Department of Energy
Washington, DC 20585

January 9, 2008

MEMORANDUM FOR DISTRIBUTION

FROM: CHARLES B. LEWIS, III
DIRECTOR
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OFFICE OF HEALTH, SAFETY AND SECURITY

SUBJECT: U.S. Department of Energy Analytical Services Program Fiscal Year 2007 Report

Attached is the Department of Energy's (DOE) Analytical Services Program (ASP) Fiscal Year (FY) 2007 Report. The report summarizes the ASP's activities, which support field implementation of analytical services in the following areas:

- Department of Energy Consolidated Audit Program (DOECAP).
- Mixed Analyte Performance Evaluation Program.
- Systematic Planning and Data Assessment Tools and Training Program.

ASP provides various benefits to the Department. These benefits include: reducing DOE liabilities associated with analytical data and the proper disposition of low-level and mixed radioactive and chemical wastes; elimination of costly redundant audits; improvement in the overall performance levels of laboratories and waste facilities, including the quality and credibility of data to support regulatory compliance and field decision-making; and application of software toolkits to enhance environmental field data collection to define and meet Data Quality Objectives.

There were 38 DOECAP audits of analytical laboratories and commercial waste treatment, storage, and disposal facilities (TSDFs) completed in FY 2007. All audited laboratories and TSDFs are under contractual agreements with field site contractors to provide analytical data services and waste disposal of low-level, mixed, and chemical wastes. The consolidated audits eliminated duplicative independent audits by the field at an estimated cost savings to the taxpayer, of over $2.3 million. A review of all corrective action plans and annual field validation during auditing activities, show that findings from the previous year's audit revealed over 90% were closed. This indicates the recognition and importance laboratories and waste facilities place in DOECAP.

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Over 120 analytical laboratories, including 15 international laboratories, participated in the Department's corporate proficiency testing program as implemented by the Radiological and Environmental Sciences Laboratory at the Idaho National Laboratory. The proficiency testing program for radiological, stable inorganic, and organic constituents assists the field by ensuring the quality of environmental data. This supports regulatory compliance requirements and milestones, and decision-making for remedial cleanup actions and site closure actions.

Software toolkits used to support the planning, design and application of environmental field sampling statistical methodologies and decision making were developed in response to field-identified needs. Training courses were also taught at three field sites using the Visual Sample Planning software and the Data Quality Objectives planning process.

If you have any questions, please contact George E. Detsis, of my staff, at (301) 903-1488 or george.detsis@hq.doe.gov.

Attachment: U.S. Department of Energy Analytical Services Program Fiscal Year 2007 Report

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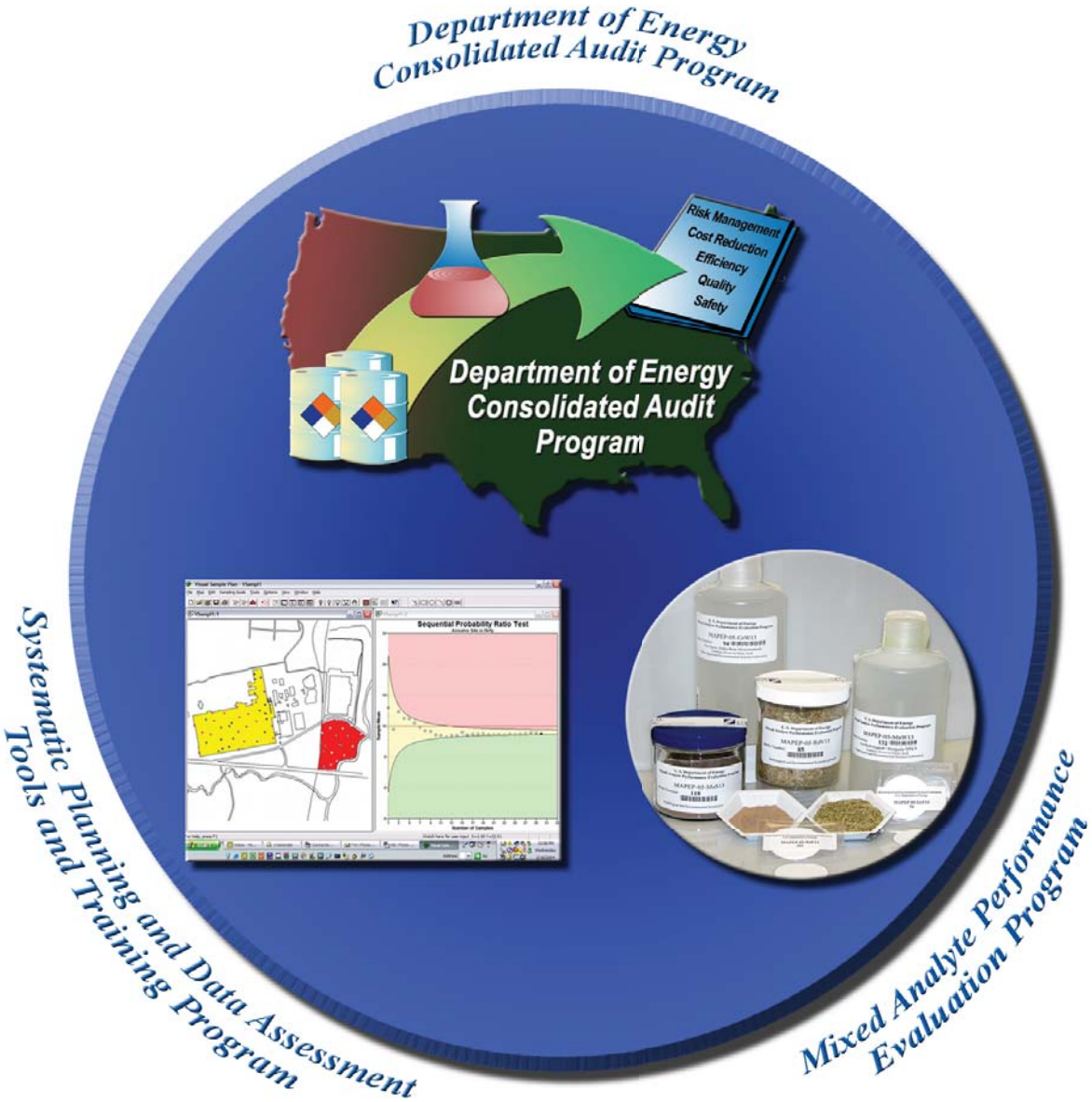
DOE Analytical Services Program
Fiscal Year 2007 Report



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U.S. Department of Energy

Office of Health, Safety and Security

Foreword

One of the priorities of the U.S. Department of Energy (DOE) is to ensure the health, safety, and security of DOE employees, contractors, and subcontractors. To provide the corporate-level leadership and strategic vision necessary to better coordinate and integrate health, safety, environment, security, enforcement, and independent oversight programs, the Secretary of Energy officially established the Office of Health, Safety and Security (HSS). HSS is committed to excellence in protecting the health and safety of DOE workers, the public, the environment, and our national security assets.

A key DOE environmental data quality focus is to ensure confidence in analytical data results and accountability in waste treatment and disposal. The ***"DOE Analytical Services Program, Fiscal Year 2007 Report,"*** provides an overview of DOE's corporate Analytical Services Program (ASP) activities. The ASP is comprised of three components: the DOE Consolidated Audit Program (DOECAP); the Mixed Analyte Performance Evaluation Program (MAPEP); and the Systematic Planning and Data Assessment Tools and Training (SPADAT) Program. The DOECAP is a consolidated audit program with DOE complex-wide participation which focuses on analytical environmental laboratories and commercial treatment, storage, and disposal facilities (TSDF) that have contractual agreements to provide services to DOE. The MAPEP program provides quality assurance oversight through the implementation of its proficiency testing program for analytical laboratories which targets radiological and non-radiological constituents. The SPADAT program focuses on the appropriate type, quantity, and quality of data used to make decisions by DOE sites in implementing their programs.

Benefits derived from the programs include: reduced Departmental liability risks associated with analytical data and the proper disposition of low-level and mixed radioactive waste; elimination of redundant audits; voluntary auditor participation from the Program line and field sites; improved audit quality and consistency; improved data quality and data reliability necessary to assure regulatory compliance and support DOE decisions; and cost avoidance, streamlined acceptance, and enhanced defensibility through the availability of tools used by site personnel to plan data gathering efforts and to assess whether the data collected meets Data Quality Objectives and supports confident decisions.

Key accomplishments of the ASP include; annual audits of 38 laboratories and TSDFs, increased site participation as auditors and points of contact; meeting or exceeding metrics for completion of audit reports and corrective action plans; validation on-the-ground of closure of over 90% of all previous year audit findings; distribution of over 1100 MAPEP samples to more than 120 laboratories (domestic and international) ensuring data quality and consistency; attainment of ISO 17025:2005 Accreditation for Radiological and Environmental Sciences Laboratory (RESL); partnership with DOE Office of Legacy Management (LM) on development of new methods and enhancements for sample planning and statistical data analysis; release of Visual Sample Plan (VSP) 5.0 to over 5000 users; and conducting VSP training at various DOE sites.

Glenn S. Podonsky
Chief Health, Safety and Security Officer

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Acronyms

A2LA ..... American Association for Laboratory Accreditation
ASP ..... Analytical Services Program
CAP ..... Corrective Action Plan
CDC ..... Center for Disease Control
DHS ..... Department of Homeland Security
DoD ..... Department of Defense
DOE ..... Department of Energy
DOECAP ..... DOE Consolidated Audit Program
DOELAP ..... DOE Laboratory Accreditation Program

EDS ..... Electronic Data System

ELAB ..... Environmental Laboratory Advisory Board

EM ..... Office of Environmental Management

EPA ..... Environmental Protection Agency

FY ..... Fiscal Year

HQ ..... Headquarters

HSS ..... Office of Health, Safety and Security

ILAC ..... International Conference on Accreditation of Laboratories

INL ..... Idaho National Laboratory

ISO ..... International Organization for Standardization

LM ..... Office of Legacy Management

MAPEP ..... Mixed Analyte Performance Evaluation Program

MaS ..... Mixed Analyte Soil

NELAC ..... National Environmental Laboratory Accreditation Conference

NIST ..... National Institute of Standards and Technology

ORO ..... Oak Ridge Office

PE ..... Performance Evaluation

POC ..... Point of Contact

PT ..... Proficiency Testing

QSAS ..... Quality Systems for Analytical Services

RCRA ..... Resource Conservation and Recovery Act

RdV ..... Radiological Vegetation

RESL ..... Radiological and Environmental Sciences Laboratory

SOP ..... Standard Operating Procedure

SPADAT ..... Systematic Planning and Data Assessment Tools and Training

TNI ..... The National Environmental Laboratory Accreditation Conference Institute

TSDF ..... Treatment, Storage, and Disposal Facility

VSP ..... Visual Sample Plan

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Executive Summary

This report provides an overview of the Department of Energy (DOE) Analytical Services Program (ASP) activities for Fiscal Year 2007 (FY07). The ASP is managed through the Headquarters Office of Health, Safety and Security (HSS), Office of Corporate Safety Analysis, Office of Corporate Safety Programs, HS-31. Component elements of the ASP are the:

- DOE Consolidated Audit Program (DOECAP);
- Mixed Analyte Performance Evaluation Program (MAPEP); and
- Systematic Planning and Data Assessment Tools and Training (SPADAT) Program.

The ASP experienced two major transitional phases during FY07. On October 1, 2006, Headquarters re-organized the ASP's line organization from the Office of Environment, Safety and Health to HSS. HSS managers received several briefings concerning the ASP, including its many benefits and values to the DOE complex and taxpayers. In February 2007, the DOECAP support services contract also experienced a transition to new contract management. The DOECAP Operations Team remained in-tact and completed a successful transfer to the new contractor parent organization; however, several audits were postponed and required rescheduling to later in the year. Audit reports and corrective action plans (CAPs) associated with these audits were completed prior to the Annual DOECAP 2007 Meeting held in Las Vegas, Nevada in late September 2007. The institutional protocols and procedures of the ASP, the dedication of its managers and staff, and voluntary line and field auditor participation made the two transitions relatively seamless and kept the program on-track, within budget, and successful while achieving program mission, goals, and objectives.

Additional information may be obtained by accessing the ASP web page at http://www.hss.energy.gov/CSA/Analysis/asp.

DOECAP

The DOECAP conducts annual audits of analytical laboratories and commercial radiological waste treatment, storage, and disposal facilities (TSDFs) that have contracts or agreements to provide services to DOE. DOECAP audits are performed on behalf of, and with the voluntary participation of, sites throughout the DOE complex and across all Departmental program line organizations. The intent of this corporate departmental program is to conduct consolidated audits eliminating redundant audits previously conducted independently by DOE field element sites. This program also achieves standardization in audit methodology, processes, procedures and lessons learned, which are applicable to DOE onsite operations. Additional information may be obtained by accessing the DOECAP Electronic Data System (EDS) at https://doecap.oro.doe.gov/.

Specific benefits derived through effective implementation of the DOECAP include:

- Risk Management
- Efficiency
- Cost Reduction
- Audit Quality
- Safety
- Data Quality

In FY07, a total of 38 DOECAP audits were conducted: 27 at commercial analytical environmental laboratories; 4 at government-owned-contractor-operated laboratories located at DOE field element sites; and 7 at commercial TSDFs disposing of, or treating, radiological waste. Those audits included initial and continuing qualification audits, and surveillance for verification of corrective actions (refer to Appendix A, FY07 DOECAP Audited Laboratories and TSDFs).

Common deficiencies cited in DOECAP laboratory findings were related to inadequate procedure content and control, failure to properly perform and document instrument calibration, and poor waste management practices. Common deficiencies cited in DOECAP TSDF findings were related to not following required

processes or a lack of complete and acceptable procedures.

The annual DOECAP audits have validated on-the-ground closure for over 90% of all findings as being properly closed within acceptable time frames. This has resulted in improved performance by the laboratories and waste facilities; increased confidence in analytical data quality; increased regulatory compliance for waste disposal, accountability, and tracking; and improved compliance with ASP and national standards.

Other FY07 DOECAP activities included the following.

- Conducting the DOECAP annual meeting (DOECAP 2007), which was attended by over 130 individuals and brought together DOECAP auditors, Headquarters and field DOECAP points of contact (POCs), analytical laboratory and TSDF representatives, senior DOE management, representatives from other ASP Programs, and representatives from other Federal agencies.
- Revising DOECAP document and audit tools included Revision 2.2 of the Quality Systems for Analytical Services (QSAS) and revisions to all laboratory and TSDF audit checklists.
- Implementing enhancements to the DOECAP EDS to increase system utility and efficiency.
- Planning and conducting an internal assessment of the DOECAP in accordance with DOECAP Procedure AD-1. This assessment was completed and a report submitted to and signed by the DOECAP Manager in September 2007.
- Participating in meetings and conferences with The National Environmental Laboratory Accreditation Conference (NELAC) Institute (TNI), the TNI Environmental Laboratory Advisory Board (ELAB), the Department of Defense (DoD), and the DOE RadWaste Summit.

A continuing programmatic challenge is the low number of Federal auditors participating in DOECAP TSDF audits. At present, the two Federal DOECAP TSDF lead auditors are provided from the DOE Oak Ridge Operations Office. In FY08, the program has identified two additional Federal personnel who will complete the process to become TSDF lead auditors. Initiatives will continue to be made by HSS to canvass all field sites and program organizations having contracts with commercial TSDFs to increase the Federal TSDF auditor pool. Similarly, efforts will continue in FY08 to encourage DOE sites and contractors participating in the DOECAP to qualify additional auditors, as well as encourage non-participating DOE sites and Program Offices to engage in the DOECAP.

MAPEP

The MAPEP provides important quality assurance oversight for environmental analytical services under contract with DOE by performing semiannual performance testing and evaluation of both DOE onsite and commercial analytical laboratories.

The MAPEP distributed two test sessions at the end of the 2007 calendar year; each distribution included mixed analyte water, mixed analyte soil, radiological vegetation and filters, and gross alpha/beta waters and filters. The number of participants continues to be over 120, including 15 international laboratories (see Appendix B). The international laboratories are participating in DOE-sponsored activities or areas of interest.

Performance reports and program information are available on the MAPEP public web page at http://www.inl.gov/resl/mapep. A password-protected MAPEP web page for participants and stakeholders is found at http://mapep.inel.gov.

Other FY07 MAPEP highlights included the following.

- Two distributions of MAPEP Series totaling 1,142 samples will result in participating laboratories reporting over 14,000 analyses.
- Analytical laboratory data quality issues continued to be identified through routine MAPEP performance testing and specialized testing for false-positive, false-negative, and sensitivity evaluations, including issues regarding antimony and refractory plutonium analyses.
- The MAPEP Web-based Reporting and Query System continues to improve by delivering electronic Letters of Concerns at the close of each Series, enhanced query routines and graphics options.
- Radiological and Environmental Sciences Laboratory (RESL) was granted accreditation for Proficiency Testing Provider comprising ISO 43, ISO 17025 and ISO 9001 on February 9, 2007 by the American Association for Laboratory Accreditation (A2LA).
- RESL continued to maintain ISO 17025:20005 General Requirements for Competence of Testing and Calibration Laboratories Accreditation after the first year survey was completed by the A2LA for the quality systems and analytical verification process supporting the MAPEP.
- The MAPEP continued to actively seek customer feedback by: participating in DOECAP bi-monthly laboratory conference calls; presenting important MAPEP information on these conference calls; and at the annual DOECAP meeting. In addition, the MAPEP actively sought feedback throughout the year from their participating laboratories, DOE Field personnel, DOE-HQ personnel and other stakeholders.
- During the year, DOE made a public announcement of an A-76 Standard Competition for RESL activities. An extraordinary effort by personnel was taken to meet milestones for the A-76 process, while at the same time minimizing program impacts.

