Administration, P.O. Box 20636, Atlanta, GA, 30320; or via email to: *9–AJV–MIAClassBComments@faa.gov.*

FOR FURTHER INFORMATION CONTACT: Bob Hildebidle, Manager, Miami ATCT/TRACON, 6400 NW 22nd St., Miami, FL 33122. Telephone: (305) 869–5402.

SUPPLEMENTARY INFORMATION:

Meeting Procedures

(a) The meeting will be informal in nature and will be conducted by one or more representatives of the FAA Eastern Service Area. A representative from the FAA will present a briefing on the planned airspace modifications. Each participant will be given an opportunity to deliver comments or make a presentation, although a time limit may be imposed to accommodate closing times. Only comments concerning the plan to modify the Miami, FL, Class B Airspace, and the Fort Lauderdale, FL, Class C Airspace areas will be accepted.

(b) The meeting will be open to all persons on a space-available basis. There will be no admission fee or other charge to attend and participate.

(c) Any person wishing to make a presentation will be asked to sign in so those time frames can be established. This will permit the panel to allocate an appropriate amount of time for each presenter. This meeting will not be adjourned until everyone on the list has had an opportunity to address the panel. This meeting may be adjourned at any time if all persons present have had an opportunity to speak.

(d) Position papers or other handout material relating to the substance of the meeting will be accepted. Participants submitting handout materials should present an original and two copies to the presiding officer. There should be an adequate number of copies for distribution to all participants.

(e) This meeting will not be formally recorded. However, a summary of the comments made at the meeting will be filed in the docket.

Information gathered through this meeting will assist the FAA in drafting a notice of proposed rulemaking (NPRM). The public will be afforded the opportunity to comment on any NPRM published on this matter.

A graphic depiction of the proposed airspace modifications may be viewed at the following URL: *https://www.faa.gov/air_traffic/flight_info/aeronav/blindurls/Visual1/.*

Agenda for the Meeting

—Sign-in
—Presentation of Meeting Procedures
—Informal Presentation of the Planned Airspace Modifications
—Public Presentations and Discussions
—Closing Comments

Authority: 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120; E.O.10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

Issued in Washington DC, on March 25, 2019.

Rodger A. Dean, Jr.,

Manager, Airspace Policy Group.

[FR Doc. 2019–06183 Filed 3–29–19; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1000, 1002, 1010, 1020, 1040, 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: Proposed rule.

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

DATES: Submit either electronic or written comments on this proposed rule by July 1, 2019.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before July 1, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of July 1, 2019. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

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

Instructions: All submissions received must include the Docket No. FDA–2018–N–3303 for ''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.'' Received comments, those filed in a timely manner (*see* **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the 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. 4312, Silver Spring, MD 20993, 301–796–6661, email: *Robert.Ochs@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

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I. Executive Summary

A. Purpose of the Proposed Rule

This proposed rule would amend and repeal certain regulations for radiation emitting electronic products and medical devices because FDA has identified the regulations as being outdated and duplicative of other means for reducing radiation exposure to the public. The Agency is proposing to update the regulations to reduce 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 proposed for amending or repealing 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 Proposed Rule

This proposed rule, when finalized, will update FDA's radiological health regulations to amend or repeal the following radiological health (21 CFR parts 1000 to 1050) parts of the general provisions:

• Repeal the radiation protection recommendations that have become outdated and unnecessary due to current FDA safety communications and other mechanisms that can provide more comprehensive recommendations to protect patients and health professionals from unnecessary radiation exposure;

• Amend the records and reporting requirements for electronic products and medical devices by 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 allow quarterly reporting for AROs that are not associated with a death or serious injury;

• Amend the applications for variances process 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. FDA is proposing to amend the regulations to require assemblers to submit assembly reports only to the purchaser, and, where applicable, to State agencies responsible for radiation protection because the Agency no longer uses the reports to plan routine inspections of newly assembled equipment;

• Amend the performance standard for laser products by reducing the regulatory requirements for: (1) Uncertified laser products that are intended to be used as a component and are incorporated into an electronic product that is then certified by the manufacturer of a finished electronic product and (2) certified and unmodified laser products that are not intended for use as a component or replacement and that are incorporated into another product; and

• Repeal the performance standards for sonic, infrasonic, and ultrasonic products because they are limited to a subset of physical therapy devices with an outdated standard. The Agency considers the premarket medical device regulations to be sufficient to ensure the

safety of ultrasonic therapy products. The current Electronic Product Radiation Control (EPRC) reporting for initial, abbreviated, and annual reports of ultrasonic products is also duplicative given the more comprehensive medical device regulations and premarket authorizations for these products.

The Agency believes the amendments in this proposed rule will help 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 proposed 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) (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 (21 U.S.C. 360kk) 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 proposed rule.

D. Costs and Benefits

This proposed rule will update 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 $62.8 million at a 7 percent discount rate and $88.2 million at a 3 percent discount rate. Annualized total cost savings are $5.93 million. We estimate the costs to read the rule for all reporting respondents. The present value costs are $1.47 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

Accidental Radiation Occurrences	ARO
Center for Devices and Radiological Health	CDRH
Centers for Medicare & Medicaid Services	CMS
Conference of Radiation Control Program Directors	CRCPD
Executive Order	EO
Electronic Product Radiation Control	EPRC
Environmental Protection Agency	EPA
Federal Food, Drug, and Cosmetic Act	FD&C Act
Food and Drug Administration	FDA, Agency or we
International Commission on Radiological Protection	ICRP
International Electrotechnical Commission	IEC
Medical Device Reporting	MDR
National Council on Radiation Protection and Measurements	NCRP
Radiation Control for Health and Safety Act	RCHSA
Quality Assurance	QA
Technical Electronic Product Radiation Safety Standards Committee	TEPRSSC

III. Background

A. Introduction

Pursuant to EOs 13771 and 13777 (Refs. 1–2), FDA has conducted a comprehensive review of the requirements and recommendation of electronic products based on their level of radiation exposure. 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 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 as practitioners and industry rely on numerous current radiation guidance documents, along with industry standards, to ensure the public health. For example, FDA recognizes that submission of quarterly reports is unnecessary given certain annual reporting requirements. The submission of initial product reports for products that are also subject to premarket authorization prior to marketing is duplicative. The recommended protections against radiation are now outdated and redundant to other Federal and State requirements and professional guidelines that apply to the education and licensing of practitioners (Refs. 3–7). Also, 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 and 61689.

