of Food and Drugs, 21 CFR part 886 is amended as follows:

PART 886—OPHTHALMIC DEVICES

■ 1. The authority citation for part 886 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

■ 2. Add § 886.5201 to subpart F to read as follows:

§ 886.5201 Intense pulsed light device for managing dry eye.

(a) *Identification.* An intense pulsed light device for managing dry eye is a prescription device intended for use in the application of intense pulsed light therapy to the skin. The device is used in patients with dry eye disease due to meibomian gland dysfunction, also known as evaporative dry eye or lipid deficiency dry eye.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) Clinical performance testing must evaluate adverse events and improvement of dry eye signs and symptoms under anticipated conditions of use.

(2) Thermal safety assessment in a worst-case scenario must be performed to validate temperature safeguards.

(3) Performance testing must demonstrate electrical safety and electromagnetic compatibility (EMC) of the device in the intended use environment.

(4) Software verification, validation, and hazard analysis must be performed.

(5) The patient-contacting components of the device must be demonstrated to be biocompatible.

(6) Physician and patient labeling must include:

(i) Device technical parameters;

(ii) A summary of the clinical performance testing conducted with the device;

(iii) A description of the intended treatment area location;

(iv) Warnings and instructions regarding the use of safety-protective eyewear for patient and device operator;

(v) A description of intense pulse light (IPL) radiation hazards and protection for patient and operator;

(vi) Instructions for use, including an explanation of all user interface components; and

(vii) Instructions on how to clean and maintain the device and its components.

Dated: January 17, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–01049 Filed 1–19–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1000, 1002, 1010, 1020, 1030 and 1050

[Docket No. FDA–2018–N–3303]

RIN 0910–AH65

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is amending and repealing 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.

DATES: This rule is effective February 21, 2023.

ADDRESSES: For access to the docket to read background documents or comments received, go to *https://www.regulations.gov* and insert the docket number found in brackets in the heading of this final rule into the ''Search'' box and follow the prompts, and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Robert Ochs, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3680, Silver Spring, MD 20993, 301–796–6661, email: *Robert.Ochs@fda.hhs.gov.*

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I. Executive Summary

A. Purpose of the Final Rule

This final rule amends and repeals certain regulations for radiation emitting electronic products and medical devices because the FDA has identified the regulations as being outdated and duplicative of other means for reducing radiation exposure to the public. The Agency is updating the regulations to amend or repeal regulations that are outdated and otherwise clarify requirements for protecting the public health against radiation exposure from specific electronic products and medical devices. The regulations being finalized for amendment or repeal are the radiation protection recommendations for specific uses, records and reporting requirements for electronic products, applications for variances, and performance standards for diagnostic x-ray systems and their major components, laser products, and ultrasonic therapy products.

B. Summary of the Major Provisions of the Final Rule

This final rule updates FDA's radiological health regulations to amend or repeal the following provisions:

- Repeal the radiation protection recommendations that have become outdated and unnecessary;
- Removing or reducing some of the annual reports and test record

requirements that are unnecessary or may be duplicative of other reporting requirements by FDA and State regulators;

- Revise the timing for submissions of reporting requirements for accidental radiation occurrences (AROs) to provide for quarterly reporting for AROs that are not associated with a death or serious injury;
- Amend the applications for variances processes to no longer require a manufacturer to submit two additional copies with the original documents;
- Amend the regulations to no longer require assemblers who install certified components of diagnostic x-ray systems to submit reports of assembly to the Agency;
- Amend the reporting requirements for manufacturers that incorporate a certified laser product to reduce reporting that is considered duplicative under certain conditions; and
- Repeal the performance standard for ultrasonic products because it is limited to a subset of physical therapy devices with an outdated standard.

The Agency believes the amendments and repeals will help to ensure that the requirements for radiation emitting electronic products and devices will continue to protect the public health and safety while reducing regulatory burdens.

C. Legal Authority

FDA is issuing this final rule under the same authority under which FDA initially issued these regulations, the device and general administrative provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act). FDA has the authority under the FD&C Act to amend the performance standard for diagnostic x-ray systems and their major components, amend the performance standard for laser products, and repeal radiation protection recommendations and the performance standard for ultrasonic therapy products, as provided for in this rule.

D. Costs and Benefits of the Final Rule

This final rule updates FDA's radiological health regulations by amending parts of the general provisions including records and reporting requirements for electronic products. Benefits are estimated in terms of cost savings. Industry cost savings are derived by estimating the savings in reduced labor resulting from the reduction in reporting, recordkeeping, and third-party disclosure requirements. Cost savings to FDA result from the reduction in labor hours required to review reports. The total present value cost savings over a 20-year time period are $69.71 million at a 7 percent discount rate and $97.89 million at a 3 percent discount rate. Annualized total cost savings are $6.58 million. We estimate the costs to read the rule for all reporting respondents. The present value costs are $1.60 million and the annualized costs calculated over a 20-year time period are $0.14 million at a 7 percent discount rate and $0.10 million at a 3 percent discount rate.

II. Table of Abbreviations/Commonly Used Acronyms in This Document

Abbreviation	What it means
ARO	Accidental Radiation Occurrences.
CDRH	Center for Devices and Radiological Health.
CFR	Code of Federal Regulations.
CRCPD	Conference of Radiation Control Program Directors.
CT	Computerized Tomography.
EO	Executive Order.
EPRC	Electronic Product Radiation Control.
EPA	Environmental Protection Agency.
FD&C Act	Federal Food, Drug, and Cosmetic Act.
FDA, Agency or we	Food and Drug Administration.
ICRP	International Commission on Radiological Protection.
IEC	International Electrotechnical Commission.
ISO	International Organization for Standardization.
MDR	Medical Device Reporting.
NCRP	National Council on Radiation Protection and Measurements.
OMB	Office of Management and Budget.
PRA	Paperwork Reduction Act of 1995.
TEPRSSC	Technical Electronic Product Radiation Safety Standards Committee.

III. Background

FDA recognizes that some records and reporting requirements for some radiation emitting electronic products and medical devices are not necessary to protect the public health and safety in compliance with the Electronic Product Radiation Control (EPRC) program (see sections 532, 534(a)(1), and 537(b) of the FD&C Act (21 U.S.C. 360ii, 360kk(a)(1), and 360nn(b))). In addition, some of the recommended protections against radiation and performance standards are now outdated and redundant to other Federal and State requirements, including professional guidelines that apply to the education and licensing of practitioners, as well numerous current radiation guidance documents and industry standards that practitioners and industry rely on to protect the public health and safety. For example, there are more recent standards that industry and FDA can rely on for the safety of ultrasonic therapy devices for physical medicine, for instance the International Electrotechnical Commission (IEC) standards 60601–2–5, *Medical electrical equipment—Part 2–5: Particular requirements for the basic safety and essential performance of ultrasonic physiotherapy equipment* (August 6, 2013) and 61689, *Ultrasonics—Physiotherapy systems—Field specifications and methods of measurement in the frequency range 0.5 MHz to 5 MHz* (January 30, 2014). FDA also recognizes that submission of certain quarterly reports is unnecessary given certain annual reporting requirements. In addition, the submission of initial product reports for products that are also subject to premarket authorization prior to marketing is duplicative. The Safe Medical Devices Act of 1990 (Pub. L. 101–629), enacted on November 28, 1990, transferred the provisions of the Radiation Control for Health and Safety Act of 1968 (Pub. L. 90–602) (formerly 42 U.S.C. 263b through n(i) *et seq.*) from Title III of the Public Health Service Act to Chapter V, subchapter C of the FD&C Act, EPRC (sections 531–542 of the FD&C Act (21 U.S.C. 360hh–360ss)). Under these provisions, FDA

administers the EPRC program to protect the public health and safety. This authority provides for developing, amending, and administering radiation safety performance standards for electronic products.

FDA is responsible for protecting and promoting the public health regarding electronic product radiation from medical devices and electronic products. Voluntary consensus standards regarding safety and essential performance have been developed and continually improved to increase the safety of these devices and products (sections 514(c) (21 U.S.C. 360d) and 531–542 of the FD&C Act). FDA believes radiation emitting electronic products and devices that comply with Federal standards and Federally-recognized consensus standards, adequately protect the public health and safety and provide a reasonable assurance of safety and effectiveness, as applicable, when properly used by trained personnel, and concern has shifted to minimizing improper uses. FDA, patients, health workers, and industry recognize that medical products that emit radiation should be used only when medically justified to answer a clinical question or to guide treatment of a disease, and that the amount of radiation used should be limited to that necessary to accomplish the clinical task (Refs. 1, 2–4).

In 2010, FDA's Center for Devices and Radiological Health (CDRH) launched an ''Initiative to Reduce Unnecessary Radiation Exposure from Medical Imaging'' (Ref. 3) to protect public health by promoting the appropriate use of radiation and safety features to minimize unnecessary radiation exposure from medical imaging. Through this initiative, FDA collaborates with other agencies and the healthcare professional community to mitigate factors contributing to unnecessary patient exposure to radiation during medical procedures. The range of electronic products marketed today is diverse with regards to radiation emission levels, product complexity, consumer use, and sales volume. The public risk associated with exposure to radiation from these products also varies significantly; however, the risks to patients can be mitigated by medical personnel only performing exams using radiation when necessary to answer a medical question, treat a disease, or guide a procedure (Ref. 4).

