Electronic Products

OMB Control Number 0910-0025
RIN-0910-AH65

SUPPORTING STATEMENT

Terms of Clearance: None.

A. Justification

1. Circumstances Making the Collection of Information Necessary

Sections 532 through 542 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360ii through 360ss) direct the Secretary of the Department of Health and Human Services (the Secretary) to establish and carry out an electronic product radiation control program to protect the public from unnecessary radiation from electronic products. Section 532 authorizes the Secretary to procure (by negotiation or otherwise) electronic products for research and testing purposes and to sell or otherwise dispose of such products. Section 534(g) directs the Secretary to review and evaluate industry testing programs on a continuing basis; and sections 535(e) and (f) direct the Secretary to immediately notify manufacturers of, and assure correction of, radiation defects or noncompliance with performance standards. The authority for records and reports is contained in sections in 537(b) through (c) of the FD&C Act. The program includes the development, issuance, and administration of performance standards to control the emission of electronic product radiation from electronic products.

FDA's regulations regarding Radiological Health are codified at 21 CFR, Chapter I, Subpart J (parts 1000 through 1050).

Proposed revisions:
FDA is proposing to amend and repeal parts of the radiological health regulations covering recommendations for radiation protection during medical procedures, certain records and reporting for electronic products, and performance standards for diagnostic x-ray systems and their major components, laser products, and ultrasonic therapy products. The Agency is taking this action to clarify and update the regulations to reduce regulatory requirements that are outdated and duplicate other means to better protect the public health against harmful exposure to radiation emitting electronic products and medical devices. This action is part of FDA's implementation of Executive Orders (EOs) 13771 and 13777. Under these EOs, FDA is comprehensively reviewing existing regulations to identify opportunities for repealing and amending regulations that will result in meaningful burden reduction while allowing the Agency to achieve our public health mission and fulfill statutory obligations.

FDA is requesting approval from the Office of Management and Budget (OMB), for revision of the information collections in its Radiological Health regulations, consistent

with the proposed rule (RIN 0910-AH65). A description of the revisions can be found in section 15 of this supporting statement.

The following requirements are not subject to review by OMB because they do not constitute a "collection of information" under the PRA: Sections 1002.31(c), 1003.10(a)-(c), 1003.11(a)(3) and (b), 1003.20(a)-(h), 1003.21(a)-(d), 1003.22(a) and (b), 1003.30(a) and (b), 1003.31(a) and (b), 1004.2(a)-(i), 1004.3(a)-(i), 1004.4(a)-(h), 1005.21(a)-(c), and 1005.22(b). These requirements apply to the collection of information during the conduct of investigations or audits (5 CFR 1320.4).

The following labeling requirements are also not subject to review under the PRA because they are a public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public (5 CFR 1320.3(c)(2)): Sections 1030.10(c)(6), 1040.10(g), and 1040.30(c)(1).

The following are descriptions of each information collection (IC) in this ICR:

Technical and safety information for users (21 CFR 1002.3)—*Third-party disclosure*
Requires manufacturers, when directed by the FDA, to provide technical and safety information to users.

Product reports (21 CFR 1002.10(a)-(k))—*Reporting*
Requires manufacturers to report to FDA product identification, product design and operation, product testing, quality control procedures, test results, and product labeling prior to the entry of the product into commerce. The following report forms are used to obtain the required information requested in 21 CFR 1002.10 for each specific product, following the applicable performance standard in parts 1020 through 1040:

- **FDA Form 3630** "Guide for Preparing Product Reports on Sunlamps and Sunlamp Products"
- **FDA Form 3632** "Guide for Preparing Product Reports on Lasers and Products Containing Lasers"
- **FDA Form 3639** "Guidance for the Submission of Cabinet X-Ray System Reports Pursuant to 21-CFR 1020.40"
- **FDA Form 3640** "Reporting Guide for Laser Light Shows and Displays"
- **FDA Form 3659** "Reporting and Compliance Guide for Television Products"
- **FDA Form 3660** "Guidance for Preparing Reports on Radiation Safety of Microwave Ovens"
- **FDA Form 3801** "Guide for Preparing Initial Reports and Model Change Reports on Medical Ultraviolet Lamps and Products Containing Such Lamps"

Product safety or testing changes (21 CFR 1002.11(a)-(b))—*Reporting*
Requires manufacturers to provide information to FDA on changes in product safety or testing.

Abbreviated reports (21 CFR 1002.12)—*Reporting*
Requires manufacturers to report abbreviated information on product safety and testing,

instead of 1002.10 reports. The following forms are used to obtain the required information:

- **Form FDA 3629** "Abbreviated Report"
- **FDA Form 3646** "Mercury Vapor Lamp Products Radiation Safety Report"
- **FDA Form 3663** "Abbreviated Reports on Radiation Safety for Microwave Products (Other than Microwave Ovens)"

Annual reports (21 CFR 1002.13(a)-(b))—*Reporting*
Requires manufacturers of products requiring an annual report as specified in table 1 of §1002.1 to report annually to FDA a summary of manufacturer records maintained in accordance with 1002.30. The following report forms are used to obtain the required information:

- **FDA Form 3628** "General Annual Report (includes Medical, Analytical, and Industrial X-Ray Products Annual Report)"
- **FDA Form 3631** "Guide for Preparing Annual Reports on Radiation Safety Testing of Sunlamps and Sunlamp Products"
- **FDA Form 3634** "Television Products Annual Report"
- **FDA Form 3636** "Guide for Preparing Annual Reports on Radiation Safety Testing of Laser and Laser Light Show Products"
- **FDA Form 3641** "Cabinet X-Ray Annual Report"
- **FDA Form 3643** "Microwave Oven Products Annual Report"

Accidental radiation occurrence reports (21 CFR 1002.20)—*Reporting*
Requires manufacturers to report to FDA the circumstances, amount of exposure, and remedial actions taken concerning any accidental radiation occurrence involving their electronic products. If a firm is also required to report the incident under 21 CFR part 803, those regulations take precedence.

