

OMB 83-I SUPPORTING STATEMENT

Final Rule: Chronic Beryllium Disease Prevention Program

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).

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.

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.

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.

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.

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.

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.

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, 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, and the basis for the decision for adopting this means of collection. Also describe any consideration of using information technology to reduce burden.

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. This includes automation of previously manual processes where appropriate.

Furthermore, the final rule requires the beryllium registry and the recordkeeping system to be developed and maintained electronically. DOE also expects that submitting CBDPP plans and notifying workers of exposure monitoring results will also be performed through electronic means.

4. Describe efforts to identify duplication. Show specifically why any similar information already available cannot be used or modified for use for the purposes described in Item 2 above.

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 (Item 5 of OMB Form 83-I), 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:

- **Requiring respondents to report information to the agency more often than quarterly;**
- **Requiring respondents to prepare a written response to a collection of information in fewer than 30 days after receipt of it;**
- **Requiring respondents to submit more than an original and two copies of any document;**
- **Requiring respondents to retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than three years;**
- **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;**
- **Requiring the use of a statistical data classification that has not been reviewed and approved by OMB;**
- **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; or

- **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.**

This collection of information has been reviewed and justified by Departmental management requirements, statutes, external regulations or interagency reporting requirements, Departmental orders or other internal DOE requirements and 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 these 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.

As previously noted, this information collection differs from collections placed on the general public in that it is placed on DOE employers. There are no statistical-type collections included and the use of statistical techniques is precluded by the management necessity for specific information regarding the contractors and their performance. Consultation with outside agencies or persons as to this information collection will not be done. It should be noted that, as often as appropriate, input from DOE contractors regarding the burden implications of new or revised collections and also solicits their input on ways to reduce the burden of existing collections and still provide DOE contractors management with sufficient information to fulfill their managerial and statutory responsibilities.

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

Only contractors or grantees receive remuneration from the Department.

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. If the hour burden on respondents is expected to vary widely because of differences in activity, size, or complexity, show the range of estimated hour burden, and explain the reasons for the variance. Generally, estimates should not include burden hours for customary and usual business practices.**
- **If this request for approval covers more than one form, provide separate hour burden estimates for each form and aggregate the hour burdens in Item 13 of OMB Form 83-I.**
- **Provide estimates of annualized cost to respondents for the hour burdens for collections of information, identifying and using appropriate wage rate categories.**

Respondents

DOE estimates that the total annual number of respondents is 1,780. This includes the 24 DOE sites affected by the rule and 1,679 workers also affected by the rule. Each of the sites are responsible for four the requirements (see Table 1) and five of the sites are responsible for another requirement (see Table 1). Thus, the sites account for 101 respondents ($24 \times 4 + 5$). The 1,679 workers are responsible for signing the consent forms, and 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 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 24 sites and thus result in 72 responses annually (24 responses for each requirement x 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, 29,101 new (incremental) samples will be collected annually under the final rule. Thus, notifying workers will involve 29,101 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 6.2 percent will have a referral exam (see Economic Analysis, Chapter 3, Table 3-11, note [e]). Thus, 1,783 exams will occur ($1,679 + [1,679 \times 0.062]$) and thus 1,783 updates of the beryllium registry will occur.

Consent forms are signed for each medical exam. As estimated above, DOE expects there to be 1,783 exams annually. Thus, 1,783 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 32,739 ($72 + 29,101 + 1,783 + 1,783$).

| 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] | 24 | 1 | 24 | 24 (100%) |
| Worker Notification of Monitoring Results [b] | 5 | 5,820 [c] | 29,101 | 29,101 (100%) |
| Signed Consent Forms for Medical Exams | 1,679 | [d] | 1,783 | 0 (0%) |
| Maintain Beryllium Registry | 24 | [e] | 1,783 | 1,783 (100%) |
| Annual Recordkeeping [f] | 24 | 1 | 24 | 24 (100%) |
| Annual Performance Feedback [g] | 24 | 1 | 24 | 0 (0%) |
| TOTALS | 1,780 | - | 32,739 | 30,932 (94.5%) |

[a] One response each year is required from each of the 24 affected sites.

[b] Only five the affected sites are expected to need to perform exposure monitoring each year. The Economic Analysis, Chapter 3, Section 3.2.4.4 estimates that these five sites will generate 29,101 exposure monitoring results each year, each requiring notification to workers.

[c] Calculated as the total number of annual responses (29,101) divided by the number of respondents (five), rounded to the nearest whole integer.

[d] 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 6.2 percent of those workers will have a referral examination to follow-up on potential beryllium-related medical issues.

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

[f] 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.

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

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 30,932 annual responses (24 each for revising the CBDPP plans annually and recordkeeping; 1,783 for maintaining the beryllium registry, and 29,101 for

notifying workers; see the previous section for details on these estimates), or 94.5 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 30,083 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 |
| Annual Revisions to CBDPP Plans | 24 | 96.8 [b] | 26.03 [b] | 2,323 [c] | 625 [c] |
| Worker Notification of Monitoring Results | 29,101 | 0 | 0.2 [d] | 0 | 5,820 |
| Signed Consent Forms for Medical Exams | 1,783 | 0.25 [e] | 0 | 446 | 0 |
| Maintain Beryllium Registry | 1,783 | 0 | 0.25 [f] | 0 | 446 |
| Annual Recordkeeping [g] | 24 | 0 | 684.5 [h] | 0 | 16,428 |
| Annual Performance Feedback [i] | 24 | 166 [j] | 0 | 3,995 | 0 |
| TOTALS | 32,739 | - | - | 6,764 | 23,319 |
| GRAND TOTALS | | - | | 30,083 | |

[a] Taken from Table 1 above.