In accordance with FDA's directive to carry out the EPRC program (see sections 532, 534(a)(1), and 537(b) of the FD&C Act), FDA prescribes and amends performance standards for electronic products to control the emission of electronic product radiation when necessary to protect the public health and safety. In establishing performance standards consistent with the statute, FDA consulted with the Technical Electronic Product Radiation Safety Standards Committee (TEPRSSC) (section 534(f) of the FD&C Act) (Ref. 5). On October 26, 2016, a TEPRSSC meeting was held and FDA presented, for consultation with TEPRSSC, proposed certain amendments to the regulations for laser, sonic, x-ray, and other radiation emitting products to best align FDA's focus with the public health need and reduce or eliminate standards or reporting that were no longer considered necessary (Ref. 5). FDA also proposed to the TEPRSSC the removal of the ultrasonic therapy performance standard with continuing reliance on medical device review prior to marketing authorization. Items in these amendments have been considered in discussions by TEPRSSC as necessary. Therefore, FDA has determined that the regulatory requirements can be adjusted to take account of the wide range of electronic products currently on the market and focus on products that pose a higher risk to the public.

A. Need for Amendments and Repeal of Certain Radiological Health Regulations

Many of the requirements in our radiological health regulations are over 30 years old. As described below and in the proposed rule (84 FR 12147, April 1, 2019) the final rule amends and repeals certain radiological health regulations to reduce regulatory requirements that are outdated and duplicative. Specifically, this final rule amends parts of the radiological health regulations covering recommendations for radiation protection during medical procedures, certain records and reporting for electronic products, applications for variances, and performance standards for diagnostic x-ray systems and their major components, laser products, and ultrasonic therapy products while still assuring the public health and safety is protected against harmful exposure to radiation emitting electronic products and medical devices.

B. Summary of Comments to the Proposed Rule

In the **Federal Register** of April 1, 2019, FDA published a proposed rule to amend the radiological health regulations (84 FR 12147). The comment period for the proposed rule closed on July 1, 2019. FDA received comments on the proposed rule from several entities including medical device associations, industry, medical and healthcare professional associations, public health advocacy groups, and individuals. While some comments object to particular sections or subsections of the proposed rule, almost all comments voice support for the objective intent of the proposed rule, to amend certain regulations to reduce regulatory burden while continuing to assure protection of the public health and safety against harmful exposure to radiation emitting electronic products and medical devices.

Some comments raise concerns or request clarification regarding:

- repealing the radiation protection recommendations,
- removing or reducing certain records and reporting requirements for electronic products,
- incorporating and expanding the policies described in FDA's Laser Notice 42 to higher powered laser products,
- amending the performance standards for laser products that incorporate certified laser systems,
- information on future technologies and other measures that may reduce or eliminate radiation exposure,
- document retention and responsibilities related to initial, supplemental, abbreviated and annual reports,
- assemblers' responsibilities for maintaining a record of report of assembly on file,
- the tracking and trending analysis related to the requirements for reports on accidental radiation occurrences, and
- additional amendments to performance standards for laser products.

C. General Overview of Final Rule

FDA considered all comments received on the proposed rule and made changes, primarily for clarity and accuracy and to be consistent with the goal of reducing the burden of regulatory requirements for radiation emitting products and medical devices without compromising patient safety. On its own initiative, FDA is also making minor technical changes to improve clarity and consistency and reduce regulatory burden. Based on the comments received on the proposed rule, FDA has made changes from the proposed rule (84 FR 12147) to include the following revisions in the codified section of this final rule:

- Include the word ''accidental'' in the definition for radiation occurrence (§ 1000.3(a)),
- include a footnote in the records and reports table clarifying laser product certification (table 1 in § 1002.1),

- include language of information needed for quarterly reporting of accidental radiation occurrences (§ 1002.20(c)(2)(ii)),
- include a paragraph with language to identify when certification and reporting is duplicative and unnecessary for laser products under § 1040.10 that incorporate a certified laser system (§ 1010.2(e)),
- identify an alternative format for identification of the month and date of the manufacture of an electronic product (§ 1010.3(a)(2)(ii)),
- clarify the options for submissions for applications for variances (§ 1010.4(b)(1)), and
- revise the title and applicability for television receivers that contain a cathode ray tube (§ 1020.10).

FDA also decided on its own initiative to include the following additional amendments to this final rule for clarity and consistency and to reduce regulatory burden:

- remove the requirement for two copies of an application for exemption of warning labels for a microwave oven that are submitted to CDRH and correct the name of the CDRH office to submit a document (§ 1030.10(c)(iv)), and
- clarify and remove the requirement that x-ray assemblers for certified accessory components submit Reports of Assembly (Form FDA 2579) to CDRH (§ 1020.30(d)(2)).

IV. Legal Authority

FDA is issuing this final rule under the same authority under which FDA initially issued these regulations, the device and general administrative provisions of the FD&C Act (21 U.S.C. 321, 351, 352, 360, 360e–360j, 360hh–360ss, 371, 374, and 381). FDA has the authority under section 534 of the FD&C Act to amend the performance standard for diagnostic x-ray systems and their major components, amend the performance standard for laser products, and repeal radiation protection recommendations and the performance standard for ultrasonic therapy products, as provided for in this final rule.

V. Comments on the Proposed Rule and FDA's Responses

We received several sets of comments on the proposed rule by the closure of the comment period, each containing one or more comments on one or more issues. We received comments from medical device associations, industry, medical and healthcare professional associations, public health advocacy groups, and individuals. We describe and respond to the comments in this section of the document. The topics for the comments are grouped based on the common themes identified below. We have grouped similar comments together under the same number so that FDA's responses could be addressed by topic, instead of each comment addressed independently, and, in some cases, we have separated different issues discussed in the same comment and designated them as distinct comments for purposes of our responses. The number assigned to each comment or comment topic is purely for organizational purposes and does not signify the comment's value or importance or the order in which comments were received.

A. General Comments on the Proposed Rule

(Comment 1) FDA received multiple comments that express support for the proposed rule and the proposals to remove outdated radiation protection recommendations and adjust the regulatory records and reporting requirements based on risk. The comments urged the Agency to maintain vigilance and continue to promote the health and safety of patients and healthcare practitioners.

(Response 1) FDA appreciates the public support for the rule. FDA intends to continue to utilize its regulatory authorities and collaborations with other governmental agencies, non-governmental organizations, and industry, among others, to promote the safe and effective use of radiation to best protect and promote public health.

B. Radiation Safety Recommendations/ Standards Comments

(Comment 2) One comment referenced multiple publications that supported FDA's proposal that the recommendations in § 1000.50 for use of gonad shielding were inconsistent with current scientific evidence and should be removed.

(Response 2) FDA agrees with the recommendation and is removing the recommendations in § 1000.50 in this final rule.

(Comment 3) One comment raised concern that by repealing the radiation protection recommendations, end-users may have difficulty finding, analyzing, and applying the appropriate standards and practices to specific clinical healthcare situations. The comment requested that FDA list the specific regulations that are outdated or duplicative and provide direction as to the appropriate current standards or practice parameters that replace the repealed regulations.

(Response 3) FDA acknowledges the concern but does not believe that repeal of the recommendations will cause difficulty in locating and applying applicable standards and practices. This final rule identifies the § 1000.50 recommendations that are being removed. FDA believes these specific recommendations are outdated and no longer relied upon by healthcare providers. Removing the recommendations eliminates information that is no longer useful. FDA identified recent, consensus recommendations in the proposed rule (Refs. 1, 2, 6–9). FDA continues to recommend that medical professionals also seek continuing education through professional societies to remain current with new technologies, standards, and best practice guidelines.

(Comment 4) Multiple comments recognized the contributions of external stakeholders to develop and incorporate radiation protection into device design, practitioner training, and best practices for standards of care. Comments stated that diagnostic imaging is an important part of the standard of care, and training and continuing education are important so that healthcare professionals know the rules, regulations, safety procedures, and best practices to benefit patients and avoid harm. The comments requested that FDA support and reference the most relevant guidelines for healthcare professionals wherever feasible.

(Response 4) FDA recognizes the importance of training and continuing education for healthcare professionals and will continue to collaborate with, and reference the work of, external organization as appropriate to develop standards. FDA believes professional societies should have the resources and knowledge to provide the most up-to-date guidelines for their members. FDA recognizes the significant and ongoing contributions that external stakeholders, such as the American Association of Physicists in Medicine, the American College of Radiology, the Health Physics Society, the Image Gently Alliance, the International Atomic Energy Agency, the Medical Imaging Technology Alliance, the Society of Interventional Radiology, the World Health Organization, and many others, have made to incorporate radiation protection into device design, practitioner training, and best practices for standards of care. For example, in 2003, the National Council on Radiation Protection and Measurements (NCRP) updated its recommendations on radiation protection in dentistry (Ref. 6). In 2012, the American Dental Association, in conjunction with FDA, updated its selection criteria for dental imaging with guidelines for the frequency of

dental radiographs and radiation exposure recommendations (Ref. 7). In 2014, the Environmental Protection Agency's (EPA) Working Group on Medical Radiation, with active FDA participation, published a document entitled ''Federal Guidance Report No. 14. Radiation Protection Guidance for Diagnostic and Interventional X-Ray Procedures'' (Guidance Report No. 3), which provides comprehensive recommendations for radiation protection to medical and dental facilities (Ref. 1). Because safety procedures and best practices are continuously revised and improved, FDA believes that specifically referencing existing guidelines in the regulations is not appropriate because it may lead to confusion or unintended consequences as practice guidelines continue to be updated.

(Comment 5) One comment acknowledges that professional organizations play a key role in developing guidance for safe use of radiation, but such guidance may not be comprehensive. The comment recommended that FDA define the organizational credentials and processes to guide the development and format of radiation use standards.