- **Form FDA 3649** "Accidental Radiation Occurrence (ARO)" report is used to obtain the required information requested in 21 CFR 1002.20.

FDA is proposing to amend the timing for submission of reporting requirements for AROs that are not associated with a death or serious injury (21 CFR 1002.20). The proposed amendment will allow manufacturers of a radiation emitting electronic product to submit quarterly summary reports of AROs that are not associated with a death or serious injury and not required to be reported under the medical device reporting regulations (21 CFR 1002.20; 21 CFR part 803). FDA believes that amending the regulations to allow summary reporting for AROs for electronic products extends the approach of eliminating or reducing duplicative reporting requirements beyond the medical device arena and promotes harmonization between this reporting and the new voluntary malfunction summary reporting for medical devices (21 CFR part 803; "Medical Devices and Device-Led Combination Products; Voluntary Malfunction Summary Reporting Program for Manufacturers" (83 FR 40973, August 17, 2018)).

Manufacturers records (21 CFR 1002.30 and 1002.31(a))—*Recordkeeping*
Requires manufacturers to keep records on test data and procedures, correspondence regarding radiation safety, and distribution records.

Distribution records (21 CFR 1002.31(c))—*Excluded under 5 CFR 1320.4*
Requires manufacturers, when requested by FDA, to provide copies of the distribution records required to be maintained by 1002.30(b).

Dealer/distributor records (21 CFR 1002.40 and 1002.41)—*Recordkeeping and Third-party disclosure*
Section 1002.40 requires dealers and distributors to retain first purchaser information, to be used by manufacturers when a product recall is instituted to ensure the radiation safety of a product. Section 1002.41 specifies that the dealer/distributor records in 1002.40 may be retained by the dealer or forwarded to the manufacturer for retention; also that the manufacturer or dealer shall retain distribution records for five years.

Exemption requests (21 CFR 1002.50(a) and 1002.51)—*Reporting*
Section 1002.50(a) specifies criteria by which manufacturers may request exemption from reporting and recordkeeping requirements when there is a low risk of injury. Section 1002.51 specifies criteria by which manufacturers may request exemption from reporting and recordkeeping requirements if the product is intended for U.S. Government use. The burdens are combined because the processes are essentially identical.

- **FDA Form 3642** "General Correspondence"

Discovery of defect or failure to comply, notification, and exemption from notification (21 CFR 1003.10, 1003.11(a)(3) and (b), 1003.20(a)-(h), 1003.21(a)-(d), 1003.22(a) and (b), 1003.30(a) and (b), 1003.31(a) and (b), 1004.2(a)-(i), 1004.3(a)-(i), 1004.4(a)-(h), 1005.21(a)-(c), and 1005.22(b))—*Excluded under 5 CFR 1320.4*
Section 1003.10(a) and (c) requires manufacturers to notify FDA when their product has a defect or fails to comply with applicable performance standards. If 21 CFR 803 also applies, that regulation takes precedence. Section 1003.10(b) requires manufacturers to notify purchasers, dealers, and distributors of product defects or noncompliance, including a description of hazard, instructions for use pending correction, and a corrective action plan. Section 1003.11(a)(3) specifies criteria by which manufacturers may refute FDA's notice of defective or noncompliant product. Section 1003.11(b) requires manufacturers, when notified by FDA, to provide information on the number of defective products introduced into commerce. Firms provide the information with the 1003.10(a) report. Section 1003.20(a)-(h) requires manufacturers to provide to FDA the same report as 1003.10(a), under different circumstances of discovery. Section 1003.21(a)-(d) specifies the content of the notification required by 1003.10(b). Section 1003.22(a) and (b) requires manufacturers to provide to FDA copies of the 1003.10 disclosure sent to purchasers, dealers or distributors. Firms provide the information with the 1003.10(a) report. Section 1003.30(a) and (b) specifies criteria by which manufacturers may request an exemption from the 1003.10 disclosure and possible

product recall. Section 1003.31(a) and (b) specifies the content of the 1003.30 report. Section 1005.21(a)-(c) specifies criteria for manufacturers or importers to request correction of noncompliant products for importation into the United States, including specific corrections, timeframe and location for completion. Such requests are made on Form FDA 766, Application for Authorization to Relabel or to perform other action of the Federal Food, Drug, and Cosmetic Act and other related Acts. Section 1005.22(b) specifies criteria for manufacturers or importers to request extension of time to bring product into compliance.

Product and sample information (21 CFR 1005.10)—*Reporting*
Requires manufacturers or their agents, when notified by FDA, to provide certain information on the product being introduced into commerce and sample being shipped to FDA for testing.

- **Form FDA 2767** "Notice of Availability of Sample Electronic Product," is used to collect the required information requested in 21 CFR 1005.10.

Identification information and compliance status (21 CFR 1005.25(a)-(b))—*Reporting*
Requires importers to report identification information and compliance status of products to FDA. Initial designations are provided in the 1002.10, 1002.11, and 1002.12 reports, so that burden is included in those sections. For each shipment, identification is made on Form 2877.

- **Form FDA 2877**, "Declaration for Products Subject to Radiation Control Standards," is used to collect the required information requested in 21 CFR 1005.25.

Alternate means of certification (21 CFR 1010.2(d))—*Reporting*
Specifies criteria for manufacturers to request alternate means of certification to a standard.

Coding system information (21 CFR 1010.3(a)-(c))—*Reporting*
Requires manufacturers to provide to FDA the coding systems if information on labels is coded and to identify each brand name, and the name and address of the individual or company for whom each product so branded is manufactured. Firms provide such information in the 1002.10, 1002.11, and 1002.12 reports, therefore the burden is included in those sections.

Variance (21 CFR 1010.4(b))—*Reporting*
Specifies criteria for manufacturers to petition FDA for a variance from a performance standard including alternate means of safety, or suitable means of safety along with reasons why the standard is inappropriate.

