U.S. Department of Energy
Office of Inspector General
Office of Audit Services

Audit Report

Confirmatory Bioassay Testing at Selected Sites

DOE/IG-0773 August 2007

Department of Energy
Washington, DC 20585

August 17, 2007

MEMORANDUM FOR THE SECRETARY

FROM: Gregory H. Friedman
Inspector General

SUBJECT: INFORMATION: Audit Report on "Confirmatory Bioassay Testing at Selected Sites"

BACKGROUND

The Department of Energy maintains a significant inventory of radioactive substances at facilities throughout the United States. To help ensure the safety of its workforce, the Department established a two-tiered approach to biological or "bioassay" testing of workers to determine whether and to what extent they may have absorbed radioactive material. The more intense process mandates biological testing and applies to the relatively few workers with significant exposure risk. When significant exposures are not expected – the situation at most sites and upon which this audit focused – the Department's contractors are required to develop a program to ensure that controls are effective in reducing exposures to radioactive substances. Specific components of the program are left to the discretion of the contractor. However, most rely on continuous air monitoring, radiological surveys, and confirmatory bioassay testing.

Prior Office of Inspector General reviews have identified problems regarding the cost-effectiveness and efficiency of the Department's bioassay monitoring program. Given the current emphasis on worker safety and the obvious dangers posed by excessive radiation exposure, we initiated this audit to determine whether contractor-developed bioassay programs were effectively administered.

RESULTS OF AUDIT

At selected sites, the confirmatory bioassay component of contractor-developed programs to monitor the effectiveness of radiological engineering and administrative controls was not functioning as intended. Specifically, our randomly selected samples revealed that:

- At the Oak Ridge National Laboratory, 16 of the 24 (about 67 percent) of the workers we sampled who regularly accessed radiological areas did not receive all scheduled tests, were either not tested at the prescribed frequency or were not tested for all of the radioactive isotopes to which they may have been exposed;

- About 20 percent (9 of 34) of the radiological workers at the East Tennessee Technology Park were not tested at the frequency prescribed for all of the isotopes to which they may have been exposed; and,

- For over 20 percent (7 of 30) of the employees at the Nevada Test Site (NTS), required documentation could not be provided indicating whether or not they were properly enrolled into the bioassay program. We also identified individuals at NTS that had either never been selected for testing despite being enrolled in the program or who were enrolled in the program but not tested as required.

Further, we concluded that site-level safeguards for the bioassay component of the contractor-developed monitoring program were inadequate and that Federal reviews by the Department were not always sufficient.

In contrast to the confirmatory bioassay program administration issues we identified, our audit revealed that individuals were being tested in accordance with site-level procedures at the Y-12 National Security Complex and the Savannah River Site. Further, to the Department's credit, we noted that sites have developed radiation protection programs for bioassay monitoring and that many of the laboratories and analysis procedures were accredited under the Department of Energy Laboratory Accreditation Program.

While these actions are noteworthy, without an improvement in the control process over personnel monitoring, Department and contractor employees may be at risk for occupational exposures to radioactive material that might not be detected. As our audit demonstrated, opportunities exist to improve the reliability and effectiveness of the confirmatory bioassay process employed by contractors. In that connection, we made several recommendations designed to ensure that monitoring and testing for radiological workers is appropriate.

We also noted other matters for consideration (described in Appendix 1) pertaining to costs associated with providing bioassay services. In particular, we observed that the sites had not fully embraced cost reduction-related recommendations made in our report on *In-Vitro Bioassay Services at Department of Energy Facilities* (DOE/IG-0458, February 2000).

MANAGEMENT REACTION

The National Nuclear Security Administration (NNSA), as well as, the Offices of Science (Science) and Environmental Management (EM) provided comments on the report. The NNSA generally agreed with the report and concurred with the recommendations. Science and EM indicated that they would work with contractors to assure that local testing regimens are clearly stated and are being accomplished, however, they did not concur with the recommendations. Those offices noted that Federal regulation does not specifically require bioassay testing and that they would not compel employees to comply with contractor-established testing programs that were designed to help ensure the effectiveness of radiological controls if the employee chose not to do so. They based

their position on the view that bioassay testing is a lagging indicator and that air monitoring, combined with radiation and contamination surveys, are the preferred options for verifying the effectiveness of protective controls.

