



Department of Energy Analytical Services Program Consolidated Audit Program- Laboratory Accreditation

Update: December 6, 2022

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Analytical Services Program Manager

Office of Sustainable Environmental Stewardship (EHSS-21)

Office of Environment, Health, Safety and Security

U.S. Department of Energy



Office of Environment, Health, Safety and Security



Agenda

- **Workshop Objectives**
- **3-Day Schedule**
- **DOE Consolidated Audit Program History and Overview**
- **DOECAP Laboratory Accreditation Program (DOECAP-AP)**
- **Analytical Services Program Departmental Support/Facility Usage Query**
- **Current DOECAP-AP PFAS Laboratories**
- **PFAS Findings and Trends**



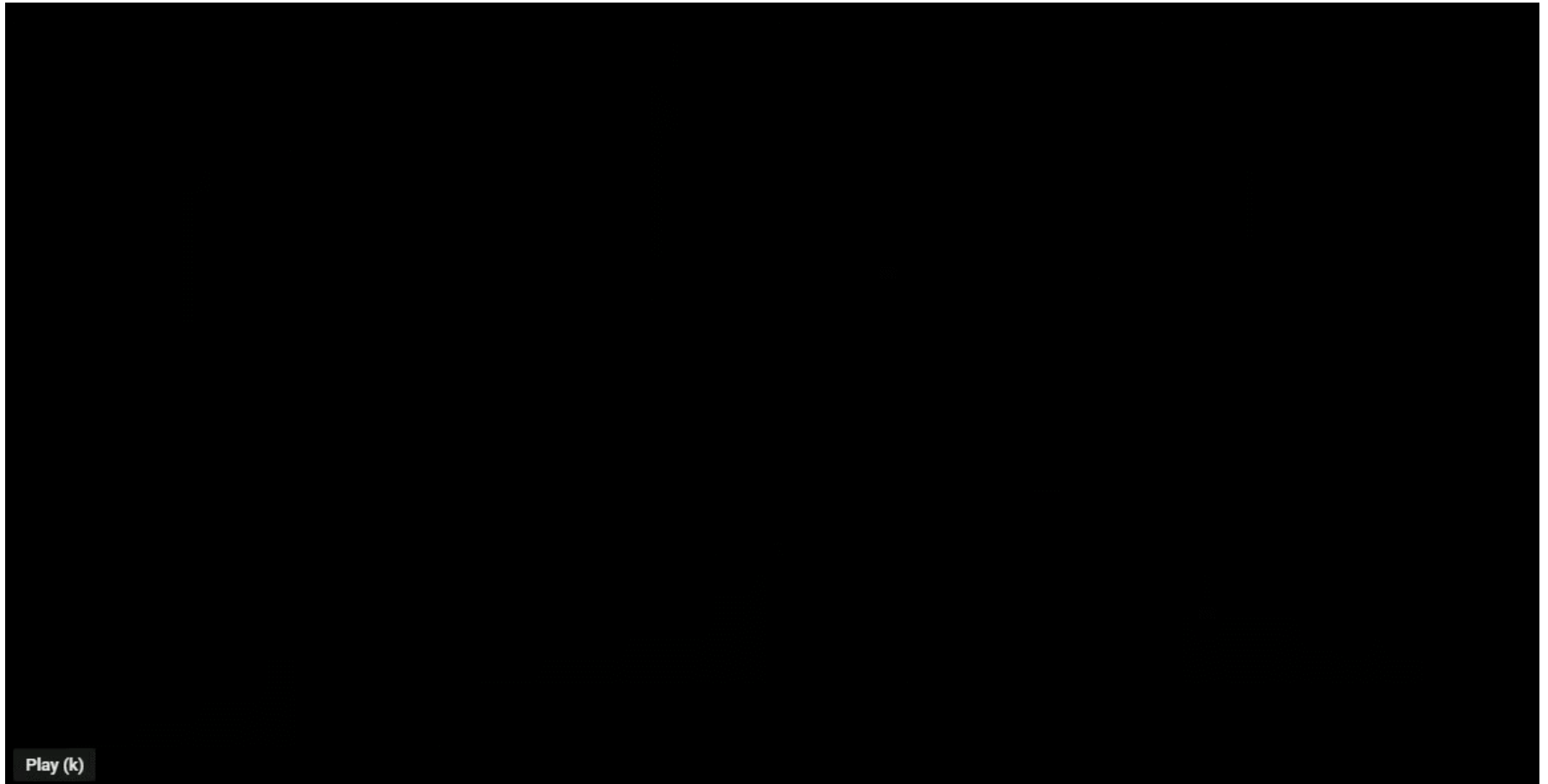
Workshop Objectives

Attendees will be able to:

