



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

Audit Report

Implementation of the Department of Energy's Beryllium-Associated Worker Registry



Department of Energy

Washington, DC 20585

April 20, 2006

MEMORANDUM FOR THE SECRETARY

FROM:

Greg Friedman
Gregory H. Friedman
Inspector General

SUBJECT:

INFORMATION: Audit Report on "Implementation of the Department of Energy's Beryllium-Associated Worker Registry"

BACKGROUND

The Department of Energy (Department) has a long history of beryllium use due to the element's broad application to many nuclear weapon and reactor operations and processes. Exposure to beryllium can cause beryllium sensitization or even Chronic Beryllium Disease, which is an often debilitating, and sometimes fatal, lung condition. In January 2000, the Department established a Chronic Beryllium Disease Prevention Program in part to reduce worker exposure to beryllium at Energy facilities.

A key component of the Prevention Program was the establishment of a Beryllium-Associated Worker Registry (Registry), designed to aggregate beryllium-associated worker information, such as exposure and medical data, from all Department sites. The Department's Office of Environment, Safety and Health (EH) planned to use the Registry as an occupational health research tool to assist it in determining the exposure profile and disease status of beryllium-associated workers and to better understand the nature of the disease. Registry policy and direction were the responsibility of EH. However, implementation was the responsibility of the individual facilities, with the Department's program offices ensuring compliance for sites under their cognizance. Operation of the Registry is a complex effort requiring the close coordination of EH, the program offices, and the Department's field sites. The Department required sites to begin submitting information to the Registry by January 2002. The objective of this audit was to determine whether the Department had established, maintained and effectively used the Registry to evaluate worker health effects associated with beryllium exposure.

RESULTS OF AUDIT

The Registry was established as planned. Yet, the Department had not maintained data completeness or accuracy; used the Registry to evaluate health effects of beryllium exposure; nor, used the Registry as initially envisioned to examine the prevalence of beryllium disease. Specifically:

- The Registry was not complete. For example, the Fernald and Miamisburg Closure Sites and Portsmouth and Paducah Gaseous Diffusion Plants had not reported any data for inclusion in the Registry. Yet, at least two of these sites had workers with known Chronic Beryllium Disease;



- A number of required data fields in the Registry had not been populated. One such field concerned the use of a respirator by workers, an important tool in preventing beryllium exposure; and,
- The Registry did not always contain accurate information. Some of the required data fields, for example, contained obvious discrepancies, such as inaccurate beryllium exposure information. These and other such fields appeared essential to the effectiveness of the Registry.

In addition, the Department had not used the Registry to evaluate the health effects of beryllium exposure or the prevalence of beryllium disease. In fact, since the January 2002 implementation, the Department had not issued even one report which relied on the data from the Registry.

We found that not all of the Department's sites had determined the applicability of the Registry reporting requirements to their operations. Further, not all of the sites involved with the Registry had corrected known data errors and deficiencies. Although EH stated that it had contacted some Department sites regarding errors in the sites' Registry submissions, EH had not followed up with Department program offices to ensure that the errors had been corrected. In addition EH had not established an implementation plan that included identifying the specific analyses, supporting data, and reports needed to use the Registry as intended as an occupational health research tool. We concluded that this was the most likely reason that occupational health reports had not been generated using data in the Registry.

The question of worker health and safety has been of primary concern to the Department for a number of years, especially given the vulnerabilities associated with the processes and materials in use throughout the complex. Since assuming agency leadership, your Administration has placed great emphasis on making the Department's work environment as safe as possible. In this vein, the Registry, from its conception, was intended to assist in the overall effort of ensuring worker health and safety. However, the audit results showed that Registry program implementation did not meet its own expectations nor was it as helpful as it could have been in achieving the worker safety objectives that you have established. While EH program officials informed us that they are committed to improving the effectiveness of the Registry, the audit report includes several recommendations to assist efforts in restructuring the Registry and, as a consequence, to advance the state of worker health and safety in the Department.