In addition, in the **Federal Register** of September 8, 2017 (82 FR 42494), FDA published a notice for request for comments and information on the ''Review of Existing Center for Devices and Radiological Health Regulatory and Information Collection Requirements'' that could be amended, repealed or replaced to achieve meaningful burden reduction while achieving FDA's public health mission. FDA received comments regarding the radiological health regulations and its performance standards. As a result, FDA is proposing to amend its regulations for requirements for certain reporting and records of electronic products by removing or reducing certain reporting, as well as repealing outdated recommendations for radiation protection and performance standards, to alleviate regulatory burden to both FDA and industry.

B. FDA's Current Statutory Framework

The FD&C Act (21 U.S.C. 301 *et seq.*), as amended, establishes a comprehensive system for the regulation of devices intended for human use.

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, entitled ''Electronic Product Radiation Control'' (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.

Under the FD&C Act, the EPRC applies to any electronic product that is defined as: (a) Any manufactured or assembled product (or component, part, or accessory of such product) which, when in operation, (i) contains or acts as part of an electronic circuit and (ii) emits (or in the absence of effective shielding or other controls would emit) electronic product radiation, or (b) any manufactured or assembled article which is intended for use as a component, part or accessory of a product described in clause (A) and which when in operation emits (or in the absence of effective shielding or other controls would emit) such radiation (see section 531(2) of the FD&C Act, 21 U.S.C. 360hh(2)).

Electronic product radiation is defined as: (a) Any ionizing or non-ionizing electromagnetic or particulate radiation or (b) any sonic, infrasonic, or ultrasonic wave, which is emitted from an electronic product as the result of the operation of an electronic circuit in such product (section 531(1) of the FD&C Act). Some products may fall under the definition of both a medical device and an electronic product (see section 201(h) of the FD&C Act for definition of a device and section 531(2) of the FD&C Act for definition of electronic product). As such, these products may be subject to the provisions of the FD&C Act and FDA's regulations that apply to medical devices and electronic products.

The EPRC program also directs FDA to prescribe performance standards for electronic products to control the emission of electronic product radiation. In establishing performance standards consistent with the statute, FDA consults with the Technical Electronic Product Radiation Safety Standards Committee (TEPRSSC), established under the Radiation Control for Health and Safety Act (RCHSA). The TEPRSSC functions to provide advice and consultation to FDA on the technical feasibility, reasonableness, and practicality of all proposed performance standards for electronic products (section 534(f) of the FD&C Act) (Ref. 8). FDA submits to TEPRSSC a proposed standard or amendment of a performance standard for an electronic product before issuing a proposed regulation in the **Federal Register** containing such standard or amendment of such standard (section 534(f)(1)(A) of the FD&C Act). TEPRSSC may also recommend electronic product radiation safety standards to FDA (section 534(f)(1)(B) of the FD&C Act).

Upon receipt of advice from TEPRSSC, responsibility for action on creating or updating performance standards rests with FDA (21 CFR 14.122(b)). Based on this advice, the creation, amendment, and revocation of performance standards for electronic products to control the emission of electronic product radiation are accomplished by rulemaking, including the opportunity for notice and comment (section 534(a)–(b) of the FD&C Act).

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 (§ 1040.10(a)) (Ref. 9). 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 proposed amendments have been considered by TEPRSSC discussions as necessary.

C. Need for Amendments to the Regulations

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. FDA believes radiation emitting electronic products and devices that comply with Federal standards provide a reasonable assurance of safety and effectiveness 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. 3, 10–12).

In 2010, FDA's Center for Devices and Radiological Health (CDRH) launched an ''Initiative to Reduce Unnecessary Radiation Exposure from Medical Imaging'' (Ref. 13) 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 health care 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. 14). In accordance with FDA's directive to carry out the EPRC program, 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.

1. Radiation Protection Recommendations

Between 1976 and 1980, FDA issued final voluntary recommendations to provide industry and practitioners with recommendations for radiological protection for specific medical procedures (see 44 FR 71728 at 71729). In the **Federal Register** of July 23, 1976 (41 FR 30327), FDA set forth recommendations for use of specific area gonad shielding on patients during medical diagnostic x-ray procedures. In the **Federal Register** of December 11, 1979 (44 FR 71728), FDA issued a final recommendation for the voluntary establishment of quality assurance (QA) programs by all diagnostic facilities. FDA encouraged each facility to implement only those recommendations that the facility determined would lead to benefits in improved image quality, reduced radiation exposure, and/or reduced costs sufficient to compensate for the costs of the action. A facility can use its QA program to optimize radiation dose for each kind of x-ray imaging examination, procedure, and medical imaging task the facility performs (Refs. 3–4, 14). In the **Federal Register** of June 17, 1980 (45 FR 40976), FDA issued a final recommendation on administratively required dental x-ray examinations. FDA recommended that dental x-ray examinations only be performed after careful consideration of the dental or other health needs of the patient, based on medical judgement necessary for diagnosis, treatment, or prevention of disease. Dental radiography is estimated to contribute much less than one percent of the total

population's exposure to all types of radiation (medical and non-medical) (Ref. 15).

Since the publication of the recommendations over the last 30 years, numerous other organizations and Federal and State agencies have developed more comprehensive recommendations on patient shielding, quality control, and the safe use of x-ray imaging in dentistry. 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. There are communities of scientific and clinical experts, often with FDA collaboration, dedicated to developing radiation safety training programs and setting qualification and accreditation standards by users and facilities that are adequate to supersede FDA recommendations. For example, in 2003, the National Council on Radiation Protection and Measurements (NCRP) updated its recommendations on radiation protection in dentistry (Ref. 4). 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. 5). 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. 14), which provides comprehensive recommendations for radiation protection to medical and dental facilities (Ref. 3).

