Dated: February 17, 2010.

Maryam I. Daneshvar,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

[60 Day–10–0639]

Centers for Disease Control and Prevention Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404–639–5960 or send comments to Maryam Daneshvar, CDC Acting Reports Clearance Officer, 1600 Clifton Road, MS–D74, Atlanta, GA 30333 or send an e-mail to *omb@cdc.gov.*

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Written comments must be received within 60 days of this notice.

Project Proposal

EEOICPA Special Exposure Cohort Petitions (OMB No. 0920–0639 exp. 7/31/2010)—Extension—National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

On October 30, 2000, the Energy Employees Occupational Illness Compensation Program Act of 2000 (EEOICPA), 42 U.S.C. 7384–7385 [1994, supp. 2001] was enacted. It established a compensation program to provide a lump sum payment of $150,000 and medical benefits as compensation to covered employees suffering from designated illnesses incurred as a result of their exposure to radiation, beryllium, or silica while in the performance of duty for the Department of Energy and certain of its vendors, contractors and subcontractors. This legislation also provided for payment of compensation for certain survivors of these covered employees. This program has been mandated to be in effect until Congress ends the funding.

Among other duties, HHS was directed to establish and implement procedures for considering petitions by classes of nuclear weapons workers to be added to the "Special Exposure Cohort" (the "Cohort"). In brief, EEOICPA authorizes HHS to designate such classes of employees for addition to the Cohort when NIOSH lacks sufficient information to estimate with sufficient accuracy the radiation doses of the employees, if HHS also finds that the health of members of the class may have been endangered by the radiation dose the class potentially incurred. HHS must also obtain the advice of the Advisory Board on Radiation and Worker Health (the "Board") in establishing such findings. On May 28, 2004, HHS issued a rule that established procedures for adding such classes to the Cohort (42 CFR part 83). The rule was amended on July 10, 2007.

The HHS rule authorizes a variety of respondents to submit petitions. Petitioners are required to provide the information specified in the rule to qualify their petitions for a complete evaluation by HHS and the Board. HHS has developed two forms to assist the petitioners in providing this required information efficiently and completely. Form A is a one-page form to be used by EEOICPA claimants for whom NIOSH has attempted to conduct dose reconstructions and has determined that available information is not sufficient to complete the dose reconstruction. Form B, accompanied by separate instructions, is intended for all other petitioners. Forms A and B can be submitted electronically as well as in hard copy. Respondent/petitioners should be aware that HHS is not *requiring* respondents to use the forms. Respondents can choose to submit petitions as letters or in other formats, but petitions must meet the informational requirements referenced above. NIOSH expects, however, that all petitioners for whom Form A would be appropriate will actually use the form, since NIOSH will provide it to them upon determining that their dose reconstruction cannot be completed and encourage them to submit the petition. NIOSH expects the large majority of petitioners for whom Form B would be appropriate will also use the form, since it provides a simple, organized format for addressing the informational requirements of a petition.

NIOSH will use the information obtained through the petition for the following purposes: (a) Identify the petitioner(s), obtain their contact information, and establish that the petitioner(s) is qualified and intends to petition HHS; (b) establish an initial definition of the class of employees being proposed to be considered for addition to the Cohort; (c) determine whether there is justification to require HHS to evaluate whether or not to designate the proposed class as an addition to the Cohort (such an evaluation involves potentially extensive data collection, analysis, and related deliberations by NIOSH, the Board, and HHS); and, (d) target an evaluation by HHS to examine relevant potential limitations of radiation monitoring and/or dosimetry-relevant records and to examine the potential for related radiation exposures that might have endangered the health of members of the class.

Finally, under the rule, petitioners may contest the proposed decision of the Secretary to add or deny adding classes of employees to the cohort by submitting evidence that the proposed decision relies on a record of either factual or procedural errors in the implementation of these procedures. NIOSH estimates that the time to prepare and submit such a challenge is 45 minutes. Because of the uniqueness of this submission, NIOSH is not providing a form. The submission will typically be in the form of a letter to the Secretary.

There are no costs to petitioners unless a petitioner chooses to purchase the services of an expert in dose reconstruction, an option provided for under the rule.

