



U.S. Department of Energy's Consolidated Audit Program (DOECAP)



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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)



DOECAP Information



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 DOECAP Audits/Fiscal Year

FY11 DOECAP Auditing Activities

26 Analytical Environmental Laboratories

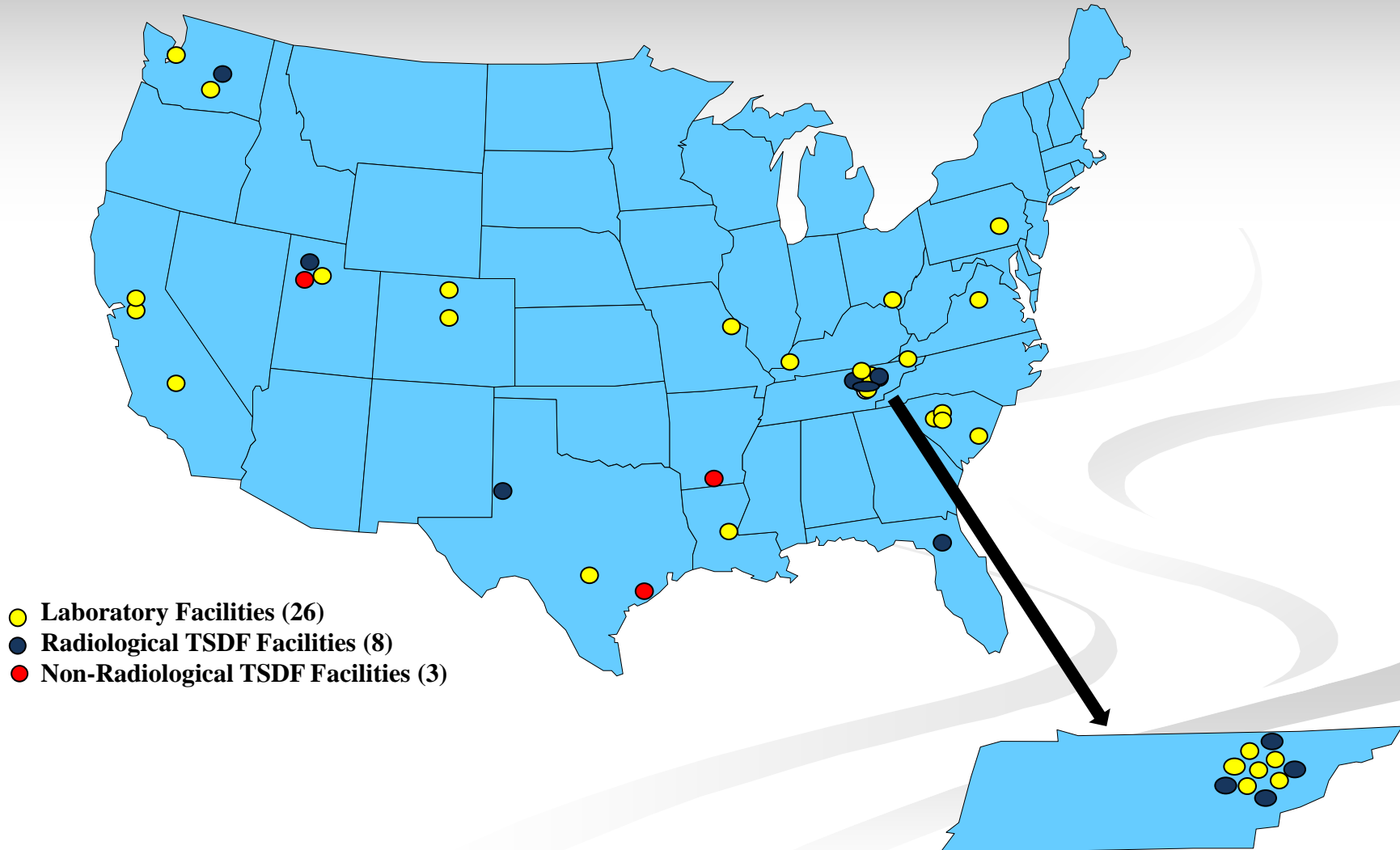
- 22 Commercial
- 4 Government Owned Contractor Operated (GOCO)

