was posted on the ONC Web site on March 25, 2011 and originally open for public comment through Friday, April 22 at 11:59 p.m. (Eastern). This notice serves to announce that the public comment period for the Plan has been extended through Friday, May 6 at 11:59 p.m. (Eastern).

In order for your comments to be read and considered, you must submit your comment via the Federal Health IT Buzz Blog: *http://www.healthit.gov/buzz-blog/from-the-onc-desk/hit-strat-plan/.*

Dated: April 19, 2011.

Erin Poetter,

Office of Policy and Planning, Office of the National Coordinator for Health Information Technology.

[FR Doc. 2011–9941 Filed 4–22–11; 8:45 am]

BILLING CODE 4150–45–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Decision To Evaluate a Petition To Designate a Class of Employees From Ames Laboratory in Ames, IA, To Be Included in the Special Exposure Cohort

AGENCY: National Institute for Occupational Safety and Health (NIOSH), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: HHS gives notice as required by 42 CFR 83.12(e) of a decision to evaluate a petition to designate a class of employees from Ames Laboratory in Ames, Iowa, 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: Ames Laboratory.

Location: Ames, Iowa.

Job Titles and/or Job Duties: All Department of Energy (DOE) employees, its predecessor agencies, and its contractors and subcontractors who worked in any area of the DOE facility.

Period of Employment: January 1, 1942 through December 31, 1970.

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

John Howard,

Director, National Institute for Occupational Safety and Health.

[FR Doc. 2011–9928 Filed 4–22–11; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Request for Information (RFI) To Identify and Obtain Relevant Information From Public or Private Entities With an Interest in Biovigilance

AGENCY: Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: This Request for Information (RFI) seeks to identify and obtain relevant information regarding the possible development of a public-private partnership (PPP) designed to facilitate the identification of risks and strategies to assure safety of the U.S. supply of blood and blood components, tissues, cells, and organs. This RFI is intended to inform the Department of Health and Human Services (HHS) regarding stakeholders, mechanisms, and approaches on issues related to developing and managing a PPP and scope of PPP activities. Replies are invited from (1) public or private entities with an interest in biovigilance, and (2) entities with experience and capabilities managing public-private partnerships (PPPs) in the biological sciences and public health domains. This RFI is for information and planning purposes only and is not a solicitation for applications or an obligation on the part of the U.S. Government to provide support for any ideas identified in response to it. Please note that the U.S. Government will not pay for the preparation of any information submitted or for its use of that information.

DATES: All responses must be received no later than 4 p.m. EDT on June 9, 2011 at the address listed below.

ADDRESSES: All responses should be e-mailed to *Biovigilance@hhs.gov* (attention Dr. Jerry Holmberg). Please limit responses to 10 pages. Include in the subject line, the following information:

- Name of the institution or site.
- Respondent, title, and full contact information.

FOR FURTHER INFORMATION CONTACT: Dr. Jerry Holmberg, Senior Advisor for Blood Safety, Office of the Assistant Secretary for Health, Office of the Secretary, U.S. Department of Health and Human Services, 1101 Wootton Parkway, Tower Building, Suite 250, Rockville, MD 20852.

SUPPLEMENTARY INFORMATION: In 2009, the Advisory Committee on Blood Safety and Availability (ACBSA) within the Department of Health and Human Services (HHS), Office of the Assistant Secretary of Health, reviewed and discussed a report on the current state of biovigilance. In that report ("Biovigilance: Efforts to Bridge a Critical Gap in Patient Safety and Donor Health" *http://www.hhs.gov/ash/bloodsafety/biovigilance/index.html*), biovigilance was defined as "a comprehensive and integrated national patient safety program to collect, analyze, and report on the outcomes of collection and transfusion and/or transplantation of blood components and derivatives, tissues, cells, and organs. This definition does not include vaccines, allergenic products, and most recombinant human proteins." Safety surveillance for plasma derivatives, while a logical part of biovigilance, already falls under FDA mandated drug adverse event reporting and is not addressed in the current HHS initiative. Among the recommendations in that report was for HHS to develop an HHS action plan to support a national biovigilance program, integration of systems within government and private sectors, and steps to enhance mechanisms for surveillance.

HHS is continuing its efforts to develop an action plan to support a national biovigilance program for blood and blood components, tissues, cells, and organs. As part of these efforts, HHS is exploring the feasibility of a PPP. HHS believes that a PPP potentially could serve as an appropriate mechanism for achieving the broad goals and mission of biovigilance. A PPP might provide the American public with a mechanism for leveraging and maximizing resources, for collaborating on research and problem solving, for creating new opportunities, and for advancing the Department's public health mission as it relates to challenges associated with disease prevention (including emerging infectious diseases or EIDs), adverse events, and process improvements.

