

**Exhibit 2. Estimated Annualized Cost Burden**

Type of data collection	Number of respondents	Total burden hours	Average hourly wage rate *	Total cost burden
Focus Groups .....	1,056	1,584	\$48.98	\$77,584
In-person/Telephone Interviews .....	1,386	3,050	46.82	142,801
Customer Satisfaction Surveys for the Decision Aid .....	550	184	25.53	4,698
Customer Satisfaction Surveys for the Summary Guides .....	6,600	550	39.55	21,753
Follow-up CME Surveys .....	1,320	110	77.64	8,540
Solicited Topic Nominations .....	2,500	208	48.07	9,999
Web site Registration .....	6,000	500	48.07	24,035
Glossary Feedback Survey .....	200	17	48.07	817
<b>Total .....</b>	<b>19,612</b>	<b>6,203</b>	<b>(<sup>1</sup>)</b>	<b>290,227</b>

<sup>1</sup> Not applicable.

\*Based upon the mean and weighted mean wages for clinicians (29–1062 family and general practitioners), policy makers (11–0000 management occupations, 11–3041 compensation & benefits managers, 13–1072 compensation, benefits & job analysis specialists, 11–9111 medical and health service managers, 13–2053 insurance underwriters and 15–2011 actuaries) and consumers (00–0000 all occupations). Focus groups include 528 clinicians (\$77.64/hr) and 528 consumers (\$20.32/hr); in-person/telephone interviews includes 528 clinicians, 330 policy makers (\$39.91/hr) and 528 consumers; customer satisfaction surveys for the decision aid includes 50 clinicians and 500 consumers; customer satisfaction surveys for the summary guides includes 1,650 clinicians, 1,650 policy makers and 3,300 consumers; follow-up CME surveys includes 1,320 clinicians; solicited topic nominations include 1,125 clinicians, 250 policy makers and 1,125 consumers; Web site registration includes 2,700 clinicians, 600 policy makers and 2,700 consumers; glossary feedback survey includes 90 clinicians, 20 policy makers and 90 consumers, National Compensation Survey: Occupational wages in the United States May 2008, “U.S. Department of Labor, Bureau of Labor Statistics.”

**Estimated Annual Costs to the Federal Government**

The maximum cost to the Federal Government is estimated to be

\$1,439,003 annually. Exhibit 3 shows the total and annualized cost by the major cost components.

**Exhibit 3. Estimated Total and Annualized Cost**

Cost component	Total cost	Annualized cost
Project Development .....	\$1,019,970	\$339,990
Data Collection Activities .....	735,405	245,135
Data Processing and Analysis .....	1,889,505	629,835
Project Management .....	557,380	185,793
Overhead .....	114,750	38,250
<b>Total .....</b>	<b>4,317,010</b>	<b>1,439,003</b>

**Request for Comments**

In accordance with the above-cited Paperwork Reduction Act legislation, comments on AHRQ's information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of AHRQ healthcare research and healthcare information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) 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 upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent

request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: May 10, 2010.

**Carolyn M. Clancy,**

*Director.*

[FR Doc. 2010-11993 Filed 5-19-10; 8:45 am]

**BILLING CODE 4160-90-M**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration**

[Docket No. FDA-2010-D-0226]

**Draft Guidance for Industry, Third Parties and Food and Drug Administration Staff; Medical Device ISO 13485:2003 Voluntary Audit Report Submission Program; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled “Medical Device ISO 13485:2003 Voluntary Audit Report Submission Program.” This draft guidance is intended to provide information on the implementation of a section of the Food and Drug Administration Amendments Act of 2007 (FDAAA), which amends a section of the Federal Food, Drug, and Cosmetic Act (the act). This guidance document describes how FDA's Center for Devices and Radiological Health (CDRH) and Center for Biologics Evaluation and Research (CBER) are implementing this provision of the law. This draft guidance is not final nor is it in effect at this time.

**DATES:** Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit

written or electronic comments on the draft guidance by August 18, 2010. Submit written or electronic comments on the collection of information July 19, 2010.

**ADDRESSES:** Submit written requests for single copies of the draft guidance document entitled "Medical Device ISO 13485:2003 Voluntary Audit Report Submission Program" to the Division of Small Manufacturers, International, and Consumer Assistance (DSMICA), Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Room 4613, Silver Spring, MD 20993 or to the Office of Communications, Outreach and Development (HFM-40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448. The draft guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 301-827-1800. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301-847-8149. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.regulations.gov>. Identify comments with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Kimberly A. Trautman, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Room 3422, Silver Spring, MD 20993, 301-796-5515, or Stephen Ripley, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852, 301-827-6210.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