MANAGEMENT REACTION

Management concurred with the report's findings and recommendations with the exception of recommendation number four, for which it proposed an acceptable alternative. Management indicated that it will implement changes to the management of the Registry based on the recommendations to improve the quality of data submitted to the Registry. Management also noted that it completed the first report on the prevalence of beryllium sensitization and Chronic Beryllium Disease using registry data, subsequent to the completion of our audit. Management's verbatim comments are included in Appendix 3.

Attachment

cc: Deputy Secretary
Under Secretary for Energy, Science and Environment
Administrator, National Nuclear Security Administration
Chief of Staff
Acting Assistant Secretary for Environment, Safety and Health

REPORT ON IMPLEMENTATION OF THE DEPARTMENT OF ENERGY'S BERYLLIUM-ASSOCIATED WORKER REGISTRY

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Implementation of Beryllium Registry

Maintenance and Use of Registry

The data in the Department of Energy's (Department) Beryllium-Associated Worker Registry (Registry) was neither complete nor fully accurate. Further, the Department had not used the Registry to evaluate health effects of beryllium exposure or the prevalence of beryllium disease, two of the objectives of the Chronic Beryllium Disease Prevention Program (Prevention Program).

Complete and Accurate Data

The Department had not maintained the Registry to ensure the data's completeness and accuracy. Specifically, the Registry did not contain data from all of the Department's sites falling under the reporting requirement, nor had all of the required data fields been populated. In addition, many of the records in the Registry were inaccurate.

Completeness

The Registry did not contain data from all of the Department's sites falling under the reporting requirements. Currently, 20 of the Department's sites have submitted data to the Registry. While the scope of audit focused primarily on the completeness of the data within the Registry, we identified additional sites that had not reported any relevant data to the Registry. Specifically, two of the Department's closure sites, Fernald and Miamisburg, had not reported any data to the Registry despite the potential for beryllium exposure based on legacy Department operations at those sites. Further, available records document the existence of beryllium-associated workers at Miamisburg. Also, there was evidence of Chronic Beryllium Disease at the Department's two leased gaseous diffusion plants at Paducah and Portsmouth; however, none of this information was reported to the Registry. A prior Office of Inspector General (OIG) report (OAS-L-05-08, June 2005), referenced concerns that the Department needed to determine the extent to which the Prevention Program was applicable to Paducah and Portsmouth. At the time, the Department informed the OIG that it recognized these issues and had initiated action to address these concerns.

In addition, not all of the required data fields in the Registry were populated. We reviewed the records from the Kansas City Plant (Kansas City), Los Alamos National Laboratory (Los Alamos), Pantex Plant (Pantex), Y-12 National Security Complex (Y-12), and Rocky Flats Closure Project (Rocky Flats), and found required data fields that were unpopulated for all of the sites. For example, none of the records tested for Kansas City, Pantex, or Rocky Flats

indicated whether respirator protection was used. In addition, medical data was missing for all of the worker records tested for Rocky Flats, as well as 20 of the 29 records tested for Los Alamos. Both respiratory protection and medical data are essential if the Office of Environment, Safety and Health (EH) is to provide complete and meaningful analyses of beryllium related issues. For instance, trend and correlation analysis cannot be made between exposure data, including the use of respiratory protection, and medical results, if data is missing from either of the fields.

Accuracy

Not all of the data reported in the Registry was accurate. We reviewed the records for Los Alamos, Pantex, and Y-12, and all had required data fields containing inaccurate data. For example at Y-12, 18 exposure records included data relating to the protective use of a respirator. However, the same set of records in another data field contained conflicting and irreconcilable information. Also, 26 records for individual workers at Pantex had a work termination date of January 1900, obviously prior to the workers' dates of birth. These exceptions were brought to the attention of representatives from both sites and we were told that efforts were being made to take corrective action. It is vital for EH to ensure the accuracy of these records, since each record is critical to tracking the beryllium work history and performing the analyses needed to mitigate further beryllium exposure.

In addition, duplicate records were found in the Registry for four sites reviewed: Y-12, Rocky Flats, Los Alamos, and Pantex. In fact, since the implementation date of January 7, 2002, one Rocky Flats exposure record was repeated 192 times in the Registry. For the same period at Pantex, 386 of the 1,805 work history records were identified in multiple sets, including one record that occurred 40 times.