11 Treatment, Storage & Disposal Facilities

- 8 Radiological
- 3 Non-radiological



FY11 DOECAP Evaluated Laboratories and TSDFs





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

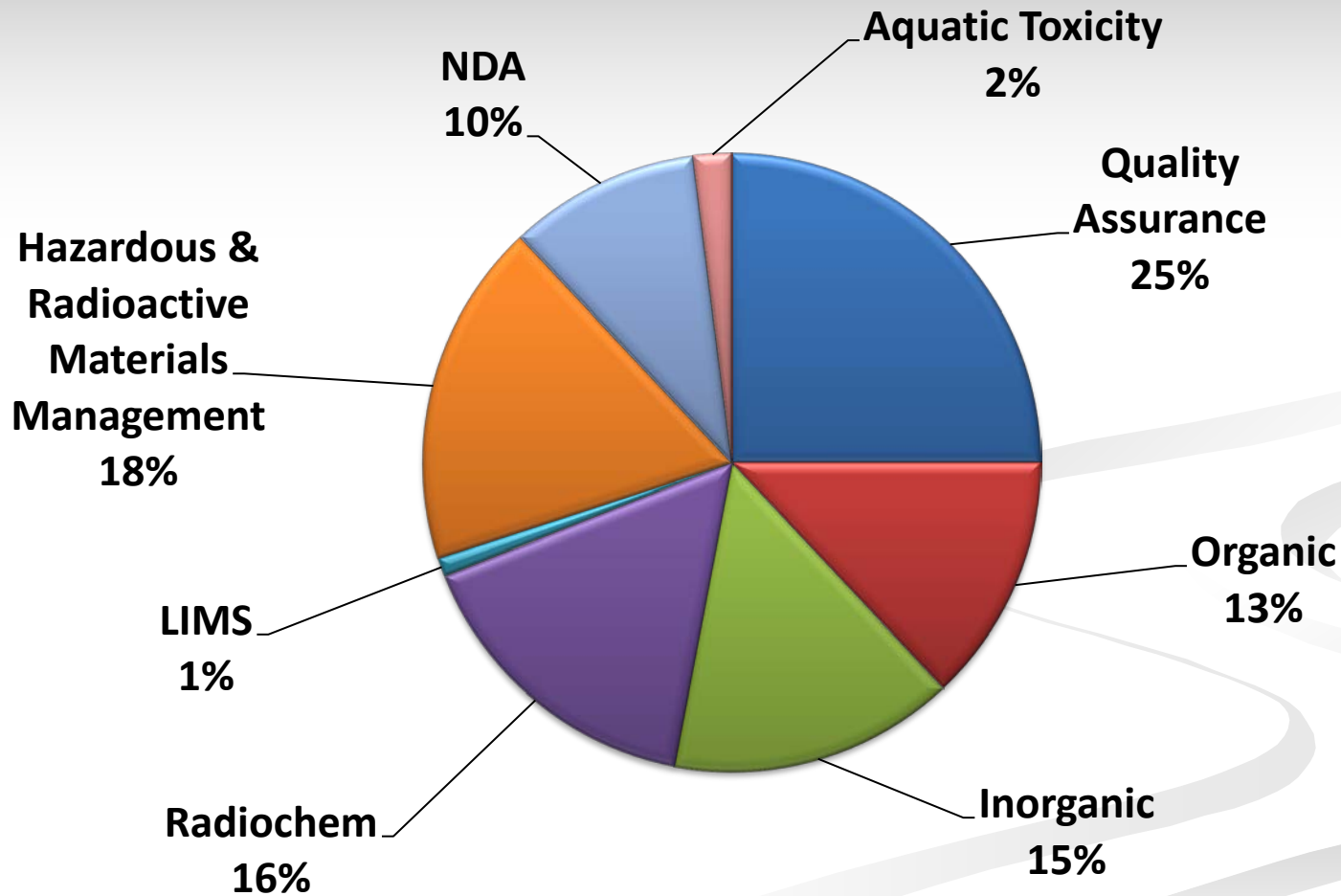


- **DOECAP conducted 37 audits in FY2011**
- **85% of all FY2010 audit findings were closed during FY2011 audits:**
 - 83% of the Lab findings
 - 89% of the TSDF findings
- **New Findings Identified Lab & TSDF since 2006:**

FY2006 = 269	FY2009 = 277
FY2007 = 374	FY2010 = 227
FY2008 = 216	FY2011 = 215



Percent Distribution of FY 2011 Lab Findings





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



Laboratory Data Quality Review





Unlabeled/Unknown Substance Discovered





Observing Laboratory Worker





Auditor at Work





DOECAP Program Team



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