SPADAT Program

Data Quality is only one of the factors that must be controlled to ensure confident, defensible decisions. DOE must not only ensure that the analytical laboratories are producing high quality results, but also that the appropriate type, quantity, and quality of data are gathered. Decisions influenced by data must employ statistically rigorous methods that account for inherent uncertainties in data. The SPADAT Program helps site personnel, in a statistically defensible manner, optimally plan data gathering efforts and assess whether the data gathered meets Data Quality Objectives (DQO) and supports confident decisions.

DOE leverages off investments made by the Environmental Protection Agency (EPA), Department of Defense (DoD), Department of Homeland Security (DHS), United Kingdom Atomic Weapons Establishment, and Center for Disease Control (CDC) to develop the Visual Sample Plan (VSP) software to support statistical sampling design and data decision assessments. During FY07, a partnership was developed with DOE-LM and several VSP additions were jointly sponsored to support trend modeling, well redundancy evaluations, analyte redundancy assessments, and geospatial plume modeling. Other major VSP additions included methods for composite (multi-increment) sampling, handling less-than-detect values, simultaneous multiple constituents, and nonlinear exponential curve modeling. With over 5000 users, including some from virtually all DOE sites and most regulating entities, VSP is widely recognized as the tool of choice for Systematic Planning and DQO implementation.

During FY07, 2.5 Day VSP training courses were provided for DOE at Grand Junction, Savannah River, Idaho National Laboratory, and Lawrence Livermore National Laboratory. Personnel from DOE, their contractors, and state and EPA regulators participated in each of these training sessions.

FY08 plans include additional Systematic Planning and VSP training courses throughout the DOE complex. The DOE-HSS/Office of Legacy Management (LM) partnership is expected to continue with new VSP methods focused on long-term monitoring. Additional VSP enhancements requested by DOE personnel will be implemented including composite sampling for hotspots, hotspot sampling given existing samples, and several mapping and layering improvements. These efforts will result in minimizing data collection costs and reducing overall sample collection field uncertainty; thereby, enhancing overall data validity and reliability.

Conclusion

In 2007, ASP activities continued to effectively support all Departmental elements with a corporate approach that provides environmental data quality assurance in a cost-effective manner. Improvement efforts included an internal assessment of the program and revision of audit tools. Issues identified during audits and performance tests were itemized for corrective action. In coordination with several other Federal agencies, the ASP continued to develop software toolkits supporting sampling plans and data assessment.

HSS will continue to support this corporate approach to the ASP in close partnership with program offices and field elements.

1.0 Department of Energy Consolidated Audit Program (DOECAP)

DOECAP conducts annual audits of analytical laboratories and commercial waste TSDFs that have contracts or agreements to provide services to DOE. DOECAP audits are performed on behalf of, and with the participation of, sites throughout the DOE complex and across all Departmental program line organizations. Additional information is available on the DOECAP EDS at https://doecap.oro.doe.gov/.

DOECAP ownership rests within the Office of HSS with a Federal ASP Manager located in Germantown, Maryland, providing overall policy direction, guidance, funding, and DOECAP complex-wide leadership. A manager from the DOE Oak Ridge Office (ORO), Office of the Assistant Manager for Environment, Safety and Health, is the DOECAP Manager who provides Federal oversight of the contractor DOECAP Operations Team which is also located in Oak Ridge, Tennessee. The DOECAP Operations Team is responsible for program administration and implementation from audit scheduling and coordination through tracking and coordinating closure of corrective actions. DOECAP Operations Team members are also qualified as DOECAP auditors. The DOECAP core organization is comprised of the ASP Manager, DOECAP Manager, and DOECAP Operations Team.

Beyond the DOECAP core organization, DOECAP lead auditors and auditors, as well as other personnel associated with the Program (i.e., Federal POCs and contractor POCs), all participate on an as-needed basis. DOE Program Offices and sites (i.e., laboratory and TSDF contract holders) participate voluntarily in DOECAP. Participation is motivated by historically demonstrated benefits which encourage lead auditors, auditors, and others to support DOECAP. These personnel have been and continue to be vital to the success and viability of DOECAP. The cost incurred by Program Offices and sites to voluntarily provide personnel to participate in DOECAP is a prudent investment, with a considerable return on investment in the form of significantly reduced costs that would otherwise have been incurred by sites by performing independent laboratory and TSDF qualification audits. The return on investment is further compounded for the Department and the taxpayer by eliminating redundant audits of the same laboratories and TSDFs performed by multiple, independent sites; hence the benefit of pooled resources under a program of consolidated DOE audits. The ability to draw upon voluntary resources from throughout the DOE complex to successfully implement DOECAP and realize significant cost savings for the Department and taxpayer, as well as increase the overall efficiency and quality of the auditing process, is part of the unique history of DOECAP. As a result of DOECAP activities, the necessity for approximately twice the number of audits (i.e., over 40 additional annual audits) throughout the DOE complex is eliminated, resulting in an estimated annual cost savings in excess of $2.3M.

1.1 Background and Scope

In the mid-1990s, the DOE Office of the Inspector General and the General Accounting Office issued reports citing inefficiency, redundancy, and ineffectiveness regarding audits of analytical laboratories conducted by the Department. The reports were critical of using funds from individual DOE field elements to perform redundant audits of the same laboratories, employing disparate audit protocol and criteria.

In response, the Office of Environmental Management (EM) mandated implementation of a consolidated, uniform audit program for conducting annual audits of analytical laboratories in support of EM field environmental decision making with the following

goals and objectives:

- Eliminate audit redundancy;
- Provide a pool of trained auditors sufficient to support consolidated audits; and
- Standardize terms and conditions of existing and proposed contracts to allow acceptance of consolidated audit results.

Photo 1.1 - DOECAP Laboratory Audit

Since that time, audits of TSDFs accepting low-level and mixed radioactive waste, have been added to the scope of DOECAP and the ASP was transferred to the Office of Environment, Safety and Health in December 2003 to provide a broader and more cross-cutting Departmental focus. Then in early FY07, ASP was transferred to HSS. The ASP continues to provide DOE beneficial services through:

- Consolidated audit planning, scheduling, and coordination achieving cost savings for the Department and taxpayers, as well as minimizing impact to contractor laboratories and TSDFs;
- Development and maintenance of standard audit procedures, including standardized audit reports;
- Development of standard qualification requirements, and establishment of a pool of DOECAP-qualified auditors and lead auditors from across the complex to support audits of both laboratories and TSDFs;
- Coordination and centralized tracking of corrective actions and closure of audit findings and observations;
- Establishment of a cadre of DOE and contractor POCs from across the complex, with bi-weekly teleconferences to update POCs and auditors of program-related activities;
- Establishment and maintenance of the EDS to share information; and
- Active participation with state and Federal regulatory agencies, as well as other industry standard-setting groups (e.g., NELAC Institute (TNI), Interagency Data Quality Task Force).

Specific benefits derived through effective implementation of the DOECAP include:

- **Risk Management** – Reduced potential liability for the Department associated with the quality of analytical data used in environmental decision making, and the proper disposition of low-level and mixed radioactive waste and chemical waste, through rigorous DOECAP qualification audits of laboratories and TSDFs. DOECAP TSDF audits also provide an alternative for satisfying requirements established in DOE Order 435.1 for the approval of non-DOE facilities for the storage, treatment, or disposal of DOE radioactive waste.
- **Cost Reduction** – Consistent savings to the Department and taxpayer of at least $2.3M annually derived through audit consolidation and eliminating the need to conduct approximately twice the number of audits throughout the DOE complex.
- **Efficiency** – Increased efficiency through the use of centralized DOECAP functions, managed pro-

cesses for communication amongst stakeholders, and technical and analytical quality standards that can be affixed to any contract.

- **Audit Quality** – Improved audit quality and consistency as a result of forming audit teams from a pool of technical experts in various areas throughout the DOE complex and through the use of standardized DOECAP processes and documents (e.g., checklists, templates).
- **Data Quality** – Improved analytical laboratory performance and data quality resulting from resolution of audit findings through implementation of the DOECAP corrective action process.
- **Safety** – Enhanced safety regarding the handling of DOE samples and waste through verification of compliance with applicable standards and regulations, including conducting of DOECAP regulatory agency reviews as part of TSDF audits.

1.2 FY07 Activities and Accomplishments

1.2.1 Program Activities and Metrics

The following summarizes key activities, as well as any associated metrics for ensuring data quality and consistency, relative to implementation of DOECAP.

Pre-Audit

The DOECAP pre-audit begins with establishing the FY audit schedule and extends to commencement of the on-site audits. The pre-audit may be sequentially segmented into six major steps implemented or facilitated by the DOECAP Operations Team, identified in Table 1.1.

The facility usage query is typically completed and the tentative audit schedule for the next FY08 developed in the fourth quarter of FY07. Audit dates are established and teams staffed as far in advance of the audit as practicable. A goal of providing audit packages to audit team members at least 14 days prior to commencement of the audit is targeted, and generally met unless delays are encountered receiving pre-audit information requested from the audited facilities. Pre-audit conference calls are typically conducted the week before the audit.

A total of 176 laboratory audit packages and 78 TSDF audit packages were distributed to audit team members in FY07.

1.	FY audit schedule developed based upon field response to 'facility usage query' (i.e., laboratories and TSDFs projected to be used by sites throughout the DOE complex)
2.	Audit date set with audited facility (i.e., laboratory or TSDF), and audit notification letter sent
3.	Lead auditor selected and audit team formed based upon sites using the audited facility, personnel availability, and shared DOECAP resources from throughout the DOE complex
4.	Pre-audit information requested from audited facility (e.g., procedures, licenses, permits) for inclusion in audit packages

Table 1.1 - DOECAP Pre-Audit Process

Audit Performance

Audits are performed following a standardized format by teams comprising a DOECAP qualified lead auditor, and an appropriate number of DOECAP qualified auditors determined by varying factors (e.g., audit scope and complexity, personnel availability, individual site interests). In addition, DOECAP auditors-in-training as well as observers may be

authorized by the DOECAP Manager to join the audit team. While DOECAP laboratory lead auditors may be either Federal or contractor personnel, DOECAP TSDF lead auditors are limited to only Federal employees due to the need for DOE accountability for low-level radioactive waste emanating from DOE sites. DOECAP checklists are used to guide auditors through each area of the audit; checklists are available online from the DOECAP EDS at https://doecap.oro.doe.gov/. The six DOECAP laboratory audit areas and associated checklists are identified in Table 1.2, and the seven DOECAP TSDF audit areas and associated checklists are identified in Table 1.3.

The previous DOECAP audit report, as well as the associated Corrective Action Plan (CAP) submitted in response by the audited facility and accepted by the DOECAP Manager, are also used by the auditors to evaluate the implementation and effectiveness of corrective actions and to determine whether those corrective actions warrant the closure of open findings previously issued by DOECAP.

1.	Quality Assurance Management Systems and General Laboratory Practices
2.	Data Quality for Organic Analyses
3.	Data Quality for Inorganic and Wet Chemistry Analyses
4.	Data Quality for Radiochemistry Analyses
5.	Laboratory Information Management Systems and Electronic Data Management
6.	Hazardous and Radioactive Materials Management

Table 1.2 - DOECAP Laboratory Audit Areas and Associated Checklists

1.	Quality Assurance Management Systems
2.	Sampling and Analytical Data Quality
3.	Waste Operations
4.	Environmental Compliance/Permitting
5.	Radiological Control
6.	Industrial and Chemical Safety
7.	Transportation Management

Table 1.3 - DOECAP TSDF Audit Areas and Associated Checklists

In addition to the on-site audit, a review is conducted at the offices of the cognizant regulatory agency(ies) as part of a DOECAP TSDF audit. Regulatory agency reviews may be conducted remotely via telephone conversations with regulatory agency personnel, followed by visits to regulatory agency offices as determined necessary.

In FY07, a total of 38 DOECAP audits were conducted: 27 at commercial analytical laboratories; 4 at government-owned-contractor-operated laboratories located at DOE field element sites; and 7 at commercial TSDFs accepting DOE low-level and mixed radioactive waste and chemical waste. While these audits were primarily initial and continuing qualification audits, four were conducted as surveillances for verification and acceptance of corrective actions.

The 31 FY07 DOECAP laboratory audits were conducted by teams comprising of a total of 144 DOECAP auditors, provided by 9 different DOE sites, for a total of 423 auditor-days on site at the audited laboratories. The 7 FY07 DOECAP TSDF audits were conducted by teams comprising of a total of 53 DOECAP auditors, provided by 9 different DOE sites, for a total of 159 auditor-days on site at the audited TSDFs. A listing of laboratories and TSDFs audited by the DOECAP in FY07 is provided in Appendix A of this report.

Photo 1.2 - DOECAP TSDF Audit

Post-Audit

The DOECAP post-audit extends from completion of on-site audit activities and issuance of the audit report through notifying the audited facility of acceptance of the proposed CAP. It includes entering new findings and updating the status of previously issued findings on the DOECAP EDS after the final audit report has been approved by the DOECAP Manager. The post-audit may be sequentially segmented into the seven major steps identified in Table 1.4.

The process for monitoring the timeliness of completing post-audit activities, first implemented in FY05 as an opportunity for program assessment and continuous improvement, continued through FY06 and FY07. A goal of completing the post-audit process within 110 days after completion of the on-site audit is the current target. The actual average was 118 days in FY07. Figure 1.1 illustrates the post-audit process and provides a comparison of target to average actual time for completing each step in FY07. Many factors have impacted the timeliness of completing the post-audit process, including the time taken to complete a factual accuracy review by the audited facility and the time required to communicate and resolve audit report issues. In light of these factors, FY07 timeliness for completing the post-audit process compared to currently targeted goals is considered acceptable.

1.	Audited facility reviews draft audit report for factual accuracy and resolves any issues with audit team, after which lead auditor submits draft audit report to DOECAP Operations Team for review
2.	DOECAP Operations Team reviews draft audit report, resolves any issues (e.g., ambiguity, incorrect references) with audit team, and submits proposed final audit report to DOECAP Manager for review and approval as well as resolution of any issues not previously resolved
3.	DOECAP Manager reviews and approves proposed final audit report, including resolution of any issues not previously settled, followed by issuance of approved final audit report to audited facility
4.	Audited facility develops CAP in response to audit findings, and submits CAP for review by audit team
5.	Audit team reviews proposed CAP, including resolution of any issues (e.g., corrective action does not adequately address finding) with the audited facility, and notifies DOECAP Operations Team of acceptance (this step is facilitated by the DOECAP Operations Team)
6.	DOECAP Operations Team processes approved CAP and submits to DOECAP Manager for acceptance
7.	DOECAP Manager reviews and accepts CAP, followed by notification of CAP acceptance sent to audited facility (includes DOECAP Operations Team entering CAP into EDS for tracking corrective actions to closure)

Table 1.4 - DOECAP Post-Audit Process

Performance will continue to be monitored and consideration will be given to improving program performance in this area, including adjusting target times based on FY05 through FY07 performance.

A concerted effort to improve the overall quality of DOECAP audit reports continued in FY07. Specific focus was placed upon clear differentiation between findings and observations and ensuring the accuracy of finding and observation citations (i.e., regulatory or programmatic bases). All DOECAP participants (auditors, laboratories, and TSDFs) are continually reminded to focus on audit report quality improvement and timeliness.

Program Participation and Support

A fundamental DOECAP premise is that most DOE sites have auditors qualified to meet certain site-specific needs, which the DOECAP leverages with existing resources to build complex-wide teams resulting in lower cost to any given site, as well as to the Department and taxpayer. Past DOECAP success has been enhanced by sites designating appropriate POCs and submitting technically qualified personnel for qualification as DOECAP auditors. Figure 1.2 identifies participants across the DOE complex that supported FY07 DOECAP audits of laboratories and TSDFs, along with the number and allocation of qualified auditors.