While the Office of Inspector General recognizes that bioassay testing for the class of individuals examined in this report was not specifically required by regulation, neither are air monitoring and radiation surveys. Rather, contractors are required to develop a program, based on site-level work environments, to verify that workers are adequately protected. Our review focused on whether the confirmatory bioassay testing component of contractor-developed protection programs – a component sanctioned and funded by the Department for many years at considerable cost – was functioning as intended. We found that it was not at the sites identified in the report. Management's comments are included in their entirety as Appendix 4.

Attachment

cc: Deputy Secretary
Administrator, National Nuclear Security Administration
Acting Under Secretary of Energy
Under Secretary for Science
Chief of Staff

REPORT ON CONFIRMATORY BIOASSAY TESTING AT SELECTED SITES

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CONFIRMATORY BIOASSAY TESTING

Background

The Code of Federal Regulations requires biological testing and monitoring as part of a program to protect individuals from the harmful effects of radiation. Department of Energy (Department) regulations specify that site contractors must develop their own method to verify that radiological engineering and administrative controls are effective in preventing radiation exposure. Contractors are permitted to take actions such as performing air monitoring, conducting radiation and contamination surveys, and using bioassay monitoring to confirm the effectiveness of such controls. At each of the sites we reviewed, contractors had elected to use confirmatory bioassay testing as a part of their protective program and had developed site-level procedures outlining testing requirements. As part of their program, contractors describe specific isotopes to which an individual may be exposed and for which testing is required by preparing Radiological Work Permits (Work Permit) that govern the conduct of operations for each work area/task. Workers are required to "sign-in" on the Work Permit each time they enter the radiological area.

Bioassay Program Administration

Our review found that the Department's site contractors had not ensured that all personnel that had regular access to radiological areas were being monitored in accordance with established site-level requirements. In particular, testing and methods used to track potential exposures did not conform to contractor-developed procedures.

Monitoring Issues

Although each of the sites visited had developed and implemented monitoring programs designed to protect workers, we identified problems with the timing and sufficiency of tests and the maintenance of work history and potential exposure records. While sites recognized the potential health consequences associated with exposure to radioactive material, we noted that some workers were not tested at the frequency prescribed by the site and others were not tested for all the potential hazards to which they may have been exposed. For example:

- At Oak Ridge National Laboratory (ORNL), over 65 percent (16 of 24) of the employees in our sample were not tested in accordance with the site's monitoring requirements. While certain individuals were not tested because of database deficiencies, the majority had not

submitted to testing as scheduled despite being notified of the requirement. Cancelled or missed appointments were supposed to be rescheduled through the bioassay system; however, rescheduled appointments were often delayed or missed. For example, one individual only met two of seven required tests over a 14-month period. During this time period, the individual worked in areas where she was potentially exposed to isotopes such as iodine-131, which may increase a person's risk for developing thyroid cancer. Although this particular individual did obtain some whole body radiation screenings (referred to as "counts") on a bi-monthly basis, she cancelled 29 of 31 scheduled appointments for bioassay testing over a 14-month period. According to a site official, this individual indicated that she did not submit to testing because she believed, based on her knowledge as a scientist, that the frequency of testing was unnecessary.

In addition, we also found instances where individuals – even though they had been tested for certain constituents – were not tested for all of the isotopes to which they may have been exposed. For example, an individual was to be tested on a quarterly basis, beginning in April 2004, for technetium-99 (TC-99), which is excreted rapidly from the body. In 2004, three appointments for this test were scheduled, all of which were cancelled. Because of the rapid excretion of TC-99, a late make-up test may not be sufficient to detect exposure. This individual continued to work in radiological areas where TC-99 was identified as an isotope of interest throughout 2004 and part of 2005.

Our ability to determine the full extent that appointments were not kept – and the site's ability to monitor the performance of its workforce in that regard – was hampered by record keeping problems. For example, a bioassay official routinely changed status records for appointments from "unmet" to "cancelled" without maintaining supporting information. This matter came to our attention when site officials provided listings that were inconsistent with previously provided data. The employee responsible for the changes stated that he made them to "clean up the system." Additionally, it was noted that certain controls built into the system could be easily circumvented by

inserting codes that could allow officials to skip entering information critical to identifying radiological intakes.

