

**OMB 83-I SUPPORTING STATEMENT**  
**Final Rule: Chronic Beryllium Disease Prevention Program**  
**OMB Control Number 1910-5112**

This supporting statement provides information regarding the Department of Energy (DOE) paperwork reduction act submission request pertaining to the Chronic Beryllium Disease Prevention Program (CBDPP). The numbered questions correspond to the order shown on the Office of Management Budget (OMB) Form 83-I, *Instructions for Completing OMB Form, 83-I*.

**A. JUSTIFICATION**

**1. Explain the circumstances that make the collection of information necessary. Identify any legal or administrative requirements that necessitate the collection. Attach a copy of the appropriate section of each statute and regulation mandating or authorizing the collection of information.**

The Department of Energy (DOE) issued a final rule 10 CFR Part 850, Chronic Beryllium Disease Prevention Program, including provisions that impose collections of information. These regulations were promulgated under authority in the Atomic Energy Act of 1954, 42 U.S.C. § 2201, and the Department of Energy Organization Act, 42 U.S.C. §§ 7191 and 7254. Copies of the relevant sections of these statutes have been attached.

DOE has a long history of beryllium use because of its broad application to many nuclear operations and processes. Inhalation of beryllium dust or particles can cause chronic beryllium disease or sensitization. Chronic beryllium disease is a chronic, often debilitating, and sometimes fatal lung disease. Beryllium sensitization is a condition in which a person's immune system becomes highly allergic to the presence of beryllium in the body.

This collection of information [submission](#) is [for re-approval of an existing ICR and DOE expects all initial requirements to have been completed](#). [The information is](#) necessary to provide DOE with the information needed to reduce the number of workers currently exposed to beryllium in the course of their work at DOE facilities managed by DOE or its contractors; minimize the levels of and potential for exposure to beryllium; and provide medical surveillance to ensure early detection of chronic beryllium disease.

**2. Indicate how, by whom, and for what purpose the information is to be used. Except for a new collection, indicate the actual use the agency has made of the information received from the current collection.**

The information is used by DOE and DOE contractor employers to manage chronic beryllium disease prevention programs, to provide information to employees, and to permit oversight of their programs by DOE management. The final rule (10 CFR 850) required collections in the following areas:

*Chronic Beryllium Disease Prevention Program Plan (Section 850.10)* – The rule requires employers to prepare and submit an initial CBDPP Plan to DOE for approval, and to submit updates of the CBDPP Plan periodically to DOE for approval. The CBDPP Plan establishes the commitment of the contractor to comply with the provisions of 10 CFR part 850, specifies the manner in which the employer proposes to comply with these provisions, also specifies those provisions that are not considered applicable and the reason for this determination, and finally indicates provisions for which regulatory relief (i.e. an exemption to 10 CFR part 850) is being sought.

DOE expects that this requirement will impose three paperwork burdens on affected DOE sites: submitting CBDPP plans under DOE N 440.1, revising the CBDPP plans submitted under DOE N 440.1 to comply with the final rule, and periodically revising the CBDPP plans to incorporate new aspects of the CBDPPs at the sites. However, under the current ICR, only paperwork burdens for revising the annual plans will be incurred since no new plans are expected to be submitted.

*Baseline Inventory (Section 850.20)* – The final rule requires employers to establish a baseline inventory of beryllium locations and operations, identify exposed and potentially exposed workers by location, and conduct sampling. In developing the inventory, the contractors are required to perform a records review and document the presence and location of beryllium on site. This requirement imposes the paperwork burden of documenting the presence and location of current and past uses of beryllium on the site and reviewing records of beryllium use. This ICR does not include paperwork burdens for this requirement since these inventories have been completed and no new inventories are expected under the current rule.

*Exposure Monitoring/Worker Notification Section (850.24)* – The final rule requires employers to notify workers of the results of exposure monitoring. This requirement imposes a paperwork burden of providing written notification to workers of the results of exposure monitoring results.

*Signed Consent Forms (Section 850.36)* – The final rule requires employers to obtain signed consent forms from workers prior to medical evaluations.

*Registry of Beryllium Workers (Section 850.39)* -The final rule requires employers to establish and maintain a registry of beryllium workers. DOE sites incur paperwork burdens to both establish (i.e., enter initial information) the beryllium registry and maintain (i.e., enter information on a recurring basis) the beryllium registry. This ICR only include paperwork burdens for maintaining the registry since these registries have been established by currently-affected sites and no new registries are expected under the current rule.