Also, over the last decade FDA has been actively engaged with other State agencies to develop and publish more modern recommendations than those identified under FDA's regulations to promote and protect public health by reducing unnecessary radiation exposure from medical imaging (part 1000 (21 CFR part 1000)). These efforts were in response to increasing use of ionizing radiation for medical imaging highlighted in the NCRP Report No. 160 (Ref. 15). FDA strives to promote patient safety through the principles of radiation protection developed by the International Commission on Radiological Protection (ICRP) (Ref. 16). For example, FDA actively works with States, which have the authority to regulate diagnostic radiology facilities. FDA routinely provides input into the model State regulations (the Suggested State Regulations) developed by the Conference of Radiation Control Program Directors (CRCPD), which include suggested regulations relating to the use of x-ray imaging in medicine and dentistry and diagnostic imaging quality assurance (Ref. 17). In addition, the Centers for Medicare & Medicaid Services (CMS) requires advanced diagnostic imaging services to be accredited by a designated accrediting organization in order to receive Medicare reimbursement. Practitioner training and radiation safety are part of the accreditation requirements (Ref. 18).

FDA has and will continue to participate actively in the development and maintenance of safety standards related to radiation protection, including IEC standards for radiography and fluoroscopy, computed tomography, interventional fluoroscopy, dental radiography, radiation therapy, laser products, and microwave ovens, among others. Manufacturers are required to conform with these standards in order to market their device in some countries, including China and Europe. Our participation in standards development is critical to advocating for industry-wide implementation of radiation protection safety features that result in a benefit to the public health and facilitates global harmonization of safety measures for radiation therapies. FDA also has and retains its authority over medical device premarket reviews, surveillance, and compliance programs—as well as the other EPRC reporting requirements and performance standards—to address radiation safety issues with respect to medical devices.

In view of FDA's continuous collaboration with States, other Federal agencies, and professional organizations, FDA has determined that the recommendations in FDA's current regulations for radiation protection during medical procedures (part 1000) are obsolete and do not address many aspects of modern radiation control and QA as articulated in more contemporary guidelines and is proposing that the recommendations be repealed. For example, the regulations for radiation emitting products provide recommendations for QA programs for imaging using film, but almost no current facilities still use film (§ 1000.55(c)(3)). FDA is proposing that it is unnecessary to revise the film quality control recommendations for new digital imaging equipment because FDA performs premarket authorization review of the digital x-ray equipment, which includes a review of the manufacturer's device labeling proposed to support a reasonable assurance of safety and effectiveness (see 21 CFR part 892). The performance standards that apply to the x-ray imaging products also still apply (see §§ 1020.30 and 1020.31 (21 CFR 1020.30 and 1020.31)). When used as intended by trained practitioners, FDA believes that digital equipment can provide more reliable high-quality images with greater potential to lower radiation exposure. As discussed above, FDA believes there are adequate recommendations and guidelines available to provide sufficient guidance on the safe use of medical x-ray modalities.

Therefore, FDA is proposing to repeal the radiation protection recommendations in the regulation because these recommendations have become outdated and there is no longer a need for FDA to specify and maintain a set of recommendations for practitioners. FDA encourages practitioners to review and apply the most current guidelines developed by professional societies (see the list of agencies and societies listed earlier in this section), along with the medical device labeling to ensure radiation protection. In addition to continued active participation in consensus standards development, FDA can also utilize its authority over device labeling and will continue to review device labeling for adequate directions for use of the product (see § 801.5 (21 CFR 801.5)). FDA will also continue its participation on collaborative efforts with stakeholders who are engaged in developing radiation safety education and standards for patient care. FDA will continue to amend specific FDA performance standards as appropriate to include aspects of radiation protection or reporting that are not already addressed by consensus standards.

2. Applications for Variances

FDA may grant a variance from one or more provisions of any performance standard under certain conditions. Upon application of variances or for amendments or extensions of variances, FDA requires manufacturers or assemblers to submit one original and two copies of the application to the Agency (§ 1010.4(b) (21 CFR 1010.4(b))). When FDA receives a new application for variance, the Agency's Dockets Management Staff will scan the original application electronically into the

docket for a specific submission. FDA has determined that the requirement for multiple copies is no longer necessary because the docket maintains an electronic version of the application and it is an unnecessary regulatory burden on manufacturers to require additional copies. Therefore, FDA is proposing to amend the applications for variances section to only require a manufacturer to submit the original to the Dockets Management Staff.

3. Records and Reports

The range of electronic products marketed today is diverse regarding radiation emission levels, product complexity, consumer use, and sales volume. FDA receives a large volume of records and reports both annually and quarterly from manufacturers of electronic products (§ 1002.1 (21 CFR 1002.1)). Industry has previously raised concerns about redundancy of information that FDA requires to be submitted to comply with both the medical device regulations and EPRC regulations for products that are both medical devices and electronic products. In the **Federal Register** of September 19, 1995 (60 FR 48374), FDA issued a final rule amending the regulations regarding requirements for recordkeeping and reporting of adverse events and other information related to radiation emitting electronic products. This rule reduced the recordkeeping and reporting requirements for some products, required only abbreviated reporting for other products, and clarified certain requirements.

Based on additional experience with these products and knowledge of their radiation risks, FDA has concluded that the record and reporting requirements for these products should be tailored to focus upon products that have the potential to pose greater risk, while reducing regulatory burdens on manufacturers, dealers and distributors of radiation emitting electronic products that pose less risk to public health (§ 1002.1). FDA also considered what categories of EPRC reports were duplicative of information that would be submitted to FDA in a premarket review of the safety and effectiveness of a new medical device. For example, an initial or abbreviated product report for an ultrasound or x-ray system is duplicative if the firm is also expected to submit a premarket 510(k) notification for a new ultrasound or x-ray system that contains the same (or more detailed) information related to radiation safety features and performance. In general, current record and reporting requirements will remain for those products that emit the highest radiation levels or are sold in the largest quantities because they present the greatest potential risks to public health. For those products that present the least public health risk or for categories of medical-devices that FDA considers the EPRC reporting to be duplicative given the medical device regulations, FDA is proposing to reduce reporting requirements.

In addition, FDA has identified medical and non-medical sonic products for which FDA believes record and reporting requirements should no longer be required. FDA believes the current record and reporting requirements for some electronic products, including ultrasonic therapy products, are an unnecessary burden and a source of confusion for these products. As a result, FDA is proposing to amend the record and reporting requirements to no longer require product reports, supplemental reports, abbreviated reports, annual reports, test records, or distribution records for certain products (see revised table 1 of § 1002.1).