- Similarly, at the East Tennessee Technology Park (ETTP), over 20 percent (9 of 34) of employees in our sample were not tested for isotopes as specified in the site's Work Permits. These individuals were not scheduled or tested at the frequency prescribed in applicable Work Permits. For example, four of these individuals were not scheduled in a timely manner, and, as a result, over 25 percent of required tests for uranium isotopes were at least three weeks delinquent. Testing for uranium isotopes, in this case, was required to be conducted monthly. While site officials told us that these individuals were eventually tested and that the testing provided adequate protection, we noted that testing intervals in each case exceeded scientifically determined test intervals contained in each Work Permit. The calculated intervals – which site officials believed to be accurate – considered factors such as radiation decay and bodily excretion rates.

- Twenty-three percent (7 of 30) of the employees in our sample at the Nevada Test Site (NTS) were tested for exposure to radiological hazards even though the site could not provide documentation supporting the need for them to be enrolled in the bioassay program. For a number of individuals in our sample, NTS was unable to provide documentation that would support entry into the bioassay program even though it was specifically required by site level policies. An NTS official stated that "it would be a research project" to reconstruct an individual's radiological work history. Without such history, NTS cannot ensure that these and other individuals should have been tested at all, at the required frequency, or for all the potential isotopes to which they may have been exposed. Since the completion of our field work, NTS officials informed us that they were now taking actions to revise existing procedures to formalize their enrollment process.

- Certain other individuals at NTS were not tested even though they were assigned to the bioassay program. We identified two radiological workers that were not selected by health physicists for testing during the three-year period we reviewed. Another employee we

evaluated was not tested at the required frequency for all the isotopes as prescribed by the bioassay testing plan to which he or she was assigned.

Site Level Controls

These conditions occurred because site-level controls designed to ensure that workers complied with bioassay requirements and methods used to select individuals for testing were not always effective. In addition, the database systems used for tracking participants and identifying them for testing were not properly maintained. Further, Departmental monitoring of the bioassay program at the sites we visited was insufficient.

Controls and Sanctions

During the course of our audit work, we identified weaknesses in the controls used to implement site-level confirmatory bioassay programs. In particular, site officials stated that much of the responsibility for compliance with bioassay program requirements rested on the individual worker and few, if any, sanctions were applied if an individual did not comply. For example, at ORNL, site officials indicated that there were no work restrictions for not submitting required confirmatory bioassay samples and we identified a number of employees that routinely cancelled bioassay appointments. Of these, one individual cancelled 19 consecutive bioassay appointments in a seven-month period. During this time, this employee was still able to perform radiological work.

We also noted inconsistencies in the design and conduct of the bioassay program at ORNL that could lead to a breakdown in the implementation of their program. Specifically, an ORNL bioassay program document states that full participation is not required for the confirmatory bioassay program, and an isolated failure by a few individuals to submit samples does not constitute a programmatic failure. However, this document does not detail what an acceptable percentage of non-participation would be and site officials would not articulate what they believed to be the appropriate level of participation. Site officials also told us that they could not demonstrate that at least one individual from each Work Permit was being tested. Without this validation, a risk exists that exposures could be undetected for a particular work activity.

Finally, a 2005 Benchmarking study of the ORNL Internal Dosimetry Program completed by the Savannah River Site as part of a peer review, noted issues similar to those we found – that a significant fraction of routine urine bioassays were not being submitted. Since confirmatory bioassay at ORNL is used to verify that engineering and administrative controls were effective in the protection of personnel from radiological hazards, the study noted that noncompliance by a large fraction of the workforce makes this claim difficult to defend. ORNL's program documentation also acknowledges the importance of its confirmatory testing program by noting that a large fraction of significant exposures have been detected through the bioassay program.

Selection Process and Program Enrollment

Methodologies used to select individual workers for testing did not always ensure that all employees received needed tests. At NTS, bioassay sampling for select projects was not based on a statistical methodology. Instead, those that have the greatest chance of exposure are supposed to be selected for testing by health physicists. While this approach was acceptable, site officials told us that, at times, they selected individuals based on their willingness to submit to testing rather than on their exposure time. Using this discretionary approach, and as illustrated by our findings at the site, individuals may never be selected for testing and the site may not be accurately reporting employee doses and/or exposure.

