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DOE TECHNICAL STANDARD

Beryllium-Associated Worker Registry Data Collection and Management Guidance



U.S. Department of Energy
Washington, D.C. 20585

AREA SAFT

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FOREWORD

1. This standard provides acceptable methods for compliance with the requirements of paragraph 10 CFR 850.39 “Recordkeeping and Use of Information.” Use of this standard is not mandatory but is encouraged to aid sites in being compliant with 10 CFR 850.39. Users should review the document and determine if it meets their purpose.
2. Comments (recommendations, additions, and deletions) that may be of use in improving this document should be addressed to:

U.S. Department of Energy
Office of Domestic and International Health Studies, AU-13
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1000 Independence Avenue, SW
Washington, DC 20585-0270

3. This standard was developed through a consensus process by staff operating the DOE Beryllium-Associated Worker Registry with expert review by data coordinators who report information to the Registry. It was developed to facilitate the routine collection, analysis, and dissemination of information on the health effects of occupational exposure to beryllium.
4. Appendix F contains a brief history of beryllium use and regulation. A list of many of the methods for beryllium capture and analysis in use today is also included.

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1. **SCOPE:** This standard provides acceptable methods for compliance with the requirements of Title 10 Code of Federal Regulations, Part 850.39 (10 CFR 850.39) “Recordkeeping and Use of Information.” It should be used by responsible employers subject to the requirements of 10 CFR 850 “Chronic Beryllium Disease Prevention Program” to guide their submission of information to the Department of Energy (DOE) Beryllium-Associated Worker Registry. Use of this standard promotes consistent reporting and efficient analysis and dissemination of information to those who need to know.
2. **BACKGROUND:** The DOE Beryllium-Associated Worker Registry (BAWR) is a DOE complex-wide internal program to help DOE conduct and improve its chronic beryllium disease prevention programs. Paragraph 10 CFR 850.39 specifies beryllium recordkeeping and reporting requirements for both DOE federal and contractor employees. The Registry contains data on DOE contractor and federal workers, the jobs they performed, their beryllium exposure monitoring results, results from screening tests for chronic beryllium disease, and the results from subsequent medical diagnostic procedures. The Office of Domestic and International Health Studies (AU-13) sponsors the development and maintenance of this technical standard. The Registry is maintained by the Beryllium Registry Data Center at the Oak Ridge Institute for Science and Education (ORISE), Oak Ridge, Tennessee.

The Registry includes several components called *data sets*. These data sets include: a roster, or listing, of all current workers who may be potentially exposed to or may have been previously exposed to beryllium; medical information related to testing for and diagnosis of beryllium-related disease; work history of beryllium jobs while employed at a DOE site; and exposure data (industrial hygiene sampling data) with calculated 8-hour time-weighted average (TWA) for that exposure.

2.1. Data Sources: Sources of information for these data include human resource organizations; medical, safety, and industrial hygiene organizations; and other organizations such as operations, maintenance, engineering, and payroll. Additional sources of information may include Workers' Compensation files; the OSHA Form 300 log; and headquarters managed databases such as the Computerized Accident and Illness Reporting System (CAIRS), the Occurrence Reporting and Processing System (ORPS), and the Occurrence Reporting Binned Information Trending Tool (ORBITT).

2.2. Site Registry Data Coordinator: A Registry data coordinator should be identified by the Site Occupational Medical Director (SOMD) at each DOE site to serve as the point of contact between the site and the Beryllium Registry Data Center at Oak Ridge. The Registry data coordinator should be responsible for coordinating activities at the site related to data collection, submitting data to the Data Center in a timely manner, receiving inquiries from the Data Center, contacting appropriate site personnel to resolve data management and collection issues, and correcting errors. It is expected that the Registry data coordinator will

interact with a variety of individuals at the site such as line managers, computer support personnel, industrial hygienists, and site medical clinic personnel. If a site should make a change in who performs the role of Registry data coordinator, the site shall notify the Beryllium Registry Data Center (see section 2.3 below) and the DOE Beryllium Registry Program Manager (see #2 in Foreword). The new Registry data coordinator will need to obtain guidance on the tasks to be done and the importance of performing this role correctly. The new Registry data coordinator should contact the Beryllium Registry Data Center to arrange a conference call for the purpose of reviewing the duties associated with this role.

2.3. Data Collection:

- 2.3.1. Each site should define the best file structure and transmitting protocol for their site, in coordination with the Beryllium Registry Data Center. All data *must* be submitted as electronic files. The Data Center is flexible as to file type and will work with each site individually to accommodate various computer systems.
- 2.3.2. All sites should have had, and been using, fully functioning data submission procedures no later than the 10 CFR 850 implementation date of January 7, 2002. Initial submissions to the Registry should have included all available data for all current beryllium-associated workers at that time.
- 2.3.3. Data must be electronically submitted semi-annually to the Beryllium Registry Data Center at the Oak Ridge Institute for Science and Education (ORISE). The reporting periods begin on January 1 and July 1. Data should be submitted within 30 days of the reporting period to:

ORISE Beryllium Registry Data Center
P.O. Box 117, MS-45
Oak Ridge, TN 37831-0117

ORISE Coordinator: Deborah Sweeney
Phone: (865) 576-3005
Fax: (865) 576-9557
Email: Deborah.Sweeney@orau.org

- 2.4. **Worker Confidentiality Protection:** To maintain the confidentiality of Registry data, the Registry data coordinator shall ensure that a unique, encrypted identification number is assigned to every worker included in the Registry. All information that is submitted to the Registry regarding a specific worker must include his or her unique encrypted identification number. As the health impact of beryllium exposure may not occur until many years after employment, the Registry data coordinator shall ensure that a system is maintained that links a worker's identity to his or her unique identification number, even after the worker

terminates employment. Because the Beryllium Registry contains only encrypted identifying information, submitting information to it is explicitly exempt from Institutional Review Board review of research protocols under 10 CFR 745 Section 101 (b)(4) that deals with Federal Policy for the Protection of Human Subjects.

Unique encrypted identifiers should not be overly simplistic, such as reversing the worker's social security number, and should not duplicate other existing identifiers. The unique identifier should not be reassigned to a different worker, even if the first worker assigned to the identifier exits the workforce at that respective site. If this worker returns to the workforce at the site, his or her unique number should be restored to this specific individual.

When a worker transfers from one DOE site to another, he or she will be reassigned a new unique encrypted identifier, coded according to the current site's encryption scheme. Former sites should advise the transferees to identify themselves as a beryllium-associated worker to the SOMD upon their arrival at the new site. The SOMD should also determine if transferred workers were included in the Beryllium Registry at the previous site. If so, the SOMD will contact the SOMD at the previous site to obtain the old identification number so that linkage can be made.

To maintain the confidential nature of the Registry, 10 CFR 850.39 (e)(2)(i) requires that the SOMD, or other designated site personnel within the occupational medicine clinic, retain the encryption key that identifies an individual worker to his or her unique identifier. The encryption key should be provided with security protection similar to other medically confidential information.

Published reports using Registry information will generally contain only summary data. It is possible that descriptions of working conditions associated with a specific case will be published to share lessons with others. Such descriptions of specific cases will avoid containing enough unique information to allow readers to identify the individuals being described.

- 2.5. Data Analysis and Dissemination:** The Registry serves as a surveillance system for current workers. It will provide DOE with information regarding adverse health outcomes associated with a specific exposure. The Registry will allow DOE to ascertain the prevalence of workers sensitized to beryllium and the number of workers who have chronic beryllium disease due to past exposure. As the database is longitudinal in nature (i.e. following workers forward in time), the data will be able to determine the number of newly sensitized workers (incidence) and characterize the development of disease based on a worker's first exposure to beryllium. In addition, the exposure monitoring data will be used to characterize levels of beryllium across the complex. Lastly, the Registry is an epidemiologic tool to evaluate hypotheses about the causation of disease. Adverse health outcomes and exposure data will be analyzed together to determine the risk of disease.

- 2.5.1. **Data Analysis:** Data sent by each site to the Data Center will be initially reviewed for completeness and accuracy. Registry staff members will use customized software to determine missing data, data that are out of range (e.g. unusual or incorrect values) and other inconsistencies. The Data Center will notify each site data coordinator of errors or omissions within 60 days of the receipt of the data. The data coordinators should submit the corrected data within 30 days of notification. Data processing and subsequent analyses will be conducted by ORISE staff under the direction of the DOE Office of Health and Safety (AU-13).

The specifications of all variables are in this technical standard. DOE uses the term “sensitization” to mean that the individual has had abnormal or borderline results on beryllium lymphocyte proliferation tests (BeLPTs) that confirm exposure and an immune system response to beryllium according to established criteria. Currently, the BAWR defines sensitization as an individual with 2 abnormal blood tests, or 1 abnormal and 2 borderline blood tests, or 1 abnormal bronchoalveolar lavage BeLPT, or a clinical evaluation with a diagnosis of beryllium sensitization. However, **the definition of beryllium sensitization is subject to change if updated in the pending 10 CFR 850 revision.**

Note: only 1 abnormal BeLPT is required for the DOL's Energy Employees Occupational Illness Compensation Program Act (EEOICP) coverage of follow-up medical costs. CBD status is identified by the occupational medicine clinic in accordance with the EEOICP. Job titles will be reviewed and categorized into a matrix of occupational categories described below.

The analytic techniques for this Registry are those appropriate for epidemiologic studies based on a longitudinal cohort or a health registry design. Analyses will progress from simple descriptive statistics to statistical modeling where appropriate. Analyses will focus on all participating sites; individual site data may be analyzed separately depending on the size of the database. Frequency distributions will be reviewed for appropriate data variables. The prevalence of beryllium sensitivity and CBD will be determined across all participating sites; when appropriate, analyses will be conducted for individual sites.

When scientifically justifiable, categories of variables with small numbers will be collapsed to ensure more stable estimates of risk. Variables that had a total frequency of 5 counts or less, and could not be reasonably combined with others will be excluded from the analysis. Measures of central tendency, the mean, median, and range will be used in the descriptive analysis of continuous variables (such as age, beryllium exposure levels, etc.). Continuous variables may be categorized based on their variance parameters for additional analyses.

Estimates of the percent of exposures exceeding the DOE action level will be used as indicators of site performance in controlling exposures. In addition, this information may be used to examine the effect of compliance on the occurrence of CBD. Categorical data such as gender, the year of first hire, work history, the BeLPT results, the year of first positive or abnormal BeLPT result, and the use of respiratory protection, will be presented as frequency distributions.

An analysis of the exposure data will be conducted separately to characterize how exposures are distributed in the workforce.

Cumulative occupational beryllium exposure for each worker may be calculated as the sum of the job specific exposures multiplied by the years of exposure in the specific job ($\sum$ (job title exposure estimate X years in the job title)). Exposure data commonly contain a high percentage of data points lower than laboratory reporting limits, called non-detectable results (left censored data). These data will be analyzed by methods adapted from survival analysis, using maximum likelihood or Kaplan-Meier product limit estimates. Both parametric and non-parametric methods are described in an Oak Ridge National Laboratory report.¹

The statistical significance level for all analyses will be set at a probability of <0.05 (two-tailed test). Significant differences between years, sites, and work histories for mean exposures and percent exceeding the DOE action level, as specified in 10 CFR 850, will be assessed using 95% confidence limits. The association between the percent of sensitized or CBD workers and the % exceeding the action level for different sites and work histories will be assessed using Pearson's product moment correlation coefficient. All analyses will be performed using appropriate statistical software, such as, SAS (SAS Institute, Cary, NC) and R (the R Foundation for Statistical Computing).

The results of the analyses will be returned to individual site industrial hygiene departments to assist them in determining compliance with exposure limits.