(Response 5) FDA disagrees with the recommendation because the EPRC does not provide for defining and enforcing criteria by which standards organizations or professional societies operate (see sections 532, 534(a)(1), and 537(b) of the FD&C Act). FDA's standards program provides FDA with the opportunity to review and rely on appropriately developed standards within the scope of the FD&C Act. FDA actively participates in the development of voluntary standards and guidelines with other organizations. FDA encourages individuals and professional societies to join and participate in the development of safety recommendations and standards to address the diversity of clinical, scientific, and other needs that apply to their profession.

(Comment 6) One comment suggested that one national set of standards, regulations and training requirements for operators is preferable to differences by state or locality. The comment included a specific example that the quality of dental radiography may vary given the lack of national requirements, especially with the introduction of new technologies, such as cone-beam Computerized Tomography (CT). The lack of a national standard may result in different approaches to radiographer training, with the potential for increased radiation exposure to patients. The comment recommended that FDA designate a specific organization as the responsible entity on all aspects of dental imaging including training of all dental personnel who perform dental imaging examinations.

(Response 6) FDA disagrees with the recommendation. The EPRC does not provide for defining and enforcing criteria by which standards organizations or professional societies operate, or for designating an organization(s) to define or enforce such requirements. FDA notes that such standards and training are generally provided for by appropriate organizations and professions, and FDA frequently collaborates with these organizations and professions. FDA supports the continuation of such efforts by these entities to educate members on best practices for safe use of radiation in their profession. For dental imaging specifically, FDA, in collaboration with the Conference of Radiation Control Program Directors (CRCPD), recently completed a nationwide survey of the use of radiation in dental imaging facilities (Ref. 10). FDA staff participated in developing a report by the National Council on Radiation Protection and Measurements (NCRP) on radiation protection in dentistry (Ref. 11). FDA has also collaborated with the American Dental Association on guidelines for the selection of patients for dental radiographic examinations (Ref. 7). FDA hopes the results of these kinds of collaborations, and other work from similar organizations, will help inform FDA and other organizations of best practices and recommendations for training and equipment standards.

(Comment 7) One comment recommended FDA withdraw the rules and regulations for the lowest risk radiation emitting electronic products first. The commenter suggested removing reporting of assembly for wall mounted x-ray generators for intraoral radiography, while maintaining reporting for handheld portable x-ray generators for use in dentistry, which are relatively new and without the same safety record.

(Response 7) FDA disagrees with the comment. FDA has taken a risk-based assessment in amending the regulations. FDA considers submission to FDA of any report of assembly for certified components of diagnostic x-ray products to no longer be necessary, while continuing to facilitate the submission of such reports of assembly, where applicable, to State agencies and purchasers. Diagnostic x-ray systems still need to meet the product-specific performance standards under part 1020 (21 Code of Federal Regulations (CFR), part 1020), including the submission of any reports of assembly of installed certified components as applicable. Diagnostic x-ray systems, including handheld dental x-ray units, will also continue to be subject to applicable medical device regulations (see, *e.g.,* 21 CFR parts 803, 807, 820, 872, and 892).

(Comment 8) Some comments support the use of international voluntary consensus standards to help ensure regulatory requirements are met. Commenters noted the benefits, including consistency in regulation, global harmonization, efficiencies, minimizing unnecessary costs and delays in patient access to innovative new devices and promoting safety, and consistency with the National Technology Transfer and Advancement Act (Pub. L. 104–113), and Office of Management and Budget's (OMB) directive Circular A–119, Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities (Ref. 12).

(Response 8) FDA agrees with these comments and will continue to participate in the development of international standards and their use for regulatory purposes as appropriate.

(Comment 9) One comment expressed interest in FDA providing information on future technologies and other measures that may reduce or eliminate radiation exposure.

(Response 9) FDA recommends that medical professionals seek continuing education through their appropriate professional societies to maintain knowledge of new technologies and best practice guidelines. With respect to medical devices, FDA's Q-Submission Program (Ref. 13) offers manufacturers the opportunity to receive feedback on their proposed regulatory pathway and test plans when developing new devices and technologies that may improve image quality and patient safety.

C. General Format and Edit Comments

(Comment 10) One comment recommended reformatting table 1 of § 1002.1 for clarity by merging and shading the category rows.

(Response 10) FDA understands the concern for readability of the regulations; however, FDA is limited in the formatting tools available for display and printing of regulations in the **Federal Register** and the CFR, as such stylistic issues are determined by the U.S. Government Publishing Office for the entire Federal government. The information will continue to be displayed in table 1 as formatted and published in the proposed rule.

(Comment 11) One comment recommended clarifying in §§ 1002.20(b) and 1010.4(b) whether

submission of both electronic and paper reports and variance requests are acceptable.

(Response 11) FDA agrees with the recommendation and is revising the language in §§ 1002.20(b) and 1010.4(b) to clarify that ''either'' electronic or paper submissions are appropriate.

(Comment 12) One comment recommended that the regulations allow for use of the International Organization for Standardization (ISO) standard date format (''YYYY–MM–DD''), which is required for medical devices in 21 CFR 801.18(a), as an alternative to the EPRC format specified in § 1010.3(a)(2)(ii).

(Response 12) FDA agrees with the recommendation and is revising the regulation to alternatively provide for use of a manufacturing symbol and date format that is in accordance with applicable FDA recognized consensus standards, such as *ISO 7000: Graphical symbols for use on equipment* and *IEC 60417: Graphical symbols for use on equipment* (Ref. 14) (see § 1010.3(a)(2)(ii) of this final rule).

D. Records and Reports Comments

(Comment 13) One comment requested clarification of the document retention requirements related to initial (§ 1002.10), supplemental (§ 1002.11), abbreviated (§ 1002.12), and annual reports (§ 1002.13). The Agency was asked to state clearly that manufacturers will no longer need to generate and retain these reports.

(Response 13) The proposed rule modified table 1 (§ 1002.1) to show that manufacturers of diagnostic x-ray products would no longer need to submit initial (§ 1002.10), supplemental (§§ 1002.11), abbreviated (§ 1002.12), and annual reports (§ 1002.13). In the final rule, we are maintaining this change. As a result, manufacturers of diagnostic x-ray systems will no longer need to generate and retain such reports related to diagnostic x-ray systems. To clarify, this modification would not remove these requirements for all products listed under table 1 (§ 1002.1 of this final rule). Many other reporting and recordkeeping requirements are unchanged including, as applicable based on the requirements in § 1002.1, the requirements for test and distribution records specified in § 1002.30.

(Comment 14) One comment requested that FDA clarify if an annual report would still be required for a diagnostic x-ray system that falls within this category due to its display being classified as a television product (§ 1020.10). The comment suggested removing the reporting requirements for such displays that are included in diagnostic x-ray systems.

(Response 14) FDA appreciates the comment and recognizes there may be confusion about reporting requirements for diagnostic x-ray systems that include television displays. FDA agrees that reporting should not be required for medical device manufacturers of diagnostic x-ray systems that use modern display technologies (*e.g.,* light emitting diode and liquid crystal display) that do not incorporate a cathode ray tube display. However, FDA believes that the reporting requirement should be maintained for displays that do contain a cathode ray tube, and were manufactured subsequent to January 15, 1970, because these types of displays generate ionizing radiation during use. FDA is therefore amending § 1020.10(a) to clarify that the television product performance standard (and thus reporting requirements) only applies to televisions/displays that contain a cathode ray tube. FDA believes EPRC reporting for such older technologies is necessary for the public health and safety to monitor the use of cathode ray tubes in televisions/displays. Given the outdated nature of the cathode ray tube technology, at this time, FDA believes this type of television display included in diagnostic x-ray systems is the only type that would continue to benefit from the annual reporting requirement. Therefore, FDA does not believe that excluding this type of television display product from the reporting requirements is appropriate at this time.

(Comment 15) One comment requested FDA to clarify how the changes in reporting would impact the process for manufacturers to receive accession numbers, which are used for customs clearance.

(Response 15) Manufacturers of diagnostic x-ray systems that are no longer required to submit product reports, and who therefore will no longer receive an accession number, will no longer need to submit an accession number when importing products (see § 1002.1, table 1 of this final rule). The import process for diagnostic x-ray systems will be the same as for other medical devices that do not require submission of product reports. Manufacturers can refer to FDA's website for more information on the imports process and program (Ref. 15).

(Comment 16) One comment mentioned the concern that if the records and reporting requirements for electronic products and medical devices are removed or reduced, then end-users will rely on state requirements, which may not have changed in many years. The comment raised concerns that in some states, repealing regulations for records and reporting requirements for electronic products and medical devices may be catastrophic if a recall on ionizing radiation equipment were issued.

(Response 16) FDA believes recordkeeping is important in case of recalls and that compliance with all applicable performance standards is important to ensure the protection of the public health and safety. The amendments do not change FDA's authority or a manufacturer's responsibilities if a product is defective or fails to comply with performance standards under section 534 of the FD&C Act. The final rule does not change any of the manufacturer, dealer, or distributer recordkeeping requirements under §§ 1002.1, 1002.30, 1002.40, or 1002.41 that are used to notify potentially impacted persons. The final amendments also do not change the reporting, notification, and requirements to perform corrective actions under part 1003 (21 CFR part 1003) for electronic product defects or failure to comply with a performance standard. Lastly, the amendments do not change any of the regulations applicable to the recall of medical devices under 21 CFR part 806. Therefore, FDA disagrees that it would be catastrophic if a recall on ionizing radiation equipment were issued following these amendments.

E. Reports of Assembly, Forms, and Guidances Comments

(Comment 17) Some comments supported amending the regulations to no longer require assemblers who install certified accessory components of diagnostic x-ray systems to submit reports of assembly (Form FDA 2579) to FDA.

(Response 17) FDA agrees with the comment. In this rulemaking, FDA is removing the requirement to submit a copy of Form FDA 2579 to FDA. Assemblers will still be required to submit a copy to the purchaser, and, where applicable, to state agencies responsible for radiation protection.