Use of the Registry

Though the Registry was implemented several years ago, EH had not used it for at least one of its intended purposes, an occupational health research tool to determine the prevalence of disease and to document health effects associated with beryllium exposures. In fact, in the past four years EH had not generated any reports using the data from the Registry. EH is currently in the process of developing such a relevant health report; however, its usefulness may be limited given the questions that have been raised regarding Registry data quality.

Data Conversion and Programmatic Oversight

Despite the fact that the Prevention Program was a Department priority, not all Department sites, including closure sites and leased facilities, had determined the extent to which the Registry reporting requirements were applicable to them. Further, the sites that had submitted data to the Registry had not corrected known data errors and EH had not followed up with Department program offices to ensure that the sites complied. Finally, EH had not established an implementation plan that included identifying the specific analyses, supporting data, and reports needed to use the Registry as an effective occupational health research tool. Consequently, the Registry effort had not resulted in the generation of a single report to assist the Department in its worker health and safety program.

Responsible EH officials indicated that they were aware of data errors in the Registry and that they had directly contacted some of the sites, such as Rocky Flats, about the sites' errors. However, we found that EH had not followed up with the appropriate program offices to ensure that the data errors submitted by field sites had been corrected. The Department worked with the Oak Ridge Institute for Science and Education (ORISE) to establish the Registry. As part of its responsibility, ORISE performed logic checks on the data received from each site to validate its credibility. Details of data errors identified in the submissions were provided by ORISE in writing to the reporting sites and to EH. However, EH did not have a comprehensive program in place to follow up with the Department program offices to ensure site compliance with Registry protocols.

In addition, EH did not have an implementation plan to ensure that the Registry was useful as an occupational health research tool. One of EH's performance measures was to maintain the Registry to determine the prevalence of beryllium disease and document the progression of health effects associated with beryllium exposure. However, EH had not designed an implementation plan that identified the frequency and type of analyses, the specific information needed to conduct such analyses, or the method of reporting results to the sites. The Department recently incorporated its Beryllium-Associated Worker Registry Data Collection and Management Guidance into a Department Technical Standard effective January 2006. However, the Technical Standard did not directly address the areas of concern noted above, nor was the use of the Technical Standard mandatory.

Ensuring Worker Health and Safety

The 2003-2006 Strategic Plan for EH states that maintaining the Registry to determine the prevalence of disease and document the progression of health effects associated with beryllium exposures is important to ensuring the safety and health of the workers at Department facilities. As a result of not being able to make full use of the Registry, four years of data had not been analyzed, data that may have assisted the Department in assuring the safety and health of its workforce.

RECOMMENDATIONS

We recommend that the Assistant Secretary for Environment, Safety and Health direct the Office of Epidemiology and Health Surveillance to:

1. Work with the appropriate Departmental program offices in order to ensure that sites:
 - a. Identify whether they are required to report to the Registry; and,
 - b. Correct existing errors and omissions.
2. Establish procedures to ensure that subsequent corrections are made in a timely and accurate manner.
3. Revise the Department's current Technical Standard to incorporate language pertaining to the Registry that defines the following:
 - a. Analyses and trends to be completed, including the required relevant data to complete the analyses; and,
 - b. Methods of summarizing and reporting the data to the sites.
4. Work with Departmental program offices and sites to adopt the revised Technical Standard in the sites' individual Chronic Beryllium Disease Prevention Programs.

MANAGEMENT REACTION

Management concurred with the findings and recommendations, with the exception of recommendation number four. In a draft of this report, we had recommended that management pursue making the revised Technical Standard mandatory for sites that are

required to report to the Registry. Instead, management proposed an acceptable alternative by suggesting that EH will work with Departmental program offices and sites to adopt the revised Technical Standard in the sites' individual Chronic Beryllium Disease Prevention Programs. EH stated that this will make the Technical Standard enforceable and mandatory under a new Worker Safety and Health Program Rule being pursued by EH. This will also allow EH the flexibility to change the Technical Standard as needed to respond to changing conditions and events.

