

All Atomic Weapons Employees who worked at the facility owned by Nuclear Metals, Inc. (or a subsequent owner) in West Concord, Massachusetts, during the period from January 1, 1980, through December 31, 1990, for a number of work days aggregating at least 250 work days, occurring either solely under this employment, or in combination with work days within the parameters established for one or more other classes of employees included in the Special Exposure Cohort.

This designation became effective on August 10, 2014. Therefore, beginning on August 10, 2014, members of this class of employees, defined as reported in this notice, became members of the SEC.

John Howard,

Director, National Institute for Occupational Safety and Health.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention (CDC)

[CDC-2014-0013, Docket Number NIOSH-274]

NIOSH Current Intelligence Bulletin: *Promoting Health and Preventing Disease and Injury through Workplace Tobacco Policies*

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

ACTION: Notice of draft document for public comment.

SUMMARY: The National Institute for Occupational Safety and Health of the Centers for Disease Control and Prevention announces the availability of a draft Current Intelligence Bulletin (CIB) entitled NIOSH Current Intelligence Bulletin: *Promoting Health and Preventing Disease and Injury through Workplace Tobacco Policies* for public comment. To view the notice and related materials, visit <http://www.regulations.gov> and enter CDC-2014-0013 in the search field and click "Search."

Public comment period: Comments must be received September 15, 2014.

ADDRESSES: You may submit comments, identified by CDC-2014-0013 and Docket Number NIOSH-274, by either of the following two methods:

- *Federal eRulemaking Portal:* <https://www.regulations.gov> Follow the instructions for submitting comments.

- *Mail:* National Institute for Occupational Safety and Health, NIOSH Docket Office, 1090 Tusculum Avenue, MS C-34, Cincinnati, Ohio 45226-1998.

Instructions: All information received in response to this notice must include the agency name and docket number [CDC-2014-0013; NIOSH-274]. All relevant comments received will be posted without change <http://www.regulations.gov>, including any personal information provided. All electronic comments should be formatted as Microsoft Word. All information received in response to this notice will also be available for public examination and copying at the NIOSH Docket Office, 1150 Tusculum Avenue, Room 109, Cincinnati, OH 45226-1998.

SUPPLEMENTARY INFORMATION: The purpose of the public review of the draft document is to help assure that the final version of the NIOSH *Current Intelligence Bulletin* meets current quality standards before it is disseminated.

Overall Questions

(1) Does the draft CIB provide useful information and recommendations?

(2) Is it reasonably clear and comprehensible?

(3) Does it include any technical errors or factual inaccuracies?

(4) Are there any critical omissions?

(5) Does it include any unnecessary information that should be deleted?

(6) Are any of the conclusions inappropriate?

(7) Are any of the recommendations inappropriate?

Background: NIOSH has previously published two formal *Current Intelligence Bulletins* entirely devoted to the issue of tobacco use. The first—*CIB 31: Adverse Health Effects of Smoking and the Occupational Environment* [DHEW (NIOSH) Publication Number 79-122]—outlined several ways in which smoking interacts with other workplace exposures to increase risk of disease and injury among workers. That document recommended that smoking be curtailed in workplaces where those other hazards are present and that worker exposure to those other occupational hazards be controlled http://www.cdc.gov/niosh/docs/1970/79122_31.html. The second—*CIB 54: Environmental Tobacco Smoke in the Workplace; Lung Cancer and other Health Effects* [DHHS (NIOSH) Publication No. 91-108]—focused on secondhand smoke in the workplace as a cause of cancer and cardiovascular disease. That document recommended eliminating tobacco smoking in the workplace as the best preventive

approach <http://www.cdc.gov/niosh/docs/91-108/>.

NIOSH has prepared a current draft *CIB: Promoting Health and Preventing Disease and Injury through Workplace Tobacco Policies* for anticipated dissemination during the 50th anniversary year of the Surgeon General's first report on the health consequences of smoking published in 1964. The draft *CIB* reflects a "strategy integrating occupational safety and health protection with health promotion to prevent worker injury and illness and to advance health and well-being" [see <http://www.cdc.gov/niosh/TWH/totalhealth.html>], embodied by NIOSH in a recently launched Total Worker Health™ (TWH™) Program.