While all DOE sites and facilities benefit from DOECAP, not all site organizations contribute auditor resources on a proportionate basis that is commensurate with their laboratory and disposal facility usage. The Oak Ridge, Savannah River Operations, and Livermore/Berkeley Site Offices continue to provide the majority of auditors that have derived benefits for the entire DOE complex. Conversely, the Richland Operations Office and the NNSA Service Center, which historically have large analytical laboratory service needs and waste shipments, are not participating on an equal basis when compared with other DOE sites that have commensurate

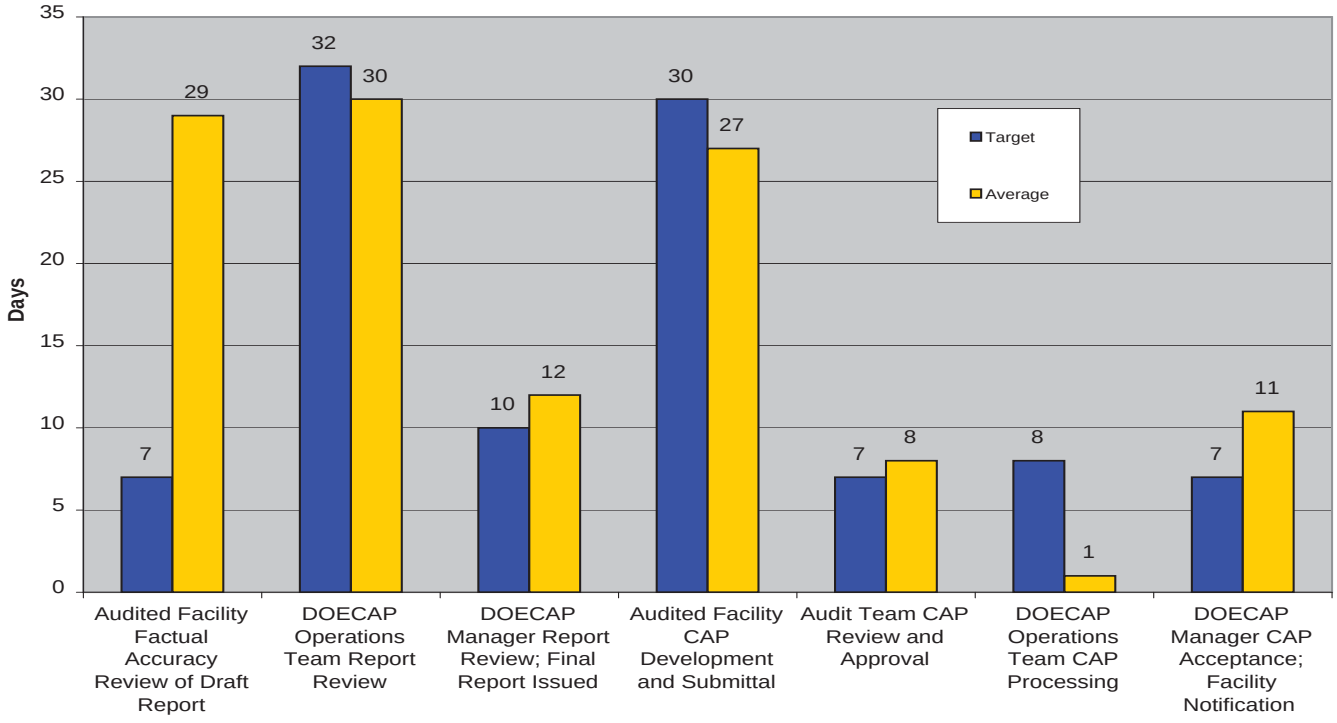


Figure 1.1 - FY07 DOECAP Post-Audit Process Timeliness

use and waste volumes; even though a few contracted commercial laboratories and/or waste vendors are located within a few miles from DOE site locations. HSS will continue efforts to promote the benefits and values of the DOECAP and encourage site active participation in the hopes that a more equal sharing of auditor resources will occur in the future.

Figures 1.3 and 1.4 illustrate DOE participation in DOECAP audits of laboratories and TSDFs, respectively, for the past 3 years.

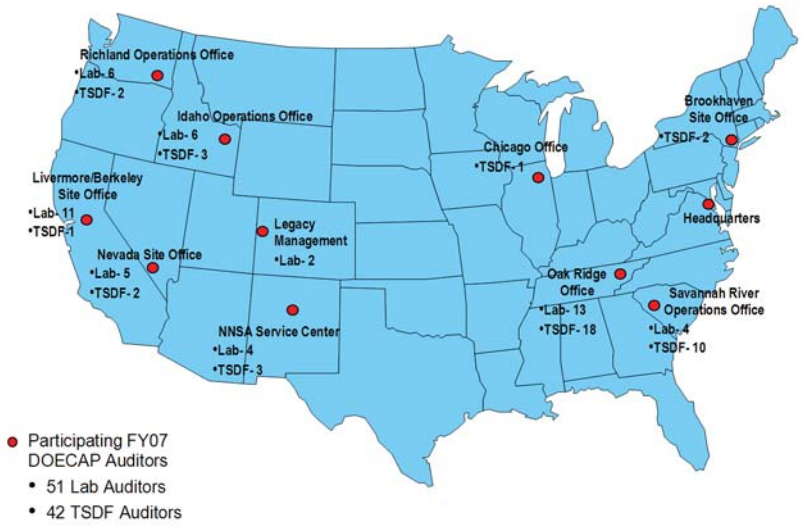


Figure 1.2 - FY07 Participating DOECAP Laboratory and TSDF Auditors

Auditor Qualification and Training

Prospective DOECAP auditors (and lead auditors) are identified by personnel at sponsoring DOE sites and are categorized in a particular audit area or areas (see Tables 1.2 and 1.3 for audit areas). Many auditors maintain qualification in multiple audit areas. Requirements are established in DOECAP Procedure AD-1, *DOECAP Policies and Practices*, regarding submittal of auditor qualification documentation, evaluation and approval. Upon approval by the DOECAP Manager, successful candidates are notified and must complete online DOECAP auditor training prior to receiving DOECAP auditor certification. Each auditor must complete at least one DOECAP audit every two years, and complete periodic online training as required, in order to maintain certification.

As illustrated in Table 1.5, the qualified DOECAP auditor pool increased slightly during FY07. Auditors from several DOE sites added during the year were able to offset losses incurred by site closures and other factors (e.g., reductions in force at other participating sites). Laboratory and TSDF lead auditor numbers remained steady for the year.

DOECAP TSDF audits are led by Federal employees due to the sensitivity and need to account for low-level and mixed radioactive waste emanating from DOE sites. As has been the case in previous years, the three DOECAP TSDF lead auditors qualified throughout FY07 were all provided by DOE-ORO.

	Laboratory	TSDF
Lead Auditors beginning FY07	9	3
Lead Auditors ending FY07	9	3
Auditors beginning FY07	46	38
Auditors ending FY07	51	42

Table 1.5 - FY07 DOECAP Lead Auditor and Auditor Qualification Status

Figure 1.3 - DOECAP Laboratory Audit Participation for Past 3 Years

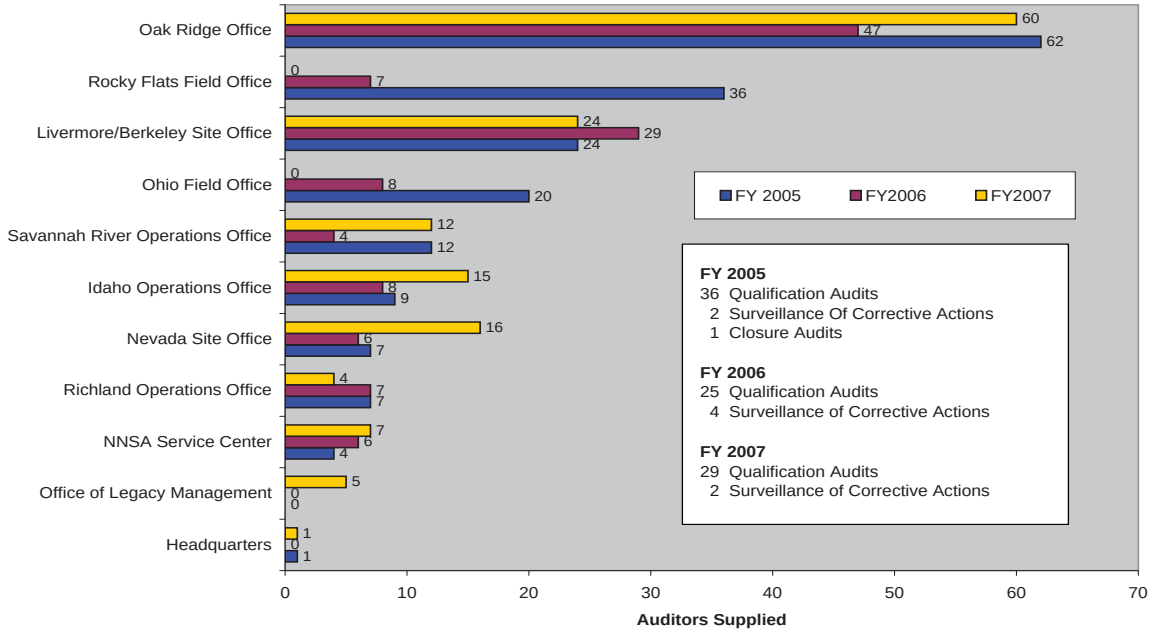
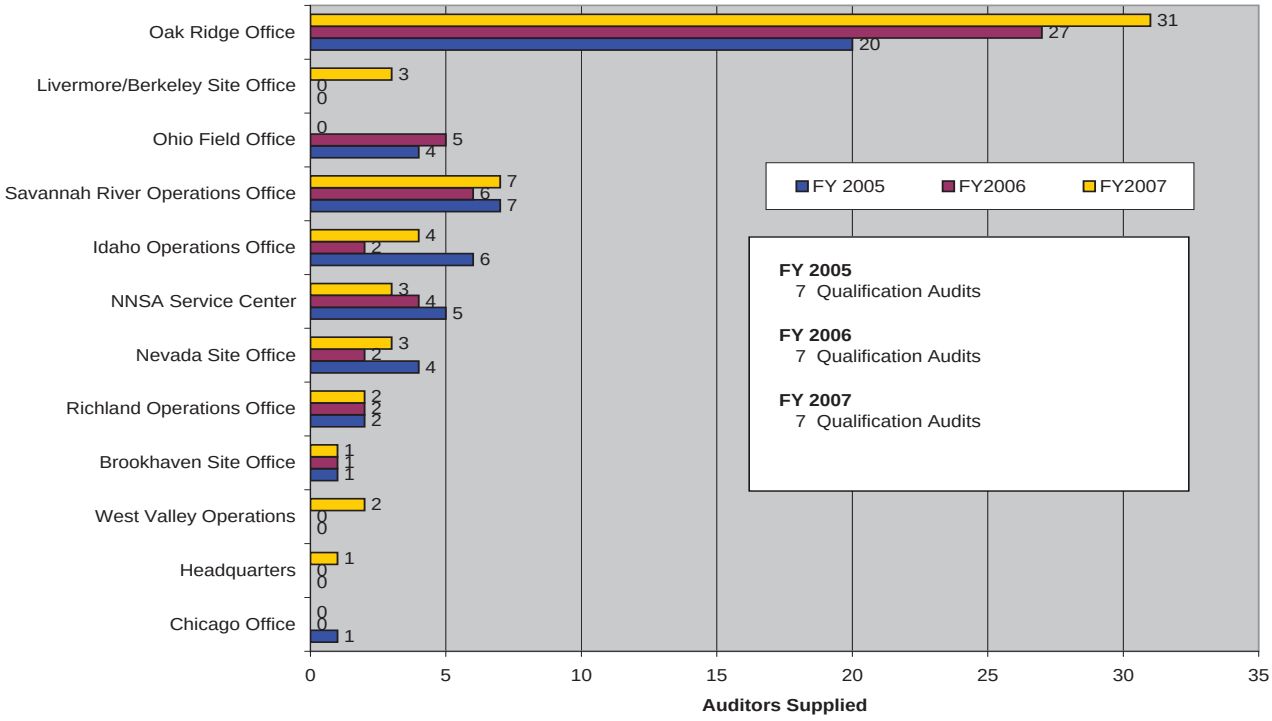


Figure 1.4 - DOECAP TSDF Audit Participation for Past 3 Years



A DOECAP auditor may be qualified in multiple audit areas. Table 1.6 illustrates the distribution of qualified DOECAP auditors at the end of FY07 per audit area. Sites are encouraged to submit prospective auditors for qualification in all audit areas, however, specific laboratory audit areas requiring additional qualified auditors include: Laboratory Information Management Systems and Electronic Data Management; Hazardous and Radioactive Materials Management; and Lead Auditor positions.

EDS Usage

One of the major tools for sharing DOECAP information is the DOECAP EDS. Due to the confidential and potentially business sensitive nature of stored information regarding audited laboratories and TSDFs, access to the inner (i.e., password-protected) portion of the EDS is limited to active DOECAP participants. Individuals are required to sign a confidentiality agreement stipulating conditions for authorized uses of the information. Access for DOECAP non-participants, including representatives of audited laboratories and TSDFs, is limited to the outer (i.e., unprotected) portion of the EDS which contains key DOECAP correspondence and documents, contractual information, and DOECAP contact information. The unprotected portion of the EDS may be accessed at https://doecap.oro.doe.gov/.

In FY07, the protected section of the EDS was accessed in excess of 6,000 times. (Note: The number of times each EDS section was accessed in FY07 is understated due to the EDS user-convenience feature added in FY06 that allows authorized users to transfer from one EDS section to the other without logging in/out or being tracked. In addition, access to the unprotected portion of the EDS is not tracked).

Proposed FY08 Audit Schedule

The DOECAP pre-audit process begins with the DOECAP Operations Team conducting a facility usage query. DOE sites are contacted and requested to identify all projected contracted services with

DOECAP Laboratory Audit Area	Auditors Qualified as of 9/30/07
Lead Auditors	9
Quality Assurance Management Systems and General Laboratory Practices	32
Data Quality for Inorganic and Wet Chemistry Analyses	18
Data Quality for Organic Analyses	21
Data for Radiochemistry Analyses	17
Laboratory Information Management Systems and Electronic Data Management	5
Hazardous and Radioactive Materials Management	9
DOECAP TSDF Audit Area	**Auditors Qualified as of 9/30/07**
Lead Auditors	3
Quality Assurance Management Systems	18
Sampling and Analytical Data Quality	9
Waste Operations	13
Environmental Compliance /Permitting	10
Radiological Control	9
Industrial and Chemical Safety	7
Transportation Management	10

Table 1.6 - FY07 DOECAP Distribution per Audit Area

analytical laboratories and TSDFs, including estimated volume (dollars) of work. Responses to the facility usage query are compiled, evaluated, and presented to the DOECAP Manager for use in developing a tentative DOECAP audit schedule for the next FY.

In order for a laboratory or TSDF to be audited by DOECAP Operations Team, generally the following basic criteria must be met:

1. Usage by more than one DOE site, and
2. Ability to staff an audit team with personnel from sites using the laboratory or TSDF, augmented by auditors from other DOECAP participating sites.

Exceptions may be made by the DOECAP Manager based on extenuating circumstances such as providing a unique analytical or waste processing capability, or the likelihood that additional DOE sites will need services from that laboratory or TSDF in the future.

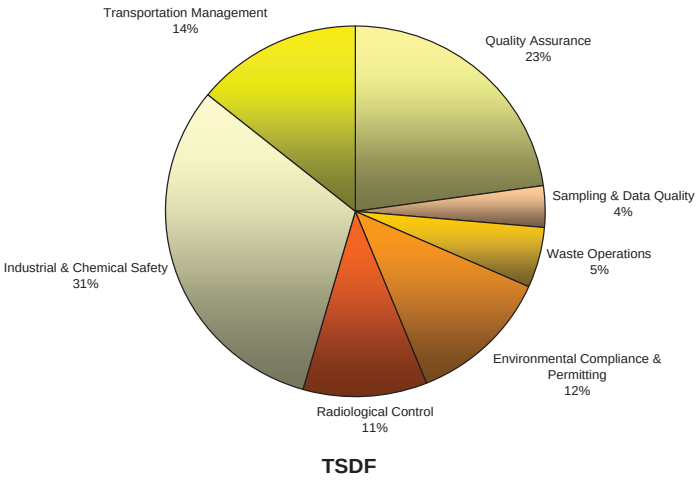
The FY08 facility usage query, completed in the beginning of the fourth quarter of FY07, resulted in the development of the tentative FY08 audit schedule covering 30 laboratories and seven TSDFs. This number of DOECAP FY08 laboratories and TSDFs indicates a consistent usage compared to those services required in FY07. While some DOE site closures (Rocky Flats, Mound, and Fernald) have decreased needs, other DOE activities such as Legacy Management have increased needs.

1.2.2 Audit Findings

A DOECAP finding is defined in DOECAP Procedure AD-1 as a factual statement issued from a DOECAP audit to document a deficiency. Findings are issued in two categories: Priority I and Priority II.

A Priority I finding represents a significant item of concern, or significant deficiency regarding key management/programmatic controls, which in and of itself represents a concern of sufficient magnitude to potentially render the audited facility unacceptable to provide services to DOE if not resolved via immediate and/or expedited corrective action(s). DOECAP issued four Priority I findings in FY07 to two analytical laboratories for: inadequate documentation of analytical sensitivity; incomplete data review processes; systemic failures in radiation protection programs and material accountability; and inadequate radiochemical technical direction. Two of these findings were subsequently corrected during the year by the responsible laboratory and confirmed as complete and acceptable through a follow-up on-site review by a DOECAP team. The two findings at the second facility are still open and DOE-related stop-work orders are in place until confirmation of acceptable closure of the findings can be obtained. All previous Priority I findings (i.e., four issued in FY05 and one issued in FY06) were closed during FY06 with follow-up DOECAP verification.

A Priority II finding represents a deficiency which in and of itself does not represent a concern of sufficient magnitude to render the audited facility unacceptable to provide services to DOE. A total of 370 Priority II audit findings were issued; 313 findings were issued from DOECAP laboratory audits and 57 findings were issued from DOECAP TSDF audits. Also in FY07, 93 percent of previously issued (i.e., issued prior to FY07) DOECAP laboratory Priority II findings were closed or became inactive, as were 94 percent of previously issued TSDF Priority II findings. The inactive finding status was added during FY06 to manage open findings previously issued to audited facilities designated as inactive DOECAP facilities (i.e., dropped from the DOECAP audit schedule due to lack of DOE related contracts), or open findings issued against a particular service no longer offered by that facility. Figure 1.5 illustrates the percent distribution of FY07 Priority II findings by audit area for laboratories and TSDFs.



