

OMB 83-I SUPPORTING STATEMENT
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 10 CFR Part 850, *Chronic Beryllium Disease Prevention Program*, which included provisions that impose collections of information (64 FR 68854). This information collection request (ICR) is a renewal, requesting approval of an existing ICR. The information continues to be 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 sites 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.

DOE and DOE contractors continue to use this information to: manage their chronic beryllium disease prevention programs, provide information to employees, and permit oversight of the programs by its management. The 10 CFR Part 850 requires collections in the following areas:

Chronic Beryllium Disease Prevention Program Plan (§ 850.10)- 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. 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 (§ 850.20) - This ICR does not include paperwork burdens for this requirement since these inventories have been completed, and no new inventories are expected.

Exposure Monitoring/Worker Notification (§ 850.24) - Requires employers to notify workers of the results of exposure monitoring. This ICR includes paperwork burdens for providing written notification to workers of the results of their exposure monitoring results.

Signed Consent Forms (§ 850.36) - Requires employers to obtain the signed consent form from workers prior to medical evaluations. This ICR includes paperwork burdens for obtaining a signed consent form (DOE F 440.1) from workers who voluntarily participate in the medical surveillance program prior to a medical evaluation.

Registry of Beryllium-Associated Workers (§ 850.39) - Requires employers to establish and maintain a registry of beryllium-associated workers. This ICR includes paperwork burdens for maintaining the registry since these registries have been established by currently-affected reporting organizations and no new registries are expected under the rule.

Recordkeeping (§ 850.39) - Requires employers to establish and maintain records related to the beryllium inventory and hazard assessment, exposure monitoring, workplace controls and medical surveillance. This ICR only includes paperwork burdens for maintaining the records of these recordkeeping systems since they have been established by the affected reporting organizations and no new systems are expected under the rule.

Performance Feedback (§ 850.40) - DOE reporting organizations continue to incur paperwork burdens in performing the performance feedback for continuous improvements to the program.

This ICR submission is a renewal, requesting approval of an existing ICR. 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 information being collected.

The 10 CFR Part 850 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. Accurate records are essential for effectively implementing the CBDPP, assessing the plan’s adequacy, and studying the relationship between workplace conditions and chronic beryllium disease. DOE further expects that both updating CBDPP plans and notifying workers of exposure monitoring results are being handled electronically through the Department’s secure e-mail system.

4. Describe efforts to identify duplication.

DOE is a self-regulating agency, therefore, its contractors are not under the Occupational Safety and Health Administration’s (OSHA’s) jurisdiction, and must comply with DOE regulations. However, DOE adopted OSHA’s permissible exposure limit for beryllium. DOE periodically contacts OSHA regarding their beryllium rule, and is not aware of any beryllium reporting requirements required by OSHA or the CDC of its employees or contractors.

This information collection applies to the management of a program required by DOE, therefore, meaningful duplication in other agencies are 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 was considered in the development of the contract requirements, and documents were minimized to the extent permitted by applicable statutory requirements and other legal and management constraints.

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 a reduction of the frequency of information collections, a 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 are 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 May 18, 2017, Volume 82, Number 95, Page 22824. The notice described the collection and invited interested parties to submit comments or recommendations regarding the collection. No comments were received.

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

There was no remuneration given for submission of any of the information other than the fact that the expense of responding was 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 was involved in the information collection the provisions for dealing with this confidential information were set forth in the contract documents, and the related Departmental regulations were 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 (5 U.S.C.552a). Other than data on individual exposures, there continues to be 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.

Burden Calculation Verification

Total Number of Unduplicated Respondents = Total Annual Responses ÷ Reports Filed Per Person: 6,113 = 16,898 ÷ ~ 2.76.¹

Total Annual Burden Hours = Average Burden per Applicant × Number of Unduplicated Respondents: 30,259 = ~ 5.04 × 6,003.

Average Burden per Collection = Average Burden per Applicant ÷ Reports Filed per Person: 1.79 = ~5.04 ÷ ~2.82.

