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Presentation Outline

• Program Overview

• Audit Checklists and Process

• Common Laboratory Findings

• DoD/DOE Joint Quality Assurance Manual

• Audited Laboratories
Findings from DOE’s Office of the Inspector General and GAO Reports

“Audit of DOE’s Commercial Laboratory Quality Assurance Evaluation Program” (June 1995)

• Some laboratories were audited numerous times by a single DOE entity; others were never audited

• Evaluation methods varied significantly from one contractor to another

• Audit results were not shared between contractors

IG and GAO findings concluded reductions in DOE Auditing of Analytical Laboratory Services was needed
What was DOE’s Response?

DOECAP

• Purpose
  • Eliminate/minimize audit redundancies
  • Standardize audit methodology, policies and procedures
  • Communicate Lessons Learned
  • Reduce overall Department risks/liabilities

• Involve all DOE line organizations/field operations

• Training auditors (Exams, auditors-in-training, Committee approval)

• Volunteer auditors -- DOE federal employees/contractors (70 auditors)
Are DOECAP Audits Accreditations?

- No Accreditations/Certifications
- Provides information to DOE program management line/field
  - risks/liabilities
  - laboratories performance improvements
  - determination whether to maintain DOE contractual agreements for analytical environmental services
  - thorough/comprehensive 3-day review with multiple disciplines evaluations
  - draft report at on-site close-out

DOECAP audits are at no cost to laboratories/waste facilities
DOECAP Justification

• Laboratory: DOE Order 414.1D, *Quality Assurance*
  • Applies directly to GOCO and commercial laboratories that perform work for the DOE
• Quality Systems for Analytical Services (QSAS)
  • Establishes a single, integrated QA program for providers of laboratory services to DOE
  • Based on TNI (NELAC), Chapter 5 (based on ISO 17025) with gray boxes to address DOE specific requirements (radiochemistry, hazardous and radioactive materials management, NDA)
• TSDF: DOE Order 435.1, *Radioactive Waste Management*
  • Requires that DOE utilize DOE facilities to manage radioactive waste
  • However, if DOE chooses to use a non-DOE waste vendor, DOE must perform an annual qualification audit of the facility
Results of Formalized DOE Auditing Program

37 DOE CAP Audits/Fiscal Year

FY11 DOE CAP Auditing Activities

26 Analytical Environmental Laboratories
   - 22 Commercial
   - 4 Government Owned Contractor Operated (GOCO)

11 Treatment, Storage & Disposal Facilities
   - 8 Radiological
   - 3 Non-radiological
FY11 DOE CAP Evaluated Laboratories and TSDFs

- Laboratory Facilities (26)
- Radiological TSDF Facilities (8)
- Non-Radiological TSDF Facilities (3)
Audit Areas

**Laboratory**
- Quality Assurance & General Laboratory Practices
- Organic Analysis
- Inorganic Analysis
- Radiochemistry Analysis
- Laboratory Information Management Systems/EDD
- Hazardous and Radioactive Materials Management
- Aquatic Toxicity
- Non-Destructive Assay

**TSDF**
- Quality Assurance
- Sampling and Analytical Data Quality
- Waste Operations
- Environmental Compliance/Permitting
- Radiological Control
- Industrial and Chemical Safety
- Transportation Management
FY 2011 Findings

• DOE CAP conducted 37 audits in FY2011

• 85% of all FY2010 audit findings were closed during FY2011 audits:
  - 83% of the Lab findings
  - 89% of the TSDF findings

• New Findings Identified Lab & TSDF since 2006:
  FY2006 = 269  FY2009 = 277
  FY2007 = 374  FY2010 = 227
  FY2008 = 216  FY2011 = 215
Percent Distribution of FY 2011 Lab Findings

- Quality Assurance: 25%
- Aquatic Toxicity: 2%
- Hazardous & Radioactive Materials Management: 18%
- NDA: 10%
- Organic: 13%
- Inorganic: 15%
- Radiochem: 16%
- LIMS: 1%

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Common Analytical Laboratory Findings

Quality Assurance
- Documentation does not meet requirements
- All required training has not been performed
- Proficiency Testing failures

Data Quality for Organic Analyses
- Inadequate performance of MDL studies
- Calibration is not being performed as required

Data Quality for Inorganic Analyses
- Inadequate SOPs or SOPs not followed
- Standards or Reagents expired or improperly labeled
Common Analytical Laboratory Findings

Data Quality for Radiochemistry
- Reference library issues
- Verification and documentation failures
- Improper calibration issues

Laboratory Information Management System
- Spreadsheet calculations and locked cells
- Software verification and validation

Hazardous and Radiological Materials Management
- SOPs not followed when receiving and opening shipping coolers
- Failure to effectively implement evaluation process for waste brokers
DoD/DOE Joint Quality Assurance Manual

- Quality Systems Manual for Analytical Services
  - DoD Benefits:
    - Expands radiochemistry methodologies
    - Sample residual and derived waste disposal, and
    - Laboratory worker Environmental Health and Safety practices
  - DOE Benefits:
    - Expands analytical methods tables
- Overall benefit to DoD/DOE is the consolidation of quality and technical requirements
Laboratory Benefits

- Single approach to satisfy the quality and technical requirements of DoD/DOE
- Reduction in preparation time for laboratory audits
- Single Quality Manual that encompasses the DoD/DOE requirements
- Incorporation of current TNI standard and the requirements of DoD/DOE
Fy11 Audited Laboratories
DoD/DOE Jointly Audited Laboratories

* BC Laboratories, Inc., Bakersfield, CA
* TestAmerica, Inc., Knoxville, TN
* Shealy Environmental Services, Inc., West Columbia, SC
* TestAmerica, Inc., St. Louis, MO
* GEL Laboratories, LLC, Charleston, SC
* TestAmerica, Inc., Arvada, CO
* TestAmerica, Inc., Richland, WA
* Davis and Floyd, Inc., Greenwood, SC
* ALS Laboratory Group, Fort Collins, CO
* American Radiation Services, Inc., Port Allen, LA
* ALS Laboratory Group, Salt Lake City, UT
Fy11 Audited Laboratories
DOE Audited Laboratories

Eberline Analytical Corporation, Oak Ridge, TN

B&W Radioisotope & Analytical Chemistry Laboratory, Lynchburg, VA

B&W Y-12 Analytical Chemistry Organization, Oak Ridge, TN

Radiological Materials Analysis Laboratory,

ORNL UT-Battelle, LLC, Oak Ridge, TN

Portsmouth Analytical Services, Piketon, OH

Caltest Analytical Laboratory, Napa, CA

Paducah Analytical Services, Paducah, KY
Fy11 Audited Laboratories (cont)

Eberline Analytical Corporation, Richmond, CA

Materials & Chemistry Laboratory, Inc., Oak Ridge, TN

Southwest Research Institute, San Antonio, TX

Lionville Laboratory, Inc., Exton, PA

Shealy Consulting, LLC, Lexington, SC

Oak Ridge Institute for Science & Education, Oak Ridge, TN

CEBAM Analytical, Inc., Bothell, WA
Unlabeled/Unknown Substance Discovered
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