(Comment 18) One comment requested clarification on whether FDA will continue to make available Form FDA 2579 for manufacturers to use for submitting to states and purchasers. A comment also suggested that the form be made available in a PDF fillable format and that it retain a document control number field.

(Response 18) FDA agrees with this request and is revising § 1020.30(d)(1) to specify that Form FDA 2579 is available online. FDA intends to make the form

PDF fillable and retain a field on the form for a document control number. However, FDA does not intend to generate or specify the format of document control numbers.

(Comment 19) One comment asked if the Agency will generate and/or require a unique document control number for each report of assembly, with a suggestion that manufacturers could develop a unique identification format for the document control numbers.

(Response 19) At this time, FDA will not generate document control numbers or define the format that manufacturers utilize. Manufacturers are welcome to develop a standardized scheme for the document control number if they wish.

(Comment 20) One comment requested FDA to clarify if manufacturers will need to keep a record of the report of assembly on file.

(Response 20) Assemblers, including manufacturers who are assembling diagnostic x-ray equipment, subject to the provisions of § 1020.30(d) will still be required under § 1002.1(c)(4) to maintain a copy of the report of assembly for 5 years.

(Comment 21) One comment requested FDA to specify what reporting guides, forms, and guidance will be removed from the FDA website.

(Response 21) The Paperwork Reduction Act (PRA) section of this final rule (section IX) identifies what forms will be removed or amended. The publication of the final rule coincides with updates to relevant FDA guidance documents for consistency with the amended regulations.

(Comment 22) Several commenters sought clarity on reporting and recordkeeping responsibilities associated with the changes in the proposed rule, including any need to document reliance on recognized consensus standards for diagnostic x-ray systems. While commenters understood some reports and forms that would no longer need to be submitted to FDA, there was uncertainty regarding certain requirements to generate and maintain test records and document compliance with the standards.

(Response 22) Manufacturers will no longer need to generate certain specific reports to submit to FDA. In finalizing the rule, FDA is withdrawing the reporting guides for reports that are no longer required to be submitted. Manufacturers will still need to maintain test and distribution records (§ 1002.30), where applicable. If a manufacturer chooses to conform to applicable recognized IEC standards in lieu of conforming to the performance standards as described in FDA guidance (Ref. 16), then manufacturers must include in their test records documentation specific to the scope of the corresponding standards.

F. Accidental Radiation Occurrences Comments

(Comment 23) Several comments supported quarterly submission for AROs that are not associated with a death or serious injury. One comment suggested that the regulations be further amended so that manufacturers of medical devices that are also electronic products only need to comply with the Medical Device Reporting (MDR) requirements.

(Response 23) ARO reporting is critical for FDA to meet its responsibility to identify and reduce unnecessary sources of radiation exposure to the public for medical and non-medical devices. Medical device manufacturers are required to report once they are aware of information that reasonably suggests the medical device may have caused or contributed to death or serious injury or there is a malfunction that, if it were to recur, is likely to cause or contribute to a serious injury or death (part 803 (21 CFR part 803)). Medical devices that also meet the definition of an electronic product must also comply with the ARO reporting requirements in § 1002.20, which requires manufacturers to report a single event, or series of events, that resulted in injurious or potentially injurious exposure of any person to electronic product radiation as a result of a malfunction due to the manufacturing, testing, or use of an electronic product. The ARO reporting program is intended to capture both serious malfunctions that require immediate action to prevent future death or injury (which overlaps with MDRs) and less-serious events (which may not overlap with MDRs) where periodic reporting would help identify unnecessary radiation exposure that may be addressed through manufacturer correction or through revisions to safety standards. For this reason, FDA believes ARO reporting requirements should be maintained even when the product is subject to part 803 reporting requirements to ensure the protection of the public health and safety under the EPRC program.

(Comment 24) One comment requested that FDA amend the regulations to state that instances in which an exposure made by a healthcare professional that is deemed to be clinically necessary is not an ARO even when it is a repeat scan or image caused by a system interruption.

(Response 24) The term ''accidental radiation occurrence'' under § 1000.3(a) includes two essential aspects to such an event. First, electronic product radiation must have been emitted. For ionizing radiation, FDA considers the use of the linear no-threshold model (*i.e.,* a threshold below the amount of ionizing radiation that is not ''potentially injurious'') (Ref. 17) as a prudent and practical approach for radiation protection. Second, the radiation emission must have been accidental, by which the Agency means that the emission was unintended and unexpected. An intended and expected radiation emission, such as an intentional repeat scan or image, does not meet the criterion of ''accidental'' and is not an ARO. To improve clarity on this distinction, FDA is amending the definition of an ARO (§ 1000.3(a) in this final rule) to include the word ''accidental'' within the definition to more clearly indicate that an ARO is an accidental event resulting in radiation exposure. With this clarification, FDA does not believe it is necessary to further amend the regulation by providing specific examples involving radiation occurrences that are not considered to be accidental.

(Comment 25) A few comments asked FDA to clarify how the tracking and trending analysis relates to the requirements in § 1002.20(a) and (b) and what would be expected as part of this new requirement.

(Response 25) FDA acknowledges there may be confusion regarding how the quarterly summary reporting with tracking and trending analysis relates to the requirements under § 1002.20(a) and (b). FDA is therefore amending § 1002.20 to clarify that: (1) the quarterly report must include information required under § 1002.20(b)(1) through (7) for each occurrence where known to the manufacturer, (2) that accidental radiation occurrences may be grouped to identify the most common circumstances and potential cause(s), including but not limited to, design changes, manufacturing, or user, and (3) that planned mitigation(s) with an assessment of effectiveness, or a justification for why mitigation is not necessary, must be associated with each occurrence or grouping of similar occurrences (see § 1002.20(c)(2)(ii) in this final rule). Such incidents should also be evaluated to determine if the accidental radiation occurrence is the result of a defect as defined in § 1003.2 of this chapter or fails to comply with an applicable Federal standard (see § 1003.10). Medical device manufacturers may be able to rely on information already being generated as

part of their corrective and preventive actions (21 CFR 820.100).

(Comment 26) A few comments asked FDA to clarify if the tracking and trending analysis applied to both immediate reports and quarterly reports.

(Response 26) The submission of the tracking and trending analysis only applies to quarterly reporting.

G. Laser Comments

(Comment 27) Several comments stated that the proposed amendments to § 1040.10 were confusing and should be clarified. The comments raised concerns about creating a circular logic path between the text proposed in § 1040.10(a)(1), which indicates the standard is not applicable to an uncertified laser product that is incorporated into an electronic product that is then certified by the manufacturer, and the certification requirements in § 1010.2(a), which requires certification when the performance standard is applicable. Commenters stated that the term ''uncertified'' in proposed § 1040.10(a)(1), along with other edits, caused confusion because certain aspects of the standard appeared to be required/applicable, while certification was not required.

Multiple comments recommended that FDA either: (1) revise or keep the original language of certain paragraphs in § 1040.10, with removal or modifications to specific sections for clarity or (2) keep the existing language in § 1040.10(a) and instead modify §§ 1002.1(c), 1010.2, and 1010.3, which would have the effect of §§ 1040.10 and 1040.11 still being required even if certification, identification, and manufacturer's reports are not required.

(Response 27) FDA agrees with the latter recommended approach (#2) to keep the existing language in § 1040.10, and instead amend § 1002.1 in table 1 and § 1010.2, consistent with the amendments in the proposed rule, to clarify when and under what conditions reporting would not need to be duplicated. In those situations, the manufacturers would be considered distributors of certified laser products, and only subject to the applicable distribution recordkeeping requirements under §§ 1002.40 and 1002.41 for the certified products (see § 1002.1, table 1, fn. 9 in this final rule). Also, we are revising § 1010.2 to identify the conditions under which a manufacturer could incorporate a certified laser product without the requirement to re-certify or re-report the product (see § 1010.2(e) of this final rule).

(Comment 28) Some comments raised concerns that the proposed language in § 1040.10(a)(2) did not clearly require products to comply with the performance standards after a certified laser was incorporated.

(Response 28) The intent of the modifications in the proposed rule was to avoid duplicative reporting of information from manufacturers who incorporate a certified laser system into a product. The certified laser system, and the product into which it is incorporated, would still be required to conform with the performance standards. Products that incorporate a certified laser product are still required to comply with the FDA's performance standards. To clarify this, we are revising § 1010.2 to clearly identify under what conditions a product that incorporates a certified laser system would be considered certified, and thus not need to be re-certified. In this final rule, all of the following conditions must be met: (1) the incorporated laser system is not a laser product intended for use as a component or replacement as described in § 1040.10(a)(1) and (2); (2) the manufacturer of the incorporated laser system certifies such laser system and meets the reporting requirements under § 1002; (3) the product incorporating the certified laser system is not independently subject to additional reporting or performance standards requirements; (4) the incorporated laser system is not modified as defined in § 1040.10(i), and all performance features that apply to the incorporated laser system under § 1040.10(f) are available on the product incorporating the certified laser system; (5) all labeling requirements that apply to the incorporated laser system under §§ 1010.2, 1010.3, 1040.10(g), and 1040.11(a)(3) are visible on the outside of the product incorporating the certified laser system, with the exception that the certification or identification labels need not be visible on the outside of products incorporating a certified Class I laser; (6) the incorporated laser system is installed in the product in accordance with the instructions provided by the manufacturer of the incorporated laser system, including instructions for placing additional externally facing labels found in subsection (v), and meeting the other conditions in the subsections; (7) the manufacturer of the product that incorporates the laser system provides the end user with information required under § 1040.10(h)(1) as provided to them by the manufacturer of the incorporated laser system; and (8) the labeling requirements under part 1010 and § 1040.10(g) for the incorporated laser system would be met in any service configuration of the product incorporating the laser system or when the incorporated laser system is removed from the product into which it has been incorporated, and reproductions of such labels are found in the user information. Manufacturers of products that do not meet these conditions would need to certify and report the product that incorporates the certified laser system based on the class of the laser product as described in § 1002.1.