At ETTP, a decision was made to change bioassay monitoring protocols for over 100 Work Permits. This modified approach monitors workers on a rotating basis rather than the prescribed frequency calculated during the development of the Work Permits. According to a site official, "the major driving force" for the change in the bioassay monitoring protocol was to reduce monitoring costs. Using this approach, ETTP realized a cost savings of about $7,000 per employee annually. While we recognize that this modified approach, if adequately justified, is an acceptable method, it was inconsistent with the project-by-project requirements established in each of the 117 existing Work Permits that were affected. ETTP stated that, based on a review of several years of bioassay and air sampling results, they believed that the same level of safety assurance was achieved with the new methodology. Site

officials, however, could not provide analytical evidence to support the change and told us that they did not perform a comparison of existing requirements to the new modified requirements for all affected Work Permits.

Weaknesses in how individuals were entered into or removed from the bioassay program also existed at several sites. At NTS, for example, a site official stated that entry into the bioassay program was an informal process based solely on the assignment of individuals to particular bioassay plans by the Health Physicist for the project rather than on actual Work Permit sign-ins. Since Work Permit sign-in records were not used to establish enrollment or testing requirements, individuals that have performed work in radiological areas might never be entered into the bioassay program. Site officials also told us that removal from the program was a manual process and that there is no formal protocol to ensure that individuals are removed when testing is no longer necessary.

Bioassay Database Systems

Problems with the accuracy and maintenance of site-level bioassay databases also contributed to selection, monitoring, and enrollment problems. For example:

- At ETTP, Work Permit sign-ins were not always being uploaded in a timely manner, delaying scheduling of bioassay appointments – a problem that lead to delinquent bioassay monitoring for a number of individuals in our sample. Site officials informed us that this delay was discovered and corrected in September 2005 and only affected log-ins over a one month period. However, many of the delays identified in our review dated back to January 2005, thereby indicating that these delays had been ongoing for at least nine months before being identified.

- At ORNL, some isotopes were not added to individual bioassay monitoring profiles for testing. Site officials indicated that they were unable to determine whether or not the problem we discovered was an isolated incident.

- At NTS, a corrupted personnel data file caused an employee in our sample that should have been

considered for testing to be excluded from bioassay monitoring. While a repair was attempted, the repair failed and went undetected until it was rediscovered by NTS officials while researching questions for this review.

- At both NTS and ORNL, database systems did not automatically remove participants from the bioassay program when monitoring was no longer necessary.

Also, we found that a number of manual overrides of the bioassay database were performed at ORNL. These overrides were performed at the discretion of the internal dosimetrist who indicated, as previously noted, that they were periodically done to "clean up the system." ORNL's database does not track historical changes and, therefore, does not always accurately reflect an individuals' monitoring history, as required.

Reviews at the Federal Level

Our review also revealed that Federal monitoring of site-level bioassay programs was inadequate. Specifically, the federal positions that provide management and review of the radiological protection programs at NTS and Y-12 had been vacant for over two years. During the time these positions were vacant, there was no evidence of formal or informal assessments being conducted at the Federal field level in this area. Once the position was filled at Y-12, a number of assessments were conducted in the area of radiological protection, which identified nine weaknesses.

Protection of Workers

Exposure to radiation is not a guarantee of harm. However, more exposure means more risk, and radiation exposure poses some risk of adverse health effect. Without an improvement in the control process over personnel monitoring, Department and contractor employees may be at increased risk for occupational exposures that might not be detected. Failure to provide an accurate total dose for employees may have an adverse impact on the health and welfare of workers. Also, if assessments at the Federal level are conducted more frequently, findings and opportunities for improvement related to radiological protection could be identified earlier and the risk of potential exposures caused by ineffective engineering or administrative controls could be reduced.

Finally, the lack of accurate exposure history may hamper the Department's ability to accurately assess future health issues. This lack of adequate exposure evidence is highlighted by the Department's experience with the Energy Employees Occupational Illness Compensation Program Act (EEOICPA) and potential legal issues surrounding incomplete occupational exposure data from past radiological work. As of the end of Fiscal Year 2006, the estimated future benefits payable to eligible individuals under the EEOICPA was $6.9 billion.

RECOMMENDATIONS

We recommend that the Administrator, National Nuclear Security Administration; the Under Secretary for Science; and the Assistant Secretary for Environmental Management, require field sites under their purview to:

1. Ensure that restrictions are in place and develop a mechanism to enforce restrictions for those that have not complied with local testing regimens, including the creation of penalties for Work Permit violations;

2. Develop mechanisms at the field project level to enable sites to accurately track an individual's radiological work activities and periodically perform a comparison of Work Permit sign-ins with work assignments;

3. Correct existing deficiencies, verify and validate the effectiveness of system controls for bioassay program databases, and ensure that data entry into the database system is timely and accurate; and,

4. Ensure that site-level bioassay requirements and/or procedures are validated through Federal management review activities.