- **Form FDA 3633** "General Variance Request" is applicable to products other than Laser Light Shows and related products and is used to obtain the required information requested in 21 CFR 1010.4.

- **Form FDA 3147** "Application for a Variance from 21 CFR 1040.11(c) for a Laser Light Show, Display, or Device" is used only by manufacturers of laser light show products to submit the required information in order to justify a variance approval.
- **Form FDA 3635** "Laser Light Show Notification" is used to obtain certain required information specified in Form FDA 3147.

Exemption from performance standards (21 CFR 1010.5(c)-(d))—*Reporting*
Specifies criteria by which manufacturers or U.S. government agencies may request an exemption (or amendment or extension) from performance standards when a product is to be used exclusively by a part of the U.S. Government and has adequate radiation emission specifications.

Alternate test procedures (21 CFR 1010.13)—*Reporting*
Specifies criteria for manufacturers to request alternate test procedures from those specified in a performance standard.

Television receiver critical component warning (1020.10(c)(4))—*Third-party disclosure*
Requires manufacturers of television receivers to permanently affix or inscribe a warning label that includes the specification of operating high voltage and an instruction for adjusting the high voltage to the specified value.

Cold cathode tubes (1020.20(c)(4))—*Third-party disclosure*
Requires manufacturers of cold cathode tubes to provide safety instructions and specifications to users.

Report of assembly of diagnostic x-ray components (1020.30(d)(1)-(d)(2))—*Reporting*
Requires individuals or companies who install certified diagnostic x-ray components to submit a report of assembly to FDA as certification that the final product meets safety regulations (Form FDA 2579). In this section, reports of assembly need not be submitted for replacement tube housing assemblies that are reinstalled in or newly assembled into existing x-ray systems; Certified accessory components under 21 CFR 1002.10; repaired components; or temporarily installed components into an x-ray system.

- **Form FDA 2579** "Report of Assembly of a Diagnostic X-ray System" is used to obtain the required information requested in 21 CFR 1020.30(d).

Information on diagnostic x-ray systems (1020.30(g))—*Recordkeeping and Third-party disclosure*
Requires manufacturers of diagnostic x-ray systems and their major components to provide assembly, installation, compatibility, and testing information to assemblers of such products, and others upon request. Section 1020.30(g)(2) requires manufacturers of diagnostic x-ray systems and their major components to provide assemblers a statement of the maximum line current of the x-ray system based on the maximum input voltage and current characteristics of the tube housing assembly compatible with rated output voltage and rated output current characteristics of the x-ray control and associated high-

voltage generator.

Diagnostic x-ray system safety and technical information (1020.30(h)(1)-(h)(4))—*Third-party disclosure*
Section 1020.30(h)(1)-(h)(4) requires manufacturers of diagnostic x-ray systems and their major components to provide safety and technical information and instructions to the purchasers and users of such products, and others upon request.

Fluoroscopic x-ray system safety and technical information (1020.30(h)(5)-(h)(6) and 1020.32(a)(1), (g), and (j)(4))—*Third-party disclosure*
Section 1020.30(h)(5) and (h)(6) requires manufacturers of fluoroscopic x-ray systems to provide safety information and instructions to the purchasers and users of such products, and others upon request. Section 1020.32(a)(1) requires manufacturers to provide to users precautions concerning the importance of remote control operation. Section 1020.32(g) requires manufacturers of radiographic systems that contain Positive Beam Limitation to provide precautions and safety information to users. Section 1020.32(j)(4) requires the manufacturers of fluoroscopic x-ray equipment to provide technical information to users.

Computed tomography (CT) equipment (1020.33(c)-(d), (g)(4), and (j))—*Third-party disclosure*
Section 1020.33(c) requires manufacturers of CT x-ray systems to provide technical and safety information to users. It is provided in the same manual as the information required in 1020.30(h), or in a separate manual devoted entirely to this information. Section 1020.33(d) requires manufacturers of CT systems to provide quality assurance information to users. Section 1020.33(g)(4) requires manufacturers of certain CT systems to provide alignment instructions to users. Section 1020.33(j) requires manufacturers of CT x-ray systems to provide specific, technical instructions concerning the use of the method provided for calculation of the CT number mean and standard deviation to users.

Cabinet x-ray systems information (1020.40(c)(9)(i)-(c)(9)(ii))—*Third-party disclosure*
Requires manufacturers of cabinet x-ray systems to provide technical, safety, maintenance, and assembly information to purchasers.

Microwave oven radiation safety instructions (1030.10(c)(4))—*Third-party disclosure*
Requires manufacturers of microwave ovens to provide legible radiation safety instructions to users. This information should be contained in a separate section and should be an integral part of requirements supplied in an enclosed cookbook or user manual.

Microwave oven safety information and instructions (1030.10(c)(5)(i)-(c)(5)(iv))—*Third-party disclosure*
Requires manufacturers of microwave ovens to provide safety information and adequate instructions to service dealers and distributors and others upon request.

Microwave oven warning labels (1030.10(c)(6)(iii))—*Third-party disclosure*
Describes warning labels on Microwave Ovens. In the history of this performance standard, the Director for the Center for Devices and Radiological Health has never determined that a specific warning is required for a microwave oven manufacturer. Therefore, this citation has been added to the burden chart with a minimal burden.

Microwave oven exemption from warning labels (1030.10(c)(6)(iv))—*Reporting*
Specifies the information to be provided to FDA when a manufacturer of microwave ovens requests an exemption from required user warning labels.

Laser products registration (1040.10(a)(3)(i))—*Reporting*
Requires manufacturers of laser products sold for use as a component or replacement to register with FDA and provide a listing by type of product in lieu of the reporting required by 1002.10.

- **Form FDA 3637** "Laser Original Equipment Manufacturer (OEM) Report" is used to obtain the required information requested in 21 CFR 1040.10(a)(3)(i).