Respondents

DOE estimates that the total annual number of respondents is 6,003. This includes the 27 DOE reporting organizations affected², and 5,976 workers also affected. All of the reporting organizations are responsible for four of the requirements (see Table 1) and 23 of the reporting organizations are responsible for another requirement (see Table 1)³. The 5,976 workers responsible for signing the consent forms are thus also counted as respondents.

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 requires 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) requires more than one response per respondent. Details of these multiple responses per respondent are provided in the notes to Table 1.

¹ Note that tildes indicate the numbers shown are rounded.

² DOE reporting to the Beryllium Registry is considered on a “reporting organization” basis, which may include either a DOE site as a whole or the individual contractors at a single DOE site (depending on how they prefer to report to DOE). DOE reporting organizations by this information collection are the 27 reporting organizations reporting BeLPT data to the 2015 Beryllium-Associated Worker Registry: Advanced Mixed Waste Treatment Project (AMWTP), Ames Laboratory (AMES), Argonne National Laboratory (ANL), Brookhaven National Laboratory (BNL), DOE Oak Ridge Office (DOE-ORO), East Tennessee Technology Park (ETTP), Fermi National Accelerator Laboratory (Fermi), Hanford Site (HAN), Idaho National Laboratory (INL), Knolls Atomic Power Laboratory (KAPL), LATA Environmental Services of Kentucky, LLC (PAD LATAKY), Lawrence Berkeley National Laboratory (LBNL), Lawrence Livermore National Laboratory (LLNL), LLNL Clean Harbors Environmental Services (LLNL CHES), Los Alamos National Laboratory (LANL), National Security Campus (NSC), National Strategic Protective Services, LLC for ETTP and ORNL (NSPS), Nevada National Security Site (NNSS), Oak Ridge National Laboratory (ORNL), Pacific Northwest National Laboratory (PNNL), Pantex Plant (PTX), Sandia National Laboratories (SNL), Savannah River Site (SRS), Stanford Linear Accelerator Center (SLAC), Y-12 Energy Solutions (Y-12 ES), Y-12 National Security Complex (Y-12), and Y-12 Navarro Research and Engineering (Y-12 NRE).

³Twenty-three reporting organizations reported exposure monitoring results to the Beryllium registry (DOE, 2015).

The requirements for revising CBDPP plans, maintaining the beryllium registry, maintaining records, and performance feedback are incurred by the 27 reporting organizations and thus result in 66 responses annually (27 responses for each requirement × 3 requirements).

For notifying employees of exposure monitoring results, DOE assumes that each monitoring occasion (*i.e.*, each time a sample is taken) will constitute a response. Based on information in the Beryllium registry, 4,853 new (incremental) samples were collected in 2015. Thus, notifying workers will involve close to 4,853 annual responses.

Consent forms are signed for each medical exam. As estimated above, DOE expects there to be 5,982 exams annually, therefore 5,982 annual responses are obtained from signed consent forms (*i.e.*, equal to the number of exams for affected workers). Note that 6 workers had follow-up medical exams so were required to sign the consent form a second time resulting in 6 more responses than respondents.

For maintaining the beryllium registry, DOE noted that only 23 reporting organizations currently report monitoring and medical examination results to the registry. DOE has assumed that each time the registry is updated constitutes a response. The registry would be updated for each medical exam. The registry reported 5,982 employees' medical screening results for 2015.⁴ Of these employees, six (0.10%) had at least two medical exams, as they were diagnosed as "sensitized" the first time (in 2015). No employees were diagnosed with CBD the first time. Thus, close to 5,976 exams will occur annually (5,976 + 6), and thus, 5,982 updates to beryllium registries will occur. The total number of annual responses is estimated to be 16,898 (27 + 4,853 + 5,982 + 5,982 + 27 + 27).

⁴ See the table entitled "Year of First Positive or Abnormal BeLPT Result for Employees that Are Sensitized or CBD" on page 16 in the 2015 Summary of The Beryllium-Associated Worker Registry.