(Comment 29) One comment raised concerns regarding the criteria for the incorporated laser system to be installed in accordance with the instructions provided by the manufacturer of the incorporated laser system. The comment stated that it would be difficult for the manufacturer of the incorporated laser system to foresee all potential installation options by other manufacturers.

(Response 29) FDA does not expect the manufacturer of an incorporated laser system to foresee all potential installation options. FDA expects that a manufacturer planning to market a laser product specifically to be certified and incorporated into other systems would identify and specify any installation options and requirements, while taking into consideration how reasonable variations in the installation instructions should be provided to customers to ensure the conditions in § 1010.2(e) are met. However, ultimately, the manufacturer of the incorporated laser system is responsible for ensuring their finished product is in compliance with all applicable regulatory requirements when certified and marketed. The manufacturer of the product incorporating the laser system is responsible for complying with the conditions in § 1010.2(e). Otherwise, those manufacturers would need to complete the certification, reporting, and other applicable laser product requirements under §§ 1002 and 1040.10. For example, if the installation instructions would result in the laser product not meeting the conditions under § 1010.2(e) (*e.g.,* instructions that would result in a required safety interlock being unavailable), then the product incorporating the certified laser would not be considered to have met the certification requirements because all conditions in § 1010.2(e) must be met.

(Comment 30) FDA received comments expressing concern with the incorporation into regulation the policies described in FDA's Laser Notice 42, including expansion of those policies into regulation for higher

powered laser products without the requirements that the products incorporating higher power lasers comply with the performance standards. A commenter questioned whether the reporting requirements and performance standard would be applicable to a product that incorporated a certified Class I laser along with an uncertified Class IV laser, and if the labeling or safety features of the final product would need to meet the Class IV performance standards. Similar comments recommended that FDA revise and extend policies of Laser Notice 42 for clarity with additional requirements to ensure safety of higher class products.

(Response 30) As noted in Response 28, this final rule is revising § 1010.2 to identify under what conditions a product that incorporates a certified laser system would be considered to have met the certification requirements. There are several conditions, all of which must be met, including that the product incorporating the certified laser system must not be independently subject to additional reporting requirements or performance standards (see § 1010.2(e)(iii) in this final rule). FDA added this clarification to the revisions under § 1010.2(e) of this final rule to ensure higher class products will continue to be subject to any applicable certification requirements, despite the incorporated laser system having met the certification requirements. For example, a Class IV laser product that incorporates a certified Class I laser does not meet the conditions in § 1010.2(e)(iii), as additional certification and reporting requirements associated with the Class IV laser still apply. In addition, the incorporated laser system must not be modified, as defined in § 1040.10(i), and all performance features that apply to the incorporated laser system under § 1040.10(f) must be available on the product incorporating the certified laser system (see § 1010.2(e)(iv) in this final rule). All labeling requirements that apply to the incorporated laser system under § 1040.10(g) must be visible on the outside of the product incorporating the certified laser system, with the exception that the certification or identification labels need not be visible on the outside of products that incorporate a certified Class I laser (see § 1010.2(e)(v) in this final rule). The incorporated laser system must be installed in accordance with the instructions provided by the manufacturer of the incorporated laser system, including ensuring any required safety features or labeling are available (see § 1010.2(e)(vi) in this final rule). The manufacturer of the product incorporating the laser system must also provide the end user with laser safety information as provided to them by the manufacturer of the incorporated laser system (see § 1010.2(e)(vii) in this final rule). In addition, the labeling requirements in part 1010 and § 1040.10(g) for the incorporated laser system must be met in any service configuration of the product that incorporates the laser system, including when the incorporated laser system is removed from the product into which it has been incorporated, and reproductions of such labels must be included in the user information (see § 1010.2(e)(viii) in this final rule).

(Comment 31) One comment recommended limiting the amendments only to the lowest class of laser products; or a subset of classes with additional clarification to address the visibility of the warning logo type and aperture label; or all classes with clarifications about the difference between ''attaching'' versus ''assembling in, embedding in, or otherwise incorporating'' a laser or laser system.

(Response 31) FDA believes that the revisions to §§ 1002.1 and 1010.2(e) that are being made in this final rule make it sufficiently clear that the manufacturer of the product incorporating the certified laser must not make modifications that would alter the availability of safety information or compliance with the standard if they wish to maintain the certification. FDA has added clarification to the revisions under § 1010.2(e)(v) and (vi) of this final rule to ensure that visibility of certain labeling requirements that apply to the incorporated laser system continue to be maintained. Any modifications that would modify the class of laser, compliance with the performance standard, visibility of required labeling, or accessibility to required safety information would not meet the conditions of § 1010.2(e) and the product would no longer be considered certified—meaning the manufacturer of the product incorporating the laser would need to complete the applicable certification and reporting requirements (see also Response 29).

VI. Effective Date

This rule is effective 30 days after the date of publication in the **Federal Register**.

VII. Economic Analysis of Impacts

A. Introduction

We have examined the impacts of the final rule under Executive Order (E.O.) 12866, E.O. 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). EOs 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). We believe that this final rule is not a significant regulatory action as defined by E.O. 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. This rule will reduce regulations that are outdated and otherwise clarify existing requirements. Because this final rule does not impose any additional regulatory burdens, we certify that this final rule will not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before issuing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $165 million, using the most current (2021) Implicit Price Deflator for the Gross Domestic Product. This final rule will not result in an expenditure in any year that meets or exceeds this amount.

B. Summary of Costs and Benefits

We estimate the benefits of this rule in terms of cost savings. We derive the cost savings to industry from the reduction in labor associated with the reporting, recordkeeping, performance standards, and third-party disclosure requirements. Similarly, cost savings to FDA result from the reduction in labor hours required to review reports. The total present-value cost savings over a 20-year time period are $69.71 million at a 7 percent discount rate and $97.89 million at a 3 percent discount rate. Annualized total cost savings are $6.58 million. We estimate the costs to read the rule for all reporting respondents. The present value costs are $1.60 million, and the annualized costs calculated over a 20-year time period are $0.14 million at a 7 percent discount rate and $0.10 million at a 3 percent

discount rate. A summary of the quantified cost savings and costs of the rule are presented in Table 1.

TABLE 1—SUMMARY OF BENEFITS, COSTS AND DISTRIBUTIONAL EFFECTS OF FINAL RULE

Category	Primary estimate	Low estimate	High estimate	Units			Notes
				Year dollars	Discount rate (percent)	Period covered	
Benefits:							
Annualized Monetized	$6.58	$6.58	$6.58	2021	7	20	
$millions/year.	6.58	6.58	6.58	2021	3	20	
Annualized Quantified					7		
					3		
Qualitative							
Costs:							
Annualized Monetized	0.14	0.14	0.14	2021	7	20	
$millions/year.	0.10	0.10	0.10	2021	3	20	
Annualized Quantified					7		
					3		
Qualitative							
Transfers:							
Federal Annualized Monetized $millions/year.					7		
					3		
From/To	From:			To:			
Other Annualized Monetized $millions/year.					7		
					3		
From/To	From:			To:			
Effects:							
State, Local or Tribal Government:							
Small Business:							
Wages:							
Growth:							

C. Summary of Regulatory Flexibility Analysis

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the rule does not impose any additional regulatory burdens, we certify that the final rule will not have a significant economic impact on a substantial number of small entities. This analysis, as well as other sections in this document and the Preamble of the final rule, serves as the Final Regulatory Flexibility Analysis, as required under the Regulatory Flexibility Act. The full preliminary analysis of economic impacts is available in the docket for this final rule (Ref. 18) and at *https://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm.*

VIII. Analysis of Environmental Impact

The Agency has determined under 21 CFR 25.30(h) and (i) and 25.34(c) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IX. Paperwork Reduction Act of 1995

This final rule contains information collection provisions that are subject to review by the OMB under the PRA (44 U.S.C. 3501–3521). The title, description, and respondent description of the information collection provisions are shown in the following paragraphs with an estimate of the annual reporting, recordkeeping, and third-party disclosure burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

Title: Electronic Products; OMB Control No. 0910–0025—Revision

Description: FDA is amending its regulations for requirements for certain reporting and records of electronic products by removing specific reporting, as well as repealing outdated recommendations for radiation protection and performance standards, and removing submission requirements for copies of certain applications and forms to alleviate regulatory burden to both FDA and industry.

The records and reporting requirements for electronic products and medical devices include various reports and records depending upon the specific type of electronic product. FDA has determined upon review of the records and reporting requirements that some of the requirements are unnecessary or may be duplicative of other reporting requirements by FDA and State regulators.

Description of Respondents: The respondents to this information collection are electronic product manufacturers, importers, and assemblers of electronic products from private sector, for-profit businesses.