In response to the other recommendations, management indicated that EH will become proactive in working with the appropriate Departmental program and Field Offices in the attempt to identify sites needing to report to the Registry as well as correct existing Registry errors and omissions. EH also intends to establish procedures to ensure that subsequent corrections are made in a timely and accurate manner. In addition, EH will analyze and report on the Registry data through the implementation of analysis and data reporting plans, with the presentation of the findings at annual scientific meetings. Management also stated that since the completion of this audit, EH had completed the first report on the prevalence of beryllium sensitization and Chronic Beryllium Disease, including exposure information, based on data submitted to the Registry.

**AUDITOR
COMMENTS**

Management's comments are responsive to our recommendations and its actions, when fully implemented, should improve the Department's ability to use the Registry as an effective occupational health research tool. We agreed with management's proposed modification to recommendation number four and we have revised the report accordingly. Management's comments are included in their entirety in Appendix 3.

Appendix 1

OBJECTIVE

The objective of this audit was to determine whether the Department had established, maintained and effectively used the Registry to evaluate worker health effects associated with beryllium exposure.

SCOPE

The audit was performed between June and December 2005, at the Oak Ridge Institute for Science and Education (ORISE) and the Y-12 National Security Complex (Y-12), both located in Oak Ridge, Tennessee. Testing procedures were performed on the data from Kansas City Plant, Kansas City, Missouri; Los Alamos National Laboratory (Los Alamos), Los Alamos, New Mexico; Pantex Plant (Pantex), Amarillo, Texas; and, Rocky Flats Closure Project, Golden, Colorado.

We also conducted interviews and obtained information relating to other sites in the Department:

- Brookhaven National Laboratory, Upton, New York;
- Fernald Closure Project near Ross, Ohio;
- Hanford Site, Richland, Washington;
- Knolls Atomic Power Laboratory, Niskayuna, New York;
- Lawrence Berkeley National Laboratory, Berkeley, California;
- Miamisburg Closure Project, Miamisburg, Ohio;
- Oak Ridge National Laboratory; Oak Ridge, Tennessee;
- Oak Ridge Operations Office, Oak Ridge, Tennessee;
- Paducah Gaseous Diffusion Plant, Paducah, Kentucky;
- Portsmouth Gaseous Diffusion Plant, Piketon, Ohio;
- Southwestern Power Administration, Tulsa, Oklahoma; and,
- Stanford Linear Accelerator Center, Menlo Park, California.

The audit covered the Office of Environment, Safety and Health's (EH) efforts to meet the Chronic Beryllium Disease Prevention Program's goal of determining the prevalence of disease and health effects associated with beryllium exposure.

METHODOLOGY

To accomplish the audit objective, we:

- Reviewed laws, regulations, policies, procedures, and contract requirements relevant to the Department's Registry;

Appendix 1 (continued)

- Held discussions with officials from EH, ORISE, and Department sites;
- Obtained and reviewed site-specific Registry data from both ORISE and Department site offices;
- Selected a judgmental sample of five of the twenty Department sites reporting Registry data to determine if the records were complete. These sites were selected based on analysis of the sites with a Prevention Program; the sites currently reporting to the Registry; and, the sites with reported beryllium operations. The completeness test was performed on the reported beryllium activities beginning January 7, 2002, and ending July 2005; and,
- Selected 30 records from Los Alamos, Pantex, and Y-12, respectively, to determine if the records were accurate. This encompassed testing whether the 1) information contained in the required data fields in the Registry was factually accurate in comparison to the information maintained at the individual Department sites that report to the Registry, and 2) existing data was reliable.

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. 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 reviewed and assessed performance measures in accordance with the Government Performance and Results Act of 1993 and concluded that EH had established a performance measure to maintain the Registry, but that the metric had not been met. In order to meet that performance measure, we included recommendations for EH to work with the appropriate program offices to ensure that sites meet the Registry requirements, and to update the current Technical Standard to include the methods of analyzing data in the Registry and summarizing and reporting the results to the sites.