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
Annual Revision to CBDPP Plans	27	1	27	27 (100%)
Worker Notification of Monitoring Results	23 [a]	211 [b]	4,853[c]	4,853 (100%)
Signed Consent Forms for Medical Exams	5,976 [d]	1.001	5,982	0 (0%)
Maintain Beryllium Registry	27	221.56 [e]	5,982	5,982 (100%)
Annual Recordkeeping	27	1 [f]	27	27 (100%)
Annual Performance Feedback	27	1	27	0 (0%)
Total	6,003 [g]	-	16,898	10,900 (64%)

[a] Only 23 of the affected reporting organizations currently report exposure monitoring results to the Beryllium registry.

[b] Calculated as the total number of annual responses (4,853) divided by the number of respondents (23), rounded to the nearest whole integer [4,853/23 = 211]. See note [d].

[c] The Beryllium registry reports 4,853, exposure monitoring results in 2015.

[d] Each affected worker is required to sign a consent form each time a medical examination is performed. The Beryllium registry reported the 5,976 employee medical screening results and noted that 6 workers were diagnosed as “sensitized” in 2015. DOE assumed that these 6 workers had a referral medical exam and signed an additional medical consent form. Therefore, DOE estimates that 5,982 (5,976 + 6) medical consent forms will be signed annually.

[e] Calculated as the total number of annual responses (5,982) divided by the number of respondents (27) [5,982/27 = 221.56]. See note [e].

[f] Recordkeeping can encompass a varied set of related and similar activities that can be reporting organization-specific. DOE has combined these varied activities into one general activity of recordkeeping and assumed one response per reporting organization for accomplishing this general activity. Burden hour estimates for each reporting organization account for the variation in the specifics of what is done at each reporting organization's site(s).

[g] 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 27 reporting organizations counts as a single respondent as do the 5,976 workers.

Electronic Responses

Table 1 above provides information on the number of responses collected electronically. As noted in question 3, 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 are handled electronically. This encompasses 10,900 annual responses (27 each for revising the CBDPP plans annually and recordkeeping; 5,982 for maintaining the beryllium registry, and 4,853 for notifying workers; see the previous section for details on these estimates), or 64 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 refers to the Economic Analysis for 10 CFR 850.

As noted above, this ICR submission is a renewal, requesting approval of an existing ICR. Thus, only annual recurring costs have been included in these estimates. DOE estimates that the CBDPP rule imposes 30,259 annual recurring hours (combined professional and clerical).

Table 2. Estimated Paperwork Burdens

Paperwork Burden	Total Annual Number of Responses [a]	Burden Hours per Response		Total Burden Hours		
		Professional	Clerical	Professional	Clerical	Total
Annual Revision to CBDPP Plans	27	96.8 [b]	26.05 [b]	2,614 [c]	703 [c]	3,317
Worker Notification of Monitoring Results	4,853	4,853	0.2 [d]	0	973	973
Signed Consent Forms for Medical Exams	5,982	0.25 [e]	0	1,496	0	1,496
Maintain Beryllium Registry	5,982	0	0.25 [f]	0	1,496	1,496
Annual Recordkeeping	27	0	685 [h]	0	18,495	18,495
Annual Performance Feedback	27	166 [j]	0	4,482	0	4,482
Total	16,898	-	-	8,591	21,667	30,259

[a] Taken from Table 1 above.

[b] The unit burden estimates vary by reporting organization. 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 2009 ICR estimated that 19 affected reporting organizations incurred total burden hours of 1,839 professional hours and 495 clerical hours annually to revise the CBDPP plans, or an average of 96.8 professional hours and 26.03 clerical hours per reporting organization. These estimates have been retained and applied to the update number of affected DOE reporting organizations.

[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 reporting organization-specific. DOE has combined these varied activities into one general activity of recordkeeping and estimated total burden hours for each reporting organization 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 (reporting organizations).

[i] Burden was calculated separately for each reporting organization 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 (reporting organizations). 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, all initial requirements have been completed and thus only annual recurring costs are incurred under this ICR. DOE estimates that the CBDPP will impose \$1.8 million in annual recurring paperwork burden costs.