*Recordkeeping (Section 850.39)* - The final rule requires employers to establish and maintain records related to the beryllium inventory and hazard assessment, exposure monitoring, workplace controls and medical surveillance. Both establishing the recordkeeping system and maintaining the records on an annual basis constitute paperwork burdens. This ICR only include paperwork burdens for maintaining the records these recordkeeping systems have been established by currently-affected sites and no new systems are expected under the current rule.

*Performance Feedback (Section 850.40)* - The final rule requires employers to establish a performance feedback process for continually evaluating and improving the CBDPP. DOE sites will incur paperwork burdens in performing the performance feedback section of the final rule.

This ICR submission, however, is for re-approval of an existing ICR. DOE expects that the initial requirements of 10 CFR 850 have been completed by respondents. Thus, as has been stated above, only recurring requirements will impose burden on the respondents since no new requirements have been added.

**3. Describe whether, and to what extent, the collection of information involves the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.**

Within existing budget and resource constraints, Department program managers and contractors continually work to apply the latest appropriate-level information collection burden and improve the timeliness and usefulness of the management information being collected.

The rule requires that the “*Registry*” of beryllium associated workers, inventory of beryllium locations and operations, hazard assessments, exposure measurements, exposure controls, and medical surveillance records are maintained electronically using existing DOE systems. Accurate records are essential for effectively implementing the chronic beryllium disease prevention program plan, assessing the plan’s adequacy, and

studying the relationship between workplace conditions and chronic beryllium disease. DOE further expects that both submitting CBDPP plans and notifying workers of exposure monitoring results will be handled electronically through the Department's secure e-mail system.

**4. Describe efforts to identify duplication.**

Since this information collection primarily applies to management of programs in DOE, meaningful duplication in other agencies is unlikely.

**5. If the collection of information impacts small businesses or other small entities describe any methods used to minimize burden.**

The impact of collecting this information from small business is considered in the development of the contract requirements and documents and is minimized to the extent permitted by applicable statutory requirements and other legal and management constraints. Furthermore, data collected during this rulemaking has indicated that no small businesses will be affected by this regulatory action. The details of this data are discussed in Chapter 6, Section 6.1 of the Economic Analysis for this rulemaking.

**6. Describe the consequence to Federal program or policy activities if the collection is not conducted or is conducted less frequently, as well as any technical or legal obstacles to reducing burden.**

The frequency of collection is dictated by sound health, safety, and management practice. When any of these conditions change to permit reduction of the frequency of information collections, the reduction is encouraged.

**7. Explain any special circumstances that would cause an information collection to be conducted in a manner inconsistent with OMB guidelines. (a) requiring respondents to report information to the agency more often than quarterly; (b) requiring respondents to prepare a written response to a collection of information in fewer than 30 days after receipt of it; (c) requiring respondents to submit more than an original and two copies of any document; (d) requiring respondents to retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than three years; (e) in connection with a statistical survey, that is not designed to produce valid and reliable results that can be generalized to the universe of study; (f) requiring the use of a statistical data classification that has not been reviewed and approved by OMB; (g) that includes a pledge of confidentiality that is not supported by authority established in statute or**

**regulation, that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; (h) requiring respondents to submit proprietary trade secret, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.**

Departmental orders and other internal DOE requirements is collected in a manner consistent with 5 CFR 1320 guidelines.

**8. If applicable, provide a copy and identify the data and page number of publication in the Federal Register of the agency's notice, required by 5 CFR 1320.8(d), soliciting comments on the information collection prior to submission to OMB. Summarize public comments received in response to that notice and describe actions taken by the agency in response to the comments. Specifically address comments received on cost and hour burden. Describe efforts to consult with persons outside the agency to obtain their views on the availability of data, frequency of collection, the clarity of instructions and recordkeeping, disclosure, or reporting format (if any), and on the data elements to be recorded, disclosed, or reported. Consultation with representatives of those from whom information is to be obtained or those who must compile records should occur at least once every 3 years -- even if the collection of information activity is the same as in prior periods. There may be circumstances that may preclude consultation in a specific situation. These circumstances should be explained.**

The Department published a 60-day Federal Register Notice and Request for Comments concerning this collection in the Federal Register on June 17, 2009, volume 74, number 115, page 28680. The notice described the collection and invited interested parties to submit comments or recommendations regarding the collection. One comment was received via email requesting a copy of the information collection itself. A copy of the supporting statement was provided to the requestor. No other comments have been received.

**9. Explain any decision to provide any payment or gift to respondents, other than remuneration of contractors or grantees.**

There is no remuneration given for submission of any of the information other than the fact that the expense of responding is treated as an allowable cost.