ESTIMATE OF ANNUALIZED BURDEN HOURS

Form name	Type of respondent	No. of respondents	No. of responses per respondent	Average burden per respondent (in hours)	Total response burden hours
Form A 83.9	Petitioner using Form A	30	1	3/60	2
Form B 83.9	Petitioner using Form B	40	1	5	200
Form B 83.9	Petitioner submission format other than Form B (as permitted by rule).	5	1	6	30
83.18	Petitioner Appealing final HHS decision (no specific form is required).	5	1	45/60	4
	Claimant authorizing a party to submit petition on his/her behalf.	20	1	3/60	1
Total	.....	100	.....	.....	237

Dated: February 18, 2010.

Maryam I. Daneshvar,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; REDS—II—Does Pre-Donation Behavioral Deferral Increase the Safety of the Blood Supply?

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Heart, Lung, and Blood Institute (NHLBI), the National Institutes of Health (NIH), will publish periodic summaries of proposed projects to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection: Title: REDS–II Does Pre-Donation Behavioral Deferral Increase the Safety of the Blood Supply?

Type of Information Collection Request: NEW. *Need and Use of Information Collection:* While it is well-accepted that deferrals, as part of the "layers of safety" concept, increase the safety of the blood supply, studies with sufficiently large sample size to quantify HIV infection and other infectious marker rates in deferred donors are lacking. Evidence in support of increased safety is frequently inferred from studies conducted in other health care settings. For example, a small hospital-based case control study conducted in Brazil examined the association between infectious markers and body tattoos. Even though tattoos are not used as a criteria to determine blood donor eligibility in Brazil, having a tattoo was associated with HCV and also with having at least one positive infectious marker. (1) Significant associations were not independently observed for HIV, HBV, syphilis or Chagas. The authors reported an overall sensitivity of 11% and specificity of 97% for the presence of a tattoo as indicator of having HIV, HCV, HBV, or syphilis infection. The researchers then estimated the impact on blood donor selection and disease marker testing using the results from their hospital-based case control study. However, the assumptions such as disease marker prevalence of as much as 15% in donors who are deferred for tattoos and a prevalence of 4% of the potential donor base having a tattoo (2) do not represent current temporary deferrals in Brazil and do not address the most common behavior-related deferrals. A more detailed and targeted assessment of the value of relevant deferrals could be used to help inform blood donation policies in Brazil.

In Brazilian blood collection centers, donor deferral is initiated either by the blood center staff, based on information disclosed by prospective donors, or by the donor through self-deferral. Either type of deferral occurs because of the belief that a donor's behavior, exposures, or history represents an increased risk to the safety of the blood supply

Although the general eligibility criteria are mandated by the Brazilian Ministry of Health, the specific criteria for screening potential donors and the procedures for implementing them may vary across the regional blood collection centers. This study will focus on sexual behavior deferrals and their impact on blood safety. The two main study aims are: (1) To assess infectious disease marker prevalence in donors who are deferred for higher risk sexual and non-injection drug use behavior; and (2) To determine if the different deferral classification procedures used by different blood centers in Brazil lead to a measurable difference in disease marker prevalence in deferred donors. To do this, deferred donors who agree to participate in this study will be asked to complete an audio computer assisted self interview (ACASI) questionnaire that measures two content areas (1) motivations for attempting to donate, (2) additional information on the deferral and other potentially undisclosed deferrable behaviors. A blood sample will be collected from the deferred donors and tested for the panel of infections currently screened for in Brazil (HIV, Hepatitis C, Hepatitis B, Human T-lymphotropic virus, syphilis, and *Trypanosoma cruzi*) using the same high-throughput laboratory reagents and procedures that are used to screen donations. These deferred donor marker rates will be compared to the marker rates among accepted donors with the same demographic characteristics. Marker rates in deferred donors will also be compared between the blood centers.

Frequency of Response: Once. *Affected Public:* Individuals. *Type of Respondents:* Adult Blood Donors. The annual reporting burden is as follows: *Estimated Number of Respondents:* 4,860; *Estimated Number of Responses per Respondent:* 1; *Average Burden of Hours per Response:* 0.33 (including administration of the informed consent form and questionnaire completion instructions); and *Estimated Total Annual Burden Hours Requested:* 1,620. The annualized cost to respondents is estimated at: $10,530 (based on $6.50 per hour). There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.