- **Identify the multiple uses of the DOECAP-Accreditation Program Summary of Findings Reports**
- **Know how to participate in program implementation and information sharing**
- **Identify laboratories and methods associated with PFAS analysis**
- **Familiarize themselves with the proposed changes in the upcoming DoD/DOE Quality Systems Manual v6.0**



PEP TALK



Office of Environment, Health, Safety and Security



3-Day Schedule

Ballrooms 2 & 3

Tuesday, December 6, 2022

Time	Session	Trainers
8:30-8:45	Introduction and Welcome	<i>Presenters:</i> <i>Debbie Rosano, Deputy Director, EHSS-20</i> <i>Steve Clark, ASP Manager, EHSS-21</i>
8:45-9:15	Training: ASP Program Updates and Changes	<i>Trainer:</i> <i>Steve Clark, EHSS-21</i>
9:15-9:30	Training: DOECAP-AP Role of the Observer	<i>Trainer:</i> <i>Gene Kumamoto, PEC</i>
9:30-10:00	BREAK	
10:00-11:15	Training: PFAS Accredited Laboratories- Hurdles and other Challenges	<i>Panel of Trainers:</i> <i>Jaimie Foxx, Enthalpy Laboratory</i> <i>Robert Mitzel (Bob), Eurofins/TestAmerica</i> <i>Jannie Shaw-Busby, GEL Laboratories</i> <i>Mike McFadden, Pace Laboratory</i>
11:15-11:45	Training: The State of your Labor Force Whether it be a laboratory technician, forklift driver, or rad tech, the labor force is becoming increasingly unstable by the day. It is getting harder to find new and experienced staff. This session will discuss the issues surrounding the current workforce shortages (Retention, Retirement, and Removed) while providing helpful information on how a facility can expand their search for future employees.	<i>Trainer:</i> <i>James A. Scheppard</i> <i>Director – Nevada San Francisco Region,</i> <i>U.S. Department of Labor</i>
11:45-1:15	LUNCH	



3-Day Schedule

Tuesday, December 6, 2022

1:15-1:30	Training: Brief Overview of The UFP-QAPP	<i>Trainer: Jake Williams, US Army Corps of Engineers</i>
1:30-1:45	PFAS @ DOE	<i>Trainer: Hannah Hidle, PEC</i>
1:45-2:15	DOE Roadmap and the PFAS Assessment Report	<i>Trainer: Debbie Rosano, DOE, EHSS-20</i>
2:15-3:00	PFAS @ DoD Learn what the Department of Defense is doing to address PFAS at their sites.	<i>Trainers: Alyssa Wingard, DoD Janice Willey, DoD</i>
3:00-3:30	BREAK	
3:30-4:45	Training: Method 1633	<i>Trainer: Janice Willey, DoD</i>
5:30-8:00	EVENING SOCIAL: General Area	



3-Day Schedule

Wednesday, December 7, 2022

Time	Session	Trainers
8:30-9:30	Training: DoD Data Validation Guidelines Learn what DoD has established for data validation guidelines and how it is improving their review and defensibility of laboratory data received.	<i>Trainer:</i> <i>Melinda McClellan,</i> <i>US Army Corps of Engineers</i>
9:30-9:45	Training: How to Request Audit Summary Reports and Why? Need a DOEAP report for your quality assurance program review or qualified supplier lists? Learn how to request the reports.	<i>Trainer:</i> <i>Heather Garrett, PEC</i>
9:45-10:15	BREAK	
10:15- 11:00	Training: PT Program Management Options	<i>Trainers:</i> <i>Brian Miller, ERA</i> <i>Larry Jassin, Eckert & Ziegler</i>
11:00-11:45	Data Validation Round-Table Discussion	<i>Facilitator:</i> <i>Debbie Rosano, EHSS-20</i>
11:45-1:15	LUNCH	
1:15-2:15	Training: History Lesson- History of Atomic Testing Learn the detailed and some little-known facts surrounding the history of atomic weapon development and testing.	<i>Trainer:</i> <i>Joseph Kent,</i> <i>Director of Education,</i> <i>National Atomic Testing History Museum</i>
2:15-2:30	BREAK	
2:30-4:00	Training: Federal Radiological Monitoring And Assessment Center (FRMAC) Laboratory Analysis Division RRM	<i>Trainer:</i> <i>Sean D. Fournier,</i> <i>Nuclear Incident Response Program</i>
4:00-4:45	Closed Meeting: Accrediting Body Quarterly Meeting	
4:00- 8:00	National Atomic Testing Museum (Directions Provided) - The museum will be opening their doors for us until 7pm.-Open to all Workshop Attendees	