**10. Describe any assurance of confidentiality provided to respondents and the basis for the assurance in statute, regulation, or agency policy.**

Where confidential information is involved in an information collection the provisions for dealing with this confidential information are set forth in the contract documents and the related Departmental regulations and are normal to the handling of management and program information by the Department.

**11. Provide additional justification for any questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private. This justification should include the reasons why the agency considers the questions necessary, the specific uses to be made of the information, the explanation to be given to persons from whom the information is requested, and any steps to be taken to obtain their consent.**

Per departmental regulations, any request for information on an individual's exposure to radiation is handled in accordance with the Privacy Act (5U.S.C.552a). Other than data on individual exposures, there is no information collected that is of a sensitive or personal nature.

**12. Provide estimates of the hour burden of the collection of information. The statement should indicate the number of respondents, frequency of response, annual hour burden, and an explanation of how the burden was estimated. Unless directed to do so, agencies should not conduct special surveys to obtain information on which to base hour burden estimates. Consultation with a sample (fewer than 10) of potential respondents is desirable.**

Respondents

DOE estimates that the total annual number of respondents is 5,799. This includes the 19 DOE sites affected by the rule<sup>1</sup> and 5,780 workers also affected by the rule. Each of the sites are responsible for four the requirements (see Table 1) and six of the sites are responsible for another requirement (see Table 1). The 5,780 workers are responsible for signing the consent forms, and are thus also counted as respondents.

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<sup>1</sup> DOE sites affected by the rule include: Argonne National Lab East, Argonne National Lab West, Fermi National Accelerator Lab, Hanford Site, Idaho National Lab, Kansas City Plant, Knolls Atomic Power Laboratory, Lawrence Berkeley National Lab, Lawrence Livermore National Lab, Los Alamos National Lab, Mound Site, National Energy Technology Lab – Albany, National Engineering and Environmental Lab, Oak Ridge East Tennessee Technology Park, Oak Ridge National Lab, Oak Ridge Y-12, Pantex Plant, Sandia National Lab, and Stanford Linear Accelerator Lab.

## Responses

Table 1 details the number of responses per respondent and the total annual responses for each Information Collection. Three of the Information Collections under this ICR will require only one response per site: annual revision to CBDPP plans, recordkeeping, and performance feedback. The other three Information Collections (worker notification, signed consent forms, and maintaining the beryllium registry) will each require more than one response per respondent. Details of these multiple responses per respondent are provided in the notes to Table 1.

The requirements for revising CBDPP plans, maintaining the beryllium registry, maintaining records, and performance feedback are incurred by the 19 sites and thus result in 57 responses annually (19 responses for each requirement  $\times$  3 requirements).

For notifying employees of exposure monitoring results, DOE used the estimates from the Economic Analysis to determine the number responses. DOE assumes that each monitoring occasion (i.e., each time a sample is taken) will constitute a response. Based on information in the EA, 17,776 new (incremental) samples will be collected annually under the final rule. Thus, notifying workers will involve 17,776 annual responses.

For maintaining the beryllium registry, DOE has assumed that each time the registry is updated will constitute a response. The registry would be updated for each medical exam. DOE estimates that each affected worker will have a medical exam each year and that 2.6 percent will have a referral exam. Thus, 5,930 exams will occur ( $5,780 + [5,780 \times 0.026]$ ) and thus 5,930 updates to beryllium registries will occur.

Consent forms are signed for each medical exam. As estimated above, DOE expects there to be 5,930 exams annually. Thus, 5,930 annual responses are obtained from signed consent forms (i.e., equal to the number of exams for affected workers).

Thus, the total number of annual responses is estimated to be 29,693 ( $57 + 17,776 + 5,930 + 5,930$ ).

**TABLE 1  
TOTAL NUMBER OF RESPONDENTS, ANNUAL RESPONSES PER RESPONDENT,  
TOTAL ANNUAL RESPONSES, AND NUMBER OF ANNUAL RESPONSE RECEIVED  
ELECTRONICALLY**

Information Collection	Total Number of Respondents Annually	Average Annual Number of Responses Per Respondent	Annual Responses	
			Total Number Annual Responses	Number of Annual Responses That Are Expected to be Electronic (Percent of Total Annual Responses)
Annual Revisions to CBDPP Plans [a]	19	1	19	19 (100%)
Worker Notification of Monitoring Results [b]	6	2,963 [c]	17,776 [d]	17,776 (100%)
Signed Consent Forms for Medical Exams	5,780	[e]	5,930	0 (0%)
Maintain Beryllium Registry	19	[f]	5,930	5,930 (100%)
Annual Recordkeeping [g]	19	1	19	19 (100%)
Annual Performance Feedback [h]	19	1	19	0 (0%)
<b>TOTALS</b>	<b>5,799 [i]</b>	<b>-</b>	<b>29,693</b>	<b>23,744 (80.0%)</b>

[a] One response each year is required from each of the 19 affected sites.

