that half of the control practices (25/50) administer CG–CAHPS data, as this percentage is unknown; while 90% of the participating current and past CAHPS practices (90/100) will submit CAHPS data, yielding 115 submissions of CAHPS patient experience data files. As indicated below, the annual total burden is estimated to be 179 hours.

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS

Data collection task	Number of respondents	Number of responses per respondent	Hours per response	Total burden hours
Office Manager Questions	150	1	5/60	12.5
Physician Interview	150	1	40/60	100
PCMH–A Assessment Tool	150 (same physicians as above).	1 (same person as above)	15/60	37.5
CAHPS Patient Experience Data Files	115	1 per practice	15/60	28.75
Total	415	1	75/60	178.75

+ The same respondent completes the Physician Interview and PCMH–A Assessment Tool and submits the CAHPS Patient Experience Data Files.

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Data collection task	Number of requests	Total burden hours	Average hourly wage rate *	Total cost burden
Office Manager Questions	150	12.5	[a] $57.44	$718.00
Physician Interview	150	100	[b] 97.33	9,733.00
PCMH–A Assessment Tool	150	37.5	[b] 97.33	3,649.88
CAHPS Patient Experience Data Files	115	28.75	[b] 97.33	2,798.24
Total	300	178.75	55.48	16,899.12

+ The same respondent completes the Physician Interview and PCMH–A Assessment Tool and submits the CAHPS Patient Experience Data Files.

* Occupational Employment Statistics, May 2015 National Occupational Employment and Wage Estimates United States, U.S. Department of Labor, Bureau of Labor Statistics. *http://www.bls.gov/oes/current/oes_nat.htm.*

[a] Based on the mean wages for *General and Operations Managers, 11–1021 within Healthcare Support Occupations,* the occupational group most likely tasked with completing the Office Manager Questions.

[b] Based on the mean wages for *Physicians and Surgeons, 29–1060,* the occupational group most likely tasked with completing the Physician Interview, PCMH–A Assessment Tool, and submitting the CAHPS Patient Experience Data Files.

Request for Comments

In accordance with the Paperwork Reduction Act, 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 health care research and health care 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.

Sharon B. Arnold,

Deputy Director.

[FR Doc. 2016–18392 Filed 8–2–16; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–2049]

Medical X-Ray Imaging Devices Conformance With International Electrotechnical Commission Standards; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the draft guidance entitled ''Medical X-Ray Imaging Devices Conformance With IEC Standards.'' This draft guidance describes FDA's policy regarding the regulation of medical x-ray imaging equipment that are subject to requirements in the Federal Food, Drug, and Cosmetic Act (the FD&C Act) and FDA's regulations that apply to medical devices and electronic products. The draft guidance also provides recommendations to industry on how to comply with the applicable requirements. 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 either electronic or written comments on the draft guidance by November 1, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

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

Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov*.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2016–D–2049 for ''Medical X-Ray Imaging Devices Conformance With IEC Standards.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov*. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm*.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

An electronic copy of the guidance document is available for download from the Internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance document entitled ''Medical X-Ray Imaging Devices Conformance With IEC Standards'' to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Robert Sauer, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5628, Silver Spring, MD 20993–0002, 301–796–3580.

SUPPLEMENTARY INFORMATION:

I. Background

This draft guidance describes FDA's policy regarding the regulation of medical x-ray imaging equipment that are subject to requirements in the FD&C Act and FDA's regulations that apply to medical devices and electronic products. In the draft guidance, FDA is seeking to harmonize performance standards prescribed under section 534 of subchapter C (Electronic Product Radiation Control (EPRC)) of the FD&C Act (21 U.S.C. 360kk) with International Electrotechnical Commission (IEC) standards, where appropriate, to help to ensure streamlined regulatory review of submissions for these products. The draft guidance also provides recommendations to industry on how to comply with the applicable requirements. FDA believes industry conformance to certain IEC standards would provide the same level of or improved protection of the public health and safety from electronic radiation as certain EPRC regulatory standards. FDA also believes conformance to certain IEC standards would be sufficient to meet the 510(k) premarket notification requirement for certain devices. FDA review of related radiological health and safety data in premarket submissions, as opposed to EPRC product reports, would maintain or improve device safety while consolidating the information manufacturers submit to FDA.

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 current thinking of FDA on ''Medical X-Ray Imaging Devices Conformance With IEC Standards.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the Internet. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* Guidance documents are also available at *http://www.regulations.gov.* Persons unable to download an electronic copy of ''Medical X-Ray Imaging Devices Conformance With IEC Standards'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1400014 to identify the guidance you are requesting.

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, including each proposed revision of an existing 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.

Reporting and Recordkeeping for Electronic Products—General Requirements—21 CFR parts 1002 through 1050—OMB Control Number 0910–0025—Revision

The draft guidance describes FDA's policy regarding the regulation of medical x-ray imaging equipment that are subject to FDA's regulations that apply to medical devices and electronic products. FDA believes industry conformance to certain IEC standards would be sufficient to meet the 510(k) premarket notification requirement for certain of these devices. FDA review of related radiological health and safety data in premarket submissions, as opposed to EPRC product reports, would maintain or improve device safety while consolidating the information manufacturers submit to FDA. Currently, information regarding the IEC standards is submitted as part of the premarket notification (approved under OMB control number 0910–0120). Under the draft guidance, if finalized, respondents may choose to submit declarations of conformity with certain IEC standards—in either a 510(k) or if no 510(k) is submitted in an Abbreviated Report under 21 CFR 1002.12(e)—instead of submitting EPRC reports for certain devices in the circumstances described in the draft guidance.