MANAGEMENT REACTION

The National Nuclear Security Administration (NNSA), as well as the Offices of Science (Science) and Environmental Management (EM) provided comments on the report. The NNSA generally agreed with the report and concurred with the recommendations.

Science and EM indicated, in their consolidated comments, that they would work with contractors to assure that local testing regimens are clearly stated and are being

accomplished; however, they did not agree with the basic tenet of the report and did not concur with any of the recommendations. Those Offices noted that Federal regulation does not specifically require bioassay testing, that such testing is optional, and that they would not compel employees to comply with contractor-established testing programs designed to help ensure the effectiveness of radiological controls if the employee chose not to do so. They based their position on the view that bioassay testing is a lagging indicator and that air monitoring, combined with radiation and contamination surveys, are the preferred options for verifying the effectiveness of protective controls.

According to Science and EM, since bioassay monitoring is not exclusively required and is not the preferred method for verifying the effectiveness of engineering controls, recommendations 1 and 2 are not necessary. Management partially agreed with recommendation 3 and agreed to work with contractors to assure that the site-level procedures referenced in the report are clearly stated and are being accomplished. Science and EM believed that recommendation 4 was only applicable to NNSA. Management's comments are included in their entirety as Appendix 4.

AUDITOR COMMENTS

NNSA's comments and planned actions are responsive to our recommendations. We do not, however, consider the consolidated comments submitted by the Offices of Science and Environmental Management to be responsive.

While the Office of Inspector General recognizes that bioassay testing for the class of individuals examined in this report is not specifically required by Federal regulation, neither are air monitoring and radiation surveys. Rather, contractors are required to develop a program, based on site-level work environments, to verify that workers are adequately protected. Our review focused on whether the confirmatory bioassay testing component of contractor-developed protection programs – a component sanctioned and funded by the Department for many years at considerable cost – was functioning as intended. We found that it was not functioning properly at the sites identified in the report. Each site had developed technical basis documentation and site-level procedures that outlined their

bioassay programs and our recommendations were meant to address issues with the implementation of these site-level requirements.

We disagree with Science and EM that recommendation 4 is only applicable to NNSA. The intent of this recommendation was to ensure that Federal management reviews over radiological protection, including bioassay monitoring, occur at all field sites. We believe that confirmatory bioassay programs at the Department's sites would benefit from such reviews and could help ensure that contractors are implementing site-developed bioassay programs.

To address management's comments and to clarify that we evaluated the sites based on their contractor-developed procedures, we made revisions to the report as necessary.

OTHER MATTERS FOR CONSIDERATION

The sites we evaluated during this audit could not identify how much they spent to implement their bioassay programs and could be paying more than necessary. The actual costs associated with providing bioassay services could not be determined and the sites' methods for collecting and analyzing costs of the bioassay program were ineffective.

Each site had developed a unique method for tracking the costs of the bioassay analyses that, in many cases, did not capture the total costs associated with monitoring. Each of the three sites that used in-house programs could only provide allocated budget amounts rather than cost per analysis figures. Our examination revealed that the cost elements considered in the budget allocations differed from site to site and we were unable to determine what was included in each of the elements. For example, the Y-12 National Security Complex budget included labor, subcontracts, organizational burden, and supplies, while the Savannah River Site included only labor, non-labor, and services purchased from other site organizations.

For the two sites that used contracted services, substantially different rates for analyses of the same isotope were to be paid. For example, in 2005, the Nevada Test Site's price for a 45-day turnaround was $140 per analysis for Americium, whereas, the East Tennessee Technology Park's price, on average, was approximately $320 per analysis. However, neither of these prices reflected the full cost of testing. For example, officials at both sites indicated that additional costs to collect and deliver the samples to the contract laboratory had been incurred, however, they were not included in the cost of providing bioassay services.

The Department of Energy (Department) could not ensure it was administering its bioassay program in the most cost-effective manner because it had not required sites to perform a make-or-buy study, nor had it established a listing of cost elements that needed to be considered when conducting such studies. For example, only one of the sites could provide a documented, comprehensive cost analysis that could be used to determine the most economical method of providing bioassay services. The other sites either had not completed a cost analysis or had conducted very limited reviews based on the support provided.