Office of Environment, Health, Safety and Security



Thursday, December 8, 2022

3-Day Schedule

Time	Session	Trainers
8:30-9:15	Training: Data Management	<i>Trainer: Dr. Dave Rich, Geotech Computer Systems, Inc.</i>
9:15-10:00	Training: Overview of Quality Systems Manual, Version 6.0 (Part 1)	<i>Trainer: John Gumper, ChemVal</i>
10:00-10:15	BREAK	
10:15-11:15	Training: Overview of Quality Systems Manual, Version 6.0 (Part 2)	<i>Trainer: John Gumper, ChemVal</i>
11:15-11:45	Training: QSM Overview: New Industrial Hygiene section	<i>Trainer: Gary Griffin, GEG Consulting, LLC</i>
11:45-1:15	LUNCH	
1:15- 1:30	Training: QSM Waivers	<i>Trainer: Tessa Landry, ChemVal</i>
1:30-2:30	Open Discussion: "Q" Delete Discussion	<i>Facilitator: Alyssa Wingard, DoD</i>
2:30-3:30	Closed Meeting: ASP Round Table Federal Staff Only	<i>Federal Staff and Site Contractors Only</i>
3:30	Adjourn	





DOECAP History and Overview

1995

**Office of the Inspector
General (OIG) Report**

- Redundant quality assurance evaluations
- No consistency, communication, or cooperation between DOE sites/contractors

1996

**Environmental
Management
Consolidated Audit
Program (EMCAP)**

- Multi-site working group
- Oak Ridge Operations Office

1999

DOE Order 435.1 Issued

- Requires Field Element Managers (FEM) to approve use of treatment, storage, disposal facilities (TSDFs) based on annual review



Early DOECAP History

2002

Assistant Secretary for
Environmental
Management (ASEM) letter

- Expecting EM programs to actively participate and support program

2003

ASEM letter

- Requires EMCAP to be the sole provider of audits of analytical laboratories and commercial radioactive TSDFs
- Standardize contract terms and conditions to allow EMCAP audit results
- Programmatic and funding responsibilities for the Analytical Services Program (ASP) were transferred from the Department of Energy's (DOE) Office of Environment Management (EM) to the Office of Environment, Safety and Health (EH), now called Office of Environment, Health, Safety and Security (EHSS)

2016

OIG Report

- DOECAP consolidates redundant audits and saves money

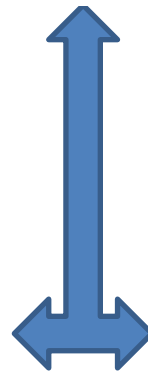


DEPARTMENT OF ENERGY
CONSOLIDATED AUDIT PROGRAM - TSDF AUDIT PROGRAM

DOECAP 

Commercial Waste TSDFs

Audits conducted by federal and contractor volunteers from throughout DOE Complex



DEPARTMENT OF ENERGY
CONSOLIDATED AUDIT PROGRAM-ACCREDITATION PROGRAM

DOECAP-AP 

Commercially-Operated Analytical Environmental Laboratories:

Assessments conducted by 3rd-party accrediting bodies (ABs), supported by DOE complex-wide federal and contractor staff



Minimize Risk to the Department

The goal is to minimize the likelihood and consequences of human fallibility and/or technical and organizational system failures.

DOECAP, as a tool, is a cooperative effort across the DOE Complex to eliminate redundant audits and reduce the unnecessary expenditure of resources and funds.