- 2.5.2. **Dissemination of Information:** Analyses of health and exposure data will be published in annual reports. Approved reports will be published on the DOE Office of Environment, Health, Safety, and Security web site and submitted to the DOE Office of Scientific and Technical Information. Participating sites will be notified of the availability of these reports and asked for comments and suggested improvements for future reports. Data analyses will also be presented at meetings of

1 ¹ Statistical Methods and Software for the Analysis of Occupational Exposure Data with Non-Detectable Values, Frome EL and Wambach PF, ORNL/TM-2005/52, <https://www.csm.ornl.gov/esh/aoed/ORNLTM2005-52.pdf>

DOE safety and health protection specialists such as those sponsored by the Energy Facility Contractors Group and the Beryllium Health and Safety Committee.

One goal of reporting will be to provide information useful for communicating beryllium hazard information to beryllium-associated workers. Operating organizations responsible for implementing the employee training requirements of 10 CFR 850 will be a target audience for the distribution of periodic reports and the solicitation of comments for suggested improvements.

- 3. ROSTER OF BERYLLIUM-ASSOCIATED WORKERS:** The Roster Data Set will be a compilation of all beryllium-associated workers submitted by the Registry data coordinator to the Data Center. The following definitions from paragraph 10 CFR 850.3 should be used to guide decisions on the DOE and DOE contractor employees who should be included in the roster.

Beryllium-associated worker means a current worker who is or was exposed or potentially exposed to airborne concentrations of beryllium at a DOE facility, including: (1) A beryllium worker; (2) A current worker whose work history shows that the worker may have been exposed to airborne concentrations of beryllium at a DOE facility; (3) A current worker who exhibits signs or symptoms of beryllium exposure; and (4) A current worker who is receiving medical removal protection benefits.

Beryllium worker means a current worker who is regularly employed in a DOE beryllium activity.

Beryllium activity means an activity taken for, or by, DOE at a DOE facility that can expose workers to airborne beryllium, including but not limited to design, construction, operation, maintenance, or decommissioning, and which may involve one DOE facility or operation or a combination of facilities and operations.

Fields marked with an asterisk (*) are required. Omission of required data will result in flagged errors described in data condition reports (see section 2.5.1. Data Analysis, section 7. REQUIRED FIELDS, and Appendix A General Questions).

3.1. Table 3 – Roster:

1.	*Site Code	Site code (provided by ORISE Data Center)
2.	*Unique ID	Unique employee identification number (to be determined by the site)

3.	*Status Code	N = New record, D = Delete record
4.	*Year Born	Year of birth, (YYYY)
5.	*Gender	Gender of worker: Male or Female, (M or F)
6.	*Employer Type	Indicate the worker's employer as Federal, Contractor, Subcontractor, or Visitor, (F, C, S, or V)
7.	*First Hire on Site Date	Date first hired to work on current site, (MM/DD/YYYY)
8.	Year Employment Ended	Year individual separated from employment at site, (YYYY)
9.	Death Date	Date of death, (MM/DD/YYYY)
10.	Immediate Cause	Text abstracted from death certificate, immediate cause
11.	Old Unique ID	Unique ID from previous site, if applicable
12.	Previous Site	Text field that contains the name of the previous site where the worker was employed as a beryllium-associated worker

- 3.1.1. **Site Code:** Identify the DOE site with a unique code. The Beryllium Registry Data Center will provide a site code to each Registry data coordinator.
- 3.1.2. **Unique ID:** Identify each beryllium-associated worker with a unique encrypted number. It will be assigned by the site and is used to link multiple records to one worker. Every record submitted to the Data Center must include the Unique ID.
- 3.1.3. **Status Code:** Indicate whether this is a new record (N) to be added to the roster or a delete record (D) for a worker already in the roster. Only a new record (N) should be submitted for workers first entering the roster. To make changes to information for workers already in the roster, the site should submit both a delete (D) and a corresponding new record (N) that will replace all previous roster

data for the worker.

- 3.1.4. **Year Born:** Provide only the year of birth (YYYY). This is a measure to help ensure privacy and prevent identification of individuals by using a specific date of birth.
- 3.1.5. **Gender:** Provide the code for the gender of the worker as either male or female.
- 3.1.6. **Employer Type:** Indicate the worker's current employment type as federal, contractor, sub-contractor, or visitor. The permanent employees of cost-plus subcontractors to a site integrating or management and operating contractor will be considered a contractor for the Registry. Visitors include visiting scientists, graduate students, research collaborators, vendors, etc.
- 3.1.7. **First Hire on Site Date:** Provide the date that the worker was hired for the first time to work on the current DOE site (MM/DD/YYYY). Personnel records for current workers normally should have been transferred to successive contractors for a number of reasons and in particular in order to calculate employee benefits. Personnel departments should have this information. Medical records for current workers likewise should be transferred to successive medical surveillance providers. The date of the worker's first medical examination should be in the current medical files and may be a reasonable surrogate for the date first hired to work on the current site if the true date is not available. If no accessible records are available, information provided by the worker can be used.
- 3.1.8. **Year Employment Ended:** Provide the year (YYYY) that the worker separated from employment at the site. Current workers should have a blank (null) value in this field. The value should remain blank (null) if the employee transfers to a different employer on site. The year of the employee's termination medical examination may be a reasonable surrogate if the true date is not available.
- 3.1.9. **Death Date:** Provide the date on which the worker's death occurred, if available, in MM/DD/YYYY format.
- 3.1.10. **Immediate Cause:** Provide text describing the immediate cause of death. Abstract the "immediate cause of death" section from the death certificate.
- 3.1.11. **Old Unique ID:** Provide unique ID from previous site (for workers who have transferred from one DOE site to another DOE site).

- 3.1.12. **Previous Site:** Provide a text field that contains the name of the most recent previous site the worker was employed at as a beryllium-associated worker and was submitted to the Registry from that site. Examples of values: Sandia, LANL, Rocky Flats. (Site names can be abbreviated and will be changed to a code number by the Registry Data Center.)

- 4. BERYLLIUM-RELATED MEDICAL SURVEILLANCE:** The Beryllium-Related Medical Surveillance Data Sets will contain the beryllium-related disease medical information obtained by the Site Occupational Medicine Director (SOMD) related to beryllium exposure and medical testing. Tables 4.1 and 4.2 contain information generated through periodic medical monitoring programs operated by occupational medicine clinics. The content and frequency of surveillance evaluations and tests offered employees will be determined by the SOMD based on policies and standards and the employee's health and work history. Findings suggestive of possible chronic beryllium disease (CBD) will usually result in a referral to a pulmonary medicine or other specialized clinic for follow-up diagnosis and care.

Tables 4.3 through 4.9 contain information from diagnostic evaluations. Obtaining copies of reports containing this information from the clinic often requires the signed release from individuals upon their return to work or in some cases individuals can provide copies themselves. No records will be available for individuals who refuse the offer of a diagnostic evaluation or refuse to release copies of reports on their evaluations. The content of a diagnostic evaluation will vary based on the health of the patient and the judgment of the clinician.

A record should be provided for each of the following tests or evaluations if they were provided during the reporting period. When a record is submitted, fields marked with an asterisk (*) are required.

4.1. Table 4.1 – Beryllium Lymphocyte Proliferation Test (LPT) Results:

A record should be submitted for each LPT result received from a testing laboratory.

1.	*Site Code	Site code (provided by ORISE Data Center)
2.	*Unique ID	Unique identifier (to be determined by the site)
3.	*Status Code	N = New record, D = Delete record
4.	*LPT date	Date of blood draw for the LPT test, (MM/DD/YYYY)
5.	*LPT result	LPT result: Normal (Negative), Abnormal (Positive), Refused, Borderline, Unsatisfactory

- 4.1.1. **Site Code:** Identify the DOE site with a unique code. The Data Center will provide a site code to each data coordinator.
- 4.1.2. **Unique ID:** Identify each beryllium-associated worker with a unique encrypted number. It will be assigned by the site and is used to link multiple records to one worker. Every record submitted to the Data Center must include the Unique ID.
- 4.1.3. **Status Code:** Indicate whether this is a new record (N) or a delete record (D) in the beryllium-related medical surveillance data for LPT test results. To make corrections to a previously submitted record the site should submit both a delete record (D) and a corresponding new record (N) that will replace the deleted record for the worker. Because the LPT results data may contain up to 3 records with identical information for Site Code, Unique ID, and LPT Date, a delete record (D) requires that all fields, including the LPT Result, be populated. Each delete record will apply to only one record in the data table, so if the site wishes to delete multiple records it should supply the proper number of delete records.
- 4.1.4. **LPT date:** Provide the date the blood was drawn for the LPT (MM/DD/YYYY).
- 4.1.5. **LPT result:** Provide the result of the LPT as Normal (Negative), Abnormal (Positive), Refused, Borderline (neither fully normal nor fully abnormal), or Unsatisfactory (a failed or uninterpretable test).

4.2. Table 4.2 – Chest x-Ray Results: Report information on the most recent chest x-ray results for individuals added to the Roster during the reporting period (if available). In subsequent reporting periods, report only new chest x-ray results obtained in that reporting period including results of chest x-rays provided due to the employee's participation in other medical monitoring or health promotion programs.

1.	*Site Code	Site code (provided by ORISE Data Center)
2.	*Unique ID	Unique identifier (to be determined by the site)
3.	*Status Code	N = New record, D = Delete record
4.	*Date CXR	Date chest x-ray, (MM/DD/YYYY)

5.	*CXR Result	Chest x-ray results, (0/0, 0/1, etc.)
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- 4.2.1. **Site Code:** Identify the DOE site with a unique code. The Data Center will provide a site code to each data coordinator.
- 4.2.2. **Unique ID:** Identify each beryllium-associated worker with a unique encrypted number. It will be assigned by the site and is used to link multiple records to one worker. Every record submitted to the Data Center must include the Unique ID.
- 4.2.3. **Status Code:** Indicate whether this is a new record (N) or a delete record (D) in the beryllium-related medical surveillance data for chest x-ray results. To make corrections to a previously submitted record the site should submit both a delete record (D) and a corresponding new record (N) that will replace the deleted record for the worker. The aggregate chest x-ray data may contain more than one record for each date reported for a worker. Therefore, a delete record (D) requires matching values for the Site Code, Unique ID, date of CXR, and CXR result. Each delete record will apply to only one record in the data table, so if the site wishes to delete multiple records it should supply the proper number of delete records.
- 4.2.4. **Date CXR:** Provide the date the chest x-ray was taken (MM/DD/YYYY).
- 4.2.5. **CXR Result:** Indicate result of chest x-ray according to the ILO (International Labor Organization code), e.g. 0/0, 0/1, etc. If the x-ray does not have the ILO codes, the evaluation of the x-ray in text form is acceptable. For more information see:
<https://www.cdc.gov/niosh/topics/chestradiography/ilo.html>

- 4.3. **Table 4.3 – Referral/Follow-Up:** A referral/follow-up record should be submitted for individuals offered referral to specialized medical clinics because of medical surveillance findings suggestive of possible CBD.