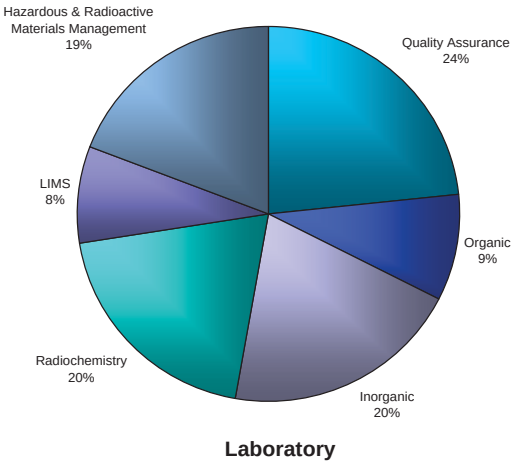


Figure 1.5 - Percent Distribution of FY07 TSDF and Laboratory Priority II Findings per Audit Area

Evaluation of Priority II findings issued to TSDFs and laboratories in FY07 did identify some common deficiencies in some audit areas. The following provides a brief overview of these issues.

- **Quality Assurance**

Formal processes for design change control are not sufficiently established or being implemented and in several instances, quality records do not contain sufficient detail and are not being maintained and stored appropriately. Also incomplete documentation and a lack of complete and acceptable standard operating procedures (SOPs) continues to be noted as a common deficiency.

- **Environmental Compliance**

Several instances of insufficient information, inadequate information, and deteriorated container labeling were noted. Labeling was not being performed per regulatory and permitting requirements.

- **Industrial and Chemical Safety**

Adequate listings of confined spaces are not being maintained and attendants are not always present when confined space entries are performed. Air monitoring practices do not consistently document results for permits, document calibration of instrumentation, and monitor for non-radiological contaminants.

Evaluation of Priority II findings issued to laboratories in FY07 reveals similar common deficiencies. The following provides an overview of laboratory Priority II findings for each audit area.

- **Quality Assurance Management Systems and General Laboratory Practices**

Most findings were related to SOPs, and generally were related to insufficient documentation and review timeliness. Either SOPs were not reviewed within the required time frame, processes defined in SOPs were not documented or not documented correctly, or laboratory personnel were not following SOPs. Calibration issues were the second most cited finding in this area, typically related to mechanical volumetric dispensing devices and measuring and test equipment.

- **Data Quality for Organic Analyses**

Findings were frequently associated with SOP discrepancies and lack of documentation, with insufficient corrective actions and calibration deficiencies being the most significant.

- **Data Quality for Inorganic and Wet Chemistry Analyses**

The most significant findings in this audit area were related to calibration. Calibration issues resulted from the laboratory failing to perform the calibration or failing to perform the calibration correctly. These issues were often related to SOP deficiencies, which was the second most common source of findings in this audit area (i.e., laboratories failed to follow calibration requirements established in SOPs).

- **Data Quality for Radiochemistry Analyses**

Deficiencies cited most commonly were inadequate SOPs. Information was often missing or incorrect regarding formulas and calculations. SOPs often did not contain information necessary to properly perform the analysis. The second most common deficiency cited was incorrect equipment and instrument calibration or inadequate calibration documentation. Several findings issued related to background determinations and combined standard uncertainties.

- **Laboratory Information Management Systems and Electronic Data Management**

The absence of SOPs in this area was the most common deficiency. Information management systems were often put into use with few, if any, SOPs. The second most common deficiency noted was inadequate or incomplete SOPs.

- **Hazardous and Radioactive Materials Management**

Findings were related to waste containers, waste storage, waste disposal and waste management. They resulted from incorrect labeling, improper storage, lack of secondary containment, and generally poor waste management practices. The second most common findings in this area were safety related, with inadequate personal protective equipment being the most identified issue.

Following the identification of these audit findings, each laboratory and waste facility is held responsible to develop and submit a formal CAP to address each finding. These CAPs are reviewed and assessed for compliance with DOECAP requirements as outline in Table 1.4. Follow-on audits have documented that 90% of these findings are being properly addressed by the audited laboratories and facilities and are able to be closed within acceptable time frames. This has resulted in improved facility performance; increased confidence in analytical data quality; increased regulatory compliance for waste disposal, accountability, and tracking; and improved compliance with QSAS and NELAC standards.

1.2.3 Program Document Revision/ Development

The following DOECAP documents and audit tools were revised during FY07.

DOE Quality Systems for Analytical Services Document (QSAS)

The QSAS establishes a single, integrated quality assurance program for analytical laboratories supporting DOE, and allows laboratories to implement a unified standard thus improving efficiency and quality in a cost-effective manner. The QSAS establishes criteria for independent assessments, implemented through DOECAP, to measure quality and promote improvement. Furthermore, the QSAS represents a significant advance toward normalizing analytical data quality requirements across various Federal agencies and

closely follows the approach taken by DoD and EPA. In fact, the QSAS is totally based on EPA's NELAC Chapter 5 – Quality System, based on ISO 17025 – General Requirements for the Competence of Testing and Calibration Laboratories, and also incorporates the EPA's "Performance Approach." However, since NELAC Chapter 5 requirements do not fully address DOE-specific analytical laboratory requirements, information associated with the implementation of these DOE requirements has been added to the QSAS.

Open technical issues from Revision 2.1 of the QSAS, issued in FY06, were resolved in Revision 2.2 which was issued in early FY07 and used for the FY07 DOECAP laboratory audit cycle. In keeping with the intent for the QSAS to be a "living document," technical issues and potential QSAS enhancements were identified and discussed by the laboratory community during the year and at the DOECAP 2007 annual meeting in September. Those discussions will lead to continuing improvements in the document and will result in the finalization of Revision 2.3 of the QSAS in early FY08 prior to commencement of the FY08 DOECAP laboratory audit cycle.

DOECAP Audit Checklists

DOECAP audit checklists are used to implement the audit process, ensure consistency and enhance efficiency. See the sub-section entitled Audit Performance in section 1.2.1 for more information regarding DOECAP checklists, which includes Table 1.2 for a listing of laboratory audit checklists and Table 1.3 for a listing of TSDF audit checklists.

The continuing process to maintain, revise and enhance DOECAP TSDF audit checklists was completed on schedule in early FY07 prior to commencement of the FY07 DOECAP TSDF audit cycle. The primary changes involved transportation updates that comply with new regulations.

The process to revise and enhance DOECAP laboratory audit checklists paralleled revisions to the QSAS and was completed on schedule in early FY07 prior to commencement of the FY07 DOECAP laboratory audit cycle. The primary changes involved a comprehensive overhaul of the inorganic chemistry checklist along with revisions to maintain consistency with QSAS Revision 2.2.

Figure 1.6 - Screen Shot of DOECAP EDS Home Page

DOECAP Auditor Training

Following approval by the DOECAP Manager, an individual is required to complete specified training in order to be certified as a DOECAP auditor. Training modules are provided online on the DOECAP EDS. Revised online training was installed on the EDS and fully functional in early FY07, making it possible for all DOECAP auditors to complete the re-training process prior to commencement of the FY07 DOECAP audit cycle.

1.2.4 EDS Enhancement

The EDS, a screen shot of which is provided in Figure 1.6, is the web-based system providing the information sharing tool and repository for DOECAP. This site is currently maintained within the scope of the DOE-ORO information technology contractor. EDS password-protected information (i.e., audit schedules and team information, audit reports, accepted corrective action plans, key program documentation, on-line training, qualification status) is accessible to designated DOECAP POCs and auditors. EDS non password-protected information (i.e., general program information and documents, contact information, links to related sites) may be accessed at https://doecap.oro.doe.gov/.

A number of improvements and enhancements were made to the EDS during FY07, including the following:

- Separating the DOECAP EDS application from the Oak Ridge DOE web site giving the DOECAP EDS its own web site. This allows for a more secure system, more stability, less "down time," unlimited space and increased system control.
- Adding a "Document Archives Feature" to enable easier navigation through the documents.
- Adding a "Printable Training Feature" at the request of auditors to allow hard-copy reference material to be obtained while on site at an audit.
- Adding a feature to allow users easy access for viewing all training materials as a reference tool.
- Adding a "Search Function" to aid in categorizing and sorting the data. This function is currently only on the Administration side but will soon be added to the Lab and TSDF sides of the EDS. Part of the search function includes an email search allowing maintenance of an up-to-date email list sorted by auditor type, POC or other combinations.
- Adding a "Pre-Audit Package Section" to the EDS. This allows auditors immediate access to the pre-audit packages as soon as the DOECAP Operations Team has the information. Only auditors on a given audit can access that audit's pre-audit material. This alleviates waiting on the mail, saves the DOECAP Operations Team time, and saves money on materials and mailing expenses. Auditors no longer have to return CDs and materials to the DOECAP Operations Team, again saving time and money on shipping. In addition, this allows the auditor continued access the pre-audit material assisting the auditors and DOECAP Operations Team with follow-up issues regarding report editing, CAP review, and CAP acceptance.

1.2.5 Internal Assessment

The first DOECAP internal assessment in accordance with DOECAP Procedure AD-1 was completed in FY07. The assessment was conducted by members of the DOECAP Operations Team. To the extent practicable, review areas were assigned to individuals who had no direct responsibility for the area being assessed. The purpose of this internal, independent assessment was to:

- Evaluate elements of DOECAP implementation for compliance with requirements established in DOECAP Procedure AD-1;
- Determine, document, and assess DOECAP implementation requirements not contained in DOECAP Procedure AD-1; and
- Evaluate adequacy of AD-1, and determine if revision to AD-1 and/or additional DOECAP procedures are required.

Assessment logistics and schedule were established and the DOECAP Operations Team member assessment areas assigned. An Assessment Plan was developed and approved by the DOECAP Manager, and assessment checklists were developed to document lines of inquiry based on requirements established in AD-1 for each program element. The assessment was completed and a report submitted and signed by the DOECAP Manager in September 2007.

1.2.6 Program Oversight

As in previous years, the ASP Manager provided DOECAP oversight through performance of the annual program review, observation of selected audits, participation in routine DOECAP conference calls and participation in the annual DOECAP meeting.

The DOECAP and budgetary reviews were conducted in April 2007 at the Federal Office Building in Oak Ridge, Tennessee, between the HSS Director, Office of Corporate Safety Programs, ASP Manager, DOECAP Manager, and DOECAP Operations Team personnel. Opportunities for improvement and potential barriers to continued DOECAP success were the focus of the review and discussions. The status of established FY07 goals was reviewed and initiatives underway to improve the program were reviewed. The ASP Manager and DOECAP Manager also met with key DOE-ORO personnel (e.g., ORO Manager, ORO Assistant Manager for Environment, Safety and Health) and program participants located in the Oak Ridge area to acknowledge DOECAP support and promote additional participation.

The ASP Manager attended four DOECAP laboratory audits (GPL, EMAX, Paragon Analytics and DataChem) during FY07 to observe implementation of the DOECAP audit process and conduct by the DOECAP audit teams. The ASP Manager also actively participated in one DOECAP laboratory audit during FY07 as a laboratory Quality Assurance auditor-in-training.

1.2.7 Annual Meeting

The DOECAP annual meeting (i.e., DOECAP 2007) was held September 17-20, 2007, in Las Vegas, Nevada, at the Embassy Suites Hotel – Convention Center Las Vegas. The meeting was attended by over 130 individuals, and brought together DOECAP auditors, Headquarters and field DOECAP POCs, analytical laboratory and TSDF representatives, senior DOE management, representatives from other ASP Programs, and representatives from other Federal agencies.

Photo 1.3 - Award Presentation at DOECAP 2007 Annual Meeting

Topics discussed during working sessions included continuing resolution of QSAS technical issues, laboratory and TSDF checklist comments, the FY08 DOECAP audit schedule, and feedback on the DOECAP from both participants, audited laboratories and audited TSDFs. Presentations were made by DOECAP representatives and participants on a variety of subjects including: program status, challenges and opportunities; DOE sites status related to FY07 and projected FY08 DOECAP participation; status of various DOE sites relative to closure; and overall updates of online DOECAP training, DOECAP EDS improvements and the Integrated Contractor Procurement Team Basic Ordering Agreement document status. Presentations were made regarding the other ASP elements; i.e., MAPEP, and the SPADAT Program. In addition, presentations from laboratory and TSDF senior management with specific attention to their DOECAP interaction and implementation from the audited facility perspective were also given. The presentations were informative and well received.

Presentations were also made on topics of general interest to DOECAP participants and audited facilities by representatives from EPA Office of the Inspector General, U.S. Navy Laboratory Quality & Accreditation Office, NELAC Institute (TNI) and the Yucca Mountain Project. Copies of meeting presentations are available on the DOECAP EDS, under either "DOECAP TSDF Documents" or "DOECAP Laboratory Documents," online at https://doecap.oro.doe.gov/.

1.2.8 TNI Participation

One goal of the DOECAP is to actively participate with state and Federal regulatory agencies, as well as other industry standard-setting groups such as the TNI, to promote interagency normalization of analytical data quality requirements.

In FY07, the ASP Manager and the DOECAP Operations Team Technical Operations Coordinator supported TNI standards development activities by participating in the NELAC interim and full meetings. The DOECAP Technical Operations Coordinator is a member of the TNI ELAB and is serving on the Measurement and Technology Workgroup, while Mr. Gary Dechant, a DOECAP auditor, is also a member of the TNI ELAB. The ASP Manager is on the TNI Board of Directors as an ex-officio member and on the TNI Laboratory Accreditation Systems Committee.

The TNI Executive Director attended the DOECAP 2007 annual meeting and gave a presentation regarding the current status of TNI, ongoing initiatives, and interfaces with the ASP.

1.2.9 Program Promotion

The ASP Manager participated in various conferences, workshops and meetings in FY07 to promote the ASP and its various component elements (DOECAP, MAPEP, and SPADAT), as well as seek cooperation and share lessons learned with other government agencies.

In March 2007, the ASP Manager attended and delivered a presentation on the DOECAP auditing activities at the Annual DoD Environmental Monitoring and Data Quality Workshop held in Albuquerque, New Mexico. The workshop brought together Federal and commercial analytical laboratory representatives to discuss auditing methodologies, policies and procedures. Discussions are continuing with the DoD to partner on a number of laboratory audits conducted between DOECAP and DoD's laboratory auditing program.

The ASP Manager gave a presentation at the Third Annual Radiation Measurements Cross Calibration Meeting held in Muscat, Oman (April 2007) on the

proficiency testing results of ten Middle East nations analytical laboratories participating in the MAPEP.

Lastly, to further understanding of waste disposal operations and challenges at TSDFs audited by DOECAP, the ASP Manager attended the Annual RadWaste Summit held in Las Vegas, Nevada (September 2007). Common DOECAP TSDF audit findings were delivered at the meeting.

1.2.10 Review of FY07 Goals

The following provides a brief summary regarding attainment of FY07 DOECAP goals, as identified in the FY06 ASP Annual Report.

- **Program Participation** – Promote DOECAP participation throughout the DOE complex.

  Promoting active DOECAP participation throughout the DOE complex continues to be a challenge due in part to site closures and budgetary restrictions, but remains the focus of continuous efforts. The best assessment of this perennial goal is defined by the continued viability of the DOECAP. Continued support from DOE sites including audit participation, conference call participation, and annual meeting participation has remained constant even as three major DOE sites (Rocky Flats, Mound, and Fernald) have been closed. Current participation is viable, although initiatives will continue to be promoted throughout FY08.

- **Auditor and Lead Auditor Qualification** – Qualify additional DOECAP auditors from all participating sites to adequately staff proposed laboratory and TSDF audits. Also, recruit Federal staff to serve as DOECAP lead auditors.

  Similar to the goal to promote DOECAP participation, this effort continues to be a challenge. In addition to site closures, these initiatives are impacted by subcontractor contract changes at individual sites, personnel changes, retirements, and individual health issues. Therefore, in the face of these conflicts, the attainment of a steady-state zero-change overall pool of auditors is considered a success. The number of DOECAP qualified auditors and lead auditors has remained constant and even increased slightly over the course of FY07. Unfortunately, the goal to recruit additional Federal staff to serve as DOECAP lead auditors was not achieved in FY07.

- **DOECAP Internal Assessment** – Conduct an internal assessment of the DOECAP.

  This goal was met through implementing the DOECAP Internal Assessment Plan and issuing the DOECAP Internal Assessment Report in September 2007. This internal assessment was based on review of program practices and implementation relative to the DOECAP Procedure AD-1. The assessment identified 61 items for improvement that will require attention in FY08.

- **Auditor Training** – Complete revision of online DOECAP auditor training modules to enhance content, improve the trainee interface, and allow continuing training.

  This goal was achieved through completion of updates to training module content, improvements to training formats, and allowing continuing training to be documented. All DOECAP qualified auditors and lead auditors were able to complete retraining on the revised modules prior to participation in FY07 DOECAP audits.

- **QSAS Revision 2.2** – Resolve remaining open technical items from QSAS Revision 2.1 and issue QSAS Revision 2.2 for use commencing with the first FY07 DOECAP laboratory audit.

  As discussed in section 1.2.3 of this report, this goal was met with the issuance of QSAS Revision 2.2. All technical issues remaining open at the time QSAS Revision 2.2 was issued, were discussed at DOECAP 2007, and a path forward for resolution was established. QSAS Revision 2.3, to be issued

prior to commencement of the FY08 DOECAP laboratory audit cycle, will incorporate resolution of all open technical issues.

- **Audit Checklists** – Revise and issue laboratory and TSDF audit checklists incorporating the accepted comments and improvements submitted by participants throughout FY06, and including the necessary changes reflecting QSAS Revision 2.2.

  As discussed in section 1.2.3 of this report, this goal was met. In addition, the FY07 goal to attain DOECAP Manager approval of the draft checklist to be used to guide TSDF audit regulatory agency reviews was also met.