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity; 21 CFR section	FDA form	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours [2]
Product reports—1002.10(a)–(k) [3].	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
Supplemental reports—1002.11(a)–(b) [3].		440	2.5	1,100	0.5 (30 minutes).	550
Abbreviated reports—1002.12 [3]	3629—General abbreviated report. 3646—Mercury Vapor Lamp Products Radiation Safety Report. 3663—Microwave products (non-oven).	54	1.8	97	5	485
Annual reports—1002.13(a)–(b) [3].	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 [3].	3649—ARO	75	4	300	2	600
Exemption requests—1002.50(a) and 1002.51 [4].	3642—General correspondence.	4	1.3	5	1	5
Product and sample information—1005.10 [4].	2767—Sample product	5	1	5	0.1 (6 minutes)	1
Identification information and compliance status—1005.25 [4].	2877—Imports declaration	12,620	2.5	31,550	0.2 (12 minutes).	6,310
Alternate means of certification—1010.2(d) [4].		1	2	2	5	10
Variance—1010.4(b) [4]	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) [4].		1	1	1	22	22
Alternate test procedures—1010.13 [4].		1	1	1	10	10
Microwave oven exemption from warning labels—1030.10(c)(6)(iv) [4].		1	1	1	1	1
Laser products registration—1040.10(a)(3)(i) [4].	3637—Original equipment manufacturer (OEM) report.	70	2.9	203	3	609
Total						102,744

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Total hours have been rounded.
[3] We have requested revision of this information collection.
[4] The burden estimate for this information collection is currently approved and included for the convenience of the reader. We have not requested revision of this line item at this time.

TABLE 3—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity; 21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours [2]
Manufacturer test and distribution records—1002.30 and 1002.31(a) [3].	1,409	1,650	2,324,850	0.12 (7 minutes)	278,982
Dealer/distributor records—1002.40 and 1002.41 [3].	2,909	50	145,450	0.05 (3 minutes)	7,273
Information on diagnostic x-ray systems—1020.30(g) [4].	50	1	50	0.5 (30 minutes)	25

TABLE 3—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]—Continued

Activity; 21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours [2]
Laser products distribution records—1040.10(a)(3)(ii) [4].	70	1	70	1	70
Total					286,350

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Total hours have been rounded.
[3] We have requested revision of this information collection.
[4] The burden estimate for this information collection is currently approved and included for the convenience of the reader. We have not requested revision of this line item at this time.

TABLE 4—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

Activity; 21 CFR section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours [2]
Technical and safety information for users—1002.3 [3]	1	1	1	12	12
Dealer/distributor records—1002.40 and 1002.41 [3]	30	3	90	1	90
Television receiver critical component warning—1020.10(c)(4) [3]	1	1	1	1	1
Cold cathode tubes—1020.20(c)(4) [3]	1	1	1	1	1
Report of assembly of diagnostic x-ray components—1020.30(d), (d)(1)–(2) (Form FDA 2579—Assembler report) [4]	1,230	34	41,820	0.3 (18 minutes)	12,546
Information on diagnostic x-ray systems—1020.30(g) [3]	6	1	6	55	330
Statement of maximum line current of x-ray systems—1020.30(g)(2) [3]	6	1	6	10	60
Diagnostic x-ray system safety and technical information—1020.30(h)(1)–(4) [3]	6	1	6	200	1,200
Fluoroscopic x-ray system safety and technical information—1020.30(h)(5)–(6) and 1020.32(a)(1), (g), and (j)(4) [3]	5	1	5	25	125
CT equipment—1020.33(c)–(d), (g)(4), and (j) [3]	5	1	5	150	750
Cabinet x-ray systems information—1020.40(c)(9)(i)–(ii) [3]	6	1	6	40	240
Microwave oven radiation safety instructions—1030.10(c)(4) [3]	1	1	1	20	20
Microwave oven safety information and instructions—1030.10(c)(5)(i)–(iv) [3]	1	1	1	20	20
Microwave oven warning labels—1030.10(c)(6)(iii) [3]	1	1	1	1	1
Laser products information—1040.10(h)(1)(i)–(vi) [4]	2	1	2	20	40
Laser product service information—1040.10(h)(2)(i)–(ii) [4]	2	1	2	20	40
Medical laser product instructions—1040.11(a)(2) [3]	2	1	2	10	20
Sunlamp products instructions—1040.20 [3]	1	1	1	10	10
Mercury vapor lamp labeling—1040.30(c)(1)(ii) [3]	1	1	1	1	1
Mercury vapor lamp permanently affixed labels—1040.30(c)(2) [3]	1	1	1	1	1
Total					15,508

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Total hours have been rounded.
[3] The burden estimate for this information collection is currently approved and included for the convenience of the reader. We have not requested revision of this line item at this time.
[4] We have requested revision of this information collection.

The estimates were generated from discussions with subject matter experts at FDA.

FDA is revising the applicability of the recordkeeping and reporting requirements for some products (§ 1002.1). We revised the burden estimates for product reports, supplemental reports, abbreviated reports, annual reports, manufacturer test and distribution records, and dealer and distributor records by reducing the number of respondents/recordkeepers to reflect the revised applicability of the recordkeeping and reporting requirements. We also revised 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:

- Form FDA 3626, ''A Guide for the Submission of Initial Reports on Diagnostic X-Ray Systems and Their Major Components''
- Form FDA 3627, ''Diagnostic X-Ray CT Products Radiation Safety Report''

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

The amended applicability of the recordkeeping requirements for dealer and distributor records (see §§ 1002.40 and 1002.41) results in a small decrease in the number of recordkeepers.

FDA is eliminating requirements for manufacturers to report model numbers of new models 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 (§ 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 (§ 1002.13(a) and (b)). FDA is not amending these annual report requirements.

FDA is amending the timing for submission of reporting requirements for AROs that are not associated with a death or serious injury (§ 1002.20). The 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 (§ 1002.20; 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 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 amending the applications for variances process (§ 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 amending 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, Form FDA 2579, to CDRH (§ 1020.30(d)(1)). FDA is also withdrawing the language that requires 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 amending the reporting requirements for manufacturers that incorporate a certified laser product to reduce reporting that is considered duplicative under certain conditions. Manufacturers that incorporate a certified laser system meeting the conditions of § 1010.2(e) are considered distributors of the certified laser and only subject to the applicable distribution recordkeeping requirements under §§ 1002.40 and 1002.41 for the certified products. Accordingly, we have reduced the number of respondents for ''Laser products information—1040.10(h)(1)(i)–(vi)'' and ''Laser product service information—1040.11(h)(2)(i)–(ii).''

FDA is repealing the performance standards for ultrasonic therapy products (§ 1050.10). We have therefore removed the burden estimate associated with § 1050.10.

We received several comments related to the proposed rule. Descriptions of the comments and our responses are provided in Section V of this document, Comments on the Proposed Rule and FDA Response. Comments and responses related to the provisions that underlie the information collection are described in the following sections: section V.B, regarding general comments; section V.E, regarding records and reports; section V.F, regarding reports of assembly, forms and guidances; section V.G, regarding accidental radiation occurrences; and section V.H, regarding laser comments. We have not made changes to the estimated burden as a result of the comments.

The information collection provisions in this final rule have been submitted to OMB for review as required by section 3507(d) of the PRA.

Before the effective date of this final rule, FDA will publish a notice in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the information collection provisions in this final rule. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

X. Federalism

We have analyzed this final rule in accordance with the principles set forth in E.O. 13132. We have determined that this rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, we conclude that the rule does not contain policies that have federalism implications as defined in the E.O. and, consequently, a federalism summary impact statement is not required.

We note that the current performance standards at § 1040.10 issued under section 534 of the FD&C Act preempt the States from establishing or continuing in effect any standard that is not identical to the Federal standard pursuant to section 542 of the FD&C Act. Those standards were issued before the E.O. We believe this preemption is consistent with section 4(a) of the E.O. which requires agencies to ''construe . . . a Federal statute to preempt State law only where the statute contains an express preemption provision or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute.'' Federal law includes an express preemption provision at section 542 of the FD&C Act that preempts the States from establishing, or continuing in effect, any standard with respect to an electronic product which is applicable to the same aspect of product performance as a Federal standard prescribed pursuant to section 534 of the FD&C Act and which is not identical to the Federal standard. (See *Medtronic, Inc.* v. *Lohr,* 518 U.S. 470 (1996); *Riegel* v. *Medtronic, Inc.,* 552 U.S. 312 (2008)). Section 542 of the FD&C Act does allow States to impose a more restrictive standard regarding emissions of

radiation from electronic products under certain circumstances.

This final rule does not impose any new performance standard requirements. This rule prescribes a reduction in Federal standards (through repeal of § 1050.10) pursuant to section 534 of the FD&C Act. This rule removes or excludes applicability of certain Federal standards, which no longer preempt any State issued performance standards to that same extent.

XI. Consultation and Coordination With Indian Tribal Governments

We have analyzed this final rule in accordance with the principles set forth in E.O. 13175. We have determined that the rule does not contain policies that would have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. Accordingly, we conclude that the rule does not contain policies that have tribal implications as defined in the Executive Order and, consequently, a tribal summary impact statement is not required.