FDA is proposing to remove the requirement 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 (21 CFR 1002.13(c))). FDA has determined that quarterly reporting of new models is unnecessary. The submission of annual reports is sufficient to provide FDA with periodic information to regulate these products, and the submission of quarterly reports has been an unnecessary burden on industry. Generally, FDA requires specified product manufacturers to submit annual reports to the Agency that summarize certain manufacturing records (see § 1002.13(a) and (b)). FDA is not amending these annual report requirements; however, FDA has determined that requiring select manufacturers to submit quarterly updates to FDA in addition to the annual report, is no longer necessary to protect the public health and safety.

FDA believes that the revisions to the reporting and recordkeeping are reasonable based on the risk of certain product categories (§ 1002.1). However, FDA is seeking public comments on other possible revisions to table 1 that may simplify the reporting requirements based on a reduction of unnecessary or duplicative reporting (§ 1002.1).

Lastly, FDA is proposing amendments to AROs by allowing any manufacturer of a radiation emitting electronic product to submit quarterly summary reports of AROs that are not associated with a death or serious injury (21 CFR 803.3(w)) and not required to be reported under the medical device reporting regulations (§ 1002.20 (21 CFR 1002.20); 21 CFR part 803). Manufacturers of electronic products are currently required, where reasonable grounds are suspected, to immediately report to FDA all AROs reported to or otherwise known to the manufacturer and arising from the manufacturing, testing, or use of any product introduced or intended for introduction into commerce by the manufacturer (§ 1002.20). FDA believes that amending the regulations to allow summary reporting for AROs not associated with a death or serious injury 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 program for medical devices (see part 803). In the **Federal Register** of August 17, 2018, FDA published the ''Voluntary Malfunction Summary Reporting Program'' Notice identifying the criteria and format for summary reporting in the quarterly reports for device malfunctions that will also be applicable to AROs (83 FR 40973). FDA is seeking public comments from manufacturers as to whether quarterly summary reports would reduce burden, and whether manufacturers have additional suggestions as to the specificity in the format, content, or timing of summary reports.

4. Diagnostic X-Ray Systems and Their Major Components

The purpose of the performance standard for diagnostic x-ray systems is to protect the public health by reducing unnecessary exposure to ionizing radiation while assuring the clinical utility of the images produced. In the **Federal Register** of June 10, 2005 (70 FR 33998), the FDA issued a final rule to amend the Federal performance standard for diagnostic x-ray systems and their major components (*i.e.,* the performance standards). Under those regulations, the performance standard requires that assemblers who install certified components of diagnostic x-ray systems must assemble, install, adjust, and test the certified components according to the instructions of the component manufacturer when these certified components are installed into a diagnostic x-ray system (§ 1020.30(d)). In addition, assemblers are responsible for filing a report of the assembly that affirms 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 (§ 1020.30(d)(1)).

Currently, all assembler reports must be on a form prescribed by CDRH and submitted to the Director of CDRH, to the purchaser, and, where applicable, to the State agency responsible for radiation protection within 15 days following assembly. FDA has determined that the reports of assembly are important for State agencies and the purchasers, but reporting to FDA is an unnecessary additional burden to the manufacturer as FDA is no longer using these reports to plan routine inspections of newly assembled equipment. Therefore, FDA is proposing to amend the regulation to remove the requirement that a manufacturer must submit a report of assembly of a certified component to the Agency. While FDA no longer needs the report to plan routine inspections of installed x-ray systems, other requirements in the performance standard for x-ray systems and their major components are unchanged. FDA also plans routine inspections of the x-ray equipment manufacturers for compliance with the quality system regulations (see 21 CFR part 820).

X-ray systems and certain components are still subject to FDA premarket review (see part 892). Compliance with FDA regulations and post-market surveillance allows monitoring the safety of installed equipment through medical device reporting (MDRs) (part 803), recalls (see 21 CFR part 806), notifications of defects (see 21 CFR part 1003), and reporting of accidental radiation occurrences (see § 1002.20). FDA believes that, as was previously described, the history of continuous efforts to reduce unnecessary radiation among manufacturers and practitioners, consensus standards development, and other regulatory authorities for compliance and surveillance all support FDA's conclusion that reports of assembly no longer need to be submitted to FDA. FDA has found the information received and reviewed in MDRs, recalls, and other means to be sufficient for ongoing efforts to inform consensus standards development, guidance, or collaboration on improved education as a better use of resources to result in a broader impact to reduce unnecessary radiation exposure and protect the public health and safety.

5. Laser Products

On December 18, 1989, in response to numerous questions regarding the applicability of regulations on laser products, and modification of a certified laser product, in situations in which a firm purchases a certified Class I laser product and incorporates it into another product for sale (§ 1040.10(i) (21 CFR 1040.10(i))), FDA issued ''Laser Notice No. 42—Clarification of Compliance Requirements for Certain Manufacturers Who Incorporate Certified Class I Laser Products Into Their Products'' (Laser Notice No. 42) (Ref. 19). In Laser Notice No. 42, FDA announced its policy that it will consider firms that incorporate unmodified, certified Class I laser products into another product to be distributors of laser products certified and reported by other manufacturers provided certain conditions were met. If this proposed rule is finalized, the exception from applicability of laser performance standards will be expanded to include all classes of certified and unmodified laser products (Class I, II, IIa, IIIa, IIIb, and IV) that are not intended for use as a component or replacement and that are incorporated into another product (see proposed amendment § 1040.10(a)(2)). These amendments, if finalized, will further streamline the regulation of finished certified laser products that are installed into another product, while providing for the same protection of the public health and safety from electronic product radiation from laser products as originally certified.

The proposed rule does not change the requirements for distributors of laser products. Distributors of laser products need not submit initial and annual reports nor apply new certification and identification labels to the outside of the final product (§§ 1010.2 and 1010.3), which remain the responsibility of the manufacturer. Instead, distributors of laser products must only comply with the recordkeeping requirements (§§ 1002.40 and 1002.41 (21 CFR 1002.40 and 21 CFR 1002.41)).