1.	*Site Code	Site code (provided by ORISE Data Center)
2.	*Unique ID	Unique identifier (to be determined by the site)
3.	*Status Code	N = New record, D = Delete record

4.	*Referral Offered Date	Date follow-up referral offered, (MM/DD/YYYY)
5.	*Follow-Up Referral	Accepted (Y) or declined (N) referral for diagnostic follow-up

- 4.3.1. **Site Code:** Identify the DOE site with a unique code. The Data Center will provide a site code to each data coordinator.
- 4.3.2. **Unique ID:** Identify each beryllium-associated worker with a unique encrypted number. It will be assigned by the site and is used to link multiple records to one worker. Every record submitted to the Data Center must include the Unique ID.
- 4.3.3. **Status Code:** Indicate whether this is a new record (N) or a delete record (D) in the beryllium-related medical surveillance data for referral or follow-up. To make corrections to a previously submitted record the site should submit both a delete record (D) and a corresponding new record (N) that will replace the deleted record for the worker. The aggregate referral/follow-up data may contain only one record for each date reported for a worker. Therefore, a delete record (D) requires matching values for the Site Code, Unique ID, and the date the referral was offered.
- 4.3.4. **Referral Offered Date:** Indicate date the follow-up referral was offered (MM/DD/YYYY).
- 4.3.5. **Follow-Up Referral:** Indicate whether this individual accepted (Y) or declined (N) a referral for a follow-up examination.

4.4. Table 4.4 – Bronchoalveolar Lavage (BAL) LPT Results: A BAL record should be provided when interpretable information is available from diagnostic evaluation reports.

1.	*Site Code	Site code (provided by ORISE Data Center)
2.	*Unique ID	Unique identifier (to be determined by the site)
3.	*Status Code	N = New record, D = Delete record
4.	*Date Lavage	Date of BAL, (MM/DD/YYYY)

5.	*Lavage Result	BAL results: Normal (Negative), Abnormal (Positive), Refused, Borderline, Unsatisfactory
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- 4.4.1. **Site Code:** Identify the DOE site with a unique code. The Data Center will provide a site code to each data coordinator.
- 4.4.2. **Unique ID:** Identify each beryllium-associated worker with a unique encrypted number. It will be assigned by the site and is used to link multiple records to one worker. Every record submitted to the Data Center must include the Unique ID.
- 4.4.3. **Status Code:** Indicate whether this is a new record (N) or a delete record (D) in the beryllium-related medical surveillance data for BAL results. To make corrections to a previously submitted record the site should submit both a delete record (D) and a corresponding new record (N) that will replace the deleted record for the worker. The aggregate BAL results data may contain only one record for each date reported for a worker. Therefore, a delete record (D) requires matching values for the Site Code, Unique ID, and date of lavage.
- 4.4.4. **Date Lavage:** Provide the date the BAL was administered (MM/DD/YYYY).
- 4.4.5. **Lavage Result:** Provide the result of the BAL LPT as Normal (Negative), Abnormal (Positive), Refused, Borderline (neither fully normal nor fully abnormal), or Unsatisfactory (an unsatisfactory test). Note: pathology results may be available even if the LPT is Normal or Negative.

- 4.5. **Table 4.5 – Transbronchial Biopsy and BAL Pathology Results:** A BAL pathology record should be provided when interpretable information is available from diagnostic evaluation reports.

1.	*Site Code	Site code (provided by ORISE Data Center)
2.	*Unique ID	Unique identifier (to be determined by the site)
3.	*Status Code	N = New record, D = Delete record
4.	*Date BX	Date of transbronchial biopsy, (MM/DD/YYYY)

5.	*BX Result	Transbronchial biopsy result, text
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- 4.5.1. **Site Code:** Identify the DOE site with a unique code. The Data Center will provide a site code to each data coordinator.
- 4.5.2. **Unique ID:** Identify each beryllium-associated worker with a unique encrypted number. It will be assigned by the site and is used to link multiple records to one worker. Every record submitted to the Data Center must include the Unique ID.
- 4.5.3. **Status Code:** Indicate whether this is a new record (N) or a delete record (D) in the beryllium-related medical surveillance data for transbronchial biopsy and BAL pathology results. To make corrections to a previously submitted record the site should submit both a delete record (D) and a corresponding new record (N) that will replace the deleted record for the worker. The aggregate transbronchial biopsy data may contain only one record for each date reported for a worker. Therefore, a delete record (D) requires matching values for the Site Code, Unique ID, and date of transbronchial biopsy.
- 4.5.4. **Date BX:** Provide the date the transbronchial biopsy and BAL were administered (MM/DD/YYYY).
- 4.5.5. **BX Result:** Indicate results of pathologist's evaluation - suggested values are: normal (negative), positive - granuloma, positive - alveolitis, and positive - interstitial thickening. Indicate all that apply. Other values and comments may be provided.

4.6. Table 4.6 – High-Resolution Computed Tomography (CT) Results:

A CT record should be provided when interpretable information is available from diagnostic evaluation reports.

1.	*Site Code	Site code (provided by ORISE Data Center)
2.	*Unique ID	Unique identifier (to be determined by the site)
3.	*Status Code	N = New record, D = Delete record
4.	*Date CT	Date of CT studies, (MM/DD/YYYY)

5.	*CT Result	CT study result
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- 4.6.1. **Site Code:** Identify the DOE site with a unique code. The Data Center will provide a site code to each data coordinator.
- 4.6.2. **Unique ID:** Identify each beryllium-associated worker with a unique encrypted number. It will be assigned by the site and is used to link multiple records to one worker. Every record submitted to the Data Center must include the Unique ID.
- 4.6.3. **Status Code:** Indicate whether this is a new record (N) or a delete record (D) in the beryllium-related medical surveillance data for CT results. To make corrections to a previously submitted record the site should submit both a delete record (D) and a corresponding new record (N) that will replace the deleted record for the worker. The aggregate CT results data may contain only one record for each date reported for a worker. Therefore, a delete record (D) requires matching values for the Site Code, Unique ID, and date of CT study.
- 4.6.4. **Date CT:** Provide the date the CT study was administered (MM/DD/YYYY).
- 4.6.5. **CT Result:** Indicate CT study result - suggested values are: normal, abnormalities consistent with CBD, opacities consistent with CBD, and abnormalities requiring medical follow-up for conditions other than CBD. Other values and comments may be provided.

4.7. Table 4.7 – Cardiopulmonary Exercise Testing (CPET) Results:

A CPET record should be provided when interpretable information is available from diagnostic evaluation reports.

1.	*Site Code	Site code (provided by ORISE Data Center)
2.	*Unique ID	Unique identifier (to be determined by the site)
3.	*Status Code	N = New record, D = Delete record
4.	*Date CPET	Date of CPET studies, (MM/DD/YYYY)

5.	*CPET Result	CPET study result, text
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- 4.7.1. **Site Code:** Identify the DOE site with a unique code. The Data Center will provide a site code to each data coordinator
- 4.7.2. **Unique ID:** Identify each beryllium-associated worker with a unique encrypted number. It will be assigned by the site and is used to link multiple records to one worker. Every record submitted to the Data Center must include the Unique ID.
- 4.7.3. **Status Code:** Indicate whether this is a new record (N) or a delete record (D) in the beryllium-related medical surveillance data for CPET results. To make corrections to a previously submitted record the site should submit both a delete record (D) and a corresponding new record (N) that will replace the deleted record for the worker. The aggregate CPET results data allow (although unlikely) more than one record for each date reported for a worker. Therefore, a delete record (D) requires matching values for the Site Code, Unique ID, date of CPET study, and CPET study result. Each delete record will apply to only one record in the data table, so if the site wishes to delete multiple records it should supply the proper number of delete records.
- 4.7.4. **Date CPET:** Provide the date the CPET study was administered (MM/DD/YYYY).
- 4.7.5. **CPET Result:** Indicate CPET study result. These studies will provide several measurements in the following categories. Suggested values should be normal or abnormal for: oxygen uptake, carbon dioxide output, gas exchange ratio, anaerobic threshold, cardiac output, blood pressure and vascular resistance, ventilation, and pulmonary gas exchange function.

- 4.8. Table 4.8 – CBD Evaluation Results:** A CBD evaluation record should be provided when interpretable information is available from diagnostic evaluation reports.

1.	*Site Code	Site code (provided by ORISE Data Center)
2.	*Unique ID	Unique identifier (to be determined by the site)

3.	*Status Code	N = New record, D = Delete record
4.	*CBD Date	Date CBD evaluation made, (MM/DD/YYYY)
5.	*CBD Result	CBD evaluation result: CBD, BeS no CBD, No BeS or CBD

- 4.8.1. **Site Code:** Identify the DOE site with a unique code. The Data Center will provide a site code to each data coordinator.
- 4.8.2. **Unique ID:** Identify each beryllium-associated worker with a unique encrypted number. It will be assigned by the site and is used to link multiple records to one worker. Every record submitted to the Data Center must include the Unique ID.
- 4.8.3. **Status Code:** Indicate whether this is a new record (N) or a delete record (D) in the beryllium-related medical surveillance data for CBD evaluation results. To make corrections to a previously submitted record the site should submit both a delete record (D) and a corresponding new record (N) that will replace the deleted record for the worker. The aggregate CBD evaluation results data may contain only one record for each date reported for a worker. Therefore, a delete record (D) requires matching values for the Site Code, Unique ID, and date of CBD evaluation.
- 4.8.4. **CBD Date:** Indicate the date that the CBD evaluation was complete (MM/DD/YYYY).
- 4.8.5. **CBD Result:** Indicate CBD evaluation result as “CBD” when the patient has a definitive diagnosis of CBD, “BeS no CBD” when the patient has been found to be sensitized to beryllium but not to have CBD, and “No BeS or CBD” when a patient has been found to not be sensitized to beryllium or to have CBD. Use the definition of CBD in use for the *Energy Employees Occupational Illness Compensation Program Act*, given in Appendix B, if the evaluation report provides findings and test results but not a definitive diagnosis.

4.9. Table 4.9 – Beryllium-Induced Dermatitis: Beryllium can cause skin diseases from contact with the more soluble forms or implantation of the less soluble forms. A record of a beryllium-induced dermatitis should be submitted if a diagnosis of a beryllium-related skin disease has been entered into the employee’s personnel medical record. The diagnosis may have been

made by the occupational medicine clinic, an individual's personal physician, or a specialist as part of a clinical evaluation for CBD.

1.	*Site Code	Site code (provided by ORISE Data Center)
2.	*Unique ID	Unique identifier (to be determined by the site)
3.	*Status Code	N = New record, D = Delete record
4.	*Date Dermatitis	Date Be-induced dermatitis diagnosed, (MM/DD/YYYY)
5.	*Dermatitis Positive	Be-induced dermatitis diagnosed: Positive, Negative, or Equivocal, (P, N, or E)

- 4.9.1. **Site Code:** Identify the DOE site with a unique code. The Data Center will provide a site code to each data coordinator.
- 4.9.2. **Unique ID:** Identify each beryllium-associated worker with a unique encrypted number. It will be assigned by the site and is used to link multiple records to one worker. Every record submitted to the Data Center must include the Unique ID.
- 4.9.3. **Status Code:** Indicate whether this is a new record (N) or a delete record (D) in the beryllium-related medical surveillance data for beryllium-induced dermatitis. To make corrections to a previously submitted record the site should submit both a delete record (D) and a corresponding new record (N) that will replace the deleted record for the worker. The aggregate beryllium-induced dermatitis data may contain only one record for each date reported for a worker. Therefore, a delete record (D) requires matching values for the Site Code, Unique ID, and date dermatitis diagnosed.
- 4.9.4. **Date Dermatitis:** Indicate the date of dermatitis diagnosis (MM/DD/YYYY).
- 4.9.5. **Dermatitis Positive:** Indicate whether beryllium-induced dermatitis was diagnosed as: Positive, Negative, or if neither fully positive nor fully negative, put Equivocal.