This draft guidance is intended to provide information on the implementation of section 228 of FDAAA, which amends section 704(g)(7) of the act (21 U.S.C. 374(g)(7)). Under this draft guidance, device manufacturers whose establishment has been audited under one of the regulatory systems implemented by the Global Harmonization Task Force (GHTF) founding members<sup>1</sup> using ISO

13485:2003 "Medical devices—Quality management systems—Requirements for regulatory purposes," may voluntarily submit the resulting audit report to FDA. If, based on that report, FDA determines there is minimal probability—in light of the relationship between the quality system deficiencies observed and the particular device and manufacturing processes involved—that the establishment will produce nonconforming and/or defective finished devices, then FDA intends to use the audit results as part of its risk assessment to determine whether that establishment can be removed from FDA's routine work plan for 1 year. The medical device ISO 13485:2003 Voluntary Audit Report Submission Program outlined in this draft guidance is another way in which FDA may leverage audits performed by other GHTF regulators and accredited third parties in order to assist the agency in setting risk-based inspectional priorities.

This notice of availability and draft guidance satisfy the public notice requirement of section 704(g)(7)(F) of the act, which provides that FDA shall give public notice of the ISO standard(s) under which FDA accepts voluntary submissions of audit reports.

##### **II. Significance of Guidance**

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on "Medical Device ISO 13485:2003 Voluntary Audit Report Submission Program." It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

##### **III. Electronic Access**

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. To receive "Draft Guidance for Industry, Third Parties and FDA Staff: Medical Device ISO 13485:2003 Voluntary Audit Report Submission Program" you may either send an e-mail request to [dsmica@fda.hhs.gov](mailto:dsmica@fda.hhs.gov) to receive an electronic copy of the document or send a fax request to 301-847-8149 to receive a hard copy. Please use the document number 1705 to

Assessment System; the European Union Notified Body accreditation system; the Therapeutics Goods Administration of Australia Inspectorate; and the Japanese Medical Device Ministry of Health, Labour and Welfare system.

identify the guidance you are requesting.

A search capability for all CDRH guidance documents is available at <http://www.fda.gov/cdrh/guidance.html>. Guidance documents are also available at <http://www.regulations.gov> or at <http://www.fda.gov/Biologics/BloodVaccines/GuidanceCompliance/RegulatoryInformation/Guidances/default.htm>.

##### **IV. Paperwork Reduction Act of 1995**

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. "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 provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

**Title:** Draft Guidance for Industry, Third Parties and FDA Staff: Medical Device ISO 13485:2003 Voluntary Audit Report Submission Program.

**Description:** Section 228 of the Food and Drug Administration Amendments Act of 2007 (FDAAA), amended section 704(g)(7) of the Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 374(g)(7)) to add the following provision:

"(F) For the purpose of setting risk-based inspectional priorities, the Secretary shall accept voluntary

<sup>1</sup> The GHTF founding members auditing systems include the Canadian Medical Devices Conformity

submissions of reports of audits assessing conformance with appropriate quality system standards set by the International Organization for Standardization (ISO) and identified by the Secretary in public notice. If the owner or operator of an establishment elects to submit audit reports under this subparagraph, the owner or operator

shall submit all such audit reports with respect to the establishment during the preceding 2-year periods.”

The “Draft Guidance for Industry, Third Parties and FDA Staff: Medical Device ISO 13485:2003 Voluntary Audit Report Submission Program” will describe how FDA’s CDRH and CBER are implementing this provision of the

law and providing public notice as required. The proposed collections of information are necessary to satisfy the previously mentioned statutory requirements for implementing this voluntary submission program.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

Type of Respondent	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Domestic or foreign device manufacturer whose establishment was audited under ISO 13485:2003	1,600	1	1,600	2	3,200

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on FDA’s experience with the founding regulatory members of GHTF, FDA expects that the vast majority of manufacturers who will participate in the Voluntary Audit Report Submission Program will be manufacturers who are certified by Health Canada under ISO 13485:2003.<sup>2</sup> In 2008, approximately

2,650 manufacturers or manufacturing sites had been certified by Health Canada.

In addition, FDA only expects firms who do not have major deficiencies or observations in their ISO 13485:2003 audits to be willing to submit their audit reports to FDA under the Voluntary

Audit Report Submission Program. FDA analyzed its inspection data from Fiscal Year (FY) 2008 (October 1, 2007 to October 1, 2008) and determined that the total number of inspections finalized in FY2008 for medical devices was 1,965. The breakdown for the 1,965 compliance decisions is as follows:

TABLE 2.—COMPLIANCE DECISION BREAKDOWN

Compliance Decision <sup>1</sup>	Number	Approximate Percentage
Official Action Indicated	148	8%
Voluntary Action Indicated	775	40%
No Action Indicated	1,025	52%
Pending Final Decision	17	1%

<sup>1</sup> June 15, 2006, Compliance Program 7382.845 Inspection of Medical Device Manufacturers Part V <http://www.fda.gov/cdrh/comp/guidance/7382.845.html#p5p5.pdf>.

