

EFCOG BEST PRACTICE #31

Consolidated Audits of Analytical Laboratories and TSDFs Leverage Resources and Improve Quality

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BRIEF DESCRIPTION OF BEST PRACTICE:

The Department of Energy's Consolidated Audit Program (DOECAP) is an organization that conducts audits of analytical laboratories and commercial mixed waste and low-level waste treatment, storage, and disposal facilities (TSDFs) that have contracts or agreements to perform services for DOE programs. DOECAP uses a formalized multi-checklist audit process with trained and qualified auditors to perform audit functions. These audit teams are composed of auditors from various contractor facilities across the DOE complex. There are approximately 33 laboratories and 6 TSDFs certified by DOECAP including 3 laboratories that perform industrial hygiene analyses.

In 2000, the Berkeley Lab began to participate in the Environmental Management Consolidated Audit Program (EMCAP, now DOECAP) by providing auditors for the EMCAP audits of analytical laboratories used by the Berkeley Lab. Since then, the Berkeley Lab has seen a significant improvement in the level of quality and performance of the analytical labs that fall under the oversight of the DOECAP. As a result, the data is more defensible. In addition, participation in this program has allowed the Laboratory to leverage its resources, resulting in a substantial benefit at a lower cost. Costs for audit preparation and follow-on activities are centralized in the DOECAP Office in Oak Ridge and all DOE facilities benefit from their activities.

Since 2001, Berkeley Lab has been using DOECAP's TSDF audit program to augment the University of California (UC) audit program to meet the DOE Order 435.1 annual confirmation requirement. Availability of TSDF audit reports through DOECAP has resulted in cost savings for Berkeley Lab's waste management compliance program. In the absence of DOECAP TSDF audit reports, Berkeley Lab would have been required to allocate more resources to its TSDF audit program to meet the DOE Order 435.1 annual facility review requirements.

DOECAP was identified as a best practice in Jessie Hill Roberson's 2/12/03 memo, "Implementation of the Environmental Management Consolidated Audit Program." In addition,

Roberson's memo directed EM programs to use DOECAP as the sole provider for audits of analytical laboratories and commercial mixed waste and low-level TSDFs.

WHY THE BEST PRACTICE WAS USED:

DOECAP participation improves the quality and the consistency of data received from analytical laboratories and reduces auditing costs. By assuring quality analytical laboratory services, the Berkeley Lab can manage analytical laboratories without impact to schedule or mission and have greater confidence that analytical data is legally defensible. DOECAP TSDF audit reports are used to meet the requirements of DOE Order 435.1 and reduce TSDF audit costs for the Berkeley Laboratory.

WHAT ARE THE BENEFITS OF THE BEST PRACTICE:

Participation in DOECAP audits has resulted in the following benefits for the Berkeley Laboratory:

- Improved analytical laboratory performance and data quality by resolving DOECAP audit findings through the corrective action process and by implementing DOECAP audit team recommendations.
- Increased expertise of the analytical audit teams due to the participation of auditors who have extensive analytical laboratory working experience. Many auditors maintain NQA-1 certification.
- Decreased resources and travel costs required to conduct analytical laboratory audits and TSDF audits.
- Increased quality of the analytical laboratory audits through the use of detailed checklists, which reference the applicable EPA method requirements and/or DOE requirements for each question. The checklists were developed to satisfy NQA-1 requirements.
- Fewer analytical laboratory audits conducted annually by the Berkeley Lab. DOECAP conducts audits of East Coast analytical laboratories and the Berkeley Lab uses solely the audit reports.
- Decreased resources needed to schedule audits, prepare checklists, consolidate analytical laboratory SOPs, QAPs, and other pre-audit documentation. (All are prepared by the DOECAP office in Oak Ridge.)
- Decreased resources needed to manage corrective actions, qualify new auditors, provide auditor training, and provide database management and information sharing. (All are provided by the DOECAP office in Oak Ridge.)

WHAT PROBLEMS/ISSUES WERE ASSOCIATED WITH THE BEST PRACTICE:

Some DOECAP requirements exceed those needed at the Berkeley Lab. For example, Berkeley Lab does not require that an analytical laboratory have a radioactive materials license for the receipt of non-radioactive "environmental" samples. In other cases, the DOECAP requirements do not fulfill the needs of the Berkeley Lab. For example, DOECAP does not audit TSDFs that manage hazardous waste only.