5. DOE BERYLLIUM WORK HISTORY AND EXPOSURE DATA:

The Beryllium Work History and Exposure Data Sets will contain information about all activities having potential beryllium exposure where the beryllium-associated worker currently works or previously had worked and the exposures associated with those activities. See section 3 above for definitions of a beryllium-associated worker. Retrospective work history information most often will be collected through questionnaires and interviews with the worker. Information from records generally will be more reliable than an individual's memory and will be preferred if readily accessible. Location, organization, and job title data on current work should be reported using terminology consistent with that used in official records to simplify investigations or studies that might become desirable in the future. The data should include working directly with beryllium, working in areas of potential beryllium exposure even if not working directly with beryllium, and activities with potential casual exposure to beryllium, such as working near an area where others are working directly with beryllium. Do not provide or submit classified data to the Registry. When a record is submitted, fields marked with an asterisk (*) are required.

5.1. Table 5.1 – DOE Beryllium Work History:

1.	*Site Code	Site code (provided by ORISE Data Center)
2.	*Unique ID	Unique employee identification number (to be determined by the site)
3.	*Status Code	N = New record, D = Delete record
4.	*Organization Code	Department/division/organization
5.	*First Beryllium Job Start Date	Date that first job involving beryllium began, (MM/DD/YYYY)
6.	*Activity	General description of the job function – see list of acceptable values
7.	*Job Title	Job title at time of potential Be exposure
8.	*Job Start Date	Date job involving beryllium began, (MM/DD/YYYY)
9.	Job Stop Date	Date job involving beryllium stopped, if applicable, (MM/DD/YYYY)

- 5.1.1. **Site Code:** Identify the DOE site with a unique code. The Data Center will provide a site code to each data coordinator.
- 5.1.2. **Unique ID:** Identify each beryllium-associated worker with a unique encrypted number. It will be assigned by the site and is used to link multiple records to one worker. Every record submitted to the Data Center must include the Unique ID.
- 5.1.3. **Status Code:** Indicate whether this is a new record (N) to be added to the beryllium work history or a delete record (D) for a record that has been previously submitted to the Registry. To make corrections to a previously submitted record the site should submit both a delete record (D) and a corresponding new record (N) that will replace the deleted record for the worker. The aggregate beryllium work history data may contain only one record for each Job Start Date reported for a worker. Therefore, a delete record (D) requires matching values for the Site Code, Unique ID, and Job Start Date.
- 5.1.4. **Organization Code:** Provide the worker's department, division, or organization code or number. The Registry data coordinator should provide a data dictionary (the code and the organization associated with that code) to the Data Center.
- 5.1.5. **First Beryllium Job Start Date:** Provide the recorded or reported date the worker began working in the first job in which he or she was potentially or actually exposed to beryllium (MM/DD/YYYY). For current workers, medical records normally will be the source of this information since they are transferred to successive medical surveillance providers and kept in the clinic. If records are not accessible, the first beryllium job start date should be obtained from the employee as reported to the best of his or her recollection. This date should consider prior employment for work involving beryllium to provide information regarding the latency of sensitization and progression to disease. If the date is not obtainable, the data coordinator should work with the DOE program manager to identify a suitable proxy.
- 5.1.6. **Activity:** A high level roll-up category that should be a general description of the job function. Provide a one-character code as selected from one of the following categories.
 - 5.1.6.1. Management (M) – Predominantly office work at a desk; first level supervisor and above.

- 5.1.6.2. Administrative Support (A) – Predominantly office work at a desk but can include tasks that involve visiting, production areas, shops, and labs. This category includes but is not limited to information technology, clerical, and secretarial staff.
- 5.1.6.3. In-House Professionals (I) – Predominantly office work at a desk typically without supervisory responsibilities. Occasional tasks outside office create opportunities for exposure.
- 5.1.6.4. Field Professionals (F) – Frequently works outside of their office in areas such as but not limited to laboratories, testing areas, and construction areas. Employees in the “Biohazard” category should be placed in this category.
- 5.1.6.5. Technical Support (T) – Workers who typically support the field professionals and have hands-on work situations.
- 5.1.6.6. Service (S) – Typically includes but is not limited to custodians, drivers, laborers, laundry workers, linemen, mail clerks, pilots, railroad engineers, records center workers, stationary engineers, utility workers, and water plant operators. These workers support and maintain the facility’s infrastructure. Most work is not performed sitting at a desk.
- 5.1.6.7. Security and Fire (E) – Typically includes protective forces and firefighters.
- 5.1.6.8. Crafts (C) – Typically includes skilled craftsmen and laborers who are members of building trade unions and engaged in construction, remodeling, or facility maintenance work.
- 5.1.6.9. Line Operators (O) – Typically workers who are directly involved in process, operation, or line activities at the facility.
- 5.1.6.10. Guests (G) – Employees on short-term assignments or internships. Typically includes guest scientists, postdoctoral fellows, co-op students, and interns. Potential for exposure dependent on job assignment.
- 5.1.6.11 Unknown (U) – Job title is missing. All possible sources should be examined and this value should

be used only if a job title for the worker cannot be ascertained.

- 5.1.7. **Job Title:** Provide the worker's job title at time of potential exposure (e.g. Machinist, Technician, or Chemical Operator). This should be the job title used in pay and other employment records.
- 5.1.8. **Job Start Date:** For each subsequent job involving potential or actual exposure to beryllium, provide the date the worker's duties, location, or job title changed (MM/DD/YYYY). This date may be recorded in medical, administrative, or exposure monitoring records. If records are not accessible the date should be the date reported by the employee to the best of his or her recollection.
- 5.1.9. **Job Stop Date:** Provide the date the worker stopped working in the job in which he or she was actually or potentially exposed to beryllium (MM/DD/YYYY). This date may be recorded in medical, administrative, or exposure monitoring records. If records are not accessible the date should be the date reported by the employee to the best of his or her recollection. If this is the current job for the worker a blank (null) value in the Job Stop Date field is acceptable.

5.2. Table 5.2 – DOE Beryllium Activities and Exposure: A record should be submitted for each beryllium exposure monitoring result. Records predominantly report the results of personal exposure monitoring aimed at determining whether an individual's full shift exposure was in compliance with the DOE action level or other 8-hour time-weighted average occupational exposure limit. In some cases a single result will be reported in several records for coworkers judged to be similarly exposed. The information included in the record will generally come from the industrial hygiene sample data sheet and analytical laboratory sample analysis report.

It is beyond the scope of this standard to detail methodologies and analytical procedures in detail, however, examples of relevant methods or procedures are referenced below. It is important to note that laboratories which determine beryllium for DOE sites for their beryllium control program are required to be accredited through the American Industrial Hygiene Association (AIHA), or an equivalent body. As such, data generated for submission to the registry must be generated through those corresponding accredited procedures.

1.	*Site Code	Site code (provided by ORISE Data Center)
2.	*Unique ID	Unique employee identifier (to be determined by the site)
3.	*Status Code	N = New record, D = Delete record
4.	*Location Identification	Location where the exposure monitoring occurred
5.	*Room/Area	Room/area where exposure monitoring occurred
6.	*Process	Free form text describing beryllium activity process
7.	Operation	Free form text describing the beryllium activity operation
8.	Task	Free form text describing the beryllium activity task
9.	*Actual Exposure	Actual exposure level or laboratory reporting limit during the sampling period in $\mu\text{g}/\text{m}^3$
10.	*Actual Exposure < Reporting Limit	Indicate whether the actual exposure is less than the laboratory reporting limit, Y/N
11.	*Exposure Sample Volume	The volume of air sampled in liters
12.	*8-hour TWA	8-hour time-weighted average exposure in $\mu\text{g}/\text{m}^3$
13.	*Exposure Method	Free form text describing the type of exposure method
14.	*Sampling Method	Describe the sampling method used
15.	*Analytic Method	Describe the analytic method used
16.	*Exposure Sampling Time	Exposure sampling time in minutes
17.	Sample Number	Sample identification number

18.	*Monitoring Date	Date monitoring was conducted, (MM/DD/YYYY)
19.	Chemical	Free form text describing beryllium chemical compound
20.	Engineering Controls	Free form text describing engineering controls
21.	PPC&E	Personal protective clothing and equipment used? Y/N
22.	*Respirator Protection	Respiratory protection used? Y/N
23.	*Respirator APF	Respiratory protection “Assigned Protection Factor”—use 1 when no respiratory is worn.

5.2.1. **Site Code:** Identify the DOE site with a unique code. The Data Center will provide a site code to each data coordinator.

5.2.2. **Unique ID:** Identify each beryllium-associated worker with a unique encrypted number. It will be assigned by the site and is used to link multiple records to one worker. Every record submitted to the Data Center must include the Unique ID.

5.2.3. **Status Code:** Indicate whether this is a new record (N) or a delete record (D) in the beryllium-related exposure data. To make corrections to a previously submitted record the site should submit both a delete record (D) and a corresponding new record (N) that will replace the deleted record for the worker. The aggregate exposure data may contain more than one record for each date that monitoring was conducted. Therefore, a delete record (D) requires matching values for the Site Code, Unique ID, Monitoring Date, and one or more other fields. If Sample Number (which can be an encrypted value) has been provided by the site the key for a delete record (D)—and the corresponding new record (N)—can be Site Code, Unique ID, Monitoring Date, and Sample Number. Sample Number is not a required field and if it is not provided the site should designate the additional field or fields that can be used to uniquely identify a record. Each delete record will apply to only one record in the data table, so if the site wishes to delete multiple records it should supply the proper number of delete records.

5.2.4. **Location Identification:** Provide the on-site code for the location within which the beryllium exposure monitoring occurred. This should

be the unique administrative code that usually will be established by the facility or property management organization for each building and area on site. The Registry data coordinator should provide a data dictionary (the code and the building or area associated with that code) to the Data Center. This cannot be null, nor can it be populated with “not available.”

- 5.2.5. **Room/Area:** Free form text that is usually one or more room numbers where the beryllium exposure monitoring occurred. For outdoor areas or buildings where room numbers are not used this should be a description in common use at the site (for example “maintenance welding shop”). If no other information is available, repeat the information provided in 5.2.4 Location Identification above. This cannot be null, nor can it be populated with “not available.”
- 5.2.6. **Process:** Free form text that describes the beryllium activity process. Process is the highest level of grouped tasks. Dry machining is an example of a process. See Appendix C for more examples. This cannot be null, nor can it be populated with “not available.”
- 5.2.7. **Operation:** Free form text that describes the beryllium activity operation. Operation is the mid-level of grouped tasks. Using a particular type of lathe is an example of an operation in the dry machining process. See Appendix C for more examples.
- 5.2.8. **Task:** Free form text that describes the beryllium activity task. Task is the lowest level of beryllium activity and is not grouped. Machine preparation is an example of a task performed in the operation of using a particular type of lathe. See Appendix C for more examples.
- 5.2.9. **Actual Exposure:** Provide the level of the worker's beryllium exposure measured during the sampling period for the Task (field 8) as determined by personal monitoring of the worker or by some other method. This will be the measured beryllium concentration during the time period the sample was collected. Examples of other methods are the use of a direct-reading instrument, field wet chemical analysis results, and presumption of an exposure based on the monitoring results of other workers performing similar tasks. The industrial hygienist needs to calculate the actual exposure before submitting data to the Site Registry data coordinator. Results below the laboratory reporting limit should be reported as concentrations calculated from the laboratory's reporting limit in the volume of air sampled. See Appendix D for an explanation of laboratory reporting limit.
- 5.2.10. **Actual Exposure < Reporting Limit:** Indicate by Y/N whether the value reported in Actual Exposure (field 9) is below the calculated

laboratory reporting limit. “Yes” indicates that the value reported in field 9 is calculated from the laboratory reporting limit.