ASP Support to the Department/ Facility Usage Query - FY2022



316 contracts throughout the DOE Complex: (**153** Lab/**163** TSDF)



\$70.9M in contracts
\$31.4M - Laboratory
\$39.5M - TSDF



33 DOE Sites & Contractors

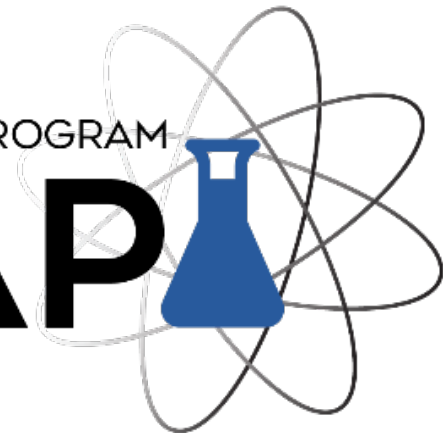


7 Program Offices Supported:
SC, EERE, EM, NA, FE, LM, NE



DEPARTMENT OF ENERGY
CONSOLIDATED AUDIT PROGRAM-ACCREDITATION PROGRAM

DOECAP-AP



Importance of the DOECAP Accreditation Program

- DOECAP-Accreditation Program (DOECAP-AP) provides DOE sites assurance that a contracted commercial laboratory is fully capable of providing accurate data analysis
- Requires third-party assessments which assure that environmental sample analysis is performed using proven methods, provide valid, reliable, and defensible data, and a managing sample waste streams responsibly
- Assessments are conducted by one of four DOECAP approved third-party accreditation bodies (ABs)
- Laboratories are assessed to the most recent version of the Department of Defense/Department of Energy (DoD/DOE) Quality Systems Manual (QSM)





Third-Party Accrediting Bodies





of DOECAP-AP Accredited Laboratories



**28 ACCREDITED LABORATORIES
PERFORMED BY APPROVED 3RD-PARTY
ACCREDITING BODIES**



**1 DOECAP AUDITED
LABORATORY - ALS
OHIO**



DOECAP-AP Laboratory Assessment Report Uses by Program Office

Reports Used to Support:	Lab Contracts	DOE Program Offices						
		EERE	EM	FE	LM	NA	NE	SC
DOE Order 435.1	10	0	3	0	0	1	0	6
NEPA Decisions and Review	3	0	3	0	0	0	0	0
DOE Order 414.1D	109	0	70	0	4	17	2	20
Qualified Supplier Lists	81	0	55	0	0	3	2	21
Quality Assurance Reviews	107	4	53	5	4	22	0	17
Basic Order of Agreement	49	0	33	0	0	4	0	12



DoD/DOE Quality Systems Manual (QSM) for Environmental Laboratories

- Provides baseline requirements for establishing and managing quality systems for laboratories performing analytical testing for DoD and DOE.
- Only approved Accrediting Bodies assess and accredit laboratories to the most recent version of the QSM.
- EHSS-21 works in conjunction with DoD to advance the interests of the Department in supporting the continued development and implementation of the QSM.
- The QSM supports DOE analytical needs with emerging contaminants, such as per- and polyfluoroalkyl substances (PFAS).



Department of Defense (DoD)
Department of Energy (DOE)
Consolidated
Quality Systems Manual (QSM) for
Environmental Laboratories

Based on ISO/IEC 17025:2005(E)
ISO/IEC 17025:2017(E)
and
The NELAC Institute (TNI) Standards, Volume 1, (September 2009)

DoD Quality Systems Manual Version 5.4
2021



7 Lab Audit Concentrations + 2 Additional Standards

QUALITY ASSURANCE
MANAGEMENT SYSTEMS
AND GENERAL
LABORATORY PRACTICES

HAZARDOUS &
RADIOACTIVE MATERIAL
MANAGEMENT

INORGANIC AND WET
CHEMISTRY

ORGANIC ANALYSIS

RADIOCHEMISTRY
ANALYSIS

LABORATORY
INFORMATION
MANAGEMENT
SYSTEMS/ELECTRONIC
DATA MANAGEMENT
(LIMS)

TNI 2016

AQUATIC TOXICITY

ISO 17025:2017

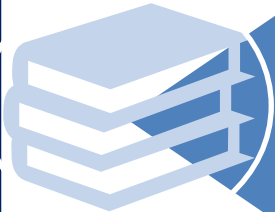


How Reports Assist the DOE Complex



DOE Order 414.1D, *Quality Assurance (QA)*: quality work based on performance and quality improvement, thorough rigorous assessments and effective corrective actions.

