Rockville, MD 20852. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–402–2071. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance document.

You may submit comments identified by docket ID number HHS–OS–OPHS–2012–0005, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Enter the above docket ID number in the ''Enter Keyword or ID field and click on ''Search.'' On the next page, click the ''Submit a Comment'' action and follow the instructions.
- *Mail/Hand delivery/Courier [For paper, disk, or CD–ROM submissions]:* Irene Stith-Coleman, Ph.D., Office for Human Research Protections, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852.

Comments received, including any personal information, will be posted without change to *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Irene Stith-Coleman, Ph.D., Office for Human Research Protections, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852, 240–453–6900; email *Irene.Stith-Coleman@hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

A. Overview

OHRP, Office of the Assistant Secretary for Health, is announcing the availability of a draft guidance document entitled ''Draft Guidance on Considerations in Transferring a Previously-Approved Research Project to a New IRB or Research Institution.'' The draft guidance document, when finalized, will represent OHRP's current thinking on this topic and will provide OHRP's first formal guidance on this topic. The draft document is intended primarily for IRBs, institutions, and investigators that may be responsible for the review, conduct, or oversight of human subjects research conducted or supported by HHS.

The guidance document would apply to non-exempt human subjects research conducted or supported by HHS. It presents common scenarios for transfer of a previously-approved research project to another institutional review board (IRB) or to a new engaged research institution, and outlines the administrative actions to be considered by IRBs, engaged institution(s), and investigators. In particular, the guidance addresses the following questions:

1. What is the regulatory background for research project transfer?

2. What actions may apply when the research project remains at the same institution, but responsibility for IRB review is transferred either from an *internal* to an *external* IRB, or from an *external* IRB to *another external* IRB?

3. What actions may apply when the research project remains at the same institution, but responsibility for IRB review is transferred from one *internal* to another *internal* IRB?

4. What actions may apply when the research project is transferred to a *new engaged institution*?

To enhance human subject protections and reduce regulatory burden, OHRP and the Food and Drug Administration (FDA) have been actively working to harmonize the agencies' regulatory requirements and guidance for human subjects research.

FDA has simultaneously published in this same issue of the **Federal Register** a draft guidance document entitled ''Guidance for IRBs, Clinical Investigators, and Sponsors, Considerations When Transferring Clinical Investigation Oversight to Another IRB'' that is similar to OHRP's draft document.

FDA and OHRP recognize that the two documents may appear somewhat different as there are minor variations in formatting and some necessary variations due to differences in the regulated entities under FDA's and OHRP's jurisdiction. The agencies wish to stress, however, that our intent was to provide harmonized guidance to IRBs, sponsors, institutions, investigators, and other entities involved in the study oversight transfer process. FDA and OHRP will continue to work closely in the development of final guidance and appreciate comments from interested parties.

II. Electronic Access

Persons with access to the Internet may obtain the draft guidance document on OHRP's Web site at *http://www.hhs.gov/ohrp/newsroom/rfc/index.html* or on the Federal eRulemaking Portal at *http://www.regulations.gov/.*

Dated: June 7, 2012.

Ivor Pritchard,

Senior Advisor to the Director, Office for Human Research Protections.

[FR Doc. 2012–14287 Filed 6–11–12; 8:45 am]

BILLING CODE 4150–36–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Decision To Evaluate a Petition To Designate a Class of Employees From the Clarksville Facility in Clarksville, TN, To Be Included in the Special Exposure Cohort

AGENCY: National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: NIOSH gives notice as required by 42 CFR 83.12(e) of a decision to evaluate a petition to designate a class of employees from the Clarksville Facility in Clarksville, Tennessee, to be included in the Special Exposure Cohort under the Energy Employees Occupational Illness Compensation Program Act of 2000. The initial proposed definition for the class being evaluated, subject to revision as warranted by the evaluation, is as follows:

Facility: Clarksville Facility.

Location: Clarksville, Tennessee.

Job Titles and/or Job Duties: Workers potentially exposed to radioactive materials while working at the Clarksville facility.

Period of Employment: January 1, 1949 to December 31, 1967.

FOR FURTHER INFORMATION CONTACT: Stuart L. Hinnefeld, Director, Division of Compensation Analysis and Support, National Institute for Occupational Safety and Health, 4676 Columbia Parkway, MS C–46, Cincinnati, OH 45226, Telephone 877–222–7570. Information requests can also be submitted by email to *DCAS@CDC.GOV*.