- 5.2.11. **Exposure Sample Volume:** This is the volume of air sampled, in liters, that was used to calculate the Actual Exposure above.
- 5.2.12. **8-hour TWA:** Provide the 8-hour TWA (time-weighted average) of the worker's beryllium exposure for the work shift as determined by personal monitoring of the worker or other method. The industrial hygienist needs to calculate the 8-hour TWA before submitting the data to the Registry data coordinator. See Appendix D for an explanation of the reporting limit. See Appendix E for calculating 8-hour TWAs for non-standard work shifts and sequential sample results including results that are less than the reporting limit.
- 5.2.13. **Exposure Method:** Free form text that describes the type of exposure measuring method used. Personal breathing zone is most common. Examples of other methods are the use of direct-reading instruments, field wet chemical analysis results, and presumption of an exposure based on the monitoring results of other workers performing similar tasks.
- 5.2.14. **Sampling Method:** Describe the sampling method used. Examples are procedures in the U.S. Department of Labor, Occupational Safety and Health Administration, OSHA Technical Manual, Fourth Edition, OSHA Instruction TED 1-0.15A, Washington, D.C., Government Institute, Inc., 1-20-99; National Institute for Occupational Safety and Health, Analytical Method 7102, Issue 2, 8-15-1994; and National Institute for Occupational Safety and Health, Analytical Method 7300, Issue 3, 3-14-2003.
- 5.2.15. **Analytic Method:** Describe the analytic method used. Examples are procedures in the U.S. Department of Labor, Occupational Safety and Health Administration, OSHA Technical Manual, Fourth Edition, OSHA Instruction TED 1-0.15A, Washington, D.C., Government Institute, Inc., 1-20-99; National Institute for Occupational Safety and Health, Analytical Method 7102, Issue 2, 8-15-1994; and National Institute for Occupational Safety and Health, Analytical Method 7300, Issue 3, 3-14-2003.
- 5.2.16. **Exposure Sampling Time:** The length of time in minutes of the sampling that generated the actual sample exposure level, Actual Exposure (field 9), or an analogous length of time if possible, if the exposure was presumed by some other method. Examples of other methods are the use of direct-reading instruments, field wet chemical

analysis results, and presumption of an exposure based on the monitoring results of other workers performing similar tasks.

- 5.2.17. **Sample Number:** Identifying number assigned to the sample that generated Actual Exposure (field 9) for tracking purposes. Sites shall ensure that the sample number does not identify the employee. Sites may use encrypted numbers.
- 5.2.18. **Monitoring Date:** The date on which the monitoring was conducted that generated the actual exposure level used in calculating the 8-hour TWA (MM/DD/YYYY). Use the date of the first day if the monitoring spans midnight.
- 5.2.19. **Chemical:** Free form text that identifies the chemical composition of the beryllium being monitored.
- 5.2.20. **Engineering Controls:** Free form text used to indicate type of engineering controls used with the Task (field 8).
- 5.2.21. **PPC&E:** Indicate by Y/N whether personal protective clothing and equipment were used with the Task (field 8).
- 5.2.22. **Respirator Protection:** Indicate by Y/N whether respiratory protection was used with the Task (field 8).
- 5.2.23. **Respirator APF:** Provide the Assigned Protection Factor for respiratory protection when it was used for the Task (field 8). The Assigned Protection Factor should be those endorsed in written respiratory protection program plans used to establish work site specific procedures. When no respirator is worn, use the value 1 for the assigned protection factor.

- 6. **TABLE RELATIONSHIPS:** All tables can be related to one another by concatenating the Site Code and Unique ID as a key. This will allow any records in any tables to be related to any other table. However, there will be some logical relationships that also exist. The Roster table is the driving source of the Registry. All medical surveillance, work history, and exposure/sampling data must match to a Roster table record via the Site Code/Unique ID key. If not, these records will be questioned and returned to the site for resolution.

The Medical Surveillance tables will not be related logically to the Work History or Activities and Exposure tables, and there can be a many-to-one relationship from the Medical Surveillance tables to the Roster table.

The Work History table will be logically related to the Roster by the Job Start and Stop Date(s) and the Year Employment Ended. A worker cannot have a Job Start Date or Job Stop Date that is later than the Year Employment Ended (i.e., they cannot be

working on a job later than their employment existed). The Activities and Exposure table will relate logically to the Work History table in a many-to-one fashion by checking the Monitoring Date field with the time window of the Job Start and Job Stop dates. The Beryllium Data Center will also check that supporting Work History data have been submitted for every worker (i.e., every Site Code/Unique ID key) reported in the Roster or Activities and Exposure data.

7. **REQUIRED FIELDS:** Every record must contain the worker's Unique ID and Site Code. This will allow all the records on an individual worker to be linked. In addition to the Unique ID and Site Code, selected fields in all the data sets should be populated every time data are submitted. These fields are indicated by an asterisk (*) in the tables.
8. **QUALITY ASSURANCE:** The Data Center performs edit and logic checks on the data as part of its quality assurance procedures. The unique employee identification number of a record submitted for the Medical Surveillance, Work History, and Exposure Data Sets must match a unique identification number of a record in the Roster Data Set. The integrity of the Activities and Exposure Data Set is achieved by maintaining the chronological order of a worker's job history. The Data Center will prepare and transmit to the data coordinator a data condition report identifying data inconsistencies and errors so they can be resolved. Data coordinators may download copies of their site's current data using the BAWR Web Application front-end to review these data for accuracy and completeness. The Data Center will notify the Office of Domestic and International Health Studies of errors data coordinators indicate are due to a systemic problem that requires management attention. AU-13 will notify DOE line management of the issue and seek their assistance in planning appropriate corrective actions.

Appendix A – Frequently Asked Questions

General Questions

Q. – Where do I get the site code?

A. – That is a number that is furnished to you by the Registry Data Center.

Q. – Will others be able to request and receive data I have submitted from my site?

A. – No. Obtaining a copy of data that were submitted from other sites requires DOE approval.

Q. – Can I get a copy of the list where numbers are assigned to each site?

A. – No. As an extra step to help protect the identity and confidentiality of the workers, this list will be maintained at the Registry Data Center and will not be given to anyone else.

Q. – Are self-identified beryllium workers to be included in the Registry?

A. – Yes.

Q. – Do I have to submit a value for all required fields?

A. –Yes. If a record is submitted, then all required fields in that record must be filled. If a required field contains a null it will be flagged as an error and returned to the site for resolution. If a value of “Not Applicable” or “N/A” is provided for a required field it will also be flagged as an error and returned.

Roster Questions

Q. – After the initial roster has been submitted, do we submit all the roster records again every six months with the changes incorporated?

A. – No. After the initial roster has been submitted, all of those workers will be in the roster forever and there is no need to submit them again unless (1) you have detected that some of the data are in error and you wish to correct them or (2) a worker terminates/retires.

Q. – At our site, it is common for an employee to jump from one employer to another. Do I fill out a roster record each time this occurs?

A. – If this is an employee that you as a site are responsible for reporting into the

Registry, then the answer is “YES.”

Q. – Suppose an employee terminates from our company. How do I submit this to the Registry?

A. – In the next submission, provide a roster delete record (Status Code=D) for this person and a corresponding new record (Status Code=N) with all of the data fields populated as needed. Upon receipt, the roster table will be scanned for this person, the previous record will be deleted, and the newest submitted record will replace it.

Medical Surveillance Questions

Q. – If I have submitted a record for a LPT and discovered that the date in that record for that LPT is wrong, how do I correct it?

A. – To correct the information for an LPT record the site should submit a delete record (Status Code=D) with the Site Code, Unique ID, LPT Date, and LPT result populated. A corresponding “new” record (Status Code=N) should be submitted at the same time with all fields populated with the correct information; this record will replace the previous (deleted) record. LPT data may contain up to 3 records with identical LPT dates. Therefore, each delete record will apply to only one record in the data table, and if the site wishes to delete multiple records it should supply the proper number of delete records.

Q. – Sometimes a beryllium-associated worker will be provided a chest X-ray and refuse the LPT. Do we submit these values anyway?

A. – Yes. Submit any test results requested by the Registry that the person may have.

Work History Questions

Q. – Due to security reasons, the job title cannot be provided. Is it acceptable to leave it blank?

A. – It is required to have some value here, so a generalization is recommended so the field is not blank. This will give some indication of what the person was doing to become identified as a beryllium-associated worker. If your security organization has approved an unclassified code word, use that word.

Q. – Are sites required to retrieve retrospective work history data for beryllium workers?

A. – According to the rule, the answer is no, although these data would increase the value of the Registry and some sites have said they can do this easily and will do so.

Activities and Exposure Questions

Q. – Again, security concerns arise with combining data from the DOE Activities and Exposure table, particularly the fields Process, Operation, and Task. What should a site do in this case?

A. – Generalizations are recommended for the values in these fields that allow the Registry to have data that are as detailed and complete as possible without breaching security restrictions. Each site has to assess their own situation and develop a data policy/procedure they are comfortable with, ensuring that security is not compromised.

Q. – The Sample Number field can be traced to an individual. To protect confidentiality, what should a site do?

A. – Notice that this field is not required, but some sites asked/recommended that it be included to make it easier to search samples for specific values or to answer questions that may arise from these data. Most sites have procedures to maintain confidentiality of sampled individuals. If a site needs to use some form of encryption, that is acceptable. This field is there primarily for the site's use.

Q. – Is there a limit to the amount of text that can be supplied for the Process field?

A. Yes, the fields for Process and Operation are limited to a maximum of 250 characters each, while the field for Task is defined as a Memo field and is virtually limitless. (Appendix C contains examples for Process, Operation, and Task.)

Appendix B – Chronic Beryllium Disease Definition

The following definition of chronic beryllium disease is provided by the *Energy Employees Occupational Illness Compensation Program Act Of 2000, As Amended*, 42 U.S.C. § 7384 *et seq.*

PART B—PROGRAM ADMINISTRATION

§ 7384L. Definitions for program administration

(13) The term “established chronic beryllium disease” means chronic beryllium disease as established by the following:

(A) For diagnoses on or after January 1, 1993, beryllium sensitivity (as established in accordance with paragraph (8)(A)), together with lung pathology consistent with chronic beryllium disease, including—

- (i) a lung biopsy showing granulomas or a lymphocytic process consistent with chronic beryllium disease;
- (ii) a computerized axial tomography scan showing changes consistent with chronic beryllium disease; or
- (iii) pulmonary function or exercise testing showing pulmonary deficits consistent with chronic beryllium disease.

(8)(A) Beryllium sensitivity as established by an abnormal beryllium lymphocyte proliferation test performed on either blood or lung lavage cells.