Laser products distribution records (1040.10(a)(3)(ii))—*Recordkeeping*
Requires manufacturers of laser products sold for use as a component or replacement to maintain distribution records in accordance with 1002.31.

Laser products information (1040.10(h)(1)(i)-(h)(1)(vi))—*Third-party disclosure*
Requires manufacturers of laser products to provide assembly, operation and maintenance instructions, technical information, legible reproductions of all label and hazard warnings, and a listing of all controls, adjustments, and procedures for operations and maintenance to users. The FDA is considering an amendment to simplify the information and harmonize with the international standards.

Laser product service information (1040.10(h)(2)(i)-(h)(2)(ii))—*Third-party disclosure*
Requires manufacturers of laser products to provide service information to dealers and distributors and to others upon request. It is provided in the same manual, as information required in 1040.10(h)(1).

Laser products recertification (1040.10(i))—*Reporting*
The reporting burden for laser products recertification is included in the burden estimate for Product Reports—1002.10. Section 1040.10(i) requires manufacturers who modify certified laser products to recertify and reidentify the product in accordance with 1010.2 and 1010.3. Thus, the firm is required to report compliance information to FDA as required by 1002.10. Manufacturers report this information on Form FDA 3632.

Medical laser product instructions (1040.11(a)(2))—*Third-party disclosure*
Requires manufacturers of certain medical laser products to provide instructions and a schedule for calibration with each product. It may be provided in the same manual as

information to purchasers required in 1040.10(h)(1).

Sunlamp products (1040.20)—*Third-party disclosure*
Describes the labeling requirements for sunlamp products and ultraviolet lamps intended for use in sunlamp products. As described above, the labeling requirements in 1040.20(d)(1)(i), (d)(2)(i), and (d)(2)(iii) are not subject to review under the PRA because they are a public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public (5 CFR 1320.3(c)(2)).

Mercury vapor lamp labeling (l040.30(c)(1)(ii))—*Third-party disclosure*
Describes the general regulations for high intensity, mercury vapor discharge lamps, specifically the labeling of these lamps. Burden in this area is considered negligible, as the imprinting of the lamps has become industry standard. Industry also has said that if this requirement were eliminated, they would continue the practice because of the cost implications of retooling all manufacturing of mercury vapor lamps.

Mercury vapor lamp permanently affixed labels (l040.30(c)(2))—*Third-party disclosure*
Describes labeling of mercury vapor discharge lamps in lieu of permanently affixing or inscribing tabs or labels on the product as required by 1010.2(b) and 1010.3(a). The manufacturer of any high intensity mercury vapor discharge lamp may permanently affix or inscribe such required tags or labels on the lamp packaging uniquely associated with the applicable lamp.

This information collection is not related to the American Recovery and Reinvestment Act of 2009.

2. Purpose and Use of the Information Collection

The respondents to this information collection are from the private sector; businesses for profit. The information collections are either specifically called for in the FD&C Act or were developed to aid FDA in performing its obligations under the FD&C Act. These requirements are placed upon manufacturers, importers, and assemblers of electronic products. The data reported to FDA and the records that are maintained allow FDA and the industry to make decisions and take actions that protect the public from radiation hazards presented by electronic products. This information refers to the identification, location, operational characteristics, quality assurance programs for, and problem identification and correction of electronic products. The data provided to users and others are intended to encourage actions to reduce or eliminate radiation exposures.

The reports are reviewed by FDA staff to determine product safety, conformance with performance standards, and adequacy of quality control testing. Potential and actual problems are resolved with the individual firm. The information supplied can be used by FDA to locate and select sample products for conformance with regulations.

Forms were designed to aid respondents in the submission of this information. In the event this information was not collected by FDA on forms, each manufacturer would have to respond in letter format with all the data now on FDA forms, requiring more time

and expense on their part. FDA would also then require written notification from FDA's Winchester Engineering and Analytical Center (WEAC), detailing all products received, from whom, returned to whom, model and chassis numbers, etc. to assure that the Agency's information coincided with their products. These extra steps to obtain information now on a form would significantly increase the cost in man-hours and duplications to both federal and industry organizations. Testing an appropriate percentage of these products to protect the public would also be hindered by any slower progress in FDA's receipt of the information.

The consequence of not obtaining the required information is that the public may unknowingly be exposed to unnecessary radiation hazards presented by electronic products. Without this information, FDA could not adequately make rational decisions and take appropriate actions to protect the public from these hazards as called for in the FD&C Act.

3. Use of Improved Information Technology and Burden Reduction

FDA has implemented several improved information technologies and methods to reduce the burden placed on manufacturers and assemblers, such as electronic transfer and optical storage of documents. This collection's forms have been designed to provide the minimum needed information in order to evaluate the product.

Well-designed forms can eventually lead to automated reviews of the submissions by software, identifying potential compliance problems and potential radiation hazards within days of receipt, reducing current time-consuming FDA processing and review times by an order of magnitude, and utilizing modern communication techniques to pass the information back to the manufacturer almost immediately.

The forms included here are portable document format (pdf) files, except form FDA 2579 is printed from the electronic submission system FDA has developed and provided for respondent use. The FDA encourages electronic filing via the FDA Electronic Submissions Gateway (FDA ESG) allowing manufacturers to create files using the CDRH eSubmitter software application, then send them via Internet through the FDA Gateway, significantly reducing the time burden of time delay and marketing restrictions placed on manufacturers and importers from 1 month to 5 minutes.

The FDA's voluntary electronic submission (eSubmitter) program utilizes information technology tools to automatically edit-check for errors in online submissions, ensure data integrity, and allow FDA staff to perform reviews, trending, and sampling analyses with greater ease. The eSubmitter software reduces the number of supplements needed, and provides data often missing from paper submissions. Additionally, as each form has been developed, the subject matter experts have streamlined the data collection and information requirements to a critical minimum, thereby reducing further the reporting burden on manufacturers.