At the same time, FDA is retaining the exception from applicability of the laser product performance standard for uncertified laser products intended to be used as a component or replacement for an electronic product that is then certified by the manufacturer of such finished electronic product (see § 1040.10(a)). Specifically, the laser product performance standards will still not apply to manufacturers of uncertified laser products intended to be used as a component or replacement in a finished electronic product that is then certified by the manufacturer, subject to certain conditions (see proposed amendment § 1040.10(a)(1)(i)–(iii)). To clarify, § 1040.10(a)(1), as proposed to be amended, describing laser products intended for use as components and excepted from the laser performance standard and the associated reporting and recordkeeping requirements found in part 1002 remain unchanged by these amendments.

Such exception from the laser product performance standards continues to not apply to removable laser systems, which must comply with the laser product performance standards as well as applicable reporting and recordkeeping requirements. Removable laser systems are designed to be incorporated in such a way that they may be removed without modification and still be capable of producing laser radiation when powered by a general energy source, such as those provided by wall transformers, batteries, or other AC or DC power (see § 1040.10(c)(2)).

Lastly, FDA is amending the Agency's address for registration and listing for manufacturers of uncertified laser products that are intended to be used as a component and are incorporated into an electronic product (see proposed amendment § 1040.10(a)(1)(iii)(A)).

6. Ultrasonic Therapy Products

Ultrasonic therapy products are both devices, under section 201(h) of the FD&C Act, and electronic products, under section 531(2) of the FD&C Act. In the **Federal Register** of February 17, 1978 (43 FR 7166), FDA issued a final rule establishing a radiation performance standard for ultrasonic therapy products for use in physical therapy manufactured on or after February 17, 1979. The standard applies to any device intended to generate and emit ultrasonic radiation for therapeutic purposes at frequencies above 16 kilohertz and to generators or applicators designed or specifically designed for use in such devices. Ultrasonic therapy devices currently must comply with the general performance standards for electronic products (part 1010), and the performance standard for ultrasonic therapy products (§ 1050.10 (21 CFR 1050.10)). The performance standard for ultrasonic therapy products only applies to ultrasonic therapy products for use in physical therapy, but not the range of other therapeutic medical ultrasound devices. Ultrasonic therapy products, also known as diathermy products, are intended to generate therapeutic deep heat within body tissues for the treatment of selected medical conditions. The safety profile of medical ultrasound products is reviewed prior to marketing authorization to consider their intended uses by trained professionals who follow the manufacturer's labeling, which labeling

is required to provide adequate directions for use (§ 801.5).

Since the time that ultrasonic therapy performance standards were finalized in 1979, other regulations now apply to the safety and effectiveness of ultrasonic therapy products. The products are subject to premarket authorization (see § 890.5300 (21 CFR 890.5300)). Additionally, FDA can perform routine inspections of the device manufacturers for compliance with quality system regulations (see part 820). Compliance with FDA's regulations and post-market surveillance also allow monitoring for the safety of equipment through medical device reporting (MDRs) (see part 803) and recalls (see part 806). EPRC notifications of defects (see part 1003) and reporting of accidental radiation occurrences (see § 1002.20) still apply. FDA finds that the history of safe use, consensus standards development, and other regulatory authorities for compliance and surveillance are adequate to reduce the burden of also needing to comply with outdated performance standards.

The basis for development of the ultrasonic therapy performance standards in 1979 is no longer relevant because FDA has since gained authority to sufficiently monitor the quality and safety of ultrasonic therapy products under the device premarket authorization review process. The premarket authorization review can take into consideration recognized IEC consensus standards and recommendations in applicable FDA's guidance document(s) as an alternative to conformance with the EPRC performance standards for the evaluation of the safety and effectiveness of such products (Ref. 9). The premarket review can determine substantial equivalence of the device performance and labeling to a predicate product or premarket approval to demonstrate a reasonable assurance of safety and effectiveness and adequate directions for use (see § 801.5).

As a result, FDA is proposing to repeal the ultrasonic therapy products performance standards because industry may conform to the recognized IEC standards for these products, which provides at least the same level of protection of the public health and safety from electronic radiation as FDA performance standards, and provides greater flexibility for changes in technology for ultrasonic therapy products. The Agency has recommended through guidance that industry should conform with IEC standards 60601–2–5 and 61689 to address the performance standards for ultrasonic therapy (part 1050). Most of industry already comply with these FDA recognized consensus standards. FDA has published an ultrasonic diathermy device guidance entitled, ''Policy Clarification and Premarket Notification [510(k)] Submissions for Ultrasonic Diathermy Devices; Guidance for Industry and Food and Drug Administration Staff'' (Ref. 20). The guidance outlines a policy that, if firms provide a declaration of conformity with the relevant provisions of the current FDA recognized versions of the IEC 60601–2–5 and IEC 61689 standards, FDA does not intend to consider whether firms comply with certain regulatory requirements (see § 1050.10).

FDA believes that the foregoing regulatory controls, such as medical device premarket review, as well as quality controls, surveillance, and recall authorities are adequate to monitor and address safety issues that arise from any reports of adverse events with these products. As a result, FDA is proposing to repeal the performance standards for ultrasonic therapy products because these standards apply to a limited subset of devices used in physical therapy (see § 890.5300) for which safety issues devices have been and will continue to be handled through premarket regulatory review processes as well as under other medical device regulatory authorities, such as MDRs and device recalls.

IV. Legal Authority

FDA is issuing this proposed 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 proposed rule.

V. Description of the Proposed Rule

A. Scope

We are proposing to amend and repeal the parts of the radiological health regulations covering recommendations for radiation protection (part 1000), certain reporting and records of electronic products (parts 1002, 1010, and 1020), and performance standards of laser products (part 1040) and ultrasonic therapy devices (part 1050). These proposed changes to the regulations are intended to reduce regulatory requirements that are outdated and otherwise clarify requirements for protecting the public health against exposure to specific radiation emitting electronic products and medical devices. This action is part of FDA's implementation of EOs 13771 and 13777.

B. Proposed Repeal of Radiation Protection Recommendations

As stated above in section III, FDA believes there are adequate recommendations from FDA, interagency work groups, and professional organizations as well as State and accreditation/certification requirements on practitioners and facilities to mitigate patients' and health professionals' exposure to radiation from medical imaging. The recommendations found in FDA's current regulations are now outdated and can be removed without impacting public health, and practitioners and industry can rely on more recent and comprehensive recommendations. FDA is proposing to repeal the following regulations for radiation protection recommendations: (1) Recommendation for the use of specific area gonad shielding on patients during medical diagnostic x-ray procedures (§ 1000.50), (2) recommendation for QA programs in diagnostic radiology facilities (§ 1000.55), and (3) recommendation on administratively required dental x-ray examinations (§ 1000.60). Also, FDA is proposing to repeal the definition of phototherapy products because it is no longer necessary with the removal of certain reporting requirements identified in records and reports for radiation emitting electronic products (§ 1000.3(s); see table 1 of § 1002.1).