Appendix C – Process-Operation-Task Examples

PROCESS	OPERATION	TASK
DRY MACHINING	HARDINGE LATHE	MACHINE PREP
DRY MACHINING	HARDINGE LATHE	OPERATING LATHE
DRY MACHINING	HARDINGE LATHE	CLEAN UP
DRY MACHINING	HARDINGE LATHE	MAINTAIN EQUIPMENT
DRY MACHINING	BRIDGEPORT MILL	MACHINE PREP
DRY MACHINING	BRIDGEPORT MILL	OPERATING MILL
DRY MACHINING	BRIDGEPORT MILL	CLEAN UP
DRY MACHINING	BRIDGEPORT MILL	MAINTAIN EQUIPMENT
POWDER OPERATIONS	BERYLLIUM PLASMA SPRAYING	POWDER/CHAMBER INSPECTION
POWDER OPERATIONS	BERYLLIUM PLASMA SPRAYING	ATTACH/REMOVE CANISTERS
POWDER OPERATIONS	BERYLLIUM PLASMA SPRAYING	LOAD SAMPLE
POWDER OPERATIONS	BERYLLIUM PLASMA SPRAYING	SPRAY OPERATION
POWDER OPERATIONS	BERYLLIUM PLASMA SPRAYING	BLOW DOWN
POWDER OPERATIONS	BERYLLIUM PLASMA SPRAYING	PART TRANSFER
ANALYSIS	ICP BERYLLIUM ANALYSIS	PREP STANDARDS
ANALYSIS	ICP BERYLLIUM ANALYSIS	INSTRUMENT ANALYSIS
ANALYSIS	ICP BERYLLIUM ANALYSIS	SAMPLE RECEIVING AND PREPARATION
ANALYSIS	ICP BERYLLIUM ANALYSIS	DATA MANAGEMENT AND REPORTS
ANALYSIS	ICP BERYLLIUM ANALYSIS	
ANALYTICAL CHEMISTRY		
POWDER OPERATIONS	BERYLLIUM PLASMA SPRAY OPERATIONS	VACUUM PUMP MAINTENANCE
POWDER OPERATIONS	BERYLLIUM PLASMA SPRAY OPERATIONS	TORCH MANIPULATOR MAINTENANCE
ES&H SUPPORT	SAMPLE COLLECTION	TAKE AIR SAMPLES
ES&H SUPPORT	SAMPLE COLLECTION	TAKE SWIPE SAMPLES
ES&H SUPPORT	SAMPLE COLLECTION	TAKE VACUUM/BULK SAMPLES
ES&H SUPPORT	INSPECTION, EVALUATION, AND INVESTIGATION	VERIFY ADMINISTRATIVE CONTROLS
ES&H SUPPORT	INSPECTION, EVALUATION, AND INVESTIGATION	PERFORM GENERAL WALKTHROUGHS
ES&H SUPPORT	INSPECTION, EVALUATION, AND INVESTIGATION	PERFORM PHYSICAL HAZARD EVALUATIONS
ES&H SUPPORT	INSPECTION, EVALUATION, AND INVESTIGATION	EVALUATE ENGINEERING CONTROLS
ES&H SUPPORT	INSPECTION, EVALUATION, AND INVESTIGATION	EVALUATE CHEMICAL HAZARDS
ES&H SUPPORT	EQUIPMENT MAINTENANCE	CLEANING AND PACKAGING
ES&H SUPPORT	EQUIPMENT MAINTENANCE	CALIBRATING, ADJUSTING, AND TROUBLESHOOTING
ES&H SUPPORT	SHORT-TERM HCP OPERATIONS	SUPPORTING A LOW RESIDUAL RISK OPERATION
ES&H SUPPORT	SHORT-TERM HCP OPERATIONS	SUPPORTING A MINIMAL RESIDUAL RISK OPERATION
ES&H SUPPORT	SHORT-TERM HCP OPERATIONS	SUPPORTING A MEDIUM RESIDUAL RISK OPERATION
CUSTODIAL/JANITORIAL	EQUIPMENT DECON	WET WIPING
CUSTODIAL/JANITORIAL	EQUIPMENT DECON	STRIPCOAT REMOVE
CUSTODIAL/JANITORIAL	EQUIPMENT DECON	HEPA FILTERED VACUUMING
CUSTODIAL/JANITORIAL	GENERAL DECON	WET MOPPING
CUSTODIAL/JANITORIAL	GENERAL DECON	STRIPCOAT REMOVE
CUSTODIAL/JANITORIAL	GENERAL DECON	HEPA FILTERED VACUUMING

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PROCESS	OPERATION	TASK
DECONTAMINATION	GENERAL DECON	APPLYING STRIPCOAT
DECONTAMINATION	GENERAL DECON	SETTING UP/TEARING DOWN
DECONTAMINATION	GENERAL DECON	REMOVING STRIPCOAT
DECONTAMINATION	GENERAL DECON	WET MOPPING
DECONTAMINATION	GENERAL DECON	WET WIPING
DECONTAMINATION	GENERAL DECON	HEPA FILTERED VACUUMING
DECONTAMINATION	EQUIPMENT DECON	SETTING UP / TEARING DOWN
DECONTAMINATION	EQUIPMENT DECON	APPLYING STRIPCOAT
DECONTAMINATION	EQUIPMENT DECON	REMOVING STRIPCOAT
DECONTAMINATION	EQUIPMENT DECON	WET MOPPING
DECONTAMINATION	EQUIPMENT DECON	WET WIPING
DECONTAMINATION	EQUIPMENT DECON	HEPA FILTERED VACUUMING
DECONTAMINATION	LAUNDRY	COLLECTING LAUNDRY
DECONTAMINATION	LAUNDRY	WASHING/DRYING LAUNDRY
DECONTAMINATION	LAUNDRY	FOLDING/STORING LAUNDRY
DECONTAMINATION	HEPA VACUUM MAINTENANCE	CHANGE PAPERBAG, MAIN & MICRO FILTERS
DECONTAMINATION	HEPA VACUUM MAINTENANCE	CHANGE ULPA/HEPA FILTERS
DECONTAMINATION	DRYER LINT COLLECTOR	REMOVING LINT
DECONTAMINATION	DRYER LINT COLLECTOR	CHANGING LINT BAG
DECONTAMINATION	OVERHEAD DECON	WET WIPING
DECONTAMINATION	OVERHEAD DECON	HEPA FILTERED VACUUMING
GLOVEBOX MAINTENANCE	INSPECTION	TRANSFER GLOVEBOX INSPECTION
GLOVEBOX MAINTENANCE	INSPECTION	PLASMA SPRAY CHAMBER GLOVEBOX INSPECTION
GLOVEBOX MAINTENANCE	GLOVE CHANGE	TRANSFER GLOVEBOX GLOVE CHANGE
GLOVEBOX MAINTENANCE	GLOVE CHANGE	PLASMA SPRAY CHAMBER GLOVEBOX GLOVE CHAN
POWDER OPERATIONS	BERYLLIUM PLASMA SPRAY MAINTENANCE	TORCH MAINTENANCE
POWDER OPERATIONS	BERYLLIUM PLASMA SPRAY MAINTENANCE	VACUUM PUMP MAINTENANCE
POWDER OPERATIONS	BERYLLIUM PLASMA SPRAY MAINTENANCE	POWDER HOPPER MAINTENANCE
POWDER OPERATIONS	GLOVEBOX MAINTENANCE	INSPECTION
POWDER OPERATIONS	GLOVEBOX MAINTENANCE	GLOVE CHANGE
PARTICULATE CONTAINER HANDLING	CYCLONE CONTAINER CHANGE-OUT	REMOVING/INSTALLING CONTAINER
PARTICULATE CONTAINER HANDLING	CYCLONE CONTAINER CHANGE-OUT	POST OPERATION CLEAN-UP
PARTICULATE CONTAINER HANDLING	DUST COLLECTOR CANISTER CHANGE-OUT	REMOVING/INSTALLING CONTAINER
PARTICULATE CONTAINER HANDLING	DUST COLLECTOR CANISTER CHANGE-OUT	POST OPERATION CLEAN-UP
FACILITY OPERATIONAL SUPPORT	SHORT TERM HCP	RESIDUAL RISK MEDIUM
FACILITY OPERATIONAL SUPPORT	SHORT TERM HCP	RESIDUAL RISK LOW
FACILITY OPERATIONAL SUPPORT	SHORT TERM HCP	RESIDUAL RISK MINIMAL
FACILITY OPERATIONAL SUPPORT	ROUTINE MAINTENANCE	
FACILITY OPERATIONAL SUPPORT	ROUTINE INSPECTION	INSPECTING SAFETY SHOWERS & EYEWASH
FACILITY OPERATIONAL SUPPORT	ROUTINE INSPECTION	INSPECTING FIRE EXTINGUISHERS
FACILITY OPERATIONAL SUPPORT	ROUTINE INSPECTION	INSPECTING EMERGENCY LIGHTING
FACILITY OPERATIONAL SUPPORT	ROUTINE INSPECTION	INSPECTING COMBUSTIBLE LOADING
ENVIRONMENTAL SAMPLING	BERYLLIUM PRECISION MACHINE SHOP	EDM MACHINING
FACILITY OPERATIONAL SUPPORT	ROUTINE SURVEILLANCE & CALIBRATION	SURVEYING HVAC SYSTEM PID/PDIP

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PROCESS	OPERATION	TASK
FACILITY OPERATIONAL SUPPORT	ROUTINE SURVEILLANCE & CALIBRATION	SURVEYING LOCAL VENTILATION ALARMS
ELECTRICAL SERVICE/INSTALLATION/REPAIR	SERVICE	
ELECTRICAL SERVICE/INSTALLATION/REPAIR	INSTALL	
ELECTRICAL SERVICE/INSTALLATION/REPAIR	REPAIR	
ELECTRICAL SERVICE/INSTALLATION/REPAIR	SCOPE WORK TICKET	
CONSTRUCTION/MAINTENANCE OPERATIONS	GENERAL MAINTENANCE	
WELDING	PIGMA WELDING	
WELDING	LEAK CHECK	
WELDING	RESTRAINED BEND	
WELDING	MAINTENANCE	

Appendix D – Laboratory Reporting Limit

The American Industrial Hygiene Association defines the laboratory reporting limit as “The lowest concentration [or amount] of analyte in a sample that can be reported with a defined, reproducible level of certainty.”² In the case of air monitoring, the reporting limit refers to the smallest amount in terms of mass of beryllium collected on air filter media that can be measured reliably. Laboratories typically report a result of “Less Than (reporting limit value)” when sample results are below the reporting limit. Such a result might be reported as “Less than 0.02 µg” for the sample. In the case of air samples collected on a filter medium, laboratories would typically divide their reporting limit by the sample volume to calculate a concentration result. For instance, the result reported to the Registry would be “Less than 0.02 µg/m³” if the sample volume is 1,000 liters (or 1 m³). This concentration value is the “Actual Exposure” value required by the Registry (table 5.2, field 9) when a result is less than the reporting limit.

Laboratory quality assurance programs generally calculate three limits: 1) an instrument detection limit based on analyses of blank samples, which establishes a value that is not likely to be a blank; 2) a method detection limit based on analyses of spiked samples, which establishes a value at which a specified level of precision and accuracy is achieved; and 3) a reporting limit, which accounts for variation in method detection limits due to factors such as differing filter media and interference from other metals in samples. Industrial hygienists monitoring beryllium exposures should inform the laboratory of their data quality objectives to avoid reporting limits that are higher than expected. One goal of the Registry is to determine whether compliance with the DOE action level is protective. The sampling and analytical methods used should be capable of demonstrating that exposures are less than that level.

² AIHA Laboratory Quality Assurance Programs (LQAP) Policy Document – Module 9, Revision 4: January 2, 2007.

Appendix E – Calculating Non-Standard Shift and Sequential Sample 8-Hour TWA

The conversion of actual exposure levels to an 8-hour TWA is a key standardizing step in the interpretation of exposure monitoring data. Calculations are simple when a worker has worn a sampler for the entire duration of their potential exposure in a shift. The actual exposure level is multiplied by the number of minutes worn and divided by 480 minutes in 8 hours. The 8-hour TWA for full shift sample results that are less than the reporting limit are calculated in the same way.

When the 8-hour TWA is calculated from sequential samples in the same work shift, each sample receives a separate record and the calculated 8-hour TWA is recorded next to each actual value used to calculate that 8-hour TWA.