These methods will be incorporated when CDRH satisfies technical and legal requirements such as data integrity for a regulated industry and comparability of data.

The use of the FDA's optical scanning and document retrieval system, IMAGE, has been modified to accommodate the eSubmitter applications for the radiological health area.

We have been consistently receiving approximately 50 percent of submissions using eSubmitter. FDA staff continues to encourage usage and provide individual assistance to industry.

4. Efforts to Identify Duplication and Use of Similar Information

FDA is the only authorized Agency to regulate the radiation from electronic products. Therefore, these activities are not duplicated anywhere else. Those electronic products that are also medical devices may be subject to additional (and different) FDA regulations under a separate section of the FD&C Act. In rare cases there has been minor duplication of information and where there has been, exemptions have been granted and the requirements changed so that the medical device reporting has precedence over electronic product reporting. Often, the documentation submitted to describe how radiation safety is assured through compliance with mandatory performance standards satisfies both medical device and electronic product reporting requirements. There is no similar information collected that can be used to carry out the enforcement of these regulations.

5. Impact on Small Businesses or Other Small Entities

We estimate that approximately 22 percent of respondents are small businesses (manufacturers, importers and assemblers of electronic products).

Efforts have been made to require the minimum amount of information possible for the Agency to make decisions and take actions to protect the public from radiation hazards presented by electronic products. Many of FDA's recordkeeping requirements are part of normal records necessary for any business practice, and the disclosure information is typically included in the manuals that are provided to purchasers with any manufactured product.

FDA has acted to minimize the burden to any firm whose product undergoes additional government testing by requiring the manufacturer or importer to ship tested products directly to Winchester Engineering and Analytical Center (WEAC) in Winchester, Massachusetts. The government often purchases the product, and/or pays all shipping and insurance charges.

FDA also maintains a CDRH website which provides firms with information pertaining to medical devices and radiological health. The Radiological Health homepage (http://www.fda.gov/Radiation-EmittingProducts/default.htm) provides all the paper-based report forms as well as the opportunity to download and install the new eSubmitter application and User Guide for electronic submission of required information. Furthermore, there is a subscription service which allows subscribers to be automatically notified by email whenever there are updates and new postings to the homepage. This helps provide answers to questions and problems with radiological health and electronic products to all firms, regardless of size.

FDA's Center for Devices and Radiological Health (CDRH), Division of International and Consumer Education (DICE), provides technical and other non-financial assistance to small firms, expressly to aid them in complying with the requirements of the Act. DICE participates in and presents conferences, workshops, and seminars on the application and interpretation of relevant regulations. They also consult with individual firms, and develop and disseminate educational materials. Staff is available to respond to questions and a toll-free telephone number was established to facilitate this communication link. Additional information on DICE may be obtained by any firm with internet access by logging onto the FDA's web site (http:\\www.fda.gov) and clicking on the Radiological Health Program link.

6. Consequences of Collecting the Information Less Frequently

The frequency of the collection requirements depends on the type of information. There are one-time product reports and annual reports. A firm introducing a new electronic product is required to prepare a one-time product report, for which the burden has been estimated to be 24 hours. Subsequent modifications to that product may require a supplemental report, which take a half hour and are only required when the new model has changes that affect the radiation hazard from the product. Again, this would be a one-time submission. Generally, all manufacturers of electronic products subject to the reporting requirements under this clearance must file an annual report, which is a production summary report. This burden has been estimated to be 18 hours, an annual burden.

If this information were obtained less frequently, fewer report reviews and evaluations of compliance could be conducted by FDA, which could potentially result in endangering the public health through unnecessary exposure to electronic radiation. In the event that this product information was not provided to FDA in a timely manner, a hazard could go undetected and the risk to the public from unnecessary radiation would be increased significantly. If information was not provided to users, distributors, or assemblers at the time of possession of the product they may be unable to make informed decisions and take actions relating to safety.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

A few of the information collection requirements are inconsistent with those outlined in 5 CFR 1320.5 because immediate health hazards require immediate action and reporting must be prompt. If FDA and the affected industry or firm did not have access to this information, equipment could not be located quickly when a particular product or system is suspected of causing harm. If an entire model line is determined to be defective, the firm must be able to locate other installations of the defective units to eliminate additional hazards.

Over the past several years, recordkeeping requirements have been significantly reduced, but the timeframe for maintaining these records (5 years) remains the same. These records are needed for significant risk products, and therefore are considered records pertaining to health which are not subject to the 3-year limit (5 CFR 1320.5(d)(2)(iv)).

If FDA did not possess this information, equipment could not be located quickly when a particular system is suspected of causing harm, and the protection of the public from significant health risks might be compromised.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

   FDA is requesting revision of the burden estimates, to reflect amendments to 21 CFR parts 1000 through 1050 in the proposed rule, "Radiological Health Regulations; Amendments to Records and Reports for Radiation Emitting Electronic Products; Amendments to Performance Standards for Diagnostic X-ray, Laser and Ultrasonic Products" (RIN 0910-AH65. FDA provided an opportunity for public comment on the information collection requirements of the proposed rule that published in the FEDERAL REGISTER of April 1, 2019 (84 FR 12147).

   FDA/CDRH's Office of Communication, Education, and Radiation Programs (OCER) staff meets on a regular basis with consumer groups such as the Consumer Electronics Association to discuss topics relating to the regulation of electronic and radiological health industries.

   FDA also routinely consults with members of industry, government, and the public through the Technical Electronic Product Radiation Safety Standards Committee (TEPRSSC) and the Radiological Devices Panel (RDP). These committees are permanent advisory committees established under sections 534(f) and 513(b) of the FD&C Act. FDA is required to consult with the TEPRSSC before establishment of or changes to standards, and the RDP advises FDA on use of radiation in the healing arts.

9. Explanation of Any Payment or Gift to Respondents

   There is no payment or gift provided to respondents of this information collection.