C. Proposed Amendment About Applications for Variances

FDA has determined that it is unnecessary for manufacturers submitting an application for variance to submit two copies of the application in addition to the original (§ 1010.4(b)). Upon receipt of a new application for variance by mail, FDA's Dockets Management Staff will scan the original application electronically into the docket for a specific submission; therefore, FDA is proposing to amend this regulation by removing the requirement for manufacturers to submit two additional copies of the application to Dockets Management Staff. Applications for variance can also be submitted electronically through the *Regulations.gov* website to Docket No. FDA–2013–S–0610 (*https://www.regulations.gov/docket?D=FDA-*

2013-S-0610) as a new comment with an upload of the variance application materials.

D. Proposed Amendments About Records and Reports

FDA has reviewed the regulations and is proposing that certain electronic product recordkeeping and reporting requirements are unnecessary for protecting the public health and safety, and therefore is proposing to simplify the applicability of the recordkeeping and reporting requirements (part 1002). In addition, FDA is proposing to change the frequency of some reports and recordkeeping, such as quarterly reporting, because they are unnecessary requirements.

1. Table 1 Revision to Applicability

FDA is proposing to amend the list of records and reports in table 1 to revise the applicability of the recordkeeping and reporting requirements for some products (§ 1002.1). FDA recognizes that, for some products, meeting the preexisting recordkeeping and reporting requirements are not necessary for protection of the public health and safety. The revisions will eliminate some requirements, clarify others, and combine some reporting requirements identified in the table. For instance, receiving reports for x-ray systems and ultrasonic systems is redundant to the medical device premarket review, which provides FDA more information on safety and effectiveness of an electronic product and medical device. These proposed amendments, if finalized, will improve protection of the public health and safety while reducing regulatory burdens on manufacturers, dealers, and distributors of radiation emitting electronic products. The amendments will remove reports that FDA no longer considers necessary low-risk products, which will allow better utilization of resources on high-priority aspects of radiation safety for products with greater risk. Therefore, FDA proposes to reduce recordkeeping and reporting requirements for some products and clarify the applicability of certain requirements for other products. The proposed revisions to table 1 are:

a. Remove the following products from all of the record and reporting requirements under part 1002: (a) Television products (§ 1020.10) with <25 kilovolt (kV) and ≥25kV and <0.1 milliroentgens per hour (mR/hr) isoexposure rate limit curve (IRLC), (b) phototherapy products, and (c) acoustic products including ultrasonic therapy (§ 1050.10), diagnostic ultrasound, medical ultrasound other than therapy or diagnostic, and nonmedical ultrasound. However, these proposed amendments do not remove the general notification of defect requirements for all electronic products (21 CFR part 1003) by manufacturers. FDA believes removing the records and reporting requirements for these types of low risk products will not undermine the protection of the public health and safety. The medical device reporting requirements (21 CFR part 803) and premarket notification requirements (21 CFR part 807, subpart E) still apply to phototherapy products and ultrasonic medical products. In the event there is an issue with the product, FDA's general notification of defect requirements and medical device regulations are sufficient for providing FDA with necessary information.

b. Remove the following products from the requirements for product reports, supplemental reports and annual reports: (a) Computed tomography, (b) x-ray systems, (c) tube housing assembly, (d) x-ray control, (e) x-ray high voltage generator, (f) beam-limiting devices, (g) spot-film devices and image intensifies manufactured after April 26, 1977, and (h) T lamps. However, these proposed amendments do not remove the general notification of defect requirements for all electronic products (21 CFR part 1003) by manufacturers. These devices continue to be regulated under the medical device regulations, including reporting requirements (21 CFR part 803) and premarket notification requirements (21 CFR part 807, subpart E) for computed tomography and x-ray systems. The reporting for T lamps is being made consistent with R lamps as FDA believes the abbreviated reporting for R and T lamps is sufficient for protection of the public health and safety.

c. Remove the following products from the requirements for abbreviated reports: (a) X-ray table or cradle, (b) x-ray film charger, (c) vertical cassette holders mounted in a fixed location and cassette holders with front panels, (d) cephalometric devices manufactured after February 25, 1978, and (e) image receptor support devices for mammographic x-ray systems manufactured after September 5, 1978. However, these proposed amendments do not remove the general notification of defect requirements for all electronic products (21 CFR part 1003) by manufacturers. These devices continue to be regulated under the medical device regulations, including reporting requirements (21 CFR part 803) and premarket notification requirements (21 CFR part 807, subpart E) for diagnostic x-ray systems and products. FDA believes that submission of test records and distribution records and continued regulation as medical devices is sufficient for protection of the public health and safety.

d. Remove the following products from the requirements for abbreviated reports and annual reports: PRODUCTS INTENDED TO PRODUCE PARTICULATE RADIATION OR X-RAYS OTHER THAN DIAGNOSTIC OR CABINET DIAGNOSTIC X-RAY (Medical). This reporting category is intended to cover other medical devices that emit radiation, such as linear accelerators. However, because there are no EPRC performance standards for this category, these reporting requirements were primarily informational only. FDA believes this reporting is unnecessary given other FDA regulations to review and classify medical devices, including premarket review to evaluate safety and effectiveness.

e. Remove the following products from the requirements for supplemental reports: (a) Television with ≥0.1mR/hr IRLC 5, (b) microwave ovens (§ 1030.10), and (c) class IIa, II, IIIa lasers and products other than class I products containing such lasers. Manufacturers of these products will continue to submit product reports and annual reports, which FDA believes is sufficient for protection of the public health and safety. FDA believes supplemental reporting is unnecessary given the information reviewed in the product reports and the relatively lower-risk of these products.

f. Remove the T lamps products from the requirements for product reports, supplemental reports, and annual reports and transfer the product to the same category as R lamps. Manufacturers of T lamps products will now instead be required to submit abbreviated reports, which FDA believes promotes consistency for the two types of lamps and provides sufficient oversight for protection of the public health and safety.

g. Remove ''diagnostic'' from ''Cabinet Diagnostic X-ray'' to match the name of the standard ''Cabinet X-Ray.''