FOR FURTHER INFORMATION CONTACT: R.M. Castellan, NIOSH, Division of Respiratory Disease Studies, Mailstop H-2900, 1095 Willowdale Road, Morgantown, West Virginia 26505-2888. Phone: (304) 285-6117.

Dated: August 7, 2014.

John Howard,

Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention.

[FR Doc. 2014-19384 Filed 8-14-14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-R-48]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of

the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by September 15, 2014.

ADDRESSES: When commenting on the proposed information collections, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be received by the OMB desk officer via one of the following transmissions:

OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395-5806 or Email: OIRA_submission@omb.eop.gov.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web site address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>.
2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov.
3. Call the Reports Clearance Office at (410) 786-1326.

FOR FURTHER INFORMATION CONTACT: Reports Clearance Office at (410) 786-1326.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Reinstatement of a previously approved collection; *Title of Information Collection:* Hospital Conditions of Participation and Supporting Regulations; *Use:* The information collection requirements described in this information collection request are needed to implement the Medicare and Medicaid conditions of participation (CoP) for 4,890 accredited and non-accredited hospitals and an additional 101 critical access hospitals (CAHs) that have distinct part psychiatric or rehabilitation units (DPUs). CAHs that have DPUs must comply with all of the hospital CoPs on these units. This package reflects the paperwork burden for a total of 4,991 (that is, 4,890 hospitals and 101 CAHs which include 81 CAHs that have psychiatric DPUs and 20 CAHs that have rehabilitation DPUs). The information collection requirements for the remaining 1,183 CAHs have been reported in a separate package under CMS-10239.

The CoPs and accompanying requirements specified in the supporting regulations are used by our surveyors as a basis for determining whether a hospital qualifies for a provider agreement under Medicare and Medicaid. CMS and the health care industry believe that the availability to the facility of the type of records and general content of records, which the supporting regulations specify, is standard medical practice and is necessary in order to ensure the well-being and safety of patients and professional treatment accountability. Subsequent to publication of the 60-day **Federal Register** notice (January 31, 2014; 79 FR 5417), the burden has been recalculated. *Form Number:* CMS-R-48 (OMB control number: 0938-0328); *Frequency:* Yearly; *Affected Public:* Private sector (business or other for-profits); *Number of Respondents:* 4,991; *Total Annual Responses:* 17,279,717; *Total Annual Hours:* 14,424,655. (For policy questions regarding this collection contact Scott Cooper at 410-786-9465.)

Dated: August 11, 2014.

Martique Jones,

*Director, Regulations Development Group,
Office of Strategic Operations and Regulatory Affairs.*

[FR Doc. 2014-19260 Filed 8-14-14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-D-1279]

Pilot Program for Qualification of Medical Device Development Tools

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is soliciting proposals to participate in a pilot program for Medical Device Development Tools (MDDT) qualification (MDDT Pilot Program). Under the MDDT Pilot Program, FDA intends to work together with developers of tools that meet the criteria for the proposed program, to determine whether certain tools may be developed and qualified in order to facilitate more predictable, efficient, and transparent regulatory evaluation when MDDTs are used to generate valid scientific evidence for medical device premarket applications.

DATES: FDA will begin accepting nominations for participation in the voluntary MDDT Pilot Program September 15, 2014.

FOR FURTHER INFORMATION CONTACT: Joan Adams-White, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3650, Silver Spring, MD 20993-0002, 301-796-5421, Joannie.Adams-White@fda.hhs.gov; or Kathryn O'Callaghan, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3614, Silver Spring, MD 20993-0002, 301-796-6349, Kathryn.ocallaghan@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of November 14, 2013 (78 FR 68459), the Food and Drug Administration (FDA) announced the availability of the draft guidance entitled "Medical Device Development Tools" (<http://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm374427.htm>) (MDDT draft guidance). When finalized, the draft guidance will represent FDA's current thinking on qualification of MDDTs for use in device development and evaluation. The proposed MDDT qualification process is intended to support the development of MDDTs—tools that manufacturers and FDA use to assess and measure the performance,