- **Additional TSDF Audit Determination** – Complete the TSDF usage query to determine if the facilities being utilized by the DOE National Metals Recycle Program warrant inclusion in the DOECAP.

  The usage query was completed in FY07, and it was determined that the TSDF contract holders associated with the DOE National Metals Recycle Program currently do not intend to participate in DOECAP. However, it did identify several non-radiological TSDF contracts that may wish to participate in DOECAP.

1.3 FY08 Goals and Challenges

The following summarizes opportunities for improvement and potential barriers to continued DOECAP success.

1.3.1 Program Participation

Site closures (i.e., Rocky Flats, Mound and Fernald) along with other factors continue to present a challenge in promoting DOECAP participation. Potential decline in DOECAP participation represents a primary barrier to continued success and viability. If DOECAP is to continue to achieve goals and objectives previously established, it is essential to increase and sustain participation throughout the complex.

While progress was made promoting DOECAP in FY06 and FY07, proposed FY08 actions/goals will continue to promote DOECAP participation throughout the DOE complex and will include:

- Increase participation within Program Secretarial Offices beyond EM, with special emphasis on National Nuclear Security Administration, Office of Science, and LM;
- Increase participation of currently identified POCs (Federal and contractor) by continuing the initiative commenced in FY06 by requesting replacements for POCs who do not currently actively participate in the DOECAP;
- Increase active participation of sites through teleconferences and the DOECAP annual meeting; and
- Identify and pursue opportunities to increase site participation, particularly sites that use DOECAP audit results without actively participating in the program.

1.3.2 Auditor and Lead Auditor Qualification

As discussed previously in this report, while progress was made with the addition of DOECAP qualified auditors and lead auditors in FY07, attrition of qualified personnel will continue to occur. Accordingly, a FY08 goal is established to continue to seek and qualify additional DOECAP auditors from all participating sites to effectively staff proposed laboratory and TSDF audits. A FY08 goal will also be to continue the recruitment of Federal staff to serve as DOECAP lead auditors.

1.3.3 DOECAP Internal Assessment

A FY08 goal is established to develop corrective actions for all issues identified through the DOECAP FY07 Internal Assessment, and to implement those actions during the course of FY08 program activities.

1.3.4 QSAS Revision 2.3

A FY08 goal is established to resolve remaining open technical items from QSAS Revision 2.2, and issue QSAS Revision 2.3 for use commencing with the first FY08 DOECAP laboratory audit.

1.3.5 Audit Checklists

A FY08 goal is established to issue revised laboratory and TSDF audit checklists incorporating accepted comments submitted by DOECAP auditors and other DOECAP participants throughout FY07, and include necessary changes reflecting QSAS Revision 2.3.

1.3.6 EDS Improvements

FY08 goals for EDS are: to establish multiple role definitions enabling enhanced search-function abilities; to create a one step login system so a separate login is not required to access the bulletin board; to devise a reading or training automatic notification and reminder for new or re-training requirements; to add an Aquatic Toxicity audit and Facility Closure to the team selections and schedules on the laboratory side and Facility Closure to the TSDF side; to complete the application accreditation process associated with writing a security plan and conducting a documented security audit of the system as required by DOE; and to update on-line Lead Auditor Training.

1.3.7 Interagency Cooperation

A FY08 goal is established to continue promotion of interaction with other governmental agencies and departments. Specifically, this will be accomplished through attendance at TNI national meetings, DoD meetings, and the RadWaste Summit by a combination of the DOECAP Manager, the ASP Manager, and other members of the DOECAP Operations Team.

1.3.8 Non-Radiological TSDF Audits

A FY08 goal is established to utilize the FY07 TSDF usage query to gather relevant information (site contracts, pertinent regulations, etc.) pertaining to Non-Radiological TSDFs, to establish preliminary audit checklists, and to perform at least one cooperative facility pilot-audit.

2.0 Mixed Analyte Performance Evaluation Program (MAPEP)

2.1 Background and Scope

The MAPEP is a performance evaluation (PE) program designed to help assure the quality and reliability of analytical data necessary to ensure regulatory compliance and support to DOE's decision making. DOE's RESL administers MAPEP under the direction and guidance of the Headquarters (HQ) Office of Corporate Safety Programs (HS-31). The MAPEP is the only PE program that targets radiological and non-radiological constituents (i.e., mixed analytes) in the same sample for quantification and analytical performance in water and soil matrices. Air filter and vegetation matrices are also prepared for radiological constituents, while gross alpha/beta samples are provided for air filter and water matrices. MAPEP participants can effectively demonstrate their proficiency in radiological, stable inorganic, and organic analyses from single-blind PE samples traceable to the National Institute of Standards & Technology (NIST). MAPEP is performance-based and does not dictate the methodology to be used for the various sample analyses.

MAPEP samples are distributed twice a year in a test session described as a Series. A MAPEP Series refers to the complete set of water, soil, vegetation and air filters per distribution. Within a Series the specific Study refers to the particular matrix and compound classification (e.g., Mixed Analyte Soil [MaS], Radiological Vegetation [RdV]). Laboratory performance on these PE samples is reported by RESL as "Acceptable" (A), "Acceptable with Warning" (W), and "Not Acceptable" (N) according to criteria described in the MAPEP Handbook, which can be found on-line at http://www.inl.gov/resl/mapep/.

Photo 2.1 - MAPEP Performance Testing Standards

Performance results are reported to the individual participants and to the appropriate DOE Field Offices, Sample Management Offices, DOE-HSS HQ, and other MAPEP stakeholders. MAPEP also provides a forum in which analytical deficiencies and areas for improvement can be identified, technical assistance can be requested, and various methodologies can be compared. Auditors from DOECAP review the results of the MAPEP performance evaluations when conducting laboratory audits.

2.2 FY07 Activities & Accomplishments

2.2.1 Sample Distribution and Program Expansion

The MAPEP distributes four matrices twice per year: mixed analyte soil, mixed analyte water, radiological analyte vegetation, and radiological analyte air filters.

In FY04 MAPEP transitioned from distributing one matrix (soil or water) per test session to providing four matrices (soil, water, air filter, and vegetation) per test session. Table 2.1 indicates the increase in total PE sample distribution by MAPEP and analyses performed by participating laboratories from FY05 through FY07. Figure 2.1 illustrates the distribution of PE samples to participating laboratories from MAPEP Series 14 in July 2005 through Series 18 by sample matrix.

Table 2.1 – Increase in Samples Distributed and Analyses by Laboratories

Fiscal Year	Series	Number of MAPEP Samples	Number of Analyses by Laboratories
FY05	13 & 14	1031	10653
FY06	15 & 16	1098	13628
FY07	17 & 18	1142*	14668*

**Includes an estimate for Series 18*

The PE samples for the MAPEP Series 18 test session will be distributed to over 120 laboratories in December 2007 (see Table 2.2). The delay of the MAPEP Series 18 test session distribution is due to RESL's involvement in an A-76 Outsourcing Competition during calendar year 2007. Section 3.1 details the process RESL has undergone throughout FY2007 in relation to this A-76 Competition. Appendix B lists the participating laboratories in Series 18, including 15 foreign laboratories.

Most foreign laboratories are participating in MAPEP as the PE program for the DOE-sponsored Radiation Measurements Cross-Calibration Project in the Middle East. This project is being facilitated by Sandia National Laboratories and the International Atomic Energy Agency. Other foreign laboratories participate in MAPEP when a DOE connection can be provided. Foreign laboratories are using MAPEP to establish

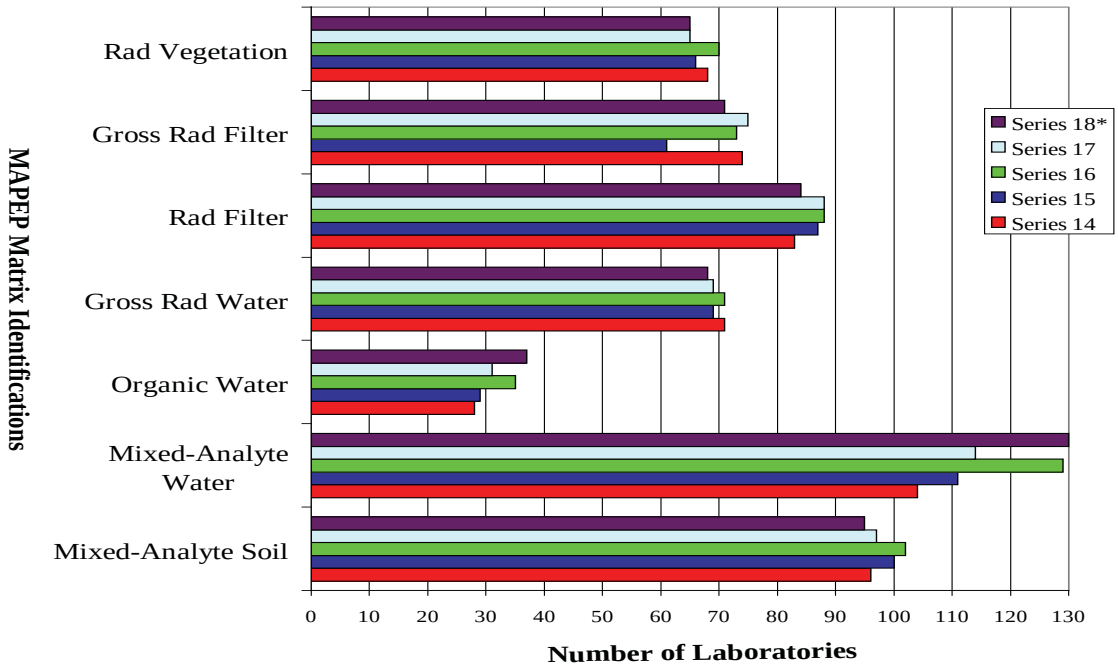


Figure 2.1 – MAPEP Distribution from 2005 to 2007

quality assurance and cross calibration of radiological measurements crucial to:

- Responding in the event of a terrorist attack (e.g., dirty bomb);
- Promoting and monitoring nuclear nonproliferation treaties;
- Providing accurate environmental surveillance; and
- Promoting overall security in the region (i.e., Middle East).

Photo 2.2 - Middle Eastern Participants in the Third Annual Radiation Measurements Cross-calibration Project Meetings, Muscat, Oman (April 2007)

2.2.2 Quality Issues Identified by MAPEP Performance Tests

Laboratories participating in MAPEP are continually reviewed and evaluated for their historical performance. Performance is evaluated within the past two or three Series and across the matrices within MAPEP. It is also evaluated for non-reporting of analytes during a false-positive test or sensitivity evaluation. MAPEP issues a Letter of Concern to a participating laboratory upon identification of a potential analytical data quality problem in MAPEP results, in order to help participants identify, investigate, and resolve potential quality issues. For example, if a laboratory reported results for Pu-239, but not for Pu-238, they would receive a "Not Acceptable" flag for Pu-238, since by reporting Pu-239, they obviously have the capability to also analyze for Pu-238. Laboratories may fail to report an analyte if they suspect it is a false-positive test or sensitivity evaluation. Laboratories have been cautioned repeatedly that they must report a result for radionuclides that they routinely analyze or readily have the capability to analyze for DOE. Fifty-two laboratories after Series 16 and forty-six laboratories after Series 17 were sent Letters of Concern. These letters represent a small fraction of all the analyses performed by MAPEP laboratories during

MAPEP Matrix Series 18	Matrix Id.	Total Labs	Foreign Labs
Mixed Analyte Soil	MaS	84	11
Mixed analyte Water	MaW	117	13
Semi-volatile Organic Water	OrW	37	0
Radiological Vegetation	RdV	54	11
Radiological Air Filters	RdF	74	10
Gross alpha/ beta Water	GrW	59	9
Gross alpha/ beta Filter	GrF	65	6

Table 2.2 – Laboratories Participating in MAPEP Series 18 (2007)

the time frames. Series 16 experienced 52 out of a total 10,653 analyses representing 0.5 percent, while Series 17 experienced 46 out of a total 13,628 analyses representing 0.3 percent. DOE HQ, DOE Field Offices, and the appropriate site contractor personnel were sent copies of these letters in an effort to ensure all stakeholders were aware of the PE results. Letters of Concern specifically address areas of significance to DOECAP, as laboratory participation in PE programs is typically assessed during a DOECAP audit. A memo detailing the criteria used for issuing a Letter of Concern can be found at http://www.inl.gov/resl/mapep and in Appendix C of this report. The sections below summarize the important quality issues identified by MAPEP during the Series 16 and 17 test sessions.

False-positive and Sensitivity Tests

In addition to laboratories demonstrating the ability to accurately report analyte concentrations well above detection limits, they should also be able to detect and accurately measure analyte concentrations at or near detection limits without incorrectly reporting false-positive results. The MAPEP program uses false-positive testing on a routine basis to identify laboratory results that indicate the presence of a particular radionuclide in a MAPEP sample when, in fact, the actual activity of the radionuclide is far below the detection limit of the measurement.

In a sensitivity evaluation, the radionuclide is present at or near the detection level, and the difference between the reported result and the MAPEP reference value is evaluated based on the combined total uncertainties. Laboratories that do not detect the targeted radionuclide are identified. It is also possible to fail a sensitivity evaluation by reporting a false-negative. In this scenario the sensitivity of the reported measurement indicates that the known specific activity of the targeted radionuclide in the sample should have been detected, but was not. In addition to identifying false-positive and false-negative results, the false-positive and sensitivity evaluation tests are designed to help participants ensure they are not under-estimating or over-inflating their total uncertainties.

False-positive tests in earlier MAPEP test sessions sometimes showed as many as 50 percent of laboratories reported false-positives for some radionuclides. MAPEP will continue to include false-positive tests while including more sensitivity evaluations. The sensitivity evaluations work in tandem with the false-positive tests. Table 2.3 provides the results of false-positive and sensitivity tests that were included in MAPEP Series 16 and 17. Figure 2.2 graphically displays Series 16 and 17 false-positive test results. Results are designated as "Acceptable" (A), "Acceptable with Warning" (W), or "Not Acceptable" (N). The laboratories show improvement over earlier performance for false-positive and sensitivity tests.

Series 16 Matrix	False-Positive Test	Sensitivity Test
Soil	NA	Co-60, Pu-239
Water	Ba, Ag, Mn-54	NA
Air Filter	Pu-239, Zn-65	NA
Vegetation	Am-241, Co-57, Pu-239	NA
Series 17 Matrix	**False-Positive Test**	**Sensitivity Test**
Soil	Hg, Se	NA
Water	Cu, Ni, Ag	NA
Air Filter	NA	NA
Vegetation	NA	NA

Table 2.3 – False-positive and Sensitivity Tests Included in MAPEP Series 16 and 17

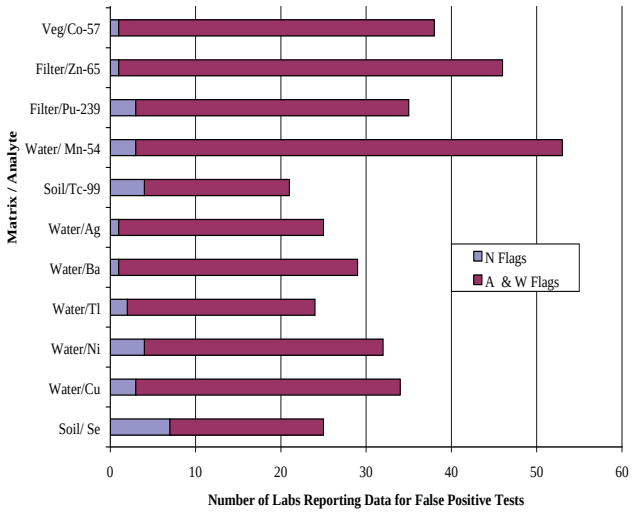


Figure 2.2 - Summary of False-positive Tests

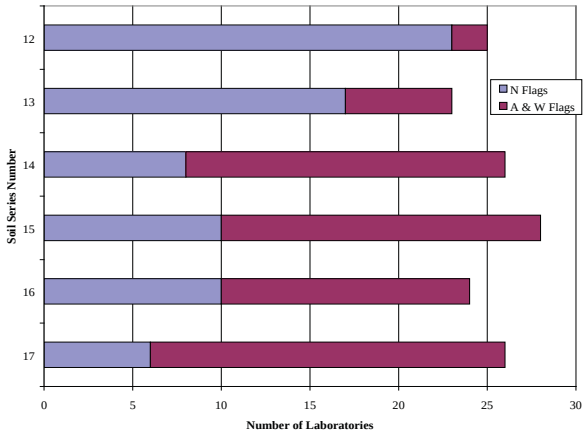


Figure 2.3 - Antimony Results for Soil Studies MaS12 – MaS17

Antimony Analysis in Soil

MAPEP has identified an area of concern for most laboratories that analyze for antimony in soil. NIST-traceable antimony standards have been spiked into the last five MAPEP soil standards starting with S10. The diluent soil contains negligible amounts of antimony so there is essentially no background contribution. In earlier test sessions, only 3 of 24 labs (S10), 2 of 23 labs (MaS12), and 6 of 23 labs (MaS13) showed "Acceptable" or "Acceptable with Warning" performance for antimony. This was improved to 18 of 26 labs (MaS14) and 18 of 28 labs (MaS15). Recent Series have shown similar laboratory performance, with "Acceptable" performance for antimony at 14 of 24 labs (MaS16) and 20 of 26 labs (MaS17). Laboratories that have received consistent "Not Acceptable" evaluations for their antimony results in soil have been sent Letters of Concern. Figure 2.3 details the recent improved performance in the determination of antimony in soil compared to earlier test sessions.

