

Dated: May 11, 2011.

**Elaine L. Baker,**

*Director, Management Analysis and Services  
Office, Centers for Disease Control and  
Prevention.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

[Docket Number NIOSH-237]

#### Strategy To Address Recommendations Issued by the Institute of Medicine in November 2010 Report; Comment Request

**AGENCY:** The 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 public comment period.

**SUMMARY:** The National Institute for Occupational Safety and Health (NIOSH), National Personal Protective Technology Laboratory (NPPTL), requests input on the NIOSH, NPPTL strategy to address the recommendations issued by the Institute of Medicine (IOM) in the November 2010 report *Certifying Personal Protective Technologies: Improving Worker Safety*. The report focuses on the need for a consistent and risk-based approach to Personal Protective Technology (PPT) conformity assessment.

**PUBLIC COMMENT PERIOD:** Written or electronic comments must be received on or before July 1, 2011.

**ADDRESSES:** You may submit comments, identified by docket number NIOSH-237, by any of the following methods:

- *Mail:* NIOSH Docket Office, Robert A. Taft Laboratories, MS-C34, 4676 Columbia Parkway, Cincinnati, OH 45226

- *Facsimile:* (513) 533-8285

- *E-mail:* [nioshdocket@cdc.gov](mailto:nioshdocket@cdc.gov)

All information received in response to this notice will be available for public examination and copying at the NIOSH Docket Office, 4676 Columbia Parkway, Cincinnati, Ohio 45226. All comments received will be available on the NIOSH Docket Web page at <http://www.cdc.gov/niosh/docket>, and in writing by request. NIOSH includes all comments received without change in the docket and the electronic docket, including any personal information provided.

**FOR FURTHER INFORMATION CONTACT:** John Sporrer, NIOSH, NPPTL, Post Office Box 18070, Building 20, Pittsburgh, PA 15236; E-mail [ppeconcerns@cdc.gov](mailto:ppeconcerns@cdc.gov), telephone (412) 386-6435.

**SUPPLEMENTARY INFORMATION:** In the November 2010 report the Institute of Medicine (IOM) made three recommendations for advancing conformity assessment for Personal Protective Technologies (PPT) in the nation. These recommendations are:

(1) Develop and Implement Risk-Based Conformity Assessment Processes for Non-Respirator PPT; (2) Enhance Research, Standards Development, and Communication; and (3) Establish a PPT and Occupational Safety and Health Surveillance System.

The report may be accessed, for free, at: [http://www.nap.edu/catalog.php?record\\_id=12962](http://www.nap.edu/catalog.php?record_id=12962).

#### Conformity Assessment Components

NIOSH, NPPTL envisions that PPT conformity assessment can involve the following components: standards, testing, inspection, certification, registration, accreditation, supplier's declaration of conformity (SDoC), communication, post-market testing and evaluation, and health surveillance. NIOSH, NPPTL is already responsible for certifying respirators for use in the United States. The management responsibilities of PPT Program conformity assessment undertaken by NIOSH, NPPTL include developing the strategy to implement the IOM recommendations.

#### Near Term Strategy

NIOSH, NPPTL intends to implement a multi-year strategy to address Recommendation 1 of the IOM report to develop and implement risk-based conformity assessment processes for non-respirator PPT.

The impacts of non-compliance (consequences of failure to provide the expected protection) are best described in terms of their potential risk to the user and the independence and rigor of conformity assessment. This relationship is described in Gordon Gillerman's *Making the Confidence Connection* published in ASTM Standardization News (2004), which can be viewed at [http://www.astm.org/SNEWS/DECEMBER\\_2004/gillerman\\_dec04.html](http://www.astm.org/SNEWS/DECEMBER_2004/gillerman_dec04.html).

#### Timeline To Address Recommendation 1

The timeline to address Recommendation 1 includes, but is not limited to the following activities conducted over a two year time period:

1. defining the standards to be included in the process;
2. identifying the PPE on the market which complies with current standards;
3. finalizing the conformity assessment terminology to be used in the effort;
4. defining low, medium, and high levels of risk;
5. assessing available sources (e.g. surveillance data) to document the risks of the PPE not working properly and the risks of noncompliance;
6. defining the level of conformity assessment, including configuration management, required for each level of risk; and
7. defining the types of PPE to be included in the framework to include those required by regulation, those desired by the user, and those that respond to specific health and safety needs in the marketplace.