John Howard,

Director, National Institute for Occupational Safety and Health.

[FR Doc. 2012–14221 Filed 6–11–12; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Decision To Evaluate a Petition To Designate a Class of Employees From the Medina Facility in San Antonio, TX, To Be Included in the Special Exposure Cohort

AGENCY: National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: NIOSH gives notice as required by 42 CFR 83.12(e) of a decision to evaluate a petition to designate a class of employees from the Medina Facility in San Antonio, Texas, to be included in the Special Exposure Cohort under the Energy Employees Occupational Illness Compensation Program Act of 2000. The initial proposed definition for the class being evaluated, subject to revision as warranted by the evaluation, is as follows:

Facility: Medina Facility.

Location: San Antonio, Texas.

Job Titles and/or Job Duties: Workers potentially exposed to radioactive materials while working at the Medina facility.

Period of Employment: January 1, 1958 to December 31, 1966.

FOR FURTHER INFORMATION CONTACT: Stuart L. Hinnefeld, Director, Division of Compensation Analysis and Support, National Institute for Occupational Safety and Health, 4676 Columbia Parkway, MS C–46, Cincinnati, OH 45226, Telephone 877–222–7570. Information requests can also be submitted by email to *DCAS@CDC.GOV*.

John Howard,

Director, National Institute for Occupational Safety and Health.

[FR Doc. 2012–14223 Filed 6–11–12; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30-Day–12–12DO]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 639–7570 or send an email to *omb@cdc.gov*. Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC or by fax to (202) 395–5806. Written comments should be received within 30 days of this notice.

Proposed Project

National Healthy Worksite Program—New—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Centers for Disease Control and Prevention (CDC) is establishing the National Healthy Worksite Program (NHWP), a comprehensive workplace health promotion program to address physical activity, nutrition, and tobacco use in the workplace. Participating worksites will create high quality workplace health programs by implementing programs, policies, and environmental supports that assist employees in adopting healthy behaviors. The NHWP will provide assistance to an estimated 100 small, mid-size, and large employers to create and expand sustainable workplace programs aimed at achieving three primary goals: (1) To reduce the risk of chronic disease among employees and their families through science-based workplace health interventions and promising practices; (2) to promote sustainable and replicable workplace health activities such as establishing a worksite committee, having senior leadership support, and forming community partnerships and health coalitions, and (3) to promote peer-to-peer business mentoring that encourages employers to be active leaders and role models in their communities around health.

Over a three-year period, the National Healthy Worksite Program will engage and recruit groups of up to 15 employers in seven selected communities, lead them through the process of building a comprehensive workplace health program, and collect evaluation information. The NHWP will also provide workplace health program training to worksites that are not participating in the NHWP. CDC may increase the number of NHWP sites that receive assistance, if funding becomes available.

CDC plans to collect information needed to select the initial group of participating NHWP worksites; to describe implementation and costs of workplace health promotion programs at these sites over the initial two-year period of support; to examine the effects of workplace health programs on employee access and opportunity to engage in activities that support a healthy lifestyle; and to quantify reductions in individual health risks and improvements in productivity. The NHWP will also assess the value of community-based training for community participants (employers not selected as participating employers). In addition, for up to one year after the two-year implementation period, CDC will collect information needed to assess program sustainability.

Participation in the NHWP is voluntary for both worksites and employees at those sites. During the development phase of the proposed information collection, CDC received comments from a variety of interested parties, and a number of instruments were revised to improve clarity. There are no costs to participants other than their time, with the exception of an in-kind contribution for large employers.

CDC will use the information collected to support the implementation efforts of employers participating in the NHWP; inform future program efforts at CDC and other Federal agencies; and develop tools, resources, and guidance to support broader workplace health efforts.

OMB approval is requested for three years. The total estimated annualized burden hours are 15,530.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Interested Employer	Employer Phone Interview Guide	69	1	20/60
Participating Employer	Organizational Assessment	66	2	30/60
	Employee Eligibility File	33	4	15/60
	Employer Information Form	33	1	30/60
	Health Screening Site Interview Form	33	2	30/60
	Discussion Guide for Steering Committee Members.	100	1	30/60