- Qualified supplier/vendor lists established



DOE Manual (M) 435.1-1, *Radioactive Waste Management Manual*, Field element managers annual review of commercial TSDFs.



Basic Ordering Agreements (BOAs) and many DOE contractors include requirements for DOECAP laboratory accreditation and/or TSDF audits in subcontracts.



PFAS Laboratory Status

Last Updated: November 7, 2022

Laboratory	DOECAP-AP Accredited to 1633	DoD-ELAP Accredited to 1633	DOECAP-AP Accredited to DOE 537.1	DOECAP-AP Accredited to 533	Accrediting Body
American Analytics					PJLA
APPL	Yes		Yes	Yes	A2LA
Bureau Veritas		Yes			PJLA
Clarkson		(Yes)			PJLA
EMSL Analytical, Cinnainson, NJ			Yes	Yes	
Enthalpy Wilmington	(Upcoming)	Yes		Yes (DoD)	ANAB
Environmental Monitoring		Yes			PJLA
Eurofins Lancaster Laboratories	(Upcoming)	Yes			A2LA
Eurofins Sacramento	Yes	Yes	Yes	Yes	ANAB
GEL Labs	Soon		Yes	Yes	A2LA
Pace Analytical Gulf Coast		Yes			A2LA
Pace South Carolina			Yes	Yes	ANAB
Pace Analytical National	Soon				A2LA
RTI					A2LA
TestAmerica Denver	Soon				A2LA
Torrent Laboratories, Milipitas, CA	Yes				PJLA
Weck laboratory, City of Industry, CA	Yes	Yes	Yes		ANAB



PFAS Findings and Trends

- In 2021, there were 4 findings and zero observations for PFAS
- In 2022, there were 16 findings and 4 observations for PFAS

Every Finding from laboratory assessments were reviewed individually for key words buried in the text such as: 537.1, 537, 533, 8327, 1633, B-24, 1621 TOF, OTM 45, B-15 or any individual PFAS target analytes



PFAS Related Findings: 2021

Standard & Version	Table or Reference	Citation	Description
ISO/IEC 17025:2005	V1M2 4.13.1.1	The laboratory shall establish and maintain procedures for identification, collection, indexing, access, filing, storage, maintenance, and disposal of quality and technical records. Quality records shall include reports from internal audits and management reviews as well as records of corrective and preventive actions.	The manual integration training was not correctly documented based on interviews with the PFAS analyst.
ISO/IEC 17025:2005	V1M2 5.2.2	The management of the laboratory shall formulate the goals with respect to the education, training and skills of the laboratory personnel. The laboratory shall have a policy and procedures for identifying training needs and providing training of personnel. The training program shall be relevant to the present and anticipated tasks of the laboratory. The effectiveness of the training actions taken shall be evaluated.	The laboratory is not following Table B-15. PFAS calibrations do not meet the requirement that analytes must be within 70-130% of true value for each standard or follow linearity requirements. (A, B below)
QSM 5.3	Table B-15	Laboratories shall follow Appendix B table requirements.	The laboratory does not always meet this standard as indicated by the following examples: The balance ID is not being recorded in the Extraction Log used for EPA Method 533. (SM)
QSM 5.3	V1M2 4.13.2.1	DoD/DOE QSM V1M2 ISO/IEC 17025:2005 4.13.2.1; TNI 2016 V1M2 4.13.2.1: The laboratory shall retain records of original observations, derived data and sufficient information to establish an audit trail.	