When calculating an 8-hour TWA from sequential samples in the same work shift that are a mix of results that are greater than and less than the reporting limit, substitute the reporting limit for values less than the reporting limit. The calculated 8-hour TWA will be above the reporting limit. For example, with two results above the reporting limit and one less than the reporting limit (RL):

$$\frac{(\text{Value}_1 \times \text{Time}_{V1}) + (\text{Value}_2 \times \text{Time}_{V2}) + (\text{RL}_1 \times \text{Time}_{\text{RL}})}{480 \text{ minutes}} = 8\text{-hour TWA}$$

Assume a worker's exposure was unmeasured for 15 minutes at the beginning of the shift while donning clean work clothing and for 30 minutes at the end of a shift while showering and donning street clothes. Also assume that the worker was monitored for a 225 minute period with a result of $0.1 \mu\text{g}/\text{m}^3$ and for a 210 minute period with a result of less than the reporting limit of $0.02 \mu\text{g}/\text{m}^3$. If the unmeasured periods are judged to have no potential for beryllium exposure, the 8-hour TWA would be:

$$\frac{(0.1 \times 225) + (0.02 \times 210)}{480} = 0.06 \mu\text{g}/\text{m}^3$$

Appendix F – Background and History of Beryllium Use and Regulation

Background

Concern about exposure to beryllium and beryllium compounds, and the relationship between these exposures and development of beryllium sensitivity and/or chronic beryllium disease is not a recent concern. By the 1930s, the physical characteristics of beryllium, beryllium compounds, and beryllium alloys had resulted in a growing industry producing a variety of products in high quantities. In addition to its use in commercial products, beryllium had become a material of major importance in military-related industries.

It was during this time that a number of reports of beryllium-associated disease appeared in European medical literature. Why these earliest reports went unnoticed or ignored is not perfectly clear. With the problems of accurately linking beryllium exposure to development of disease, it is understandable that these early reports overlooked the possibility of a direct exposure – disease relationship. Other factors, including the rapidly growing use of beryllium products in the military, were also responsible for limited acknowledgement of the potential for health problems.

It is worth noting that the famed United States Public Health Service Bulletin, known as the Fairhall Report, declared that beryllium was toxicologically inert and suggested that the apparent toxicity reportedly associated with beryllium was actually attributable to fluorides or oxyfluorides in the beryllium compounds. Later, following rigorous review of the Fairhall Report, numerous errors in experimental planning and design were identified in the research upon which the Fairhall Report was based. Thirty years later, the United States Public Health Service issued another report retracting its earlier concurrence with the Fairhall Report. Nevertheless, the Fairhall Report findings were accepted as fact by those in the beryllium production, manufacturing, and use industries for many years. It would be many more years before the health effects of exposure to beryllium were recognized and appropriate regulatory controls put in place.

Regulations

The path toward development of regulations for control of beryllium exposures was an arduous one. During and after the period overshadowed by the Fairhall Report, a number of scientists reported a variety of dermal and respiratory illnesses in beryllium workers and in non-workers living near beryllium plants. Merrell Eisenbud was heavily involved in this early investigation of production emissions, air pollution, neighborhood exposure, and resulting disease. Studies of these events and affected populations resulted in the establishment of the first regulatory limits for emissions of beryllium from plants and for worksite atmospheres. The limits adopted in 1949 were (1) in-plant maximum concentration of 25 μg beryllium/ m^3 of air, (2) in-plant concentration not to exceed 2 $\mu\text{g}/\text{m}^3$ of air averaged over an eight-hour day, and (3) to protect the general public in the vicinity of a beryllium plant, a concentration not to exceed 0.01 $\mu\text{g}/\text{m}^3$ of air as a monthly average concentration. These limits were sometimes referred to as “Eisenbud levels” and have

remained the bases for control of beryllium exposures to the present day. The first two limits were also accepted and adopted by the American Industrial Hygiene Association, the American Conference of Governmental Industrial Hygienists, and the American National Standards Institute. In 1972, Eisenbud's levels were also adopted as a consensus standard by the Occupational Safety and Health Administration (OSHA) shortly after its creation. In 1974, Eisenbud's third level pertaining to persons living in areas around beryllium plants was adopted by the United States Environmental Protection Agency (EPA) as a National Emissions Standard for Hazardous Air Pollutants and, later, in Section 112 of the Clean Air Act.

The Department of Energy and Department of Defense have been the largest users of beryllium. Since the early 1940s, many thousands of workers at DOE and DOD plants or facilities have worked with beryllium and had the potential for exposure. These U.S. departments have also been among the most involved groups in the study of beryllium and its possible health effects, and the DOE took steps to initiate a comprehensive beryllium worker health program. Following years of aggressive data collection and analysis of beryllium activities, exposure measurements, and disease occurrence, a public notice of intent to establish a chronic beryllium disease prevention program (CBDPP) was published in 1998 (63 FR 66940). Within the notice of intent, DOE requested comments, data, and any other relevant information from the public and industry for consideration in developing the beryllium worker health program. Following receipt and consideration of numerous comments and other relevant information, DOE published the final rule of 10 CFR Part 850 Chronic Beryllium Disease Prevention Program in 1999. A draft of a comprehensive implementation guide (DOE G 440.1-7A) to assist line managers in meeting responsibilities required by the CBDPP was issued in 1999 and updated in 2001. In 2006, DOE published a final rule establishing and implementing a formal worker safety and health program (WSHP) which also included some updating of the CBDPP. The WSHP, including the amendments to the CBDPP Rule, went into effect in 2007.

Chronic Beryllium Disease Prevention Program

The CBDPP was designed to decrease the occurrence of chronic beryllium disease among federal and contractor workers and other individuals performing work at any DOE facility. Primary goals of the CBDPP are to reduce the number of workers who are currently exposed to beryllium or who are likely to be exposed, to reduce the potential for exposure or the level of exposure to current workers through implementation or increased implementation of appropriate engineering and work practice controls, to establish a medical monitoring program for workers exposed to beryllium to ensure early detection and treatment of disease, and to establish a formal and continuing program to monitor the effectiveness of the CBDPP including continual improvement. The Rule adds a final goal of collecting consistent data for scientific and medical study of the cause of CBD.

Beryllium-Associated Worker Registry

As an integral part of the Rule, the responsible employer(s) at all DOE facilities are required to establish and maintain a "beryllium-associated worker registry" (BAWR). More specifically, Section 850.34 (Medical Surveillance), subsection (a)(4) prescribes that each responsible employer is required to establish and maintain a list of beryllium-

associated workers who may be eligible for protective measures. Subsection (a)(4) provides further details regarding the basis for inclusion in the BAWR, rules regarding protection of identities of BAWR registrants, and descriptions of additional relevant data and information to be included with each registrant in the BAWR.

Beryllium-Associated Worker Registry - Data Collection and Management Guidance

In 2005, DOE published a BAWR Technical Standard (DOE-STD-1187-2005) for use by responsible employers subject to the DOE CBDPP as a guide for submitting information and data to DOE. Although use of the technical standard was not mandatory, the standard presented acceptable methods for meeting the requirements in 10 CFR 850.39 pertaining to “Recordkeeping and Use of Information.” A revision of the BAWR technical standard was published in June 2007.

CBDPP – Importance of Adequate Monitoring

For reasons not entirely clear, the number of CBD cases diagnosed between 1970 and 1984 appeared to decline. This led most of those involved in the beryllium industries or beryllium studies to assume that current exposure limits were protective and that CBD cases were occurring only among workers exposed to high levels of beryllium many decades earlier. This assumption was proven false. Epidemiology studies by Cullen et al. in 1987, two studies at National Jewish Medical Research Center (NJMRC) in 1993, and a subsequent study of Y-12 workers provided clear evidence that adherence to the OSHA standard of 2 $\mu\text{g}/\text{m}^3$ (Eisenbud level) and implementation of numerous worker exposure controls had not prevented new cases of beryllium disease. Furthermore, an increasing number of CBD cases following minimal exposure were identified. These and other factors stress that the importance of appropriate and adequate industrial hygiene monitoring cannot be overstated if the CBDPP is to accomplish the goals of the Final Rule.

Who to Monitor

The CBDPP Final Rule is explicit in defining the requirements for who shall be monitored to comply with the Rule. Section 850.2 – Applicability declares that all DOE and DOE contractor employees involved in present or past activities with known or potential beryllium exposure are to be included in the CBDPP. This includes federal employees and visitors. Identification of the appropriate population to be included in the beryllium industrial hygiene monitoring program is of primary importance for reasons of compliance with the Rule, legal liability, and many believe, moral obligation. It can reasonably be argued that exclusion of individuals from the program, who rightfully should be monitored, is a much more critical error than inclusion of individuals in the program who may not need to be monitored. While one policy does not satisfy the Rule regarding inclusion of all beryllium-associated workers and may result in missed sensitization or CBD cases, practicing the second, all-inclusive policy, will likely affect analytical results due to misclassification and population dilution factors. These problems illustrate the importance of knowing where beryllium operations were conducted or inventories stored, and who were present in these beryllium areas. Information regarding beryllium operations and inventory areas is likely to be more readily available than an accurate accounting of all individuals who were (ever) in these beryllium areas. This is because operations areas, particularly in large industrial facilities, are typically quite stable due to costs of renovation

and moving equipment. In contrast, identifying all individuals who may have worked in or visited an area (for any number of reasons) may be quite challenging.

The difficulties in identifying the appropriate population for monitoring should suggest several elements to add to the monitoring policy, if not already present. First and foremost, and pertaining to current operations, a rigid policy should be implemented that requires all individuals entering the beryllium area to be logged in. This does not have to be difficult or onerous, but there should be no exceptions. For facility employees, a simple badge scanning procedure would be appropriate. For temporary workers or visitors, a hardcopy login sheet may be necessary. Of course, all login data should be stored in a readily retrievable form and maintained in a safe and appropriately qualified records repository.

Another problem that should be recognized and addressed is that of communications between operations personnel actually involved in beryllium work and the industrial hygiene personnel responsible for monitoring these individuals. A number of situations can occur where individuals are exposed, or at least potentially exposed, but no monitoring is performed. Examples of scenarios in which this may happen include the following:

1. Worker enters or reenters beryllium area for activities assumed to present no potential for exposure.
2. Worker performs activities with definite potential for exposure under a work permit with no allowance for exposure.
3. Worker performs activities without appropriate personal protective equipment.
4. Visitor is allowed in beryllium area for observation only, but is not announced, trained, or given appropriate personal protective equipment.
5. Discrepancies pertaining to type or form of material, or type or length of operation are provided to industrial hygiene personnel.

These or other situations that prevent or hinder appropriate industrial hygiene monitoring of beryllium-associated workers or visitors may result in non-compliance with the CBDPP, and possibly detrimental health effects.

A final challenge in accurately determining the population of beryllium-associated individuals is identifying those workers who have very limited or remote potential for exposure. Individuals that fall into this category include workers in laundry, transportation, local delivery, housekeeping, facility maintenance, crafts, environmental, laboratory, quality control, and other departments. Often, workers in these departments are perceived to have extremely low or zero risk of exposure. History has shown, however, that this is not typically the case. To fully comply with the CBDPP, Section 850.2 – Applicability, industrial hygiene staff, in cooperation with the operations staff and acting on behalf of the responsible employer, is required to identify and conduct industrial hygiene monitoring for beryllium on all current DOE federal and contractor workers and any other individuals (including visitors) defined as “beryllium workers.” The term “beryllium worker” is defined in the Rule as those current workers or others who are “regularly employed in a DOE beryllium activity” and who are exposed to beryllium or

have potential for exposure to beryllium. This applies to all workers regularly employed in beryllium activities and any others who may have limited, casual, or remote potential for exposure. It should be noted that the population subject to exposure monitoring is different from the population of “beryllium-associated workers” as defined in the Rule. The term “beryllium-associated worker” includes all those defined as “beryllium workers” plus current workers who may have had past exposure or potential exposure to airborne beryllium at a DOE facility. Airborne beryllium exposure would include exposure from resuspension of surface dust containing beryllium. Finally, although not explicitly covered in 10 CFR 850, it is worth noting that beryllium sensitization can occur through dermal exposure. As such, DOE requires the use of appropriate clothing and equipment that protect workers against the hazards of skin and eye contact with beryllium.