We relied on computer-processed data to accomplish our audit objective. Our procedures included gaining an understanding of the process for inputting information into the sites' databases and incorporating it into the Registry at ORISE, as well as the security access to the Registry to determine if the data was sufficiently

Appendix 1 (continued)

reliable. Based on this, we decided to perform additional tests of Registry data to accomplish our objective. Various computer assisted audit tools were used to perform queries and testing of the databases received from both ORISE and the Department sites. The completeness and accuracy of the data is addressed in the body of the report.

Management waived an exit conference.

Prior Audit Report

- *Occupational Safety and Health - Government Responses to Beryllium Uses and Risks* (GAO/OCG-00-6, May 2000). The Government Accountability Office (GAO) was asked to obtain information on beryllium as a hazardous material and report on the health and safety controls over its use. GAO found that from the 1960s to the 1990s, the Department of Energy had taken action to assess and to respond to risks associated with exposure to beryllium. Specifically, the Department improved working conditions at its facilities and implemented medical testing for its current and former workers during the 1980s and 1990s after new cases of Chronic Beryllium Disease were identified during the 1980s. From 1984 through 1999, 149 Department workers had been diagnosed with definite or possible Chronic Beryllium Disease. In 1999, the Department issued a rule that established new worker safety controls, such as increased use of respirators and assessing hazards associated with work tasks, for its facilities that use beryllium. The Department also proposed a compensation program for its workers affected by Chronic Beryllium Disease, which had been introduced as legislation in the Congress.



Department of Energy

Washington, DC 20585

April 5, 2006

MEMORANDUM TO: GEORGE W. COLLARD
ASSISTANT INSPECTOR GENERAL FOR PERFORMANCE AUDITS
OFFICE OF INSPECTOR GENERAL

FROM: C. RUSSELL H. SHEARER *C. Russell H. Shearer*
ACTING ASSISTANT SECRETARY FOR
ENVIRONMENT, SAFETY AND HEALTH

SUBJECT: Response to Audit Report on "Implementation of the Department of Energy's Beryllium-Associated Worker Registry"

The Office of Epidemiology and Health Surveillance (EH-53) has reviewed the recommendations cited in the Inspector General (IG) audit report on the "Implementation of the Department of Energy's Beryllium-Associated Worker Registry." The Beryllium Registry was developed as an occupational health research tool to help us understand the complex development of and risk factors for chronic beryllium disease. As with other longitudinal databases, it is the accumulation of data over time that differentiates this database from others. The significance of analytic findings will increase as the database accumulates depth over time. Issues arising in the operation of the Registry are being worked and resolved. We will implement changes to the management of the Beryllium Registry based on these recommendations to improve the quality of data submitted to the Registry. Our response to the report and each recommendation listed follows.

Recommendation 1: The Office of Environment, Safety and Health (EH) agrees with this recommendation. The Chronic Beryllium Disease Prevention Program (CBDPP) Final Rule title 10, Code of Federal Regulations, part 850.10 (10 CFR 850.10) states that "the responsible employer at a DOE facility must ensure that a CBDPP is prepared for the facility..." Only the responsible employer (i.e., the site contractor) has the knowledge of activities and operations at a given Department of Energy (DOE) site needed for implementing *all* aspects of the Rule, including self-reporting and sending accurate and complete data to the Registry. The head of the Field Element has primary responsibility for assuring contractors comply with requirements of 10 CFR 850. EH cannot identify all sites falling under the reporting requirement. However, to encourage the self-identification of sites that are required to submit data to the Registry, EH will become proactive in working with the appropriate departmental program and site offices. As such, EH-53 will undertake the following action plan: all Departmental Elements and site offices will be formally contacted and reminded of the requirements under 10 CFR 850 within 3 months of this response. Departmental Elements and site offices will be asked to ensure that the responsible employers are in compliance with the Registry reporting requirements. EH will provide each Departmental Element and site office with semiannual progress reports pertaining to the quality of data submitted as indicated by excessive numbers of errors, omissions, or nonresponse to Data Center inquiries. A point of contact to resolve Registry concerns will be solicited in order to help resolve existing errors and omissions. This action will be completed within 6-8 months from the response to this audit. We expect the promulgation of 10 CFR 851 (effective May 2007) to have a positive impact on the submission and quality of the data. EH will be better able to hold the responsible employer accountable with enforcement through potential civil penalties under 10 CFR 851.