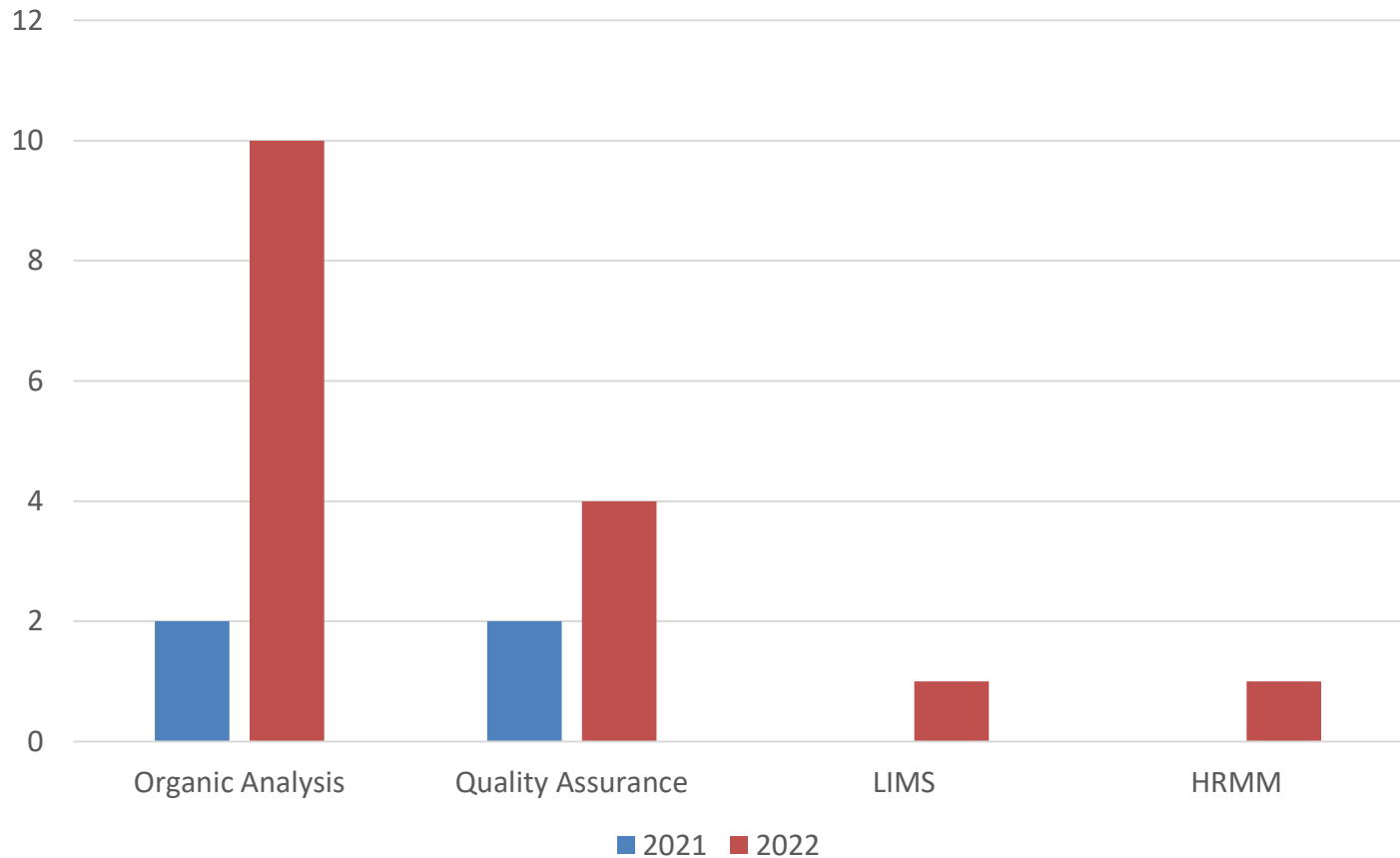
Examples of PFAS Related Findings: 2022

Standard & Version	Table or Reference	Citation	Description
TNI 2009; TNI 2016	V1M2 4.2.8.5	Laboratories shall maintain SOPs that accurately reflect all phases of current laboratory activities, such as assessing data integrity, corrective actions, handling customer complaints, and all methods.	SOP DV-LC-0040, Rv 0 for PFAS. was not up to date.
QSM 5.4	V1M4 1.5.2.1 (f)	After each DL determination, the laboratory must establish the LOD by spiking a quality system matrix at a concentration of at least 2 times but no greater than four times the DL (i.e., 2x DL = LOD Spike = 4x DL).	The spike concentrations for the LOQ/MDL for PFAS water were less than the applicable limits in the laboratory SOP. This issue was documented in the data review of the LOQ review for EPA 1633 water for compounds: PFOA, PFDoS
QSM 5.4	V1M1 3.1.2	PT providers will be required to maintain proficiency in an ISO/IEC 17043:2010(E) accredited PT program for all analytes, matrices, and methods that are included in the laboratory's scope of work as defined in the subcontracts issued by DOE sites.	No PT was completed for soil PFAS.
TNI 2009	V1M2 1.6.2	An initial DOC shall be conducted prior to using any method.	An IDOC has not been performed for all analytes in EPA Draft Method 1633.