Biovigilance is an area of growing importance, with a potential role in any of the following areas:

- Identifying strategies for protecting recipients and living donor health;

- Identifying processes that reduce medical errors and improve donor/patient outcomes in blood transfusions, and tissue and organ transplantations;
- Reporting and analyzing adverse events, including medical "near misses" and patient adverse reactions;
- Identifying emerging infectious disease prevalence and incidence in donors and recipients, both quickly and effectively;
- Informing public health and regulatory policy, and reimbursement decisions; and,
- Contributing to and collaborating on research studies, including research that provides a basic understanding of recipient outcomes so as to inform future surveillance activities.

Specific areas and activities in which a biovigilance PPP is likely to be involved may include:

- Safety and surveillance—Identifying areas where greater safety and surveillance measures are needed.
- Process improvement—Proposing new processes or process enhancements to improve blood and blood component, tissue, cell, and organ safety for donors and recipients.
- Standards and measurements—Identifying areas where standards are lacking or need additional development; proposing definitions for standards; defining measurement approaches or best practices for collecting measurement data.
- Research and analysis—Identifying research needs; proposing and conducting short and long-term research studies; identifying knowledge gaps that prevent effective surveillance or reporting; proposing strategies for closing these gaps.
- Data repositories, infrastructure and policies—Identifying requirements for new data repositories and related infrastructure; developing policies for data sharing, access, privacy and confidentiality; establishing and operating such data repositories and related infrastructure (or contractually arranging for the operation).
- Baseline data, data quality, measurement, and collection—Establishing baseline data and associated quality standards for measurement and collection of that data.
- Goal setting—Establishing targets or goals for improved outcomes.
- Reporting—Issuing regular and periodic reports on progress, trends, adverse outcomes, and corrective actions to improve patient safety and donor health.
- Innovation in technologies and post-marking surveillance of new technologies.

Interested stakeholders in biovigilance may include any of the following, and/or others:

- Foundations and non-profit entities with an interest or responsibilities in biovigilance, in particular those with a public advocacy mission related to supply, access, safety, use, or payment of blood, tissues, cells and organs and/or those with expertise in PPPs;
- Recipients of blood or blood components, tissues, cells, or organs;
- Donors, potential donors, and donor families;
- Healthcare facilities, including transfusion services and transplant centers;
- Pharmaceutical, diagnostic, and other related biotechnology companies offering products, services, medical equipment, or technology;
- Organizations engaged in collecting, recovery banking, preserving, distributing or processing blood, organs, or tissues, or cells;
- Insurance companies, self-insured entities, and other payers;
- IT and database companies;
- Professional, research, and academic organizations;
- Other U.S. Federal, State, or local government groups with an interest or responsibilities in biovigilance; and,
- Managing partners or consultancy firms.

Information Requested

The Assistant Secretary for Health has charged a biovigilance working group, with membership from the HHS Operating Divisions, to define the foundational elements and operating framework for a National Biovigilance Program within HHS and for a PPP. This framework for a National Biovigilance Program will propose a set of high-level strategic goals, priorities, and key initiatives for the next five years. In developing the framework, HHS will take into account the feasibility, as well as foundational elements and basic operating framework for a PPP.

HHS is interested in exploring a biovigilance PPP that could achieve its mission through collaboration among public sector entities (*e.g.,* government agencies and institutions) and private sector entities. Private sector entities include, but are not limited to academia; non-governmental organizations (NGOs); philanthropic institutions; patient groups; blood bank operators; blood, tissue, cell, and organ establishments or manufacturers, transplant centers, and professional societies; and other members of the blood, tissue, cells, and organ communities. Under such a partnership, all partners might engage in the development of an operating structure and policies that will meet the broad goals of biovigilance as well as serving the needs and interests of the partners. Due to the expanding role of blood transfusion, and tissue, cell and organ transplantation in the healthcare sector, sustained involvement among partners might be needed for the foreseeable future.

This RFI is being issued to notify the public that HHS is exploring the feasibility of a PPP as an approach for achieving the broad goals of biovigilance. This RFI, moreover, is being issued to encourage all interested parties to comment on any aspect of a PPP. This may include any of the following:

- General or organizational issues:
  - Scope, key priorities, goals, or initiatives for the PPP in the first five years;
  - Key PPP challenges and critical success factors.
- Structural issues, such as:
  - Governance structure, operating and voting rules, and decision-making processes for the PPP;
  - Funding mechanisms and models for both the start-up period (during the initial 6–18 months) and the long term, to support sustained funding for an ongoing collaboration.
- Partner issues, including:
  - Identification of potential partners;
  - Management approaches for optimizing public and private-sector involvement.
- PPP scope and activities:
  - Project and research selection strategies in evaluation of the suitability of projects, partners, and overall internal decision-making structure;
  - Standards and measurements (definition, development, implementation)
  - Data collection through surveillance;
  - Analysis of data;
  - Public policy influence and development;
  - International biovigilance.
- PPP Management issues, such as:
  - Expertise and experience in managing a PPP, particularly in the biological sciences and public health domains;
  - Expertise and input on applicable research agendas. This could include how the PPP functions with regard to direct solicitation of research applications, how funding decisions are made, and the performance of administrative or oversight functions for such

projects;
- Fund-raising experience;
- Fiscal management experience, including management of the flow of funds among the partners.