Most laboratories are determining antimony with the hot acid leaching methods associated with EPA Method 3050. EPA Method 3050 (and the updated EPA Method 3050B) use multiple techniques for the preparation of soil samples, which means a laboratory must choose (if allowed by their DOE contract) the appropriate analytical technique for the specific analyte determination. The wording of EPA Method 3050B may also lend itself to varying interpretations regarding which sample preparation technique should be used. However, the method states:

> *"Section 7.5 may be used to improve the solubility and recoveries of antimony, barium, lead, and silver when necessary. These steps are optional and are not required on a routine basis."*

A letter received from representatives of the EPA HQ - Office of Solid Waste and Emergency Response confirmed that antimony in soil requires the use of the alternative Section 7.5 digestion technique to recover the environmentally available antimony. The EPA letter is on file with the MAPEP Coordinator.

Misidentification of Isomers in Organic Compounds

The largest issue of concern for the target organic components has historically been the misidentification of

isomers that exhibit chromatographic retention times very close to one another. Reporting laboratories that fail to accurately validate the quantitation of components reported have received Letters of Concern for misidentification of those isomers. These Letters of Concern alert a participating laboratory to investigate problem areas and initiate corrective actions. DOE field elements maintaining contractual agreements with laboratories that have reported inaccurate test results are also notified through Letters of Concern. DOECAP also follows-up with laboratories which are audited for corrective actions of failed proficiency testing results. The number of letters being issued, however, has remained small; usually about one per sample distribution.

2.2.3 MAPEP Web-based Reporting and Query System Developments

MAPEP has been continually improving the data reporting and data review portion of the Web Site (http://mapep.inl.gov). The following items have been completed as of June 2007:

- provide participants and DOE site personnel with electronic Letters of Concern at the close of each series, and
- provide improved data processing tools and routines.

The changes in the current MAPEP system are a continuation of the effort to fully automate MAPEP data reporting, data evaluation, and customer report portions of the MAPEP system. Figure 2.4 illustrates one of the many query and graphic options available within the MAPEP Web Based System. Although these efforts cannot be construed as a final effort, it will eventually close the circle on the MAPEP project to create a fully automated data handling system for the administration of the program as well as for the reporting of customer data.

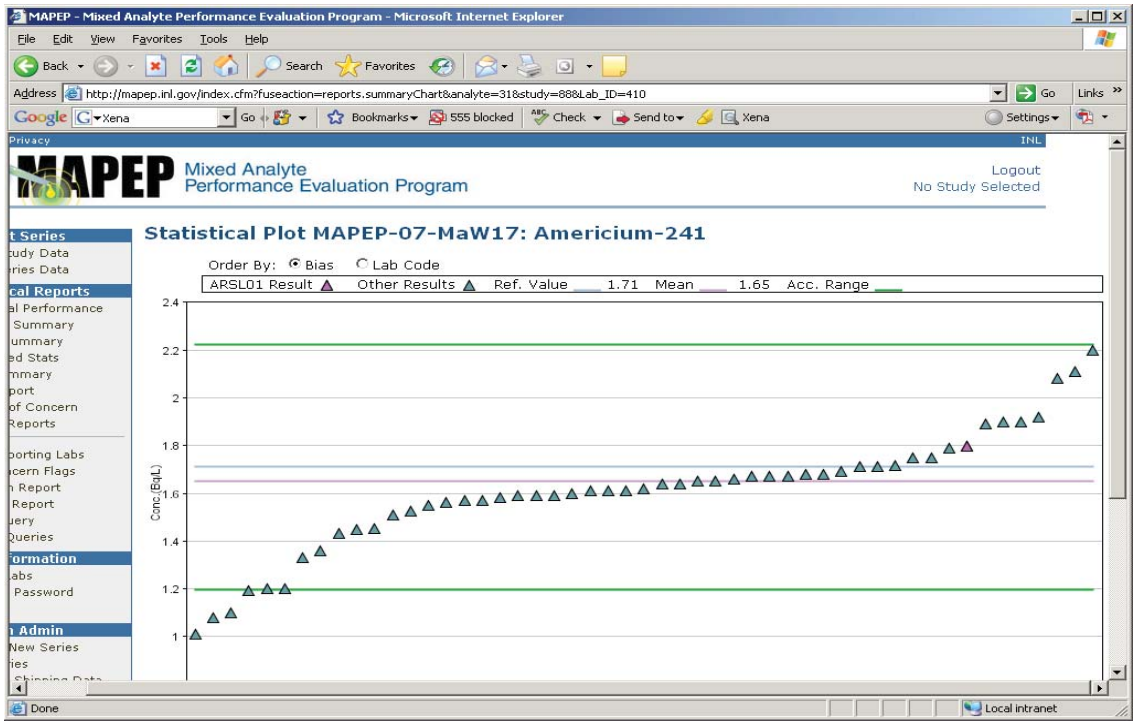


Figure 2.4 - MAPEP Web-based Reporting and Query System Online Graphics

2.2.4 Management and Program Assessments

A-76 Competition

As prescribed in the Office of Management and Budget Circular A-76, dated May 29, 2003, RESL in September of 2006 was notified of DOE's formal public announcement for a Standard Competition that would be conducted in Fiscal Year 2007. The Standard Competition was for a measurement of quality assurance and technical support activities performed at RESL, located at DOE's Idaho National Laboratory. RESL specializes in radiation measurements, calibrations and analytical chemistry. Major programs include the DOE Laboratory Accreditation Program (DOELAP), MAPEP, and the Radiological Measurements Assurance Program. RESL's broad range of chemical separation, measurement, and analytical standards development and preparation capabilities allows it to serve as the federal reference laboratory for these programs. RESL scientists also provide expert analytical chemistry support to DOE-Idaho, the Idaho National Laboratory site contractor, the United States Geological Survey, the Department of Army, and other DOE sites and program offices. The projected end date for the competition will be in December 2007. The A-76 effort took a significant amount of time and effort away from the MAPEP activities in order to accomplish milestones required in the competition. This has resulted in the delayed distribution of Series 18.

ISO 17025 Accreditation

RESL has completed the process of aligning the laboratory's quality systems and procedures to the ISO 17025:2005 General Requirements for Competence of Testing and Calibration Laboratories. ISO 17025:2005 Accreditation was granted by A2LA on January 25, 2006.

Photo 2.3 - Packaging MAPEP Waters for Shipment

Proficiency Testing Provider Accreditation (ILAC G13 and ISO Guide 43)

RESL has completed revising the MAPEP quality systems and procedures in accordance with the ISO 43 Proficiency Testing by Interlaboratory Comparisons as detailed in the International Conference on Accreditation of Laboratories (ILAC) Guide 13:2000. Accreditation was granted by the A2LA for Proficiency Testing Provider on February 9, 2007.

Traceability of RESL to the National Institute of Standards & Technology (NIST)

RESL is currently designated by DOE HS-31 as the reference laboratory for the DOELAP and MAPEP. The Radiological Traceability Program provides for an annual exchange by NIST and RESL of test materials containing a number of radionuclides in various sample matrices (soil, water, air filter, vegetation, synthetic urine, and synthetic fecal). It is designed to provide a mechanism for evaluating the ability of RESL scientists both to prepare test materials of known radionuclide activities, and to correctly analyze test materials of unknown activities. Performance testing standards

are prepared by NIST, sent to RESL and analyzed by RESL for evaluation by NIST. In addition to assuring the measurement processes of RESL are traceable, RESL also sends prepared performance testing standards to NIST for verification of the known reference values. The two-way exchange of performance testing standards assures that the preparation and measurement processes at RESL are traceable to NIST. The first year of the two year cycle for the Radiological Traceability Program traceability of MAPEP radionuclides and matrices to NIST will be completed by the end of the calendar year 2007.

2.2.5 MAPEP Presentations at DOECAP Annual Meeting 2007

MAPEP maintains a close working relationship with DOECAP. The MAPEP Team prepared and presented site updates, program updates and performance testing topics at the DOECAP 2007 meeting in Las Vegas during the week of September 17, 2007. MAPEP continues working with DOECAP by participating in the bi-monthly conference calls and interacting with DOECAP participants and laboratories during the year and at the annual DOECAP meetings.

2.3 FY08 Goals and Challenges

The following provides a summary of the goals and opportunities for improvement for the MAPEP in the coming year.

- Continue developing strategies for increased participation by domestic and international participant laboratories.
- Continue MAPEP chemists' participation in TNI subcommittees for establishing acceptance criteria for radionuclides in environmental performance testing programs and annual proficiency testing frequency (Appendix D).
- Complete RESL's re-accreditation for Proficiency Testing Provider and ISO 17025 Chemical Testing Competency by A2LA.
- Complete a review of current MAPEP participating domestic laboratories to determine their continuing involvement with DOE field and program line organizations.
- Expand MAPEP chemists' program for providing additional technical assistance to participating laboratories.
- Complete the change in distribution times for MAPEP samples from the January-July time frame to a March-September time frame.
- Explore opportunities to promote MAPEP and its importance to the present and future needs of the DOE Complex in documenting and assuring the quality of environmental analyses.

Photo 2.4 - Chemist Analyzing MAPEP PE Samples by Liquid Scintillation Counting for Strontium-90

3.0 Systematic Planning and Data Assessment Tools and Training (SPADAT) Program

Systematic planning is essential to ensure high quality data are gathered to support decisions. Too often the right quality and quantity of data are not obtained the first time resulting in significant cost increases and time delays. In an effort to make the right decisions the first time, systematic planning and statistical data assessment tools are being developed and deployed across the entire DOE complex through the SPADAT Program. Understanding and controlling uncertainties and inherent variations in data used to support key decisions is critical to ensure confident decisions. DOE is supporting the development of Data Quality Objectives (DQO) based methods and tools and providing training to facilitate better, faster, and cheaper approaches to meet regulator requirements while minimizing data gathering and assessment burdens for DOE site applications including accelerated cleanup, facility decommissioning, and legacy management.

3.1 Background and Scope

Data collection and analysis are key elements in DOE's data-driven decision making. It is vital that the data obtained in support of these decisions are the right type, quality, and quantity to support defensible, confident decisions. DOE has embraced the concept of systematic planning for data gathering efforts prior to sampling to ensure the data will support the decisions that must be made with sufficient confidence. Moreover, DOE recognizes the need to account for all inherent sampling and analytical uncertainties using valid statistical techniques when evaluating sample results.

The SPADAT Program develops and deploys expert, user-friendly software that employs sophisticated statistical methods for designing and defensible sampling plans and performing statistical analyses in a visually appealing environment. This technology is transferred throughout DOE through intensive hands-on training sessions. Tools from the SPADAT Program are being employed at every major DOE site.

3.1.1 Visual Sample Plan (VSP)

VSP is a sampling design and statistical assessment software tool that helps the more than 5,000 world-wide users determine the number and location of samples required to be taken to support a variety of data-driven decisions. Once data are gathered, VSP is used to perform data quality assessments and statistical tests to determine whether decisions can be supported with required levels of confidence. Based on the DQO and Systematic Planning philosophy, VSP provides DOE sites with statistically defensible approaches to data gathering and assessment. Leveraging off VSP acceptance and investments by EPA, DoD, DHS, United Kingdom Atomic Weapons Establishment, CDC, and others, DOE is supporting VSP development focused on accelerated cleanup, legacy management, and decommissioning.

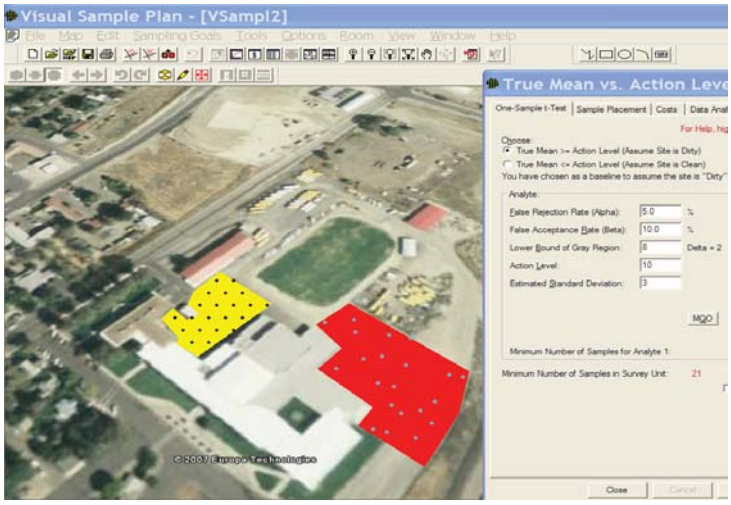


Figure 3.1 – VSP Screen Shot Illustrating Example of Multiple Sample Plans

VSP interfaces with Geographical Information Systems and Autocad systems such that maps, floor-plans, or high resolution images can be imported into VSP and sampling locations visualized. VSP supports a variety of statistical sampling approaches including simple random, systematic, sequential, stratified, rank-set, collaborative, adaptive cluster, transects, and judgmental. Decisions based on mean results or individual measurements and trends are supported.

Some of the specific illustrations of how VSP is being used on DOE sites include sampling designs and data analysis for decommissioning or decontaminating buildings such as the T building at DOE's Mound Site (Figure 3.2). Other applications include sampling of soils, surface water, sediments, groundwater, and streams.

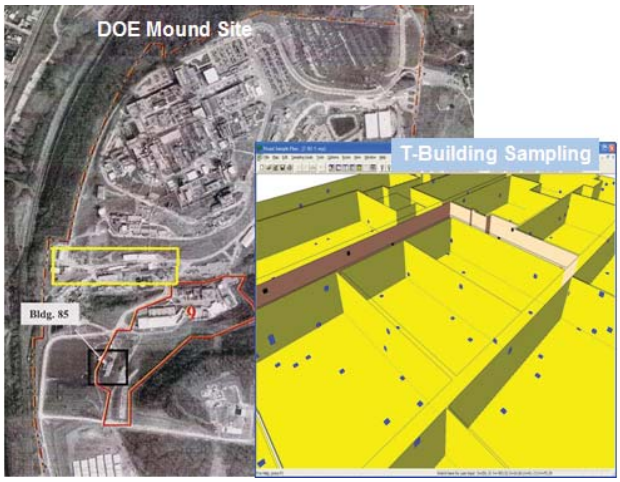


Figure 3.2 – T-Building Sampling Scheme at DOE Mound Site

3.1.2 Training at DOE Sites

Several training courses have been developed and provided to support DOE's efforts to ensure that data gathered substantiate defensible decisions. The objective is to institutionalize systematic planning for environmental decision-making and provide the tools necessary to support all aspects of systematic planning and the DQO Process. The most difficult aspects of the DQO process involve explicit management of decision errors and optimal sampling design.

These training courses have been provided at most major DOE sites and have been very well received. The courses are providing site personnel with the approaches and tools necessary to develop optimal sampling and analysis plans which are easily communicated to and readily agreed to by regulators and other stakeholders.

Photo 3.1 – VSP Class Participants Working Through VSP Case Studies on Their Own Laptops

3.2 FY07 Activities and Accomplishments

3.2.1 VSP New Developments

In FY07 the SPADAT Program supported the addition of several new methods and enhancements to VSP. These additions were in response to items identified by DOE users as their high priority wish-list for future VSP developments. Each of these new developments are outlined and illustrated below.

- **Geostatistical Analysis and Mapping**

  For most DOE sites, samples tend to demonstrate some spatial dependencies such that samples close together tend to be correlated where the correlation between samples diminishes as the distance between samples increases. For several years, DOE users have requested a geostatistical analysis routine be added to VSP that accounts for those spatial dependencies. With the new geostatistical analysis module, spatial variograms and kriging options are now available. These interpolate between samples and produce excellent plume and contaminant concentration maps as illustrated in Figure 3.3.

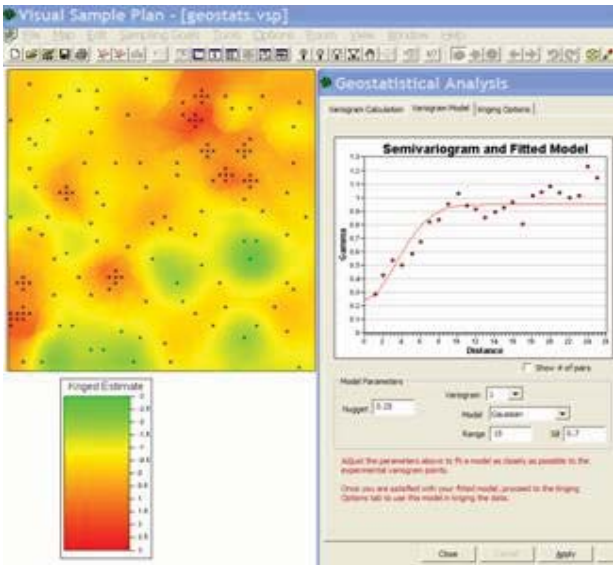


Figure 3.3 - VSP Geostatistical Variogram and Map Showing Areas of High and Low Contamination

- **Less-Than-Detection Statistical Analyses**

  Many DOE sites encounter situations where some of their data are below the detection limits and are reported as less-than-detect values. Often decision makers would substitute values of zero, one-half the detection limit, or the detection limit for those less-than-detect values, causing biased or erroneous summary statistics and decisions. New unbiased methods for handling less-than-detect values in statistical tests were added to VSP. These unbiased methods produce unbiased estimates of means, standard deviations and confidence intervals used for decision making purposes.