10. Assurance of Confidentiality Provided to Respondents

    Section 537 of the FD&C Act states that the Secretary shall not disclose any information which contains or relates to a trade secret or other matter referred to in section 1905 of Title 18 of the United States Code. Information provided under this collection is handled in a manner to comply with this requirement and the FDA regulations implementing the Freedom of Information Act, 21 CFR part 20. All information provided will be protected from inappropriate disclosure.

    CDRH's Privacy Officer is conducting a privacy review of this information collection and will submit a privacy impact assessment, if appropriate, to the FDA privacy office for review prior to finalization of the rulemaking.

11. Justification for Sensitive Questions

    The information collection does not include questions about sexual behavior and attitudes, religious beliefs, or other matters that are commonly considered private or sensitive in nature.

12. Estimates of Annualized Burden Hours and Costs

12 a. Annualized Hour Burden Estimate

Respondents to this collection of information are electronic product manufacturers, importers, and assemblers. The burden estimates were derived by consultation with FDA and industry personnel, and are based on actual data collected from industry, including recent product report submissions. An evaluation of the type and scope of information requested was also used to derive some time estimates.

The revised estimates made for the proposed rule, "Radiological Health Regulations; Amendments to Records and Reports for Radiation Emitting Electronic Products; Amendments to Performance Standards for Diagnostic X-ray, Laser and Ultrasonic Products" (see section 15 for a detailed description of the revisions), were generated from discussions with subject matter experts at FDA. We have requested comments on these estimates.

Table 1.--Estimated Annual Reporting Burden

Activity/ 21 CFR Section	FDA Form	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours[1]
Product reports—1002.10(a)-(k)	3639—Cabinet x-ray 3632—Laser 3640—Laser light show 3630—Sunlamp 3659—TV 3660—Microwave oven 3801—UV lamps	1,149	2.2	2,529	24	60,685
Product safety or testing changes—1002.11(a)-(b)		440	2.5	1,100	0.5	550
Abbreviated reports —1002.12	3629—General abbreviated report 3646—Mercury vapor lamp (R & T lamps) 3663—Microwave products (non-oven)	54	1.8	97	5	485
Annual reports—1002.13(a)-(b)	3628—General 3634—TV 3641—Cabinet x-ray 3643—Microwave oven 3636—Laser 3631—Sunlamp	1,410	1.3	1,833	18	32,994
Accidental radiation occurrence reports —1002.20	3649—ARO	75	4	300	2	600
Exemption requests —1002.50(a) and 1002.51	3642—General correspondence	4	1.3	5	1	5
Product and sample information—1005.10	2767—Sample product	5	1	5	0.1	1

Table 1.--Estimated Annual Reporting Burden

Activity/ 21 CFR Section	FDA Form	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours[1]
Identification information and compliance status—1005.25	2877—Imports declaration	12,620	2.5	31,550	0.2	6,310
Alternate means of certification—1010.2(d)		1	2	2	5	10
Variance—1010.4(b)	3633—General variance request 3147—Laser show variance request 3635—Laser show notification	350	1.1	385	1.2	462
Exemption from performance standards—1010.5(c) and (d)		1	1	1	22	22
Alternate test procedures—1010.13		1	1	1	10	10
Microwave oven exemption from warning labels—1030.10(c)(6)(iv)		1	1	1	1	1
Laser products registration—1040.10(a)(3)(i)	3637—Original equipment manufacturer (OEM) report	70	2.9	203	3	609
Total						102,744

[1] Total hours have been rounded.

Table 2.--Estimated Annual Recordkeeping Burden

Activity/ 21 CFR Section	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours[1]
Manufacturers records—1002.30 and 1002.31(a)	1,409	1,650	2,324,850	0.12	278,982
Dealer/distributor records—1002.40 and 1002.41	2,909	50	145,450	0.05	7,273
Information on diagnostic x-ray systems—1020.30(g)	50	1	50	0.5	25
Laser products distribution records—1040.10(a)(3)(ii)	70	1	70	1	70
Total					286,350

[1] Total hours have been rounded.

Table 3.--Estimated Annual Third-Party Disclosure Burden

Activity/ 21 CFR Section	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure	Total Hours[1]
Technical and safety information for users—1002.3	1	1	1	12	12
Dealer/distributor records—1002.40 and 1002.41	30	3	90	1	90
Television receiver critical component warning—1020.10(c)(4)	1	1	1	1	1
Cold cathode tubes—1020.20(c)(4)	1	1	1	1	1
Report of assembly of diagnostic x-ray components—1020.30(d), (d)(1), and (d)(2) (form FDA 2579—Assembler report)	1,230	34	41,820	0.30	12,546
Information on diagnostic x-ray systems—1020.30(g)	6	1	6	55	330
Statement of maximum line current of x-ray systems—1020.30(g)(2)	6	1	6	10	60
Diagnostic x-ray system safety and technical information—1020.30(h)(1)-(h)(4)	6	1	6	200	1,200
Fluoroscopic x-ray system safety and technical information—1020.30(h)(5)-(h)(6) and 1020.32(a)(1), (g), and (j)(4)	5	1	5	25	125
CT equipment—1020.33(c)-(d), (g)(4), and (j)	5	1	5	150	750
Cabinet x-ray systems information—1020.40(c)(9)(i)-(c)(9)(ii)	6	1	6	40	240
Microwave oven radiation safety instructions—1030.10(c)(4)	1	1	1	20	20
Microwave oven safety information and instructions—1030.10(c)(5)(i)-(c)(5)(iv)	1	1	1	20	20
Microwave oven warning labels—1030.10(c)(6)(iii)	1	1	1	1	1
Laser products information—1040.10(h)(1)(i)-(h)(1)(vi)	2	1	2	20	40
Laser product service information—1040.10(h)(2)(i)-(h)(2)(ii)	2	1	2	20	40
Medical laser product instructions—1040.11(a)(2)	2	1	2	10	20
Sunlamp products instructions—1040.20	1	1	1	10	10

Table 3.--Estimated Annual Third-Party Disclosure Burden

Activity/ 21 CFR Section	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure	Total Hours[1]
Mercury vapor lamp labeling—1040.30(c)(1)(ii)	1	1	1	1	1
Mercury vapor lamp permanently affixed labels —1040.30(c)(2)	1	1	1	1	1
Total					15,508

[1] Total hours have been rounded.