This RFI is for information and planning purposes only and should not be construed as a solicitation or as an obligation on the part of HHS. HHS does not intend to award a grant or contract to pay for the preparation of any information submitted or for the use of such information by HHS. Acknowledgment of receipt of responses may not be made, nor will respondents be notified of the evaluation by HHS of the information received. No basis for claims against HHS shall arise as a result of a response to this request for information or to the use of such information by HHS as either part of our evaluation process or in developing specifications for any subsequent announcement. Any proprietary information submitted should be clearly marked for confidentiality.

Dated: April 20, 2011.

James J. Berger,

Associate Public Health Advisor for Blood, Organ, and Tissue Safety.

[FR Doc. 2011–9966 Filed 4–22–11; 8:45 am]

BILLING CODE 4150–41–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30 Day–11–0020]

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) 639–5960 or send an e-mail to *omb@cdc.gov.* Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395–5806. Written comments should be received within 30 days of this notice.

Proposed Project

Coal Workers' Health Surveillance Program (CWHSP)—OMB 0920–0020–Reinstatement With Change—National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

This submission will incorporate the National Coal Workers' X-Ray Surveillance Program 42 CFR 37 (0920–0020) and National Coal Workers' Autopsy Study 42 CFR part 37.204 (0920–0021) into one complete package which will be called the Coal Workers' Health Surveillance Program (CWHSP). Upon OMB approval, 0920–0021 will be discontinued. CWHSP is a congressionally-mandated medical examination program for monitoring the health of underground coal miners, established under the Federal Coal Mine Health and Safety Act of 1969, as amended in 1977 and 2006, PL–91–173 (the Act). The Act provides the regulatory authority for the administration of the CWHSP. This Program, which includes both a health surveillance and an autopsy component, has been useful in providing tools for protecting the health of miners (whose participation is entirely voluntary), and also in documenting trends and patterns in the prevalence of coal workers' pneumoconiosis ('black lung' disease) among miners employed in U.S. coal mines. During the early 1970s, one out of every three miners examined through the CWHSP who had worked at least 25 years underground had evidence of pneumoconiosis on their chest x-ray. An analysis among over 25,000 miners who participated in the x-ray Programs from 1996 to 2002 indicated that the proportion of affected individuals had decreased to about one in 20. However, recent surveillance analyses and research studies have confirmed that the prevalence of 'black lung' disease is increasing, there is regional clustering of rapidly progressive pneumoconiosis cases, and coal miners have a higher risk of disease if they perform certain jobs, work in smaller mines, or are from certain geographic areas. Importantly, young coal miners are developing the disabling and lethal forms of 'black lung'.

Demographic and logistical information is gathered from coal mine operators and participating x-ray facilities. Participating miners also provide health and work histories, and participating physicians report radiographic findings. The Centers for Disease Control and Prevention's National Institute for Occupational Safety and Health, Division of Respiratory Disease Studies, 1095 Willowdale Road, Morgantown, WV 26505, also called the Appalachian Laboratory for Occupational Safety and Health (ALOSH), is charged with administration of this Program.

From October 1, 1999 through September 30, 2002, the Mine Safety and Health Administration (MSHA), in consultation with NIOSH, conducted a pilot health surveillance program for both underground and surface miners (The Miners' Choice Program). The Miners' Choice Program has been continued as an extension of the CWHSP (currently called the Enhanced Coal Workers' Health Surveillance Program—ECWHSP). This extension of the CWHSP currently operates utilizing a mobile examination unit which travels to mining regions to provide locally accessible and more comprehensive health surveillance, including chest radiography, spirometry, and blood pressure screening.

Under the Act, the provision of periodic chest x-ray examinations is specifically mandated, and the x-rays are to be supplemented by such other tests as the Secretary deems necessary. In addition to radiographically-apparent pneumoconiosis, miners are at risk for the development of chronic obstructive pulmonary disease (COPD). Chest radiographs alone cannot provide a measure of airflow obstruction and therefore often miss important lung disease. For this reason, spirometry, a simple breathing test, is an additional component that is particularly useful for the health assessment of miners. Periodic medical history and spirometry tests have been recommended by NIOSH for both surface and underground coal miners since 1995, to facilitate preventive actions, increase miners' participation in programs for early detection of disease, and improve the derivation of representative estimates of the burden, distribution, and determinants of occupational lung disease in relation to coal mining in the U.S. Finally, unrecognized hypertension has previously been observed among many miners, and the ECWHSP offers blood pressure screening as a safe, simple, and inexpensive test, which can help target initiation of proven health conserving medications.

The National Coal Workers' Autopsy Study (NCWAS) provides standardized lung specimens for ongoing scientific research as well as information to the next-of-kin regarding the presence and extent of coal workers' pneumoconiosis (black lung) in the lungs of the deceased miner. The Consent Release and History Form is primarily used to obtain written authorization from the next-of-kin to perform an autopsy on the deceased miner. Because a basic reason for the post-mortem examination is research (both epidemiological and clinical), a minimum of essential information is collected regarding the deceased miner,