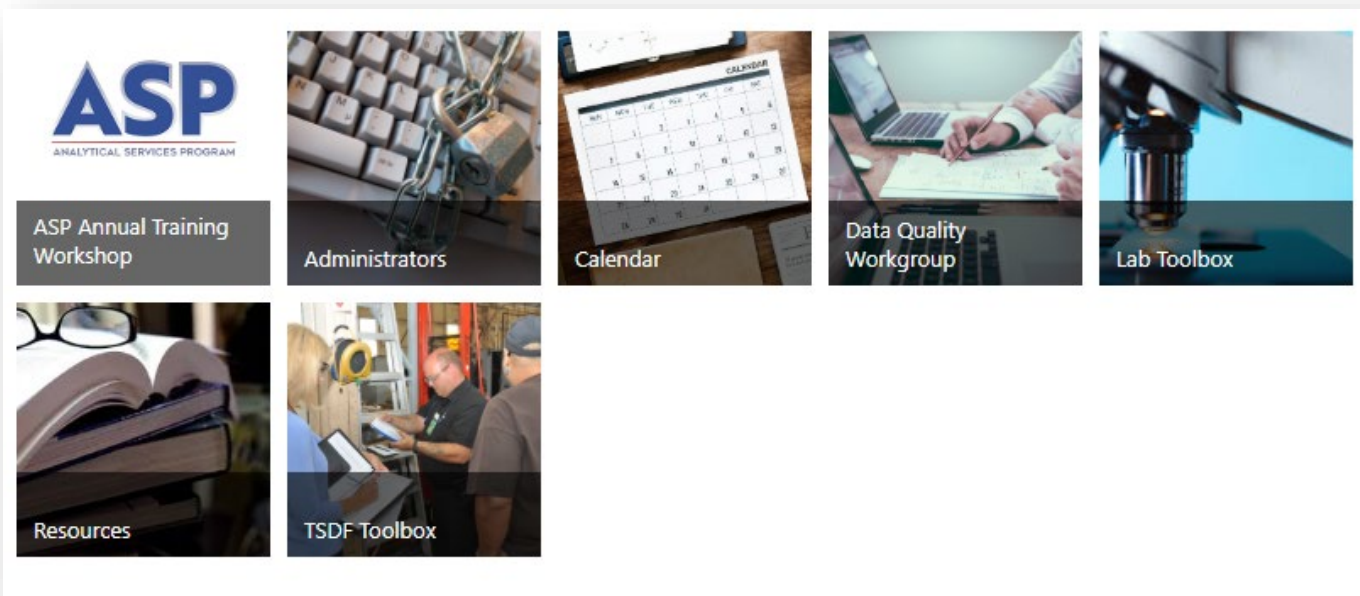


DOECAP SharePoint



Auditors and TSDF representatives are given access

- Calendar of scheduled assessments/audits
- DOECAP archived presentations and meetings
- Assessment and audit uploads
- Procedures
- Archived checklists
- DoD/DOE QSM v5.3
- ASP Training Workshop Presentations





Questions