12b. Annualized Cost Burden Estimate

We expect that the information collection will be satisfied by regulatory affairs professionals. We have updated the hourly wage rate estimates.

To determine the estimated savings in reduced labor, activities associated with this information collection are valued using 2016 mean base wages for regulatory affairs specialists as reported by Payscale.com (http://www.payscale.com/research/US/Job=Regulatory_Affairs_Specialist/Salary, accessed 11-08-17). After accounting for benefits and overhead by multiplying the mean base wage by 2, the adjusted mean hourly wage rate is $63.96 ($31.98 x 2). The base mean hourly wage was estimated by dividing the national average annual salary of $63,956 by 2,000 annual work hours.

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Regulatory Affairs Professional	404,602	$63.96	$25,878,343

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

There are no capital or operating/maintenance costs associated with this collection.

14. Annualized Cost to the Federal Government

FDA estimates that 15 full time equivalent (FTE) positions participate in activities under the Radiation Control for Health and Safety Act. An average full time equivalent (FTE) employee is projected to cost FDA's Center for Devices and Radiological Health (CDRH) $213,944 (rounded),* which consists of the employee's salary and any overhead which accompanies that employee. Therefore, the estimated annualized burden to government for this information collection is $3,209,160 per year ($213,944 x 15 FTEs).

* Based on the FY 2017 FDA Budget Request – Executive Summary – All Purpose Table.

Proposed rule:

The cost savings to FDA are based on the number of hours eliminated for the annual reporting requirement. Since annual reporting refers to reports that are submitted to FDA for review, a reduction in reporting would result in labor cost savings for FDA. As reported in the revised burden estimate, we estimate that 23.9 percent of the total annual reporting burden hours will be eliminated as a result of this proposed rule if finalized. Multiplying this percentage by the total number of FTEs, we estimate a labor reduction equivalent to 3.59 FDA FTEs would result from the elimination of the specified annual reporting requirements (15 x 23.9 percent). Multiplying the annual FTE cost by the number of FTEs reduced yields an annual cost savings to FDA of $768,013 ($213,944 x 3.59). As summarized in the "Radiological Health Regulations; Amendments to Records and Reports for Radiation Emitting Electronic Products; Amendments to Performance Standards for Diagnostic X-ray, Laser and Ultrasonic Products Preliminary Regulatory Impact Analysis," the present value cost savings to FDA over a 20-year time period of $8,136,344 at a 7 percent discount rate and $11,426,099 at a 3 percent discount rate, and the annualized cost savings are $768,013.

15. Explanation for Program Changes or Adjustments

The number of respondents/responses per respondent for each IC has been adjusted as appropriate to reflect the proposed amendments to 21 CFR parts 1000 through 1050. As a result of these amendments, the total estimated burden for this ICR has decreased by 67,392 hours (previously 471,994 hours; now 404,602 hours).

FDA is proposing to revise the applicability of the recordkeeping and reporting requirements for some products (21 CFR 1002.1). We revised the burden estimates for product reports, abbreviated reports, and annual reports by reducing the number of respondents to reflect the revised applicability of the recordkeeping and reporting requirements. We also proposed to revise form FDA 3646 "Mercury Vapor Lamp Products Radiation Safety Report" (now listed under Abbreviated Reports consistent with the revision of § 1002.1) and removed the following forms:

- FDA Form 3626 "A Guide for the Submission of Initial Reports on Diagnostic X-Ray Systems and Their Major Components"
- FDA Form 3627 "Diagnostic X-Ray CT Products Radiation Safety Report"
- FDA 3638 "Guide for Filing Annual Reports for X-Ray Components and Systems,"
- FDA Form 3644 "Guide for Preparing Product Reports for Ultrasonic Therapy Products"
- FDA 3645 "Guidance for Preparing Annual Reports for Ultrasonic Therapy Products,"
- FDA 3647 "Guide for preparing Annual Reports on Radiation Safety Testing of Mercury Vapor Lamps"
- FDA Form 3661 "Guide for the Submission of an Abbreviated Report on X-ray Tables, Cradles, Film Changers or Cassette Holders Intended for Diagnostic Use"
- FDA Form 3662 "Guide for Submission of an Abbreviated Radiation Safety Reports on Cephalometric Devices Intended for Diagnostic Use"

The proposed revised applicability of the recordkeeping and reporting requirements for dealer/distributor records (1002.40 and 1002.41) may result in a small decrease in the number of respondents. However, upon calculating and rounding the estimated annual number of respondents, we have determined there is no change to the current burden estimate for this information collection.

FDA is eliminating requirements for new models of a model family to report model numbers of a model family that do not involve changes in radiation emission or requirements of a performance standard in quarterly updates to their annual reporting (21 CFR 1002.13(c)). We have removed the burden estimate associated with 1002.13(c). Generally, other subsections require specified product manufacturers to submit annual reports to FDA which summarize certain manufacturing records (21 CFR 1002.13(a) and (b)). FDA is not amending these annual report requirements.

FDA is proposing to amend the timing for submission of reporting requirements for AROs that are not associated with a death or serious injury (21 CFR 1002.20). The proposed amendment will allow manufacturers of a radiation emitting electronic product to submit quarterly summary reports of AROs that are not associated with a death or serious injury and not required to be reported under the medical device reporting regulations (21 CFR 1002.20; 21 CFR part 803). FDA believes that amending the regulations to allow summary reporting for AROs for electronic products extends the approach of eliminating or reducing duplicative reporting requirements beyond the medical device arena and promotes harmonization between this reporting and the new voluntary malfunction summary reporting for medical devices (see 21 CFR part 803; "Medical Devices and Device-Led Combination Products; Voluntary Malfunction Summary Reporting Program for Manufacturers" (83 FR 40973, August 17, 2018)).