HOW THE SUCCESS OF THE BEST PRACTICE WAS MEASURED:

- An EH-24 audit confirmed that quality assurance requirements for analytical laboratory data were met.
- Non-conformances from analytical laboratories have decreased over the years.
- Costs to conduct audits have decreased since manpower dedicated to audits has decreased from 3-4 auditors/audit to 1 auditor/audit.

- East Coast audits have been eliminated.

DESCRIPTION OF PROCESS EXPERIENCE USING THE BEST PRACTICE:

In the early '90s, the Berkeley Lab conducted audits of analytical laboratories using auditors trained in quality assurance but without working experience in an analytical laboratory. In 1995, the Berkeley Lab joined with Lawrence Livermore National Laboratory (LLNL) in the procurement of analytical laboratory services. The cooperative efforts between the Berkeley Lab and the LLNL led to the formation of joint technical audit teams that had previous analytical laboratory working experience. The Berkeley Lab gained in sharing technical experts provided by the LLNL. In 2000, the Berkeley Lab began participating in EMCAP (now DOECAP) audits. The Berkeley Lab provides three DOECAP-qualified auditors [Organic Data Quality (1) and Radiochemistry Data Quality (2)] for DOECAP audits of analytical laboratories. The Berkeley Laboratory has benefited from the expertise of highly qualified and experienced staff from the other DOE facilities. Participation in DOECAP audits has substantially increased the quality of analytical laboratory audits for the Berkeley Lab due to the strength of the auditors from across the DOE complex.

DOECAP audits of analytical laboratories are divided into separate modules that include the review of the following subject areas:

Module 1: General Laboratory Practices and Quality Assurance Management

Module 2: Organic Data Quality

Module 3: Inorganic Data Quality

Module 4: Radiochemistry Data Quality

Module 5: Laboratory Information Management System & Electronic Data Deliverables

Module 6: Hazardous Waste and Radioactive Materials Management

Typically one or two auditors review each subject area. Auditors are pre-qualified by the DOECAP office in Oak Ridge and must meet minimum educational, training, and work experience requirements. For the review, checklists are used that provide consistency from audit to audit and between different auditors. In addition, the detail and breadth of the DOECAP audit checklists have improved the quality of the audits.

The DOECAP office in Oak Ridge performs the preparation activities for the audits of analytical laboratories, including audit scheduling. This scheduling not only includes taking into consideration the time constraints of the analytical lab but also coordinates the participation of the auditors from the different DOE facilities. The DOECAP office compiles all pre-audit documents for the audit team, including laboratory quality assurance plans, standard operating procedures, corrective actions from previous audits, organizational charts, audit checklists, and audit report templates.

After the audit is completed, the audit team provides the analytical laboratory with an exit meeting and a copy of the draft audit report. The analytical laboratory has two weeks to review the report for factual accuracy. Any request for changes by the analytical laboratory is coordinated through the DOECAP office. Once the audit report is complete, the audit team submits the final report to the DOECAP office, where a copy of the final report is maintained for distribution to any DOE site that might request a copy. The DOECAP office tracks to closure all findings that require corrective action. When significant findings are found that severely impact DOE operations, the DOECAP office sends out an e-mail to all DOE facilities notifying them of the finding so that facilities can take immediate and appropriate action.

Since 1997, as an environmental prudent practice, the Berkeley Lab has been using audited facilities for treatment and disposal of its hazardous and radioactive wastes (including mixed wastes). This practice was established to decrease the Berkeley Lab's future liabilities associated with waste disposal. To accomplish this, the Berkeley Lab participated in the University of California (UC) Cooperative Audit Program that was managed by LLNL. The UC program audited

hazardous waste and radioactive/mixed waste treatment and disposal facilities that were used for managing UC waste. To participate in this program, the Berkeley Lab committed to provide one audit team member for two TSDF audits per year and cover the associated costs.

DOECAP audits support the implementation of Environmental Management Systems, which must be integrated into Integrated Safety Management Systems. DOECAP audits also satisfy the requirements of the following DOE Orders:

- DOE Order 414.1, Quality Assurance
- DOE Order 435.1, Radioactive Waste Management
- DOE Order 450.1, Environmental Protection Program

ISM CORE FUNCTION AND GUIDING PRINCIPLE TO WHICH THE BEST PRACTICE RELATES

Core Function 1: Define Scope of Work	Principle 4: Balanced Priorities
Core Function 2: Analysis of Hazards	
Core Function 3: Develop and Implement Hazard Controls	Principle 5: Identification of Safety Standards and Requirements; Principal 6: Hazard Controls Tailored to Work Being Performed