[b] Only six of the affected sites are expected to need to perform exposure monitoring each year.

[c] Calculated as the total number of annual responses (17,776) divided by the number of respondents (6), rounded to the nearest whole integer. See note [d].

[d] The Economic Analysis, Chapter 3, Section 3.2.4.2 estimates that of a total 29,101 exposure monitoring results would be generated at affected sites and 1,236 workers would be exposed or potentially exposed to beryllium above the action level (23.544 results per exposed worker). Recent DOE data indicates that there were 755 workers exposed or potentially exposed to beryllium above the action level in 2007; this number was extrapolated to estimate 17,776 total exposure monitoring results ( $775 \times 23.544 = 17,776$ ).

[e] Each affected worker is required to sign a consent form each time a medical examination is performed. DOE estimated that each affected worker will have an annual medical examination and that 2.6 percent of those workers will have a referral examination to follow-up on potential beryllium-related medical issues.

[f] The Beryllium registry must be updated once for each medical examination, which is the same as the number estimated in note [e] above.

[g] Recordkeeping can encompass a varied set of related and similar activities that can be site-specific. DOE has combined these varied activities into one general activity of



recordkeeping and assumed one response per site for accomplishing this general activity. Burden hour estimates for each site account for the variation in the specifics of what is done at each site.

[h] Each site is required to perform an assessment of the CBDPP program annually.

[i] This is not the sum of the column, but reflects the number of unique respondents counted in the column. As stated above, each of the 19 sites counts as a single respondent as do the 5,780 workers.

### Electronic Responses

Table 1 above provides information on the number of responses that DOE expects to be collected electronically. As noted in question 3, the final rule requires both the beryllium registry and recordkeeping to be accomplished through electronic means. DOE further expects that both submitting CBDPP plans and notifying workers of exposure monitoring results will be handled electronically. This encompasses 23,744 annual responses (19 each for revising the CBDPP plans annually and recordkeeping; 5,930 for maintaining the beryllium registry, and 17,776 for notifying workers; see the previous section for details on these estimates), or 80.0 percent of the total number of responses.

### Burden Hours

Table 2 below summarizes the estimates of the annual burden hours for each of the requirements. The notes to Table 2 provide details of the estimates for each of the requirements. Where appropriate, DOE has referred to the Economic Analysis for 10 CFR 850.

As noted above, this ICR submission is for re-approval of an existing ICR and DOE expects all initial requirements to have been completed. Thus, only annual recurring costs have been included in these estimates. DOE estimates that the CBDPP rule will impose 25,024 annual recurring hours (combined professional and clerical).

<b>Paperwork Burden</b>	<b>Total Annual Number of Responses [a]</b>	<b>Burden Hours Per Response</b>		<b>Total Burden Hours</b>	
		<b>Professional</b>	<b>Clerical</b>	<b>Professional</b>	<b>Clerical</b>
Annual Revisions to CBDPP Plans	19	96.8 [b]	26.03 [b]	1,839 [c]	495 [c]
Worker Notification of Monitoring Results	17,776	0	0.2 [d]	0	3,555
Signed Consent Forms for Medical Exams	5,930	0.25 [e]	0	1,483	0
Maintain Beryllium	5,930	0	0.25 [f]	0	1,483

Registry					
Annual Recordkeeping [g]	19	0	685 [h]	0	13,015
Annual Performance Feedback [i]	19	166 [j]	0	3,154	0
<b>TOTALS</b>	<b>29,693</b>	-	-	<b>6,476</b>	<b>18,548</b>
<b>GRAND TOTALS</b>		-		<b>25,024</b>	

[a] Taken from Table 1 above.

[b] The unit burden estimates vary by site. These numbers represent the average burden calculated as the total burden hours for each labor category divided by the total annual responses. See note [c] for details.

[c] The previous ICR estimated that 24 affected sites incurred total burden hours of 2,323 professional hours and 625 clerical hours annually to revise the CBDPP plans, or an average of 96.8 professional hours and 26.03 clerical hours per site. These estimates have been retained and applied to the update number of affected DOE sites

[d] Economic Analysis, Chapter 3, Section 3.2.4.4.

[e] The Economic Analysis (Chapter 3, Section 3.2.14.6) assumes 0.25 hours per consent form for workers to review and sign the form.

[f] Economic Analysis, Chapter 3, Section 3.2.14.2.