The following proposed changes to table 1 of § 1002.1 include deletions that are indicated in a bold font and by a strikethrough and replacements shown in bold font:

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Table 1.--Record and Reporting Requirements by Product

	Manufacturer						Dealer & Distributor
Products	**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	X	X
X-ray system [4]	~~X~~	~~X~~		~~X~~	X	X	X
Tube housing assembly	~~X~~	~~X~~		~~X~~	X	X	
X-ray control	~~X~~	~~X~~		~~X~~	X	X	X
X-ray high voltage generator	~~X~~	~~X~~		~~X~~	X	X	X
X-ray table or cradle			~~X~~		X	X	X
X-ray film changer			~~X~~		X	X	
Vertical cassette holders mounted in a fixed location and cassette holders with front panels			~~X~~		X	X	X
Beam-limiting devices	~~X~~	~~X~~		~~X~~	X	X	X
Spot-film devices and image intensifiers manufactured after April 26, 1977	~~X~~	~~X~~		~~X~~	X	X	X
Cephalometric devices manufactured after February 25, 1978			~~X~~		X	X	
Image receptor support devices for mammographic X-ray systems manufactured after September 5, 1978			~~X~~		X	X	X
CABINET X-RAY (1020.40)							
Baggage inspection	X	X		X	X	X	X
Other	X	X		X	X	X	

Manufacturer							Dealer & Distributor
Products	**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**
PRODUCTS INTENDED TO PRODUCE PARTICULATE RADIATION OR X-RAYS OTHER THAN DIAGNOSTIC OR CABINET ~~**DIAGNOSTIC**~~ X-RAY							
Medical			~~**X**~~	~~**X**~~	X	X	
Analytical			X	X	X	X	
Industrial			X	X	X	X	
TELEVISION PRODUCTS (1020.10)							
~~**<25 kilovolt (kV) and**~~ <0.1 milliroentgen per hour (mR/hr) IRLC [5] [6]			X [8]	X [6]			
~~**≥25kV and <0.1mR/hr IRLC [5]**~~	~~**X**~~	~~**X**~~		~~**X**~~			
≥0.1mR/hr IRLC [5]	X [8]	~~**X**~~		X	X	X	
MICROWAVE/RF							
MW ovens (1030.10)	X [8]	~~**X**~~		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							
~~**Phototherapy products**~~	~~**X**~~	~~**X**~~					
Laser products (1040.10, 1040.11)							
Class I lasers and products containing such lasers [7]	X [8]			X	X		

Manufacturer							Dealer & Distributor
Products	**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**
Class I laser products containing class IIa, II, IIIa, lasers [7]	X			X	X	X	
Class IIa, II, IIIa lasers and products other than class I products containing such lasers [7]	X	~~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)							
~~**T lamps**~~	~~**X**~~	~~**X**~~		~~**X**~~			
R lamps and T lamps			**X**				
~~**ACOUSTIC**~~							
~~**Ultrasonic therapy (1050.10)**~~	~~**X**~~	~~**X**~~		~~**X**~~	~~**X**~~	~~**X**~~	~~**X**~~
~~**Diagnostic ultrasound**~~			~~**X**~~				
~~**Medical ultrasound other than therapy or diagnostic**~~	~~**X**~~	~~**X**~~					
~~**Nonmedical ultrasound**~~			~~**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).

[4] Systems records and reports are required if a manufacturer exercises the option and certifies the system as permitted in § 1020.30(c).

[5] Determined using the isoexposure rate limit curve (IRLC) under phase III test conditions (§ 1020.10(c)(3)(iii)).

[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 Class I laser products that do not by virtue of their design allow human access to laser radiation in excess of the accessible emission limits of Class I specified in § 1040.10(d), as determined in accordance with § 1040.10(e), under any condition of operation, maintenance, service, or failure (e.g., Class I optical disc products, laser printers).

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FDA is seeking public comments on other revisions to table 1 that may simplify the table and reduce unnecessary or duplicative reporting (§ 1002.1).

2. Eliminating citation reserved.

FDA is proposing to eliminate the citation reserve under § 1002.2 because it is no longer necessary.

3. Eliminating quarterly updates to the annual reports.

FDA is proposing to eliminate the requirement 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)). 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 reporting requirements.

4. Reporting of AROs.

FDA is proposing to amend the timing for submission of reporting requirements for AROs that are not associated with a death or serious injury (§ 1002.20). The proposed amendment will allow manufacturers of a radiation emitting electronic product to submit quarterly summary reports of AROs that are not associated with a death or serious injury and not required to be reported under the medical device reporting regulations (§ 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 beyond the medical device arena and promotes harmonization between this reporting and the new voluntary malfunction summary reporting program for medical devices (part 803; 83 FR 40973).

E. Proposed Amendment About Diagnostic X-ray Systems and Their Major Components

FDA is proposing to amend the reports of assembly requirements for major components of diagnostic x-ray systems to no longer require assemblers who install certified components to submit a report of assembly, Form FDA 2579, to CDRH (Ref. 21) (§ 1020.30(d)). FDA will withdraw the language to require submission to ''the Director'' in this subsection, but will still publish a PDF form online for assemblers to download, complete, and provide to applicable States and purchasers as required.

F. Proposed Amendments About Laser Products

FDA is proposing to amend the laser product regulations to clarify and add exceptions to the applicability of the laser product performance standards (see §§ 1040.10 and 1040.11) to: (1) Uncertified laser products that are intended to be used as a component and are incorporated into an electronic product that is then certified by the manufacturer of a finished electronic product and (2) a manufacturer who incorporates an unmodified laser product into another product when such laser product is not intended for use as a component or replacement and such laser product is certified by the manufacturer of such laser product, subject to certain conditions (§ 1040.10(a)). In addition, FDA is amending the Agency's address for registration and listing for manufacturers of uncertified laser products that are intended to be used as a component and are incorporated into an electronic product (§ 1040.10(a)(1)). The new address that manufacturers are required to submit their registration and listing is the Director, Division of Radiological Health, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G609, Silver Spring, MD 20993–0002. Alternatively, reports may be submitted electronically through FDA's eSubmitter (Ref. 22).