Based on an analysis of recent submissions from Fiscal Year (FY) 2015, approximately 93 percent of manufacturers of Class II medical x-ray imaging devices, including CT, fluoroscopy, and stationary x-ray systems, claimed conformance to an applicable IEC standard. Accordingly, we believe that the majority of manufacturers of Class II medical x-ray imaging systems would choose to continue to submit declarations of conformity to these IEC standards and not submit EPRC product reports, supplemental reports, and annual reports under the guidance. The other 7 percent of manufacturers of Class II medical x-ray imaging devices and likely a subset of these 93 percent may choose to submit product reports, supplemental reports, and annual reports.

In FY 2015, there were 22 Class II product reports and 13 Class I product reports for x-ray imaging devices submitted to FDA. Therefore, we expect a reduction of 34 respondents to the estimated burden for the product reports, supplemental reports, and annual report information collections in table 1 of this document. Because 13 of these x-ray imaging devices are 510(k)-exempt, Class I devices, we would expect an increase of 13 respondents to the estimated burden for the information collection related to Abbreviated Reports in table 1 of this document (as these manufacturers would be submitting their declarations of conformity in these reports), which corresponds to an expected reduction of 13 respondents to the estimated burden for the product reports, supplemental reports, and annual reports information collections in table 1 of this document. This equals an overall reduction of 1,395 hours in OMB control number 0910–0025.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1,2,3]

Activity/21 CFR section	FDA form	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Product reports—1002.10(a)–(k).	3626—Diagnostic x-ray 3627—CT x-ray 3639—Cabinet x-ray 3632—Laser 3640—Laser light show 3630—Sunlamp 3646—Mercury vapor lamp 3644—Ultrasonic therapy 3659—TV 3660—Microwave oven 3801—UV lamps	1,466	1.1	1,613	24	38,712
Product safety or testing changes—1002.11(a)–(b).		966	1.5	1,449	0.5	725
Abbreviated reports—1002.12.	3629—General abbreviated report 3661—X-ray tables, etc. 3662—Cephalometric device 3663—Microwave products (non-oven).	73	2	146	5	730

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1,2,3]—Continued

Activity/21 CFR section	FDA form	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Annual reports—1002.13(a)–(b).	3628—General 3634—TV 3638—Diagnostic x-ray 3641—Cabinet x-ray 3643—Microwave oven 3636—Laser 3631—Sunlamp 3647—Mercury vapor lamp 3645—Ultrasonic therapy	1,466	1	1,466	18	26,388

[1] This table includes the recalculated burden estimate only for information collections (ICs) that are applicable to this draft guidance. It does not include all ICs approved under OMB control number 0910–0025. The draft guidance, if finalized, would be a reduction to the burden estimate for these ICs, except that the Abbreviated reports IC increases. We have described the overall reduction in the text of this document. However, to avoid confusion, we have not included a total burden estimate in this table because such a total would include ICs that are not applicable to the draft guidance.

[2] There are no capital costs or operating and maintenance costs associated with this collection of information.

[3] Totals may not sum due to rounding.

The 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 807, subpart E have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 801 have been approved under OMB control number 0910–0485; the collections of information in 21 CFR part 820 have been approved under OMB control number 0910–0073. The collections of information in 21 CFR parts 1002 through 1050 are approved under OMB control number 0910–0025.

Dated: July 28, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–18300 Filed 8–2–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0375]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Agreement for Shipment of Devices for Sterilization

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by September 2, 2016.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0131. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, Three White Flint North 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Agreement for Shipment of Devices for Sterilization—21 CFR 801.150—OMB Control Number 0910–0131—Extension

Under sections 501(c) and 502(a) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 351(c) and 352(a)), nonsterile devices that are labeled as sterile but are in interstate transit to a facility to be sterilized are adulterated and misbranded. FDA regulations in § 801.150(e) (21 CFR 801.150(e)) establish a control mechanism by which firms may manufacture and label medical devices as sterile at one establishment and ship the devices in interstate commerce for sterilization at another establishment, a practice that facilitates the processing of devices and is economically necessary for some firms.

Under § 801.150(e)(1), manufacturers and sterilizers may sign an agreement containing the following: (1) Instructions for maintaining accountability of the number of units in each shipment, (2) acknowledgment that the devices that are nonsterile are being shipped for further processing, and (3) specifications for sterilization processing. This agreement allows the manufacturer to ship misbranded products to be sterilized without initiating regulatory action and provides FDA with a means to protect consumers from use of nonsterile products. During routine plant inspections, FDA normally reviews agreements that must be kept for 2 years after final shipment or delivery of devices (§ 801.150(a)(2)).

The respondents to this collection of information are device manufacturers and contract sterilizers. FDA's estimate of the reporting burden is based on data obtained from industry over the past several years. It is estimated that each of the firms subject to this requirement prepares an average of 20 written agreements each year. This estimate varies greatly, from 1 to 100, because some firms provide sterilization services on a part-time basis for only one customer, while others are large facilities with many customers. The average time required to prepare each written agreement is estimated to be 4 hours. This estimate varies depending on whether the agreement is the initial agreement or an annual renewal, on the format each firm elects to use, and on the length of time required to reach agreement. The estimate applies only to those portions of the written agreement that pertain to the requirements