Because FDA only expects firms who do not have major deficiencies or observations to be willing to submit their audit reports to FDA under the Voluntary Audit Report Submission Program, FDA only expects to receive audit reports that would have been classified by FDA as No Action Indicated (NAI).

Assuming that the percentage breakdown of compliance decisions for all inspections conducted in FY2008 can be extrapolated and applied to audits of manufacturers certified under ISO 13485:2003 by Health Canada, FDA can estimate the number of Canadian establishments that would have had an inspection classified as an NAI. Since 52 percent of all compliance decisions resulted in a NAI decision, FDA estimates that 1,378 of the facilities certified under ISO 13485:2003 by

Health Canada (52 percent of the total 2,650 facilities) would have had an inspection classified as an NAI. Since FDA only expects to receive audit reports that would have been classified by FDA as NAI, FDA expects 1,378, or approximately 1,400, audit reports to be submitted.

Since FDA expects that the vast majority of manufacturers who will participate in the Voluntary Audit Report Submission Program will be manufacturers certified by Health Canada under ISO 13485:2003, FDA expects the number of reports to be submitted from manufacturers certified by regulatory systems established by other founding GHTF members to be minimal. For purposes of calculating the reporting burden, FDA estimates that approximately 10 percent of total audit reports submitted under this program

will be from these other manufacturers. Since 90 percent of the audit reports are expected to be submitted by manufacturers certified by Health Canada (approximately 1,400 audit reports as calculated previously in this document), then the total number of audit reports FDA expects to receive in a year is 1,556, or approximately 1,600, audit reports.

FDA further estimates that the gathering, scanning, and submission of the audit reports, certificates, and related correspondence would take approximately 2 hours.

This draft guidance also refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 820 have been approved

<sup>2</sup> The majority of these manufacturers are also certified under ISO 13485:2003 by the European Union Notified Body accreditation system.

under OMB control number 0910–0073 and the collections of information for the Inspection by Accredited Persons Program have been approved under OMB control number 0910–0569.

## V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 17, 2010.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2010–12098 Filed 5–19–10; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Arthritis and Musculoskeletal and Skin Diseases; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Arthritis and Musculoskeletal and Skin Diseases Advisory Council.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Arthritis and Musculoskeletal and Skin Diseases Advisory Council.

*Date:* June 15, 2010.

*Open:* 8:30 a.m. to 12 p.m.

*Agenda:* To discuss administrative details relating to the Council's business and special reports.

*Place:* National Institutes of Health, Building 31, 31 Center Drive, Conference Room 6, Bethesda, MD 20892.

*Closed:* 1 p.m. to 5 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Building 31, 31 Center Drive, Conference Room 6, Bethesda, MD 20892.

*Contact Person:* Laura K. Moen, PhD, Director, Division of Extramural Research Activities, NIAMS/NIH, 6701 Democracy Blvd., Ste. 800, Bethesda, MD 20892, 301–451–6515, [moenl@mail.nih.gov](mailto:moenl@mail.nih.gov).

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

(Catalogue of Federal Domestic Assistance Program Nos. 93.846, Arthritis, Musculoskeletal and Skin Diseases Research, National Institutes of Health, HHS)

Dated: May 14, 2010.

**Jennifer Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 2010–12151 Filed 5–19–10; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Allergy and Infectious Diseases; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Institute of Allergy and Infectious Diseases Special Emphasis Panel, Mechanisms of Protein Homeostasis.

*Date:* June 14, 2010.

*Time:* 1 p.m. to 5 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6700B Rockledge Drive, 3201, Bethesda, MD 20817. (Telephone Conference Call)

*Contact Person:* Brandt R. Burgess, PhD, Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institutes of Health/NIAID, 6700B Rockledge Drive, MSC 7616, Bethesda, MD 20892–7616, 301–451–2584, [bburgess@niaid.nih.gov](mailto:bburgess@niaid.nih.gov).

*Name of Committee:* National Institute of Allergy and Infectious Diseases Special Emphasis Panel, Emergence and Evolution of Coronavirus Pathogens.

*Date:* June 15, 2010.

*Time:* 1 p.m. to 5 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6700B Rockledge Drive, 3201, Bethesda, MD 20817. (Telephone Conference Call)

*Contact Person:* Brandt R. Burgess, PhD, Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institutes of Health/NIAID, 6700B Rockledge Drive, MSC 7616, Bethesda, MD 20892–7616, 301–451–2584, [bburgess@niaid.nih.gov](mailto:bburgess@niaid.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: May 14, 2010.

**Jennifer Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 2010–12156 Filed 5–19–10; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Heart, Lung, and Blood Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which