[g] Recordkeeping can encompass a varied set of related and similar activities that can be site-specific. DOE has combined these varied activities into one general activity of recordkeeping and estimated total burden hours for each site to perform all of these activities. The Economic Analysis for the final rule (Chapter 3, Section 3.2.17.2) provides details on these estimates.

[h] See note [f] above. This number represents the average burden from the Economic Analysis for the final rule calculated as the total number of burden hours divided by the number of respondents (sites).

[i] Burden was calculated separately for each site from data made available during the rulemaking.

[j] This number represents the average burden calculated as the number of burden hours divided by the number of respondents (sites). See Economic Analysis, Chapter 3, Section 3.2.18.

**13. Provide an estimate of the total annual cost burden to respondents or record keepers resulting from the collection of information.**

Table 3 summarizes the estimated annual recurring costs for this ICR. The notes to Table 3 provide details on the how these costs were derived, including the estimated hourly labor costs. As noted above, DOE expects that all initial requirements have been completed and thus only annual recurring costs are incurred under this ICR. DOE estimates that the CPDPP will impose \$1.23 million in annual recurring paperwork burden costs.

<b>TABLE 3 ESTIMATED ANNUAL COSTS OF PAPERWORK BURDENS</b>				
<b>Paperwork Burden</b>	<b>Burden Hours [a]</b>		<b>Cost of Burden Hours</b>	
	<b>Professional</b>	<b>Clerical</b>	<b>Professional</b>	<b>Clerical [b]</b>

Annual Revisions to CBDPP Plans	1,839	495	\$168,692 [c]	\$16,706
Worker Notification of Monitoring Results	0	3,555	\$0	\$119,981
Signed Consent Forms for Medical Exams	1,483	0	\$143,718 [d]	\$0
Maintain Beryllium Registry	0	1,483	\$0	\$50,051
Annual Recordkeeping	0	13,015	\$0	\$439,256
Annual Performance Feedback	3,154	0	\$289,316 [c]	\$0
<b>LABOR CATEGORY TOTALS</b>	<b>6,476</b>	<b>18,548</b>	<b>\$601,726</b>	<b>\$625,994</b>
<b>GRAND TOTALS</b>	<b>25,024</b>		<b>\$1,227,720</b>	

[a] Burden hours taken from Table 2.

[b] The hourly wage of clerical time was taken from BLS data for Office and Administrative Support Occupations (SOC 43-0000) (<http://www.bls.gov/oes/current/oes430000.htm>) and equaled \$15.00. The hourly wage from BLS was marked up by a factor of 2.25 (see Economic Analysis, Chapter 3, Section 3.1.3) to reflect benefits and overhead. The hourly labor cost used here was \$33.75 per hour.

[c] DOE has assumed that industrial hygienists would perform these tasks. The labor hour cost for industrial hygienists hours was derived from information provided by the sites in the final rulemaking. The average cost per site from the Economic Analysis was updated to current (third quarter 2008) dollars using the Employment Cost Index from BLS (<http://www.bls.gov/ncs/home.htm>, Series ID CIS2010000000000). The hourly labor cost used here was \$91.73 per hour.

[d] Workers perform this task. The labor hour cost for workers hours was derived from information provided by the sites in the final rulemaking. The average cost per site from the Economic Analysis was updated to current (third quarter 2008) dollars using the Employment Cost Index from BLS (<http://www.bls.gov/ncs/home.htm>, Series ID CIS2010000000000). The hourly labor cost used here was \$96.91 per hour.

#### **14. Provide estimates of annualized cost to the Federal government.**

As noted above in Question 1, the Department is not involved in the collection or maintenance of this data. Accordingly, there is no cost to the Federal Government.

#### **15. Explain the reasons for any program changes or adjustments reporting in Items 13 or 14 of the OMB Form 83-I.**

~~There are no program changes or adjustments reporting.~~ This is a request for an extension of a currently approved collection. DOE expects that the initial requirements of 10 CFR 850 have been completed. Thus, the only recurring requirements as noted in Item 12 will impose burden on the respondents since no new requirements have been added.

#### **16. For collections of information whose results will be published, outline plans for tabulation, and publication.**

This information collection will not be published for statistical use.

**17. If seeking approval to not display the expiration date for OMB approval of the information collection, explain the reasons that display would be appropriate.**

The Department is not seeking approval to not display the expiration date for OMB approval of this information collection.

**18. Explain each exception to the certification statement identified in Item 19. "Certification for Paperwork Reduction Act Submission," of OMB 83-I.**

The Department is not requesting any exceptions to the certification statement provided in Item 19 of OMB Form 83-I.