PFAS Related Findings by Concentration

DOECAP-AP PFAS Related Findings

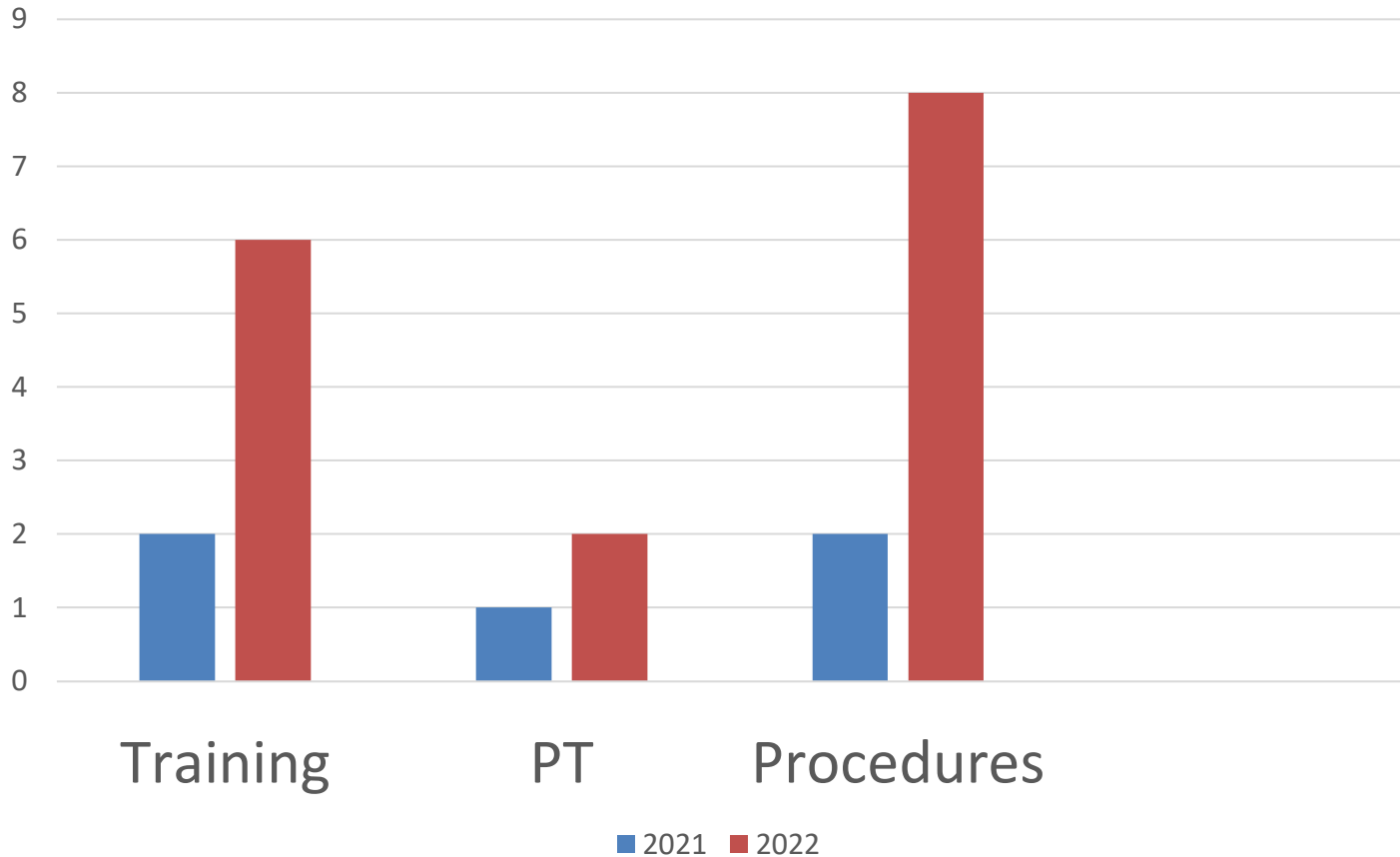


Office of Environment, Health, Safety and Security



PFAS Related Findings by Concentration

DOECAP-AP PFAS Related Findings





Questions or Comments?

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