XII. References

The following references marked with an asterisk (*) are on display at the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they also are available electronically at *https://www.regulations.gov.* References without asterisks are not on public display at *https://www.regulations.gov* because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. They also can be purchased as a pdf or as hard copy (or both together, at a discounted price) from NCRP (*www.ncrponline.org*). FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

*1. EPA, Interagency Working Group on Medical Radiation, Federal Guidance Report No. 14. ''Radiation Protection Guidance for Diagnostic and Interventional X-Ray Procedures,'' 2014, available at *https://www.epa.gov/sites/production/files/2015-05/documents/fgr14-2014.pdf.*

2. NCRP, ''Radiation Dose Management for Fluoroscopically-Guided Interventional Procedures,'' Report No. 168, 2010, available at *https://ncrponline.org/publications/reports/ncrp-report-168/.*

*3. FDA, CDRH Health, ''Initiative to Reduce Unnecessary Radiation Exposure from Medical Imaging'' (2010), available at *https://www.fda.gov/radiation-emitting-products/initiative-reduce-unnecessary-radiation-exposure-medical-imaging/white-paper-initiative-reduce-unnecessary-radiation-exposure-medical-imaging#:~:text=practicing%20medical%20community.-,Initiative%20to%20Reduce%20Unnecessary%20Radiation%20Exposure%20from%20Medical%20Imaging,CT%2C%20fluoroscopy%2C%20and%20nuclear%20medicine.*

*4. FDA, ''Medical X-ray Imaging,'' available at *https://www.fda.gov/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/MedicalImaging/MedicalX-Rays/default.htm.*

*5. 2016 TEPRSSC Meeting, October 25–26, 2016, available at *https://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Radiation-EmittingProducts/TechnicalElectronicProductRadiationSafetyStandardsCommittee/ucm526004.htm.*

6. NCRP, ''Radiation Protection in Dentistry,'' Report No. 145, 2003, available at *https://ncrponline.org/publications/reports/ncrp-reports-145/.*

*7. American Dental Association and FDA, ''Dental Radiographic Examinations: Recommendations for Patient Selection and Limiting Radiation Exposure,'' revised: 2012, available at *https://www.fda.gov/media/84818/download.*

*8. The American College of Radiology publishes and regularly updates Practice Parameters, Technical Standards, and Appropriateness Criteria®, available at *https://www.acr.org/Quality-Safety/Appropriateness-Criteria.*

*9. ICRP, ''The 2007 Recommendations of the International Commission on Radiological Protection. ICRP publication 103.'' *Annals of the ICRP.* 2007;37(2–4):1–332, available at *http://www.icrp.org/publication.asp?id=ICRP%20Publication%20103.*

10. Nationwide Evaluation of X-Ray Trends (NEXT), ''Tabulation and Graphical Summary of the 2014–2015 Dental Survey.'' February 2019. CRCPD Publication-E–16–2, available at *https://cdn.ymaws.com/www.crcpd.org/resource/collection/81C6DB13-25B1-4118-8600-9615624818AA/E-19-2_2014-2015_Dental_NEXT_Summary_Report.pdf.*

11. NCRP, ''Radiation Protection in Dentistry and Oral and Maxillofacial Imaging. Report No. 177,'' 2019, available at *https://ncrponline.org/shop/reports/report-no-177/.*

*12. OMB directive Circular A–119, ''Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities,'' available at *https://www.federalregister.gov/documents/2016/01/27/2016-01606/revision-of-omb-circular-no-a-119-federal-participation-in-the-development-and-use-of-voluntary.*

*13. FDA, ''Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program,'' May 7, 2019, available at *https://www.fda.gov/media/114034/download.*

14. IEC 60417:2002 DB, ''Graphical Symbols for Use on Equipment,'' available at *https://webstore.iec.ch/publication/2098.*

*15. FDA, Import Program, available at *https://www.fda.gov/industry/import-program-food-and-drug-administration-fda.*

*16. FDA, ''Medical X-Ray Imaging Devices Conformance with IEC Standards,'' May 8, 2019, available at *https://www.fda.gov/media/99466/download.*

17. NCRP, ''Management of Exposure to Ionizing Radiation: Radiation Protection Guidance for the United States. Report No. 180,'' 2018, available at *https://ncrponline.org/shop/reports/report-no-180-management-of-exposure-to-ionizing-radiation-radiation-protection-guidance-for-the-united-states-2018-2018/.*

*18. Economic Analysis of Impacts: 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, available at *https://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm.*

List of Subjects

21 CFR Parts 1000 and 1002

Electronic products, Radiation protection, Reporting and recordkeeping requirements, X-rays.

21 CFR Part 1010

Administrative practice and procedure, Electronic products, Exports, Radiation protection.

21 CFR Part 1020

Electronic products, Medical devices, Radiation protection, Reporting and recordkeeping requirements, Television, X-rays.

21 CFR Part 1030

Electronic products, Microwave ovens, Radiation protection.

21 CFR Part 1050

Electronic products, Medical devices, Radiation protection.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 1000, 1002, 1010, 1020, 1030, and 1050 are amended as follows:

PART 1000—GENERAL

■ 1. The authority citation for part 1000 continues to read as follows:

Authority: 21 U.S.C. 360hh–360ss.

■ 2. Amend § 1000.3 by revising paragraph (a) and removing paragraph (s) and redesignating paragraphs (t) and (u) as paragraphs (s) and (t).

The revision reads as follows:

§ 1000.3 Definitions.

* * * * *

(a) *Accidental radiation occurrence* means a single accidental event or series of accidental events that has/have resulted in injurious or potentially injurious exposure of any person to electronic product radiation as a result of the manufacturing, testing, or use of an electronic product.

* * * * *

Subpart C—[Removed]

■ 3. Remove subpart C, consisting of §§ 1000.50, 1000.55, and 1000.60.

PART 1002—RECORDS AND REPORTS

■ 4. The authority citation for part 1002 continues to read as follows:

Authority: 21 U.S.C. 352, 360, 360i, 360j, 360hh–360ss, 371, 374.

■ 5. Amend § 1002.1 by revising table 1 to read as follows:

* * * * *

TABLE 1 TO § 1002.1—RECORD AND REPORTING REQUIREMENTS BY PRODUCT

Products	Manufacturer						Dealer & distributor
	Product reports 1002.10	Supplemental reports 1002.11	Abbreviated reports 1002.12	Annual reports 1002.13	Test records 1002.30(a) [1]	Distribution records 1002.30(b) [2]	Distribution records 1002.40 and 1002.41
DIAGNOSTIC X-RAY [3] (1020.30, 1020.31, 1020.32, 1020.33):							
Computed tomography					X	X	X
X-ray system [4]					X	X	X
Tube housing assembly					X	X	
X-ray control					X	X	X
X-ray high voltage generator					X	X	X
X-ray table or cradle					X	X	X
X-ray film changer					X	X	
Vertical cassette holders mounted in a fixed location and cassette holders with front panels					X	X	X
Beam-limiting devices					X	X	X
Spot-film devices and image intensifiers manufactured after April 26, 1977					X	X	X
Cephalometric devices manufactured after February 25, 1978					X	X	
Image receptor support devices for mammographic X-ray systems manufactured after September 5, 1978					X	X	X
CABINET X RAY (1020.40):							
Baggage inspection	X	X		X	X	X	X
Other	X	X		X	X	X	
PRODUCTS INTENDED TO PRODUCE PARTICULATE RADIATION OR X-RAYS OTHER THAN DIAGNOSTIC OR CABINET X-RAY:							
Medical					X	X	
Analytical			X	X	X	X	
Industrial			X	X	X	X	
TELEVISION PRODUCTS (1020.10):							
<0.1 milliroentgen per hour (mR/hr) IRLC [5]			X [8]	X [6]			
≥0.1mR/hr IRLC [5]	X [8]			X	X	X	
MICROWAVE/RF:							
MW ovens (1030.10)	X [8]			X	X	X	
MW diathermy			X				
MW heating, drying, security systems			X				
RF sealers, electromagnetic induction and heating equipment, dielectric heaters (2–500 megahertz)			X				
OPTICAL:							
Laser products (1040.10, 1040.11)							
Class I lasers and products containing such lasers [7 9]	X [8]			X	X		
Class I laser products containing class IIa, II, IIIa, lasers [7 9]	X			X	X	X	
Class IIa, II, IIIa lasers and products other than class I products containing such lasers [7 9]	X			X	X	X	X
Class IIIb and IV lasers and products containing such lasers [7]	X	X		X	X	X	X
SUNLAMP PRODUCTS (1040.20):							
Lamps only	X						
Sunlamp products	X	X		X	X	X	X
Mercury vapor lamps (1040.30)							
R lamps and T lamps			X				

[1] However, authority to inspect all appropriate documents supporting the adequacy of a manufacturer's compliance testing program is retained.
[2] The requirement includes §§ 1002.31 and 1002.42, if applicable.
[3] Report of Assembly (Form FDA 2579) is required for diagnostic x-ray components; see § 1020.30(d)(1)–(3) of this chapter.
[4] Systems records and reports are required if a manufacturer exercises the option and certifies the system as permitted in § 1020.30(c) of this chapter.
[5] Determined using the isoexposure rate limit curve (IRLC) under phase III test conditions (§ 1020.10(c)(3)(iii)) of this chapter.
[6] Annual report is for production status information only.
[7] Determination of the applicable reporting category for a laser product shall be based on the worst-case hazard present within the laser product.

[8] Manufacturers are exempt from product reports (§ 1002.10) and abbreviated reports (§ 1002.12), except the first product or abbreviated report for each category of: television products; microwave ovens; and products that are Class I laser under any condition of operation, maintenance, service, or failure (*e.g.,* Class I optical disc products, laser printers).

[9] Manufacturers that incorporate a certified laser system meeting the conditions of 21 CFR 1010.2(e) are considered distributors of the certified laser and only subject to the applicable distribution recordkeeping requirements under §§ 1002.40 and 1002.41 for the certified products.

§ 1002.13 [Amended]

■ 6. Amend § 1002.13 by removing paragraph (c).

■ 7. Revise § 1002.20 to read as follows:

§ 1002.20 Reporting of accidental radiation occurrences.

(a) Manufacturers of electronic products shall, where reasonable grounds for suspecting that such an incident has occurred, report to the Director, Center for Devices and Radiological Health, all accidental radiation occurrences reported to or otherwise known to the manufacturer and arising from the manufacturing, testing, or use of any product introduced or intended to be introduced into commerce by such manufacturer. Reasonable grounds include, but are not necessarily limited to, professional, scientific, or medical facts or opinions documented or otherwise, that conclude or lead to the conclusion that such an incident has occurred.