The report indicates that the leased gaseous diffusion plants at Paducah and Portsmouth did not report data to the Registry. It should be noted that 10 CFR 850 applies only to: (1) DOE offices responsible for operations; (2) DOE contractors; and (3) current DOE employees or other workers at a DOE facility. The



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Portsmouth and Paducah Gaseous Diffusion Plants are United States Enrichment Corporation facilities that are covered by the Occupational Safety and Health Administration standards (29 CFR 1910.1000); DOE has no jurisdiction over them. While we encourage the submission of data from these facilities, we cannot compel them to submit data or follow the requirements of 10 CFR 850. The report also states that Fernald and Miamisburg (Mound) had not reported data to the Registry. We will make that specific point in our notification of Departmental Elements.

Recommendation 2: We agree with this recommendation. CBDPP 10 CFR 850.39 (Recordkeeping and the use of information) states that the responsible employer must semiannually transmit electronic records to the EH-53 Data Center. The responsible employer is required to provide accurate and reliable data to the Registry in a timely manner. To improve the quality of the data and to ensure that corrections are made in a timely manner, the following action will be undertaken: EH-53 will establish a procedure to ensure that subsequent corrections will be made in a timely and accurate manner. This procedure will be established within 6-8 months after the submission of this response. Under this procedure, Departmental Elements and site offices will be provided with the technical guidance standard for data submission to the Registry. The data center will conduct logic and error checks within 2 months of receiving data. Registry data coordinators at each site will continue to receive e-mail notification regarding the quality of the data, including errors, illogical data, and omissions. The data coordinator will have 1 month to respond either by submission of the corrected data, or through a resolution of the problem with the data center. After that 1-month period, the responsible Departmental Element and site office will be notified to ensure that corrective action is completed. To enhance data collection efforts, EH-53 will convene a regular meeting of all the site contractor data coordinators to review the data reporting requirements in the technical standard. The first meeting is scheduled for the end of April 2006.

Recommendation 3: We agree with this recommendation. EH will develop an analysis plan for the data as a supplemental document to the Technical Standard which we expect to be completed within 6 months of this response. The supplemental document will include descriptive measurements, such as disease incidence and prevalence, as well as statistical measurements using epidemiologic methods to examine trends and the association between exposure and disease prevalence. A data reporting plan will be developed to report the analytic findings back to the sites, and include methods to distribute the information to Environment, Safety and Health program managers and staff, workers, and the public. This plan will be complete between 6-8 months after this response has been submitted. Summaries of our findings, including methods and data reports, will also be presented annually at scientific meetings.

Recommendation 4: We disagree with this recommendation. The Beryllium Registry Technical Standard (DOE-STD-1187-2005) was developed to provide nonmandatory guidance for contractors in order to minimize ambiguities and to recommend reporting requirements for data submitted to the Beryllium Registry. The IG has recommended that the technical standard become mandatory (i.e., through incorporation in a rule) in order to improve the quality of the data submitted by the contractors. Using the rulemaking process for this activity would reduce EH's flexibility to change the technical standard as needed to respond to changing conditions and events. As an alternative, EH will work with the Program and Field Offices (as part of 851 Rule Implementation and Workshops) to demonstrate the value of adopting DOE-STD-1187-2005 in the site CBDPP. We expect this activity to take 1 year. Adoption of the Technical Standard in the site's CBDPP makes it enforceable and "mandatory" under the new Worker Safety and Health Program Rule (10 CFR 851).

Since the completion of the IG audit, EH-53 has completed the first report, "Beryllium Worker Health Surveillance through 2004," based on data submitted to the Registry. The report is descriptive in nature; it provides information about the prevalence of beryllium sensitization and chronic beryllium disease, and exposure information across the DOE complex. The data from the report will be sent to the sites, posted on the EH Web site, and presented at a scientific meeting within 2 months of this report response.

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