Similar issues with costs were identified in *In-Vitro Bioassay Services at Department of Energy Facilities,* (DOE/IG-0458, February 2000). The report found that bioassay analyses had not been obtained at the lowest prices available and recommended that the Department establish a cost schedule – a standard set of cost elements – to be used in determining the most efficient way of obtaining bioassay services and also assure that sites maintain sufficient cost records to evaluate program cost against the cost schedule. While the Department did develop a standard cost schedule in response to our recommendation, it was only applied to make-or-buy analyses and, as we noted, the majority of the sites we reviewed had not conducted such analyses. It is unclear whether the Department fully addressed the recommendation to require site contractors to maintain sufficient cost records. However, we believe that had the recommended actions been taken, managers would have a better idea how they compared to other sites and benchmarks could have been established.

SUGGESTION FOR IMPROVEMENT

The Department should revisit the recommendations made in our previous report and implement standard cost elements that would enable the sites to compare and analyze the cost of bioassay services and would permit the preparation of comprehensive cost-benefit analyses. All sites that have the need for bioassay services should be required to analyze the costs of bioassay services using standard cost elements and maintain sufficient cost records.

OBJECTIVE

To determine whether contractor-developed confirmatory bioassay programs were being administered in an effective manner.

SCOPE

We conducted the audit from January 2006 to May 2007 at Department's Headquarters in Germantown, Maryland; the Savannah River Site (SRS) in Aiken, South Carolina; the Nevada Test Site (NTS) in Nye County, Nevada; the East Tennessee Technology Park (ETTP), the Y-12 National Security Complex (Y-12), and Oak Ridge National Laboratory (ORNL) in Oak Ridge, Tennessee.

In addition, we conducted audit work at the Tonopah Test Range in Tonopah, Nevada, and the Yucca Mountain Project in Nye County, Nevada. However, neither of these sites have routine bioassay programs, therefore, we did not include any of the information from these sites in the report.

METHODOLOGY

To accomplish the audit objective, we:

- Selected a discovery sample of employees with routine access to radiological areas at selected sites;
- Analyzed bioassay requirements, appointments and test results for selected employees;
- Reviewed applicable Federal regulations, Department Orders, and other guidance related to bioassay monitoring;
- Obtained and reviewed internal dosimetry technical basis documents and site-level policies and procedures related to bioassay monitoring at selected sites;
- Obtained and reviewed Radiation Protection Programs at selected sites;
- Obtained and reviewed Noncompliance Tracking System reports and Radiological Awareness/Event Reports for selected sites;

- Held discussions with officials from SRS, NTS, ETTP, Y-12, and ORNL regarding the Department's bioassay monitoring program; and,
- Held discussions with Headquarters officials regarding site bioassay monitoring programs and programmatic responsibilities.

The audit was performed in accordance with generally accepted Government auditing standards for performance audits and included tests of internal controls and compliance with laws and regulations to the extent necessary to satisfy the audit objective. Accordingly, the audit included reviews of Department and regulatory policies, procedures, and performance measures related to the Department's Bioassay Program. We assessed performance measures in accordance with the *Government Performance and Results Act of 1993* and concluded that the Department had not established performance measures related to bioassay monitoring programs. Because our review was limited, it would not necessarily have disclosed all internal control deficiencies that may have existed at the time of our audit. We obtained and reviewed the computer processed data made available to us in order to achieve our audit objective. We validated the reliability of such data, to the extent necessary to satisfy our audit objective, by tracing it to source documents or other supporting information. Also, since bioassay databases formed the basis of most of the testing, we evaluated the input controls over these systems.

Management waived an exit conference.

PRIOR REPORTS

Office of Inspector General Reports

- *In-Vitro Bioassay Services at Department of Energy Facilities* (DOE/IG-0458, February 2000). The report found that the Department of Energy's (Department) contractors did not obtain bioassay analyses at the lowest prices available. Although discounts were available under Department-wide subcontracts, two of the Department's contractors issued their own subcontracts for bioassay analyses with rates that were higher than the Department-wide rates. Also, three contractors paid substantially different rates for similar or identical analyses performed by the same subcontractor. These conditions occurred because the Department did not require contractors to use the Department-wide subcontracts and consolidate requirements into a single, cost-effective basic ordering agreement. As a result, the Department incurred unnecessary costs of about $495,000 during FYs 1998 and 1999. The report also noted that the audit team could not determine if the Department obtained bioassay analyses at the lowest prices available for 74 percent of the analyses reviewed because the three in-house laboratories were not required to capture the actual cost of specific analyses performed.