(b) Such reports shall be submitted either electronically through Center for Devices and Radiological Health eSubmitter or addressed to the Food and Drug Administration, Center for Devices and Radiological Health, ATTN: Accidental Radiation Occurrence Reports, Document Mail Center, 10903 New Hampshire Ave., Bldg. 66, rm. G609, Silver Spring, MD 20993–0002, and the reports and their envelopes shall be distinctly marked ''Report on 1002.20'' and shall contain all of the following information where known to the manufacturer:

(1) The nature of the accidental radiation occurrence;

(2) The location at which the accidental radiation occurrence occurred;

(3) The manufacturer, type, and model number of the electronic product or products involved;

(4) The circumstances surrounding the accidental radiation occurrence, including causes;

(5) The number of persons involved, adversely affected, or exposed during the accidental radiation occurrence, the nature and magnitude of their exposure and/or injuries and, if requested by the Director, Center for Devices and Radiological Health, the names of the persons involved;

(6) The actions, if any, which may have been taken by the manufacturer, to control, correct, or eliminate the causes and to prevent reoccurrence; and

(7) Any other pertinent information with respect to the accidental radiation occurrence.

(c) If a manufacturer:

(1) Is required to report to the Director under paragraph (a) of this section and also is required to report under part 803 of this chapter, the manufacturer shall report in accordance with part 803; or

(2) Is required to report to the Director under paragraph (a) of this section and is not required to report under part 803 of this chapter, the manufacturer shall:

(i) Immediately report incidents associated with a death or serious injury in accordance with paragraphs (a) and (b) of this section; and

(ii) Either immediately report incidents not associated with a death or serious injury individually or compile such incidents for submission in a quarterly summary report with tracking and trending analysis of that data in accordance with paragraphs (a) and (b) of this section. The quarterly report must cover information required under paragraphs (b)(1) through (7) of this section for each occurrence were known to the manufacturer. Occurrences may be grouped to identify the most common circumstances and potential cause(s), including but not limited to, design changes, manufacturing, or user. Planned mitigation(s) with an assessment of effectiveness, or a justification for why mitigation is not necessary, must be associated with each occurrence or grouping of similar occurrences. A manufacturer need not file a separate report under this section if an incident involving an accidental radiation occurrence is associated with a defect or noncompliance and is reported pursuant to § 1003.10 of this chapter.

PART 1010—PERFORMANCE STANDARDS FOR ELECTRONIC PRODUCTS: GENERAL

■ 8. The authority citation for part 1010 continues to read as follows:

Authority: 21 U.S.C. 351, 352, 360, 360e-360j, 360hh-360ss, 371, 381.

■ 9. Amend § 1010.2 by adding paragraph (e) to read as follows:

§ 1010.2 Certification.

* * * * *

(e) Laser products under § 1040.10 of this chapter that incorporate a certified laser system (laser product) will be considered to have met the certification requirements in this section if all of the following conditions are met:

(1) The incorporated laser system is not a laser product intended for use as a component or replacement as described in § 1040.10(a)(1) and (2) of this chapter;

(2) The manufacturer of the incorporated laser system has certified such laser system under this section and meets the reporting requirements under part 1002 of this chapter;

(3) The product incorporating the certified laser system is not independently subject to additional reporting or performance standards requirements;

(4) The incorporated laser system is not modified as defined in § 1040.10(i) of this chapter, and all performance features that apply to the incorporated laser system under § 1040.10(f) are available on the product incorporating the certified laser system;

(5) All labeling requirements that apply to the incorporated laser system under §§ 1010.2, 1010.3, 1040.10(g), and 1040.11(a)(3) of this chapter are visible on the outside of the product incorporating the certified laser system, with the exception that the certification or identification labels need not be visible on the outside of products incorporating a certified Class I laser;

(6) The incorporated laser system is installed in accordance with the instructions provided by the manufacturer of the incorporated laser system, including instructions for placing additional externally facing labels found in paragraph (e)(5) of this section, and meeting the other conditions in paragraphs (e)(1) through (8) of this section;

(7) The manufacturer of the product that incorporates the laser system provides the end user with information required under § 1040.10(h)(1) of this chapter as provided to them by the manufacturer of the incorporated laser system; and

(8) The labeling requirements under part 1010 and § 1040.10(g) of this chapter for the incorporated laser system would be met in any service configuration of the product incorporating the laser system or when the incorporated laser system is removed from the product into which it had been incorporated, and reproductions of such labels are found in the user information.

■ 10. Amend § 1010.3 by revising paragraph (a)(2)(ii) to read as follows:

§ 1010.3 Identification.

* * * * *

(a) * * *

(2) * * *

(ii) The month and year of manufacture shall be provided clearly and legibly, without abbreviation, and with the year shown as a four-digit number as follows in this paragraph. Alternatively, a manufacturer may utilize a manufacturing symbol and date format that conforms with an applicable FDA recognized consensus standard.

Manufactured: (Insert Month and Year of Manufacture.)

* * * * *

■ 11. Amend § 1010.4 by revising paragraphs (b) introductory text, (b)(1), and (b)(2) introductory text to read as follows:

§ 1010.4 Variances.

* * * * *

(b) *Applications for variances.* If you are submitting an application for variances or for amendments or extensions thereof:

(1) You must either:

(i) Submit the variance application and supporting materials to CDRH by email using the *RadHealthCustomerService@fda.hhs.gov* mailbox; or

(ii) Submit an original copy of the variance application by mail to: U.S. Food and Drug Administration, Center for Devices and Radiological Health, Document Mail Center, Bldg. 66, Rm. G609, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002.

(2) The application for variance shall include the following information:

* * * * *

PART 1020—PERFORMANCE STANDARDS FOR IONIZING RADIATION EMITTING PRODUCTS

■ 12. The authority citation for part 1020 continues to read as follows:

Authority: 21 U.S.C. 351, 352, 360e–360j, 360hh–360ss, 371, 381.

■ 13. Amend § 1020.10 by revising paragraph (a) to read as follows:

§ 1020.10 Television receivers with cathode ray tubes.

(a) *Applicability.* The provisions of this section are applicable to television receivers with cathode ray tubes manufactured subsequent to January 15, 1970.

* * * * *

■ 14. Amend § 1020.30 by revising paragraphs (d)(1) and (d)(2)(ii) to read as follows:

§ 1020.30 Diagnostic x-ray systems and their major components.

* * * * *

(d) * * *

(1) *Reports of assembly.* All assemblers who install certified components shall file a report of assembly, except as specified in paragraph (d)(2) of this section. The report will be construed as the assembler's certification and identification under §§ 1010.2 and 1010.3 of this chapter. The assembler shall affirm in the report that the manufacturer's instructions were followed in the assembly or that the certified components as assembled into the system meet all applicable requirements of §§ 1020.30 through 1020.33. All assembler reports must be on a form (Form FDA 2579 made available at *https://www.fda.gov/about-fda/reports-manuals-forms/forms*) prescribed by the Director, Center for Devices and Radiological Health. Completed reports must be submitted to the purchaser and, where applicable, to the State agency responsible for radiation protection within 15 days following completion of the assembly.

(2) * * *

(ii) Certified accessory components;

* * * * *

PART 1030—PERFORMANCE STANDARDS FOR MICROWAVE AND RADIO FREQUENCY EMITTING PRODUCTS

■ 15. The authority citation for part 1030 continues to read as follows:

Authority: 21 U.S.C. 351, 352, 360, 360e–360j, 360hh–360ss, 371, 381.

■ 16. Amend § 1030.10 by revising paragraph (c)(6)(iv) introductory text as follows:

§ 1030.10 Microwave ovens.

* * * * *

(c) * * *

(6) * * *

(iv) Upon application by a manufacturer, the Director, Center for Devices and radiological Health, Food and Drug Administration, may grant an exemption from one or more of the statements (radiation safety warnings) specified in paragraph (c)(6)(i) of this section. Such exemption shall be based upon a determination by the Director that the microwave oven model for which the exemption is sought should continue to comply with paragraphs (c)(1) through (3) of this section under the adverse condition of use addressed by such precautionary statement(s). An application shall be submitted to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Copies of the written portion of the application, including supporting data and information, and the Director's action on the application will be maintained by the Dockets Management Branch for public review. The application shall include:

* * * * *

PART 1050—[REMOVED AND RESERVED]

■ 17. Under the authority of 21 U.S.C. 351, 352, 360, 360e–360j, 360hh–360ss, 371, 381, part 1050 is removed and reserved.

Dated: January 4, 2023.

Robert M. Califf,

Commissioner of Food and Drugs.

[FR Doc. 2023–00922 Filed 1–19–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF JUSTICE

Office of Justice Programs

28 CFR Part 94

[Docket No.: OJP (OVC) 1539]

RIN 1121–AA78

International Terrorism Victim Expense Reimbursement Program

AGENCY: Office of Justice Programs, Justice.

ACTION: Adoption of interim rule as final; technical corrections.

SUMMARY: The Office for Victims of Crime (''OVC'') is promulgating this final rule for its International Terrorism Victim Expense Reimbursement Program (''ITVERP''), in order to finalize the interim final rule published on April 11, 2011, which removed a regulatory limitation on the discretion of the Director of OVC to accept claims filed more than three years after the date that an incident is designated as an incident of international terrorism. This final rule also makes non-substantive technical corrections to update citations to reflect the current location of the cited provisions.

DATES: This final rule is effective January 20, 2023.

ADDRESSES: For further information, see the ITVERP website at *http://www.ojp.usdoj.gov/ovc/intdir/itverp.*

FOR FURTHER INFORMATION CONTACT: Victoria Jolicoeur, ITVERP, Office for