- **Hotspot Designs With Measurement Uncertainty**

  One of the most used VSP features by DOE staff and contractors is the Hotspot sampling design module. Previous versions of this module did not account for the fact that due to measurement error a sample could be obtained within a hotspot area, but not be detected as an elevated result. New methods were developed that account for measurement uncertainties when designing a sampling plan for hotspot detection (see Figure 3.4). These new methods are applicable for sampling within buildings, soils, sediments, or any 2-D surface layer.

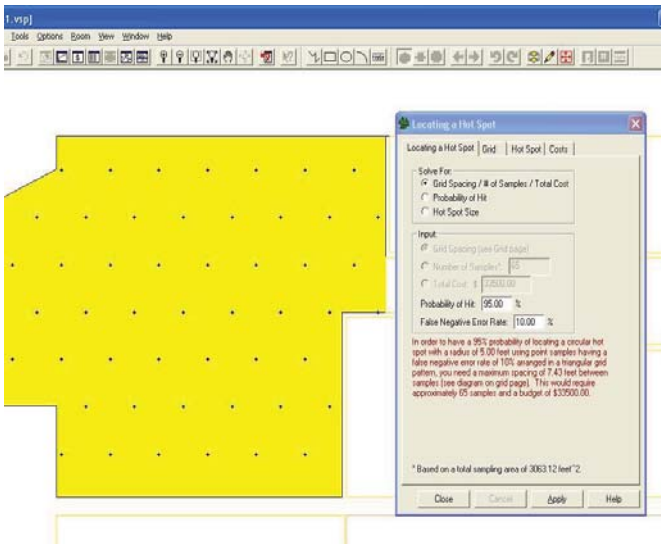


Figure 3.4 – Hotspot Sampling within a Building Adjusting for False-negative Rate

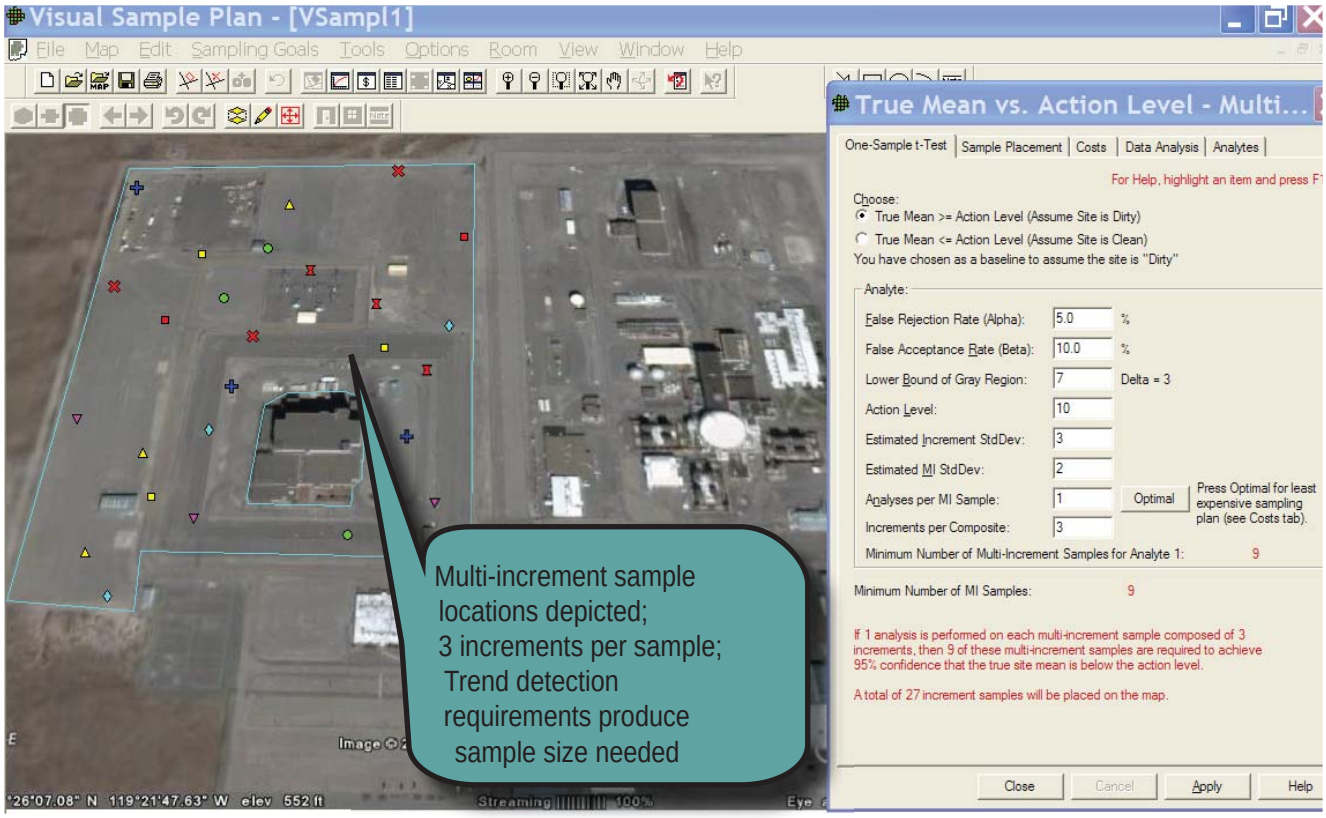


Figure 3.5 - VSP Multi-increment Sampling Module Showing Map and User Dialog Box

- **Multi-Increment Optimal Sampling**

  Many DOE sites recognize that for some contaminant constituents of concern, a more representative sample would be obtained if several increment samples were taken across the spatial domain and then combined into a single composite or multi-increment sample. They then face the question of what is the optimal number of increments versus the number of composites. Methods were developed and deployed in VSP to determine the optimal number of increments and composites for various site conditions and spatial variations. Figure 3.5 illustrates shows how multi-increment sampling can be used to characterize a site.

- **Map and Coordinate View Enhancements**

  Several new features were added to VSP to address items that DOE staff and contractors had requested. These include: support for Latitude / Longitude maps; establishing a lines for areas command for creating outlines around sample areas that don't currently have them; creating a color by value command to automatically color samples as well as sample areas based on the value of a built-in or user-defined parameter; establishing a snap edges command to perfectly align edges and corners of adjacent sample areas when they do not exactly match up; and creating a bisect command to split a sample area into one or more parts.

3.2.2 DOE HSS/Office of Legacy Management (LM) Partnership

A VSP training session was held for the DOE-LM in Grand Junction, CO followed by a workshop to discuss additional LM needs for systematic planning and statistical analysis tools. DOE-LM had already been using VSP on several of its' sites and recognized the significant cost savings, streamlined acceptance by regulators, and time savings that this SPADAT program offers. Several enhancements to the trend modules developed under the FY06 SPADAT program were identified and many new methods were recommended and prioritized.

During FY07, a partnership was formed between DOE-HSS and DOE-LM providing additional funding to support VSP developments targeting LM needs and supporting specific tasks that would directly benefit LM as well as other DOE sites. These additions are listed below.

- **Well Redundancy Evaluation Methods**

  DOE-LM sites and other DOE sites have extensive well monitoring networks. Significant cost savings may be achieved if wells determined to be redundant could be removed from service or sampled less frequently. A new well redundancy evaluation module was added to VSP patterned after analyses performed on Hanford's well network. This method explores the spatial relationships of contaminant concentration data between wells and helps the user determine how many wells might be eliminated while preserving important plume information.

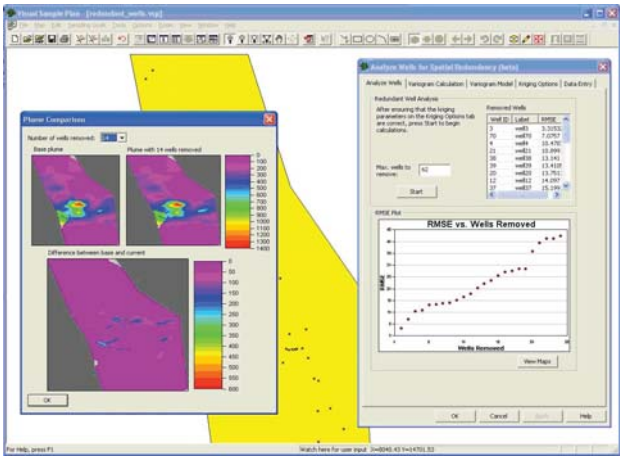


Figure 3.6 - Well Redundancy Module Showing Plume Map and Uncertainty Before and After Removing 14 Wells from this Site

- **Nonlinear Trends and LOWESS Smoothing Functions**

  Much of the LM and DOE site monitoring data follow nonlinear decreasing trends. In FY06, linear trend models and statistical tests were added but no nonlinear trend evaluation methods were available. In FY07, new methods were added to VSP to estimate, test for, and visualize a nonlinear exponential trend and to determine the optimal frequency of sampling in order to detect such a trend. LOWESS smoothing fits were also added. These are shown in Figure 3.7.

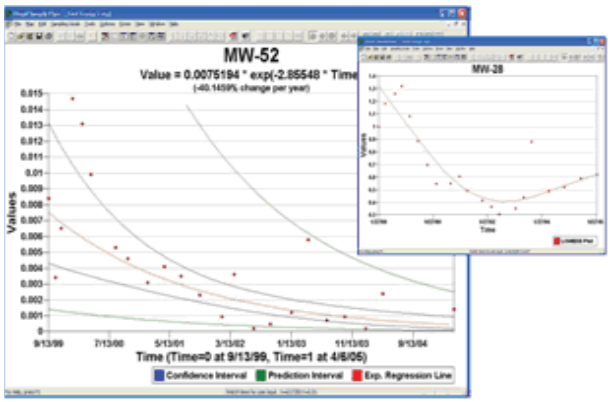


Figure 3.7 - Exponential Curve Fit (left) with Confidence and Prediction Intervals Shown. LOWESS Curve Fit (right insert) for a Well.

- **Well Grouping Analyses**

  Instead of analyzing data from a single well, trend analyses are needed for a group of wells such as up-gradient and down-gradient wells. New options for defining well groupings and performing statistical trend analyses for each group of wells were added in FY07. Figure 3.8 shows a site with wells categorized into four groups with the trend plots for each well in one of the groups. This feature will help DOE staff and contractors to perform analyses quickly and efficiently with a high degree of visualization of trends and patterns across the site.

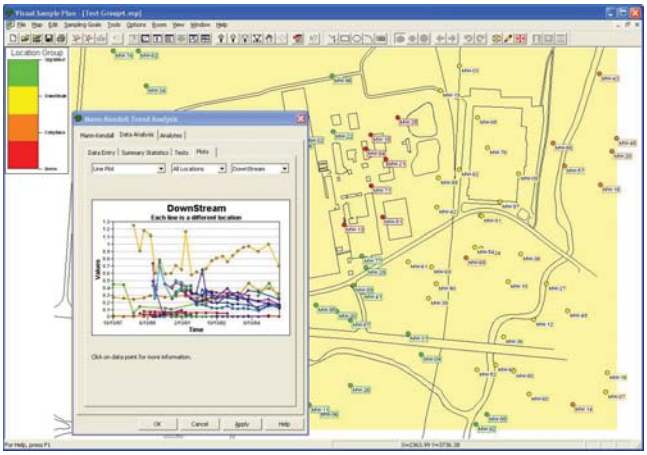


Figure 3.8 – Site Map Showing Groups of Wells and Trends Over Time for Each Well within a Group.

- **Resource Conservation and Recovery Act (RCRA) Startup VSP Version**

  Some DOE-LM sites are under RCRA programs and personnel requested a version of VSP that allowed the user access to only the RCRA supported VSP modules. All VSP modules that provided methods specifically identified in RCRA guidance documents were identified. On the VSP startup menu a new RCRA version was added giving the user access only to RCRA supported methods in VSP.

- **Analyte Reduction Evaluations**

  Whenever a monitoring well is sampled, the laboratory analyzes for many different constituents of concern. The cost of analysis varies greatly between constituents. A new method for evaluating the correlation between constituents was added in FY07. This method provides a mechanism for evaluating whether some inexpensive analyte can serve as a surrogate for more expensive analytes. If so, less frequent analyses for the expensive analytes may be possible, resulting in significant cost savings without loss of information.

3.2.3 Training at DOE Sites

Several training activities sponsored by the SPADAT Program were accomplished during FY07. To become proficient in the many leveraged VSP enhancements supported by DOE, EPA, DoD, DHS, and CDC, DOE offers a 2.5 day VSP training course. This training was conducted previously at Oak Ridge, Los Alamos National Laboratory, Sandia, Hanford, Pantex, Las Vegas, and Mound. In FY07, this course was conducted for DOE site personnel and affiliated regulators at Grand Junction, Lawrence Livermore National Laboratory, Savannah River Site, and Idaho National Laboratory.

Photo 3.2 - VSP Expert Training Gives Users Experience with Many VSP Features and Modules

Course evaluations have been extremely positive with many participants stating this has been the best, most useful training they have received in some time. Site personnel are armed with tools that can help them produce timely, defensible sampling designs and to perform statistical assessments. The courses involve not only DOE staff and contractors, but also regulators and tribes.

The hands-on VSP course provides the participants an opportunity to work through over 18 case studies using various VSP modules and gives them experience in manipulating and visualizing results. By using VSP, site managers working with regulators can quickly evaluate trade-offs between sampling designs and together develop optimal, defensible approaches.

3.3 FY08 Goals and Challenges

The following provides a summary of opportunities for SPADAT Program improvement.

3.3.1 VSP Additions and Appropriate Use of Software Tools

At each of the VSP Expert training courses, a wish-list is generated by the DOE and regulator participants. This wish-list outlines the statistical methods and VSP enhancements that DOE sites feel would be most valuable to add in the future to help them meet their site needs. DOE-HSS plans to support development of some of those VSP methods and enhancements in FY07 and out-years. Some of these improvements include:

- Redesign all dialogs to be in sentence form for ease of use;
- Hotspot detection with existing sample/well locations;
- Add Map/Building Layering Capability;
- Add Outlier Tests and Cost tab to Trend Modules;
- Add Trend Change Detection Methods;
- Add Quasi/random/adaptive fill/systematic options to all sample placement tabs;
- Add 3-D Hotspot Sampling Options;
- Add Stream Sampling Option;
- Improve Sequential and Collaborative Sampling Module;
- Add a Compare Average to Background Nonparametric Unequal Sample Size Module;
- Add a Construct Conf Interval; Nonparametric Method; and
- Include composite sampling over gridded rows/columns to pinpoint hotspots.

3.3.2 Expand and Revamp Training

The initial VSP training has been offered to most DOE sites. However, there are many additional methods and features that have been added which were not covered during the 2.5 day training course. Also, some long-time VSP users have become very proficient with the basic VSP functions, but require additional training

Figure 3.9 - VSP Training Sites

to allow them to use some of the more sophisticated methods (i.e., geostatistical and combined judgment/ probabilistic sampling routines).

In FY08, the 2.5 day VSP training course will be redesigned into two adjacent courses, a beginners/ intermediate course and an advanced course. The beginners/intermediate course will be offered first followed by a 1 or 1.5 day advanced course. Although use of VSP is widespread across the DOE complex, there remains a significant need for the beginners/ intermediate course. This is substantiated by the full attendance at the courses offered to date and the number of people that have not been able to attend given the course size limitations. The advanced course will provide additional training on the new more technically challenging VSP modules and procedures.

Development of the Expert Mentor concept will help guide the user through appropriate selection of statistical sampling design approaches and site/map and sample area setup. This will also be included in the revamped training course to ensure that DOE leverages the investments in VSP by other agencies. Continued training and VSP development will be pursued.