FDA is also proposing to amend the applications for variances process (21 CFR 1010.4(b)) to no longer require a manufacturer to submit two additional copies with the original documents. While this amendment would not generate any substantive change to the information collection, respondents may realize a small monetary savings from the usual and customary administrative expenses associated with the preparation of the copies.

FDA is proposing to amend the reports of assembly requirements for major components of diagnostic x-ray systems to no longer require assemblers who install certified components to submit a report of assemblies, FDA Form 2579, to CDRH (21 CFR 1020.30(d)(1)). FDA also proposes to withdraw the language to require submission to "the Director" in this subsection, but will still publish a PDF form online for assemblers to download, complete, and provide to applicable States and purchasers as required. We have moved the corresponding information collection burden estimate from reporting to third-party disclosure burden and revised form FDA 2579.

FDA is proposing to amend the laser products regulation to add an exception to the applicability of the laser product performance standards (see 21 CFR 1040.10 and 1040.11) to a manufacturer who incorporates an unmodified laser product into another

product when such laser product is not intended for use as a component or replacement and such laser product is certified by the manufacturer of such laser product, subject to certain conditions (21 CFR 1040.10(a)). We have reduced the number of respondents in our burden estimate to reflect the amendment.

FDA is proposing to repeal the performance standards for ultrasonic therapy products (21 CFR 1050.10). We have removed the burden estimate associated with § 1050.10.

The ICs have been adjusted as follows:

Activity/ 21 CFR Section	Adjustment to Total Annual Responses	Adjustment to Average Burden per Response	Adjustment to Total Hours
Reporting:			
Product reports—1002.10(a)-(k)	-551	0	-13,235
Product safety or testing changes—1002.11(a)-(b)	-100	0	-50
Abbreviated reports—1002.12	-11	0	-55
Annual reports—1002.13(a)-(b)	-325	0	-5,850
Quarterly updates for new models—1002.13(c) [paragraph removed]	-168	-0.5	-84
Accidental radiation occurrence reports—1002.20	+99	0	+198
Exemption requests—1002.50(a) and 1002.51	0	0	0
Product and sample information—1005.10	0	0	0
Identification information and compliance status—1005.25	0	0	0
Alternate means of certification—1010.2(d)	0	0	0
Variance—1010.4(b)	0	0	0
Exemption from performance standards—1010.5(c) and (d)	0	0	0
Alternate test procedures—1010.13	0	0	0
Report of assembly of diagnostic x-ray components—1020.30(d), (d)(1), and (d)(2) [moved to Third-Party Disclosure Burden]	-41,820	-0.30	-12,546
Microwave oven exemption from warning labels—1030.10(c)(6)(iv)	0	0	0
Laser products registration—1040.10(a)(3)(i)	0	0	0
Total reporting contribution to adjustment total			**-31,622**
Recordkeeping:			
Manufacturers records—1002.30 and 1002.31(a)	-397,650	0	-47,718
Dealer/distributor records—1002.40 and 1002.41	-10,050	0	-502
Information on diagnostic x-ray systems—1020.30(g)	0	0	0
Laser products distribution records—1040.10(a)(3)(ii)	0	0	0
Total recordkeeping contribution to adjustment total			**-48,220**
Third-party disclosure:			
Technical and safety information for users—1002.3	0	0	0
Dealer/distributor records—1002.40 and 1002.41	0	0	0
Television receiver critical component warning—1020.10(c)(4)	0	0	0
Cold cathode tubes—1020.20(c)(4)	0	0	0
Report of assembly of diagnostic x-ray components—1020.30(d), (d)(1), and (d)(2) [moved from Reporting Burden]	+41,820	+0.30	+12,546
Information on diagnostic x-ray systems—1020.30(g)	0	0	0
Statement of maximum line current of x-ray systems—1020.30(g)(2)	0	0	0

Activity/ 21 CFR Section	Adjustment to Total Annual Responses	Adjustment to Average Burden per Response	Adjustment to Total Hours
Diagnostic x-ray system safety and technical information—1020.30(h)(1)-(h)(4)	0	0	0
Fluoroscopic x-ray system safety and technical information—1020.30(h)(5)-(h)(6) and 1020.32(a)(1), (g), and (j)(4)	0	0	0
CT equipment—1020.33(c)-(d), (g)(4), and (j)	0	0	0
Cabinet x-ray systems information—1020.40(c)(9)(i)-(c)(9)(ii)	0	0	0
Microwave oven radiation safety instructions—1030.10(c)(4)	0	0	0
Microwave oven safety information and instructions—1030.10(c)(5)(i)-(c)(5)(iv)	0	0	0
Microwave oven warning labels—1030.10(c)(6)(iii)	0	0	0
Laser products information—1040.10(h)(1)(i)-(h)(1)(vi)	-1	0	-20
Laser product service information—1040.10(h)(2)(i)-(h)(2)(ii)	-1	0	-20
Medical laser product instructions—1040.11(a)(2)	0	0	0
Sunlamp products instructions—1040.20	0	0	0
Mercury vapor lamp labeling—1040.30(c)(1)(ii)	0	0	0
Mercury vapor lamp permanently affixed labels—1040.30(c)(2)	0	0	0
Ultrasonic therapy products—1050.10(d)(1)-(d)(4), (f)(1), and (f)(2)(iii) [section removed]	-1	-56	-56
Total third-party disclosure contribution to adjustment total			**+12,450**

16. Plans for Tabulation and Publication and Project Time Schedule

    There are no plans to publish the collection of information under these regulations for statistical use unless requested by Congress in accordance with section 533 of the FD&C Act.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

    FDA will display the OMB expiration date as required by 5 CFR 1320.5.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

    There are no exceptions to the certification.