How to Monitor

Assuming the appropriate individuals have been identified as beryllium workers, a second critical element for meeting the requirements prescribed in the CBDPP is determining how to monitor the population. Ideally, to monitor the exposure of this population with a high level of confidence in the results, each individual in the population would be monitored for their entire work shift, every work day. In addition, monitoring would always be by personal sampling and would always be appropriate for the type and form of material being worked. In some/many operations this ideal policy would require two or more sampling setups worn by the worker to determine a time-weighted-average concentration and to possibly detect excursions occurring during the worker’s shift. A monitoring program of this type would be extraordinarily expensive and almost impossible to manage. The amount of equipment required, the number of industrial hygiene personnel needed to oversee, facilitate, and troubleshoot the monitoring procedure, and the cost of analyses would be excessive for most operations. Realistically, the task for the industrial hygiene staff specified within the CBDPP is to design and implement a robust and manageable program that fulfills all of the requirements specified in the Rule. An acceptable monitoring program would provide the following:

1. All areas that may have airborne particulate concentrations of elemental beryllium or insoluble beryllium compounds or alloys containing 0.1 percent beryllium are identified through baseline beryllium inventory and hazard assessments.
2. All current DOE federal and contractor workers and any other individuals who perform work at DOE facilities (beryllium workers) are monitored.
3. All beryllium workers are monitored either as individuals or as members of a statistically-based similar exposure group (SEG).
4. Exposure monitoring programs are managed by a qualified individual such as a certified industrial hygienist (CIH).
5. All actual sampling are performed by individuals with “sufficient” knowledge and experience.

Finally, all aspects of the monitoring program should be focused on the goal of preventing future cases of beryllium sensitization and CBD. Industrial hygiene monitoring that documents, contains, and reduces exposures will help achieve this goal.

Sampling Methodology

There are two main considerations for conducting a successful exposure monitoring program – an intelligent strategy and a careful implementation. In development of an exposure assessment strategy, ordinarily the primary questions for consideration are:

1. What are possible or likely exposures?
2. Who are potentially exposed?
3. What is/are the appropriate sampling method(s)?
4. How often should sampling occur?

Within the confines of the CBDPP, the first two questions have already been defined. The manager of the beryllium exposure assessment program is obligated by the Rule to conduct exposure assessments for all employees defined as beryllium workers. With regard to determining appropriate sampling methods, part of this question is also addressed in the Rule, 850.24. As discussed earlier, while daily monitoring of every beryllium worker may be desirable, DOE has determined that, to prevent placing an unreasonable burden on responsible employer(s), a statistically-based approach will adequately characterize the exposure profile for these workers. The Rule clearly infers that sampling may be done on individuals or on similar exposure groups (SEGs) when exposure to all members of the SEG will be adequately represented by the group sample(s). This places responsibility on the industrial hygiene staff to define each beryllium SEG as accurately as possible. Any misclassification of workers among SEGs will necessarily produce inaccurate exposure data for those misclassified workers. Two factors noted in the Background section of the Rule that should be considered when assembling SEGs are (1) for many years, engineering controls designed to reduce airborne exposure to beryllium in higher risk operations did not do enough to reduce the incidence of sensitization and CBD and (2) beryllium sensitization and CBD can occur even in conditions of low beryllium. Also, early research at beryllium processing facilities showed that risk of sensitization and CBD was underestimated when workforces were surveyed only once. Assignment of beryllium workers to SEGs should be done through a consistent and well documented procedure. Without such controls, time, change in industrial hygiene personnel, and change in beryllium activities will all contrive to induce misclassification among groups of workers designated as SEGs.

Also clearly defined in the Rule is the requirement that exposure measurements for the beryllium SEGs be subject to a credible statistical analysis for acceptance. This condition should not be taken lightly since it will require considerable effort to choose the number of workers to monitor, the number of samples collected, and the frequency of monitoring. In addition to these questions/decisions, the industrial hygiene staff will need to address more basic questions relevant to their monitoring program including sampler location, flow rate, sampling time, collection media (type, pore size), and others. The overriding principle for all of these methodological questions or decisions should always be the desire to generate the most accurate exposure data possible for the population of beryllium workers.

Sample Analysis

Many methods exist for both the capture and the analysis of samples obtained as part of an

exposure monitoring program. Most should be familiar to industrial hygiene professionals who will choose the most appropriate for their situation. A few commonly used methods for beryllium determination are provided below, along with example governing or adopted agency reference method numbers. However, a comprehensive review of analytical methods is beyond the scope of this technical standard. Other accredited or validated methods procedures may exist or be developed, and the choice of technique used should be based on each facility's specific needs.

1. Graphite Furnace Atomic Absorption Spectroscopy (GFAAS) is a full evaluation method applicable to airborne sampling with a 0.5 to 10 $\mu\text{g}/\text{m}^3$ concentration range. Vaporization in a graphite coated furnace of collected samples after they have been ashed with nitric acid and sulfuric acid enables spectroscopic analysis for beryllium at a wavelength of 234.9 nm. GFAAS can give good detection limits with a small sample size, but does take some time for analysis and requires careful chemical interference risk reduction.

NIOSH/CDC Method 7102 (filter) by GF-AAS

2. Inductively Coupled Plasma Atomic Emission Spectroscopy (ICP-AES) using nitric/perchloric acid ashing, aqua regia ashing, or hot block/HCL/HNO₃ digestion are simultaneous elemental analyses requiring inter-element correction factors and judicious wavelength selection for the spectroscopic analysis. Limit range varies with the type of analytical machine used, but can be as sensitive as 0.005 $\mu\text{g}/\text{m}^3$ to 2000 $\mu\text{g}/\text{m}^3$ in a 500L sample. Example methods include:

NIOSH/CDC Method 7300 (filter) by ICP-AES (2003)

NIOSH/CDC Method 7301 (filter) by ICP-AES (2003)

NIOSH/CDC Method 7303 (filter) by ICP-AES (2003)

Note that these methods may not adequately recover refractory forms of beryllium. If samples include refractory forms of beryllium, inclusion of sulfuric and/or hydrofluoric, or ammonium bifluoride may provide better recover of beryllium.

Determination of metals and metalloids in airborne particulate matter by ICP-AES is also covered in the following ISO and ASTM procedures.

ISO 15202-1: 2004

ISO 15202-2: 2012

ISO 15202-3: 2012

ASTM International D7035

3. ICP-AES for filter, wipe, and bulk sampling expands ICP-AES for sample collection using personal sampling pumps, wipe samples, or bulk samples. Detection range still varies with the type of instrument used, but most should cover an acceptable detection range, such as 0.01 to 5 $\mu\text{g}/\text{mL}$ in a 50mL solution.

OSHA ID-125G (filter, wipe, bulk) by ICP-AES (2002)

NIOSH/CDC Method 9102

4. Inductively Coupled Plasma Mass Spectrometry (ICP-MS) is a similar method to ICP-AES, using an inductively coupled plasma source to dissociate the sample. Mass spectrometry of the large number of ions released can result in excellent detection limits, down to parts per trillion with fast semi-quantitative screening. Consideration should be taken for established mass-related spectral interferences, along with the low upper limit on dissolved solids. Two advantages of ICP-MS over ICP-AES are a smaller sample volume needed and speed of analysis, but at an increased cost and requiring a higher skill level to operate.

ISO/DIS 17294-1: 2003

ISO 17294-2: 2002

EPA Method 6020A: 1998

5. Field-Portable Fluorometry can detect total beryllium (not compound specific) of levels from 0.005 to 6 $\mu\text{g}/\text{m}^3$ for an air sample of 1000 L or surface wipe using the NIOSH/CDC methodologies. High iron or titanium concentrations can cause minor interference which can be minimized by filtering the sample extract after letting its solution sit for some hours. Detection utilizes a beryllium specific optically fluorescent dye to analyze a solution of beryllium in a weakly acidic medium, often aqueous ammonium bifluoride. The dyed solution is analyzed with a fluorometric instrument which can vary in range with manufacturer and calibration, requiring proficiency in specific fluorometers. The simplicity and speed of this method, coupled with its field portable nature can be advantageous to field workers, allowing rapid analysis of samples on site. Methods for using fluorometry with high-throughput robotic liquid handling systems have also been developed. Example procedures include, but are not limited to:

NIOSH/CDC Method 7704 (air) by Field-Portable UV/VIS Fluorometry

NIOSH/CDC Method 9110 (surface) by Field-Portable UV/VIS Fluorometry

ASTM International D7202-5 by Field-Portable UV/VIS Fluorometry

ASTM International D7202-11 by Field-Portable UV/VIS Fluorometry

6. Dry sampling, wipe sampling, and tape sampling are standard practices for collection of settled dust for subsequent determination of beryllium and beryllium compounds. Vacuum and micro-vacuum collection of settled dust samples using wipe sampling methods has been found to reach or exceed 75% collection efficiency from smooth hard surfaces, making it less accurate than other sampling methods and should be used only if wet wipe sampling or vacuum sampling is inappropriate.

ASTM E1216 Adhesive tape sampling of smooth surfaces

ASTM D5438 Vacuum cleaner method for carpeted or bare floor surfaces

ASTM D7144 Micro-vacuum sampling

ASTM D6966 Wipe surface sampling

ASTM D7296 Dry wipe surface sampling

The National Technology Transfer and Advancement Act of 1995 (NTTAA) and Public Law 104-113 directs federal agencies to participate in the development of voluntary consensus standards and to adopt them instead of using in-house procedures. Voluntary consensus methods under development between ASTM International and ISO promote open discussion amongst a group of people with diverse knowledge, background, and expertise, covering a balance of users, producers, and those with general interest. Qualities of these methods are further enhanced by strict balloting, procedures of due process, and requirements for method precision and bias/uncertainty statements.

CONCLUDING MATERIAL

Review Activity:

Headquarters Offices

Environmental Management, EM
Fossil Energy
Environment, Health, Safety & Security
National Nuclear Security Administration
Nuclear Energy
Science

Field and Operations Offices

Chicago Operations Office
Idaho Operations Office
Los Alamos Field Office; EM
Los Alamos Field Office; NNSA
NNSA Service Center
Oak Ridge Operations Office
Office of River Protection
Richland Operations Office
Savannah River Operations Office

Area and Site Offices

Argonne Area Office
Brookhaven Area Office
Fermi Area Office
Kansas City Site Office
Livermore Site Office
Nevada Site Office
Paducah Site Office
Pantex Site Office
Sandia Site Office
Savannah River Site Office
Y-12 Site Office

National Laboratories

Ames Laboratory
Argonne National Laboratory
Brookhaven National Laboratory
Fermi National Accelerator Laboratory
Idaho National Laboratory

National Laboratories (continued)

Lawrence Berkeley National Laboratory
Lawrence Livermore National Laboratory
Boston University
Clean Harbors Environmental Services
Envirocon, Inc.
Los Alamos National Laboratory
National Energy Technology Laboratory
Oak Ridge National Laboratory
Pacific Northwest National Laboratory
Sandia National Laboratories

Facilities

Advanced Mixed Waste Treatment Project
East Tennessee Technology Park
Hanford Site
Knolls Atomic Power Laboratory
LATA Environmental Services of Kentucky
National Security Campus
National Strategic Protective Services
Nevada National Security Site
Oak Ridge Institute for Science and Education
Paducah Site
Pantex Plant
Portsmouth Gaseous Diffusion Plant
Rocky Flats Closure Project
Savannah River Site
Southwest Power Administration
SLAC National Accelerator Laboratory
Wackenhut Security Services, Inc.
Y-12 National Security Complex
Atkins Nuclear Secured
Navarro Research and Engineering
URS Corporation

Preparing Activity:

DOE-AU-13

Project Number:

SAFT-0111