NIOSH, NPPTL will develop a draft risk-based strategy and solicit public comment on the strategy. NIOSH, NPPTL will conduct face-to-face and virtual public meetings to discuss the PPT conformity assessment strategy during the strategy development process. The proposed strategy will be published and is expected to serve as a reference for standards development organizations.

Stakeholder input to the NIOSH, NPPTL strategy to address the recommendations provided in the IOM report may be submitted to NIOSH Docket 237 until July 1, 2011.

Dated: May 11, 2011.

**John Howard,**

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

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10292]

#### Agency Information Collection Activities: Proposed Collection; Comment Request

**AGENCY:** Centers for Medicare & Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS) is publishing the following summary of proposed collections for public comment. Interested persons are invited to send

comments regarding this 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.

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* State Medicaid Health Information Technology (HIT) Plan, Planning-Advance Planning Document and Update, Implementation Advance Planning Document (IAPD) and Update, and Annual IAPD to implement section 4201 of the American Reinvestment and Recovery Act of 2009; *Use:* To assess the appropriateness of States' requests for Federal financial participation for expenditures under their Medicaid Electronic Health Record Incentive Program related to health information exchange, CMS staff will review the submitted information and documentation in order to make an approval determination for the APD. CMS is issuing an updated IAPD template to reduce the burden on States by clearly indicating the information required for a successful submission; *Form Number:* CMS-10292 (OMB #: 0938-1088); *Frequency:* Yearly, once, occasionally; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 56; *Total Annual Responses:* 56; *Total Annual Hours:* 448. (For policy questions regarding this collection contact Richard Friedman at 410-786-4451. For all other issues call 410-786-1326.)

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web Site address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>, or E-mail your request, including your

address, phone number, OMB number, and CMS document identifier, to [Paperwork@cms.hhs.gov](mailto:Paperwork@cms.hhs.gov), or call the Reports Clearance Office on (410) 786-1326.

In commenting on the proposed information collections please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in one of the following ways by *July 18, 2011*:

1. *Electronically.* You may submit your comments electronically to <http://www.regulations.gov>. Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) accepting comments.

2. *By regular mail.* You may mail written comments to the following address:

CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier CMS-10292, Room C4-26-05, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: May 13, 2011.

**Martique Jones,**  
*Director, Regulations Development Group, Division B, Office of Strategic Operations and Regulatory Affairs.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Health Resources and Services Administration**

**Agency Information Collection Activities: Proposed Collection: Comment Request**

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104-13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for

submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, e-mail [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or call the HRSA Reports Clearance Officer at (301) 443-1129.

*Comments are invited on:* (a) The proposed collection of information for the proper performance of the functions of the agency; (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.

**Proposed Project: Free Clinics FTCA Program Application (OMB No. 0915-0293)—Revision**

Under 42 U.S.C. 233(o) and HRSA BPHC Policy Information Notice 2011-02, "Free Clinics Federal Tort Claims Act (FTCA) Program Policy Guide," the FTCA Free Clinic Program requires free clinics to submit annual, renewal, and supplemental applications for the process of deeming qualified health care professionals, board members, officers, and contractors for FTCA malpractice insurance coverage. It is proposed that the application forms be modified to comply with the Patient Protection and Affordable Care Act section 10608, amending 42 U.S.C. 233(o)(1), as well as upgrade the application to provide for an electronic submission. The modifications include: (1) Inclusion of board members, officers, employees, and contractors into one comprehensive application, and (2) a fully electronic application that can be submitted electronically via e-mail or the internet. It is anticipated that these modifications will decrease the time and effort required by the current OMB approved FTCA application forms.

The annual estimate of burden is as follows:

Instrument	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
Free Clinics FTCA Program Application .....	200	1	200	14	2800
Total .....	200	.....	200	.....	2800

E-mail comments to [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or mail the HRSA

Reports Clearance Officer, Room 10-33, Parklawn Building, 5600 Fishers Lane,

Rockville, MD 20857. Written comments