- *Audit of the Department of Energy's Commercial Laboratory Quality Assurance Evaluation Program* (DOE/IG-0374, June 1995). The audit found that the Department's method of performing quality assurance evaluations of commercial analytical laboratories was not cost effective or efficient. Contractors at many of the Department's sites conducted multiple evaluations of the same commercial laboratory. In addition, methods used to perform evaluations and report results varied among contractors. Finally, quality assurance evaluation results were not communicated to other contractors. These problems occurred because the Department's quality assurance policy guidance did not require development and implementation of a coordinated commercial laboratory quality assurance program. The Department did not require contractors to coordinate efforts, develop uniform standards and methods, or to communicate the results of their evaluations to other contractors.

Department of Energy
Office of Science
Washington, DC 20585

July 20, 2007

MEMORANDUM FOR RICKEY R. HASS
ASSISTANT INSPECTOR GENERAL
FOR FINANCIAL, TECHNOLOGY AND
CORPORATE AUDITS
OFFICE OF INSPECTOR GENERAL

FROM: GEORGE J. MALOSH
CHIEF OPERATING OFFICER
OFFICE OF SCIENCE

SUBJECT: Response to Inspector General's Draft Report, "Confirmatory Bioassay Testing at Selected Sites"

Thank you for the opportunity to review and comment on the draft report, "Confirmatory Bioassay Testing at Selected Sites." The following is a consolidated response developed between the Office of Science and the Office of Environmental Management.

Bioassay programs for DOE contractors include testing that is mandatory, in compliance with DOE requirements, as well as testing that is discretionary and not required by DOE. The DOE requires mandatory bioassays for radiological workers who are likely to receive a committed effective dose equivalent of 100 millirem per year. This DOE requirement is found in 10 CFR 835.402. For perspective, there are only a small number of radiological workers who fall into this category, where bioassays are required by DOE.

In addition to this mandatory bioassay testing requirement, DOE contractors are also required to verify the effectiveness of engineering and process controls for containing radioactive materials and reducing radiation exposures. This requirement is found in 10 CFR 835.401(a). To meet this requirement, contractors have the option of performing air monitoring in the workplace, radiation and contamination surveys, and optional bioassays for additional employees who are not expected to receive a committed effective dose equivalent of 100 millirem per year. Of those options, additional employee bioassays are not considered the first choice because they are a lagging indicator, and such bioassays are not required by DOE.

The vast majority of employees who submit bioassay samples fall into this latter category of workers for whom testing is optional and discretionary, and not required by DOE. For the employees who are required to have bioassays, DOE enforces a very strict standard of care. For employees who are not required to have bioassays, DOE does not have any

reason to require that they continue with the testing if they choose not to, especially in light of the fact that the preferred alternative for verifying the effectiveness of engineering controls is to perform air monitoring in the workplace along with other radiation and contamination surveys.

Management Response:

DOE agrees that it is important to enforce a very strict standard of care for radiological workers who are monitored because they are expected to receive a committed effective dose equivalent of 100 millirem per year, and DOE expects its contractors to rigorously and proactively ensure that suitable restrictions are in place and enforced.

The issues identified in this report relate to monitoring that is discretionary and not related to compliance with the DOE requirements for bioassay programs, as specified in 10 CFR 835.401(a) and 10 CFR 835.402. DOE will work with the contractors to assure that the discretionary procedures in the "local testing regimens" referenced in the report are clearly stated in site procedures and are being accomplished.

Attached are the DOE responses to each audit recommendation. If you have any questions related to this response, please contact Barry Parks at 301-903-9649 or barry.parks@science.doe.gov.

Attachment

cc: Joni Boone, EM-43
Richard Speidel, NA-66
Merley Lewis, CF-1.2
Robert Goldsmith, EM-62
Robyne Johnston, HS-1.23

Attachment

SC and EM Management Response to Recommendations:

Recommendation 1: Ensure that restrictions are in place and develop a mechanism to enforce restrictions for those that have not complied with local testing regimens, including the creation of penalties for Work Permit violations.