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

[c] Information provided by the sites as part of the original rulemaking indicated that 15 affected sites incurred total burden hours of 2,211 professional hours and 523 clerical hours annually to revise the CBDPP plans (Economic Analysis, Chapter 3, Section 3.2.1.3). The 2003 ICR added nine DOE sites to the number of affected sites. DOE assumed that these nine new sites would incur a total 112 professional hours and 72 clerical hours to revise CBDPP plans.

[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 calculated as the 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 recordkeepers resulting from the collection of information. (Do not include the cost of any hour burden shown in Items 12 and 14).

- **The cost estimate should be split into two components: (a) a total capital and start-up cost component (annualized over its expected useful life); and (b) a total operation and maintenance and purchase of services component. The estimates should take into account costs associated with generating, maintaining, and disclosing or providing the information. Include descriptions of methods used to estimate major cost factors including system and technology acquisition, expected useful life of capital equipment, the discount rate(s), and the time period over which costs will be incurred. Capital and start-up costs include, among other items, preparations for collecting information such as purchasing computers and software; monitoring, sampling, drilling and testing equipment; and record storage facilities.**
- **If cost estimates are expected to vary widely, agencies should present ranges of cost burdens and explain the reasons for the variance. The cost of purchasing or contracting out information collection services should be a part of this cost burden estimate. In developing cost burden estimates, agencies may consult with a sample of respondents (fewer than 10), utilize the 60-day pre-OMB submission public comment process and use existing economic or regulatory impact analysis associated with the rulemaking containing the information collection, as appropriate.**
- **Generally, estimates should not include purchases of equipment or services, or portions thereof, made: (1) prior to October 1, 1995, (2) to achieve regulatory compliance with requirements not associated with the information collection, (3) for reasons other than to provide information or keep records for the government, or (4) as part of customary and usual business or private practices.**

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 \$1.34 million in annual recurring paperwork burden costs.

| TABLE 3 | | | | |
|--|-------------------------|-----------------|-----------------------------|---------------------|
| ESTIMATED ANNUAL COSTS OF PAPERWORK BURDENS | | | | |
| Paperwork Burden | Burden Hours [a] | | Cost of Burden Hours | |
| | Professional | Clerical | Professional | Clerical [b] |
| Annual Revisions to CBDPP Plans | 2,323 | 625 | \$196,572 [c] | \$20,081 |
| Worker Notification of Monitoring Results | 0 | 5,820 | \$0 | \$186,997 |
| Signed Consent Forms for Medical Exams | 446 | 0 | \$39,872 [d] | \$0 |
| Maintain Beryllium Registry | 0 | 446 | \$0 | \$26,057 |
| Annual Recordkeeping | 0 | 16,428 | \$0 | \$527,832 |
| Annual Performance Feedback | 3,995 | 0 | \$338,057 [c] | \$0 |
| LABOR CATEGORY TOTALS | 6,764 | 23,319 | \$574,501 | \$760,967 |
| GRAND TOTALS | 30,083 | | \$1,335,468 | |

[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 \$14.28. The hourly wage from BLS was marked up by a factor of 2.25 (see Economic Analysis) to reflect benefits and overhead. The hourly labor cost used here was \$32.13 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 (fourth quarter 2005) dollars using the Employment Cost Index from BLS (<http://www.bls.gov/ncs/home.htm>, Series ID ECU10002I). The hourly labor cost used here was \$84.62 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 (fourth quarter 2005) dollars using the Employment Cost Index from BLS (<http://www.bls.gov/ncs/home.htm>, Series ID ECU10002I). The hourly labor cost used here was \$89.40 per hour.

14. Provide estimates of annualized cost to the Federal government. Also, provide a description of the method used to estimate cost, which should include quantification of hours, operational expenses (such as equipment, overhead, printing, and support staff), and any other expense that would not have been incurred without this collection of information. Agencies also may aggregate cost estimates from Items 12, 13, and 14 in a single table.

The Department's estimated cost reflects charges incurred to support the collection of reporting information, information verification, registry and system maintenance, recordkeeping and performance feedback.

The estimated annualized cost to the Department for the data is based on FY 2005 costs. In FY 2005, DOE estimates that it incurred a total cost of approximately \$1,335,468. This represents approximately 23,319 hours of clerical work at an average hourly rate of \$14.28 combined with approximately 6318 hours of industrial hygienists' work at an hourly rate of

\$84.62 and approximately 446 hours of labor work at an hourly rate of \$89.40 .Therefore the annualized cost to the Federal Government is 1,335,468. For more information Table 3 provides an outline of the estimated annual recurring costs for this ICR.

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

The number of total annual responses requested for the extension of this collection increased due to a revised estimate of the number of sites included in this program. Originally, when the final rule 10 CFR Part 850, Chronic Beryllium Disease Prevention Program was published, DOE listed 30,876 responses. This was the number based on those who responded to the initial call for the Chronic Beryllium Prevention Program, however since that date several other sites included under this rule have necessitated the implementation of the program as well. Though the number of responses is estimated to increase, the total amount of burden hours is expected to decrease as a result of previous overestimations in time and cost.

16. For collections of information whose results will be published, outline plans for tabulation, and publication. Address any complex analytical techniques that will be used. Provide the time schedule for the entire project, including beginning and ending dates of the collection information, completion of report, publication dates, and other actions.

This information collection will not be published for statistical use. All such DOE collections are handled by the Energy Information Administration (EIA).

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.

This collection of information this has been reviewed and justified by Departmental management requirements, statutes, external regulations or interagency reporting requirements, Departmental orders or other internal DOE requirements and meet the requirements listed in the "Certification for Paperwork Reduction Act Submissions."