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Appendix A

FY07 DOECAP Audited Laboratories and TSDFs

FY07 DOE Audited Laboratories	
AAL – Assaigai Analytical Laboratories, Inc., Albuquerque, NM	ACC - Accura Laboratories, Inc., Norcross, GA
ACO - BWXT ACO at Y-12, Oak Ridge, TN	ARS - American Radiation Services, Inc., Port Allen, LA
BCL - BC Laboratories, Inc., Bakersfield, CA	CAL - Caltest Analytical Laboratory, Napa, CA
CAI - CEBAM Analytical, Inc., Seattle, WA	DCS - DataChem Laboratories, Inc., Salt Lake City, UT
DFL - Davis and Floyd, Inc., Greenwood, SC	EMAX - EMAX Laboratories, Inc., Torrance, CA
ESO - Eberline Services, Inc., Oak Ridge, TN	ESR - Eberline Services, Inc., Richmond, CA
FGL - FGL Environmental Laboratory, Santa Paula, CA	GEL - General Engineering Laboratories, LLC, Charleston, SC
GPL – GPL Laboratory, Frederick, MD	LLI - Lionville Laboratory, Inc., Lionville, PA
MCL - Materials and Chemistry Laboratory, Oak Ridge, TN	PAL - USEC Paducah Analytical Laboratory, Paducah, KY
PAR - Paragon Analytics, Inc, Fort Collins, CO	PORTS - USEC Portsmouth Analytical Laboratory, Piketon, OH
RMAL - Oak Ridge National Laboratory, RMAL, Oak Ridge, TN	RACL – Radioisotope and Analytical Chemistry Laboratory, BWXT, Lynchburg, VA
S&ME, Inc., Knoxville, Knoxville, TN	SEI - Shaw Environmental and Infrastructure, Oak Ridge, TN
SES – Shealy Environmental Services, Inc., Cayce, SC	SRI - Southwest Research Institute, San Antonio, TX
STA - Severn Trent Laboratories, Inc., Colorado, Arvada, CO	STK - Severn Trent Laboratories, Inc., Knoxville, Knoxville, TN
STR - Severn Trent Laboratories, Inc., Richland, Richland, WA	STS - Severn Trent Laboratories, Inc., St. Louis, Earth City, MO (audit plus follow-up surveillance)

DOECAP AUDITED TSDFs	
DSSI - Diversified Scientific Services, Inc., Kingston, TN	EST - Energy Solutions, LLC, Oak Ridge, TN
ESU – Energy Solutions of Utah, Clive, Utah	M&EC - Materials and Energy Corporation, Oak Ridge, TN
PEC - Pacific EcoSolutions LLC, Richland, WA	PFF- Perma-Fix of Florida, Gainesville, FL
WCS - Waste Control Specialists, LLC, Andrews, TX	

Appendix B

MAPEP Series 18 Participating Laboratories

United States Laboratories

Laboratory Name	Contact City	Contact State
222-S Laboratory	Richland	WA
Accura Analytical Laboratory, Inc.	Norcross	GA
AFIOH/SDRR	Brooks City-Base	TX
Alabama Department of Environmental Management	Montgomery	AL
American Radiation Services, Inc.	Port Allen	LA
Analytical Support Operations - Radiochemical Processing Lab	Richland	WA
AREVA NP Environmental Laboratory	Westboro	MA
Argonne National Laboratory	Argonne	IL
Argonne National Laboratory/Analytical Chemistry Lab	Argonne	IL
Assaigai Analytical Laboratories	Albuquerque	NM
ATL International, Inc.	Germantown	MD
BC Laboratories, Inc.	Bakersfield	CA
BWXT Pantex - D&RMG	Amarillo	TX
BWXT Services - Radioisotope & Analytical Chemistry Laboratory	Lynchburg	VA
BWXT Y-12, Analytical Chemistry Organization Laboratory	Oak Ridge	TN
California Department of Health Services	Richmond	CA
Caltest Analytical Laboratory	Napa	CA
Carlsbad Environmental Monitoring and Research Center	Carlsbad	NM

Laboratory Name	Contact City	Contact State
CH2M Hill Applied Science Laboratory	Corvallis	OR
CH2M Hill RadCon Program Count Room	Richland	WA
Davis & Floyd, Inc.	Greenwood	SC
Department of Environmental Health & Safety	Raleigh	NC
Durateck, Inc. - Bear Creek Lab	Oak Ridge	TN
Eberline Services	Richmond	CA
Eberline Services Oak Ridge Laboratory	Oak Ridge	TN
Eberline Services, Inc.	Albuquerque	NM
EMAX Laboratories, Inc	Torrance	CA
Energy Northwest Environmental Services	Richland	WA
EnergySolutions, LLC	Clive	UT
Environmental Radiation Laboratory	Atlanta	GA
Environmental Science Lab PNNL/ESL	Richland	WA
Environmental, Inc., Midwest Lab	Northbrook	IL
ETTP	Oak Ridge	TN
Fermi National Accelerator Laboratory (FermiLab)	Batavia	IL
Fernald Project	Harrison	OH
FGL Environmental	Santa Paula	CA
Florida Dept. of Health Environmental Laboratory	Orlando	FL
Florida Dept. of Health, Mobile Environmental Radiological Lab	Orlando	FL
FUSRAP	Berkeley	MO
GEL Laboratories, LLC	Charleston	SC
Georgia Power Company Environmental Laboratory	Smyrna	GA
GPL Laboratories, LLLP	Frederick	MD

Laboratory Name	Contact City	Contact State
Hazards Control Analytical Lab	Livermore	CA
ICP Analytical Laboratories Department	Idaho Falls	ID
Idaho National Laboratory	Idaho Falls	ID
ISU - Department of Physics/Health Physics/EAL	Pocatello	ID
Jefferson Laboratory	Newport News	VA
Kennedy Space Center, HP Laboratory	Kennedy Space Center	FL
Lawrence Berkeley National Laboratory	Berkeley	CA
Lawrence Livermore Laboratory	Livermore	CA
Lawrence Livermore National Laboratory	Livermore	CA
Lawrence Livermore National Laboratory - EMRL	Livermore	CA
Lawrence Livermore National Laboratory - HWRL	Livermore	CA
Lawrence Livermore National Laboratory ERAD	Livermore	CA
Life Science Laboratories, Inc.	East Syracuse	NY
Lionville Laboratory Incorporated	Exton	PA
Los Alamos National Laboratory	Los Alamos	NM
MDPH-Radiation Control Program	Jamaica Plain	MA
NASA Plum Brook Reactor Facility Lab	Sandusky	OH
National Air and Radiation Environmental Laboratory	Montgomery	AL
New Jersey Dept. of Health & Senior Services, PHEL, ECLS	Trenton	NJ
Northeast Laboratory Services, Inc.	Waterville	ME
Nuclear Technology Services, Inc.	Roswell	GA
Oak Ridge National Laboratory - Internal Dosimetry Group	Oak Ridge	TN
Ohio Department of Health Laboratory	Reynoldsburg	OH

Laboratory Name	Contact City	Contact State
ORISE/ESSAP	Oak Ridge	TN
Outreach Technologies, Inc.	Broken Arrow	OK
Pace Analytical Services Waltz Mill Site	Madison	PA
Pacific Northwest National Laboratory	Richland	WA
Paragon Analytics a Division of DataChem Laboratories, Inc.	Fort Collins	CO
Public Health Laboratories	Shoreline	WA
Radioactive Material Analysis Laboratory	Oak Ridge	TN
Reactor Technology Complex (RTC) Radioanalytical Laboratory	Scoville	ID
Region 5 EQC Tritium Lab	Aiken	SC
RSA Laboratories, Inc.	Hebron	CT
S&S Onsite Analytical	Findlay	OH
Sandia National Lab - Industrial Hygiene Analytical Chemistry Lab	Albuquerque	NM
Sandia National Laboratories, Radiation Protection Sample Diagnostics	Albuquerque	NM
Sanford Cohen and Associates, Inc.	Montgomery	AL
Santa Susana Field Laboratory	Canoga Park	CA
SC Dept. Health and Environmental Control Radiological Laboratory	Columbia	SC
Scientific Laboratory Division	Albuquerque	NM
SECRA ETTP count lab	Oak Ridge	TN
Severn Trent Laboratories Richland	Richland	WA
SLAC	Menlo Park	CA
Southwest Research Institute	San Antonio	TX
Savannah River Site Environmental Monitoring Laboratory	Aiken	SC
STL Denver	Arvada	CO

Laboratory Name	Contact City	Contact State
STL Knoxville	Knoxville	TN
STL St. Louis	Earth City	MO
Teledyne Brown Engineering - Environmental Services	Knoxville	TN
TestAmerica - Morgan Hill	Morgan Hill	CA
Texas Department of State Health Services Laboratory	Austin	TX
U.S. EPA Office of Radiation and Indoor Air	Las Vegas	NV
UniTech Services Group	Springfield	MA
United States Enrichment Corporation	Paducah	KY
UNLV Radioanalytical Service Laboratory	Las Vegas	NV
U.S. Army Yuma Proving Ground / Material Analysis Lab	Yuma	AZ
USEC, Inc.	Piketon	OH
Washington Closure Hanford	Richland	WA
Waste Sampling and Characterization Facility	Richland	WA
West Valley Nuclear Services	West Valley	NY
WI, DPH, Radiation Protection Section	Madison	WI
WIPP Laboratories	Carlsbad	NM
Wisconsin State Laboratory of Hygiene	Madison	WI
WSRC/Savannah River national Laboratory/ADS	Aiken	SC
WVDP Environmental Laboratory	West Valley	NY
WVDP Radiation Protection Lab	West Valley	NY

International Laboratories

Laboratory Name	Contact City	Contact Country
Chemical Analysis Laboratory	Al-Jaubaiha	Jordon
Environmental Radiation Protection Division	Sharq	Kuwait
Food and Environment Monitoring Center	Muscat	Oman
Instituto de Radioprotecao e Dosimetria	RJ	Brazil
International Atomic Energy Agency	Seibersdorf	Austria
National Radiation Laboratory	Christchurch	New Zealand
Qatar University - Nuclear Physics Lab	Doha	Qatar
Radiation Measurements Laboratory	Amman	Jordan
Radiation Protection Bureau ERHD NMS	Ottawa	Canada
Radiation Protection Service	Weston	Canada
Radioecology	Al-Jadria	Iraq
Royal Scientific Society - Radiation Measurements Lab	Al-Jubaiha	Jordan
Soreq NRC	Yavne	Israel
The Supreme Council for the Environment and Natural Resources	Doha	Qatar
Veterinary Laboratories Agency	Surrey	United Kingdom

Appendix C

Memo Detailing Criteria for the MAPEP Letters of Concern

The following provides a brief overview of the policies and processes associated with issuing and responding to a Mixed Analyte Performance Evaluation Program (MAPEP) Letter of Concern, and its significance to the Department of Energy's Consolidated Audit Program (DOECAP).

The MAPEP issues a Letter of Concern to a participating laboratory upon identification of a potential analytical data quality problem in the MAPEP results, in order to help participants identify, investigate, and resolve potential quality issues. Letters of Concern have been issued since 1996, shortly after the beginning of the MAPEP program. A copy of the Letter of Concern is also sent to DOE/contractor oversight Points of Contact (POCs), including DOE Field Office and Headquarters POCs, and contractor Sample Management POCs. Issued to be informative and not punitive, each Letter of Concern states, "This letter is solely intended to alert your laboratory to a potential quality concern that you may wish to investigate for corrective action." A Letter of Concern is issued to any participating laboratory that demonstrates:

"Not Acceptable" performance for a targeted analyte in a given sample matrix for the two most recent test sessions (e.g., Pu-238 in soil test 13 "+N" (+36% bias), Pu-238 in soil test 14 "-N" (-43% bias));

"Not Acceptable" performance for a targeted analyte in two or more sample matrices for the current test session (e.g., Cs-137 in water test 14 "+N" (+38%), Cs-137 in soil test 14 "+N" (+45%));

Consistent bias, either positive or negative, at the "Warning" level (greater than +/- 20% bias) for a targeted analyte in a given sample matrix for the two most recent test sessions (e.g., Sr-90 in air filter test 13 "+W" (+26%), Sr-90 in air filter test 14 "+W" (+28%));

Quality issues (flags other than "Acceptable") that weren't identified by the above criteria for a targeted analyte in a given sample matrix over the last three test sessions (e.g., Am-241 in soil test 12 "-N"(-47%), Am-241 in soil test 13 "+W" (+24%), Am-241 in soil test 14 "-N" (-38%)).

Any other performance indicator and/or historical trending that demonstrate an obvious quality concern (e.g., consistent "false-positive" results for Pu-238 in all tested matrices over the last three test sessions).

A review period (about two weeks) is provided at the close of each MAPEP test session, prior to the release of final results to DOE stakeholders and the general public, when any laboratory may question or appeal performance evaluation results. All laboratories have the opportunity to respond to a Letter of Concern by contacting the MAPEP Coordinator, and many frequently do so. In addition, laboratories can request additional MAPEP standards at any time for verification of measurement processes, and many have utilized this option.

Letters of Concern specifically address an area of significance to the DOECAP, as laboratory participation in performance evaluation (PE) programs is typically assessed during a DOECAP audit. The DOECAP QSAS, Revision 2.1, (i.e., pages 83 and 84) identifies the corrective action and documentation required for a laboratory to address PE program failure. For two consecutive failures, the laboratory is required to develop and document corrective action(s) to address the cause(s) within 21 days. Corrective action documentation must be available for review during DOECAP audits, and the same documentation should be available for any clients or other stakeholders. If the DOECAP issues a finding in the area of PE performance, including any finding derived from

or associated with a MAPEP Letter of Concern, the laboratory has the opportunity to respond and perform corrective actions through the DOECAP process.

In addition to issuing Letters of Concern, the MAPEP Team provides technical assistance whenever requested, to both MAPEP participants and DOE/contractor oversight personnel. That assistance has helped resolve many quality issues, thereby improving the quality of analytical services and ultimately reducing potential DOE liability. MAPEP

Letters of Concern are instrumental in this process by providing a method of communication that focuses attention on analytical performance, and when used as intended, assists laboratories and DOE/contractor oversight personnel avoid potential quality problems and/or correct quality issues in a timely manner.

It is also important to note that the DOE field site management/personnel, and/or its DOE contractor, that enter into a contractual agreement with an analytical laboratory for field data services, have an important responsibility. They are responsible for assuring that the corrective actions needed to remedy the data discrepancy, as identified by the performance evaluation and testing of MAPEP, satisfy the Department's obligations and provide confidence in the quality, validity, and reliability of the analytical data.

Please contact Guy Marlette or Mary Verwolf for additional information.

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Appendix D

Guidance for Proficiency Testing

Proficiency testing (PT) in the DOE-HSS Analytical Services Program is much more than just a quick check of laboratory performance. PT unequivocally demonstrates the analytical capability of laboratory personnel and procedures at the time of testing. When PT is performed with external standards that use known concentrations of the target analytes, it is one of the best indicators of day-to-day laboratory performance available.

Data validation, onsite assessments, and all other forms of quality control/quality assurance provide a certain degree of oversight and validation, but must be weighed against an analytical laboratory being able to produce acceptable PT results. Too much emphasis is given to quality control measures that cannot even address fundamental questions regarding the accuracy and precision of the reported analytical data. PT with known standards not only addresses the accuracy and precision questions, but also gives laboratories an opportunity to troubleshoot internal quality control problems, provides a proof of process for new analytical methods, can be used to qualify or monitor analysts on specific procedures, and serves many other collateral functions. Passing multiple PTs over time builds confidence in a laboratory's analytical data; but failing multiple PTs over time, ultimately brings the analytical data reported by a laboratory into question. Thus, trending laboratory PT performance over time is one of the most efficient and powerful quality assurance tools available.

PT data are essential for successful onsite assessments. Without the PT data, the assessors are essentially blind and can easily miss critical quality issues. Assessors need the performance data to ensure that the quality systems under review are functional and provide reliable data that are both accurate and precise. Data validation, internal quality control, and operating procedures may appear impeccable, but the performance data can still show that the laboratory reports erroneous analytical results. The PT data can help focus the assessment in areas where performance is known to need improvement, identify the quality control deficiencies, and help provide the technical assistance necessary to improve laboratory performance. Onsite assessments and proficiency testing are complementary, not independent of each other.

The frequency of PT sessions must not over burden the participating laboratories, but the PT is specifically designed to test routine procedures, not research projects. PT samples and routine samples are to be treated and handled the same, from sample preparation through sample analysis. DOE PT samples are full-volume, real-world natural matrix samples homogeneously spiked with National Institute of Standards and Technology (NIST) traceable standards whenever feasible. Single analytes in purified sample media do not realistically challenge analytical methods. By using full-volume, natural matrix material, participants can use their routine sample preparation and analytical procedures. They also cannot "cheat" by analyzing a purified, concentrated solution that was supposed to be diluted and/or compare results between concentrated and diluted sample analyses. The PT acceptance criteria are also designed for routine measurements, therefore several PT samples annually should not place undo hardship on even small laboratories. There is no cost for DOE PT participation or PT sample shipping. Technical assistance is provided upon request. Reporting requirements are not difficult, and they certainly fall within the realm of laboratory customer service for a routine client. Following specific instructions and being able to make simple unit conversions is not a daunting task for laboratory professionals. Contrary to the opinions of many, simple reporting errors are not trivial. Units and decimal places are important. A salary of 50,000 cents is significantly different than a salary of 500,000

dollars. If simple reporting errors are made on "important" PT samples, the reliability of routine reporting is questionable. Objections to frequent PT participation based on any of the above arguments seem warrantless and insubstantial.

The frequency of PT sessions should allow time for feedback from participants and permit time for the laboratory to make necessary corrective actions or other adjustments. If PT sessions become too infrequent, however, the continuity among test sessions will be lost and the PT will no longer reflect day-to-day laboratory performance. Poor performance can not be identified by trending infrequent PT data for several years, thus PT becomes an exercise with little value added. ***The typical analytical laboratory is too dynamic for just one PT session annually. Staff turnover, loss of key personnel, changes in procedures or instrumentation, etc., can directly impact performance. Environmental laboratories under contract with the Department of Energy (DOE) have historically been required to participate in at least four PT sessions annually, one each quarter. After the termination of several federal PT programs, DOE is now on a semi-annual PT schedule***. The quality control personnel from the DOE contracted laboratories were surveyed to determine the desired PT sample matrices and testing frequency. The survey showed a strong desire by the participating laboratories to receive at least two proficiency test sessions per year, each with a full suite of sample matrices and radiological, inorganic, and organic target analytes. ***DOE strongly recommends a minimum of two PT sessions annually, and this recommendation is supported by the majority of our PT participants.***

An important point for the DOE Analytical Services Program is that PT not only tests for laboratory performance, it also helps improve laboratory performance. ***From DOE's perspective, it is preferable to help a cooperative laboratory with poor performance identify and correct their errors as opposed to cancelling contracts and seeking new and unknown service providers.*** The PT identifies performance deficiencies that must be corrected, and technical assistance is provided upon request to help solve these deficiencies. After an iterative process the deficiencies are eventually eliminated and the analytical performance improved. Anytime a deficiency is corrected due to PT participation, the analytical performance of the laboratory is improved. The mechanism for analytical improvement seems self evident and should not be surprising. Correct sample preparation methods, properly calibrated instruments, integrity from the analyst, etc., are all necessary for quality results. By themselves, however, they are not sufficient to ensure quality or demonstrate proficiency. Demonstrated proficiency comes from PT with external standards that have known analyte concentrations. Testing analytical performance against known standards needs to be emphasized whenever the quality of analytical data is being examined.

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