Table 3. Estimated Annual Costs of Paperwork Burden

Paperwork Burden	Burden Hours [a]			Wages		Cost of Burden Hours		
	Professional	Clerical	Total	Professional	Clerical	Professional	Clerical	Total
Annual Revision to CBDPP Plans	2,614	703	3,317	\$121.38 [c]	\$35.91 [b]	\$317,277	\$25,245	\$342,522
Worker Notification of Monitoring Results	0	973	973	\$121.38	\$35.91	\$0	\$34,940	\$34,940
Signed Consent Forms for Medical Exams	1,496	0	1,496	\$128.23 [d]	\$35.91	\$191,826	\$0	\$191,826
Maintain Beryllium Registry	0	1,496	1,496	\$121.38	\$35.91	\$0	\$53,721	\$53,721
Annual Recordkeeping	0	18,495	18,495	\$121.38	\$35.91	\$0	\$664,155	\$664,155
Annual Performance Feedback	4,482	0	4,482	\$121.38	\$35.91	\$544,007	\$0	\$544,007
Total	8,592	21,667	30,259	-	-	\$1,053,110	\$778,062	\$1,831,171

[a] Burden hours taken from Table 2.

[b] The hourly wage of clerical time was taken from BLS's Occupational Employment Statistics data for Office and Administrative Support Occupations (SOC 43-0000) in 2015 and equals \$15.96. The hourly wage was marked up by a factor of 2.25 (see Economic Analysis, Chapter 3, Section 3.1.3) to reflect benefits and overhead. The resulting loaded hourly wage is \$35.91 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 reporting organizations in the final rulemaking. The average cost per reporting organization from the Economic Analysis was updated to current (2016 Q4) dollars using the Employment Cost Index from BLS. The hourly labor cost used here was \$121.37 per hour.

[d] Workers perform this task. The labor hour cost for worker hours was derived from information provided by the reporting organizations in the final rulemaking. The average cost per reporting organization from the Economic Analysis was updated to current (2016 Q4) dollars using BLS' Employment Cost Index. The hourly labor cost used here was \$128.23 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. The collection or maintenance of data at DOE reporting organizations is performed under contracts with DOE or the prime contractor at the site. DOE contractors are reimbursed through their contracts for the costs of complying with requirements in 10 CFR 851 which is represented in the total annual cost burden for respondents.

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

This ICR submission is a renewal, requesting approval of an existing ICR. The initial requirements of 10 CFR 850 were originally estimated as being associated with a burden of 5,059 hours for 3,046 responses annually for 13 reporting organizations.

The change in the number of responses and respondents under this ICR (a total of 30,259 burden hours for 16,898 responses annually for 27 reporting organizations, as noted in Item 12) are due to an adjustment in agency estimates. Namely, DOE has updated the number of respondents and respondents using data from the 2015 Beryllium-Associated Worker Registry, and updated wages to 2017\$. DOE also notes that the burden hours and responses have increased over time because more workers are volunteering to participate in the medical surveillance program and having to sign the consent form for medical evaluations.

There are no changes in the ICR due to program changes due to agency discretion, 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. This ICR submission is a renewal, requesting approval of an existing ICR.

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. This ICR submission is a renewal, requesting approval of an existing ICR.

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. This ICR submission is a renewal, requesting approval of an existing ICR.

Sources:

1. Bureau of Labor Statistics. 2016. Occupational Employment Statistics (OES) - May 2015 - National. Available at <https://www.bls.gov/oes/tables.htm> (Accessed April 26, 2016).

2. Bureau of Labor Statistics. 2017. Employment Cost Index (Series ID CIS2010000000000I). Available at <https://data.bls.gov/timeseries/CIS2010000000000I> (Accessed February 25, 2017).
3. Department of Energy (DOE). 1999. Chronic Beryllium Disease Prevention Program Final Rule: Economic Analysis.
4. Department of Energy (DOE). 2015. 2015 Beryllium-Associated Worker Registry Summary. Available at <https://energy.gov/ehss/beryllium-associated-worker-registry> (Accessed March 12, 2018).