Management Response: DOE agrees that it is important to enforce a very strict standard of care for radiological workers who are monitored because they are expected to receive a committed effective dose equivalent of 100 millirem per year, and DOE expects its contractors to rigorously and proactively ensure that suitable restrictions are in place and enforced. However, DOE non-concurs with this recommendation, because it is not related to compliance with the DOE requirements for bioassay programs, as specified in 10 CFR 835.401(a) and 10 CFR 835.402. The procedures in the "local testing regimens" referenced in the report are strictly discretionary on the part of the contractor and are not required by DOE. The ability for DOE to enforce compliance with either statutory or contractual requirements is already in place through the use of civil penalties and/or contractual fee reductions. Any Work Permit violations which result in noncompliance with DOE requirements would be managed with these existing enforcement mechanisms. Because there is no issue with meeting DOE requirements, no corrective actions will be taken.

Recommendation 2: Develop mechanisms at the field project level to enable sites to accurately track an individual's radiological work activities and periodically perform a comparison of Work Permit sign-ins with work assignments.

Management Response: DOE is committed to ensuring that accurate records are kept for documenting occupational doses, and contractors are expected to comply with DOE requirements as set out in their Radiological Protection Program. However, DOE non-concurs with this recommendation, because there are a number of acceptable mechanisms for accomplishing this goal. As long as the contractors can demonstrate compliance with the DOE requirements for bioassay programs in 10 CFR 835.401(a) and 10 CFR 835.402, there is no benefit for specifying the exact mechanisms for doing so. No corrective actions will be taken for this recommendation.

Recommendation 3: Correct existing deficiencies, verify and validate the effectiveness of system controls for bioassay program databases, and ensure that data entry into the database system is timely and accurate.

Management Response: DOE expects its contractors to take proactive measures to ensure that databases and other recordkeeping and scheduling tools maintain accurate dosimetry records, for those workers being monitored as required by 10 CFR 835.401(a) and 10 CFR 835.402. DOE partially concurs with this recommendation, on the basis that all of the database issues identified in the report are in regard to bioassays that are strictly discretionary on the part of the contractor and are not required by DOE.

Action Plan: The issues identified in this report relate to monitoring that is discretionary and not related to compliance with the DOE requirements for bioassay programs, as specified in 10 CFR 835.401(a) and 10 CFR 835.402. DOE will work with the contractors to assure that the discretionary procedures in the "local testing regimens" referenced in the report are clearly stated in site procedures and are being accomplished.

Estimated Completion Date: DOE will complete this action plan within one year from issuance of the report.

Recommendation 4: Ensure that site-level bioassay requirements and/or procedures are validated through Federal management review activities.

Management Response: This recommendation was specific to NNSA sites and NNSA's response is under a separate cover. No corrective action will be taken for EM and SC sites.

Department of Energy
National Nuclear Security Administration
Washington, DC 20585

MEMORANDUMM FOR Rickey R. Hass
Assistant Inspector General
for Financial, Technology, and Corporate Audits

FROM: Richard M. Speidel 7/30-07
Director
Policy and Internal Controls Management

SUBJECT: Revised Comments to Draft Confirmatory Bioassay Testing Report; A06PT015/2006-02016

The National Nuclear Security Administration (NNSA) appreciates the opportunity to provide revised comments to the Inspector General's (IG) draft report, "Confirmatory Bioassay Testing at Selected Sites." NNSA's original comments stated that we did not agree with the premise of this report as we understood it. After discussions with several of your auditors, NNSA is revising its comments to the draft report.

NNSA appreciates the IG commenting on the fact that the Y-12 complex is testing individuals in accordance with its site-level procedures. These site-level procedures are above and beyond what is required in the Code of Federal Regulations for bioassay programs. Therein is the premise for this report as we now understand it, to determine whether the site specific confirmatory bioassay programs are being administered in an effective manner.

NNSA generally agrees with the report and its corresponding recommendations. NNSA will further evaluate what its next steps should be to implement corrective measures and/or monitor efficient operations. We will provide quarterly status reports, as necessary, until such time as the IG and NNSA agree that corrective actions are complete.

Should you have any questions about this response, please let me know.

cc: Frank Russo, Senior Advisor, Environment, Safety and Health
Karen Boardman, Director, Service Center
David Boyd, Senior Procurement Executive

IG Report No. DOE/IG-0773

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