G. Proposed Repeal of Ultrasonic Therapy Products Performance Standard

FDA is proposing to repeal the performance standard for ultrasonic therapy products (§ 1050.10). The standard can be repealed because it is limited to a subset of physical therapy devices with an outdated standard in FDA's current regulations (see § 890.5300), but for which safety issues for these devices have been and will continue to be handled through medical device premarket regulatory processes, as well as under other medical device regulatory authorities, such as MDRs and device recalls.

VI. Proposed Effective Date

FDA proposes that any final rule that may issue based on this proposal become effective 30 days after the date of publication of the final rule in the **Federal Register**.

VII. Preliminary Economic Analysis of Impacts

A. Introduction

We have examined the impacts of the proposed rule under E.O. 12866, E.O. 13563, E.O. 13771, 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). E.O. 13771 requires that the costs associated with significant new regulations ''shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations'' (Ref. 1). We believe that this proposed 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 proposed rule will reduce regulations that are outdated and otherwise clarify existing requirements. Because the proposed rule does not impose any additional regulatory burdens, we certify that the proposed 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 $150 million, using the most current (2017) Implicit Price Deflator for the Gross Domestic Product. This proposed rule would not result in an expenditure in any year that meets or exceeds this amount.

B. Summary of Costs and Benefits

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 $62.8 million at a 7 percent discount rate and $88.2 million at a 3 percent discount rate. Annualized total cost savings are $5.93 million. We estimate the costs to read the rule for all reporting respondents. The present

value costs are $1.47 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.

TABLE 2—SUMMARY OF BENEFITS, COSTS AND DISTRIBUTIONAL EFFECTS OF PROPOSED RULE

Category	Primary estimate	Low estimate	High estimate	Year dollars	Discount rate (%)	Period covered (years)	Notes
Benefits:							
Annualized Monetized $millions/year	$5.93 $5.93	$5.93 $5.93	$5.93 $5.93	2016 2016	7 3	20 20	
Annualized Quantified					7 3		None.
Qualitative						None.	
Costs:							
Annualized Monetized $millions/year	$0.14 $0.10	$0.14 $0.10	$0.14 $0.10	2016 2016	7 3	20 20	
Annualized Quantified					7 3		
Qualitative							
Transfers:							
Federal Annualized Monetized $millions/year					7		None.
				3			
From/To	From:			To:			
Other Annualized Monetized $millions/year					7		None.
				3			
From/To	From:			To:			
Effects:							
State, Local, or Tribal Government: No estimated effect..							
Small Business: No estimated effect.							
Wages: No estimated effect.							
Growth: No estimated effect.							

In line with E.O. 13771, in table 3 we estimate present and annualized values of costs and cost savings over an infinite time horizon. Based on these cost savings, this proposed rule would be considered a deregulatory action under E.O. 13771.

TABLE 3—EO 13771 SUMMARY TABLE

[In $ millions 2016 dollars, over a perpetual time horizon]

	Primary (7%)	Lower bound (7%)	Upper bound (7%)	Primary (3%)	Lower bound (3%)	Upper bound (3%)
Present Value of Costs	$1.47	$1.47	$1.47	$1.47	$1.47	$1.47
Present Value of Cost Savings	84.65	84.65	84.65	197.52	197.52	197.52
Present Value of Net Costs	−83.18	−83.18	−83.18	−196.05	−196.05	−196.05
Annualized Costs	0.10	0.10	0.10	0.04	0.04	0.04
Annualized Cost Savings	5.93	5.93	5.93	5.93	5.93	5.93
Annualized Net Costs	−5.82	−5.82	−5.82	−5.88	−5.88	−5.88

C. Summary of Regulatory Flexibility Analysis

FDA has examined the economic implications of the proposed rule as required by the Regulatory Flexibility Act. If a rule will have a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would lessen the economic effect of the rule on small entities. Because the proposed rule does not impose any additional regulatory burdens, we certify that the proposed rule will not have a significant economic impact on a substantial number of small entities.

We have developed a comprehensive Preliminary Economic Analysis of Impacts that assesses the impacts of the proposed rule. The full preliminary analysis of economic impacts is available in the docket for this proposed rule (Ref. 23) and at *https://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm.*

VIII. Analysis of Environmental Impact

We have 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 proposed rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520). The collections of information in parts 1002 through 1050 have been approved under OMB control number 0910–0025, Electronic Products. The amendments in this proposed rule, if finalized, necessitate revisions to OMB control number 0910–0025. A description of revisions to the annual reporting, recordkeeping, and third-party disclosure burden estimates is given in the PRA, *Description* section of this document. 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.

Tables 4, 5, and 6 describe revisions to the burden estimates, as well as the other information collections currently approved under OMB control number 0910–0025. For the convenience of the reader, we have noted for each information collection whether we are requesting revision.

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

Title: Electronic Products.

Description: FDA is proposing to amend 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 annual reports and test 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 4—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
Product safety or testing changes—1002.11(a)–(b) [3].		440	2.5	1,100	0.5 (30 minutes)	550
Abbreviated reports—1002.12 [3].	3629—General abbreviated 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

TABLE 4—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

Activity; 21 CFR section	FDA form	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours [2]
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 request 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 do not request revision of this line item at this time.

TABLE 5—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]
Manufacturers 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
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 request 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 do not request revision of this line item at this time.

TABLE 6—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

TABLE 6—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]—Continued

Activity; 21 CFR Section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours [2]
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 do not request revision of this line item at this time.
[4] We request revision of this information collection.

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

FDA is proposing to revise the applicability of the recordkeeping and reporting requirements for some products (§ 1002.1). We revised the burden estimates for product reports, abbreviated reports, and annual reports by reducing the number of respondents to reflect the revised applicability of the recordkeeping and reporting requirements. We also proposed to 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 proposed revised applicability of the recordkeeping and reporting requirements for dealer/distributor records (see §§ 1002.40 and 1002.41) may result in a small decrease in the number of respondents. However, upon calculating and rounding the estimated annual number of respondents, we have determined there is no change to the current burden estimate for this information collection.

FDA is eliminating requirements for 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 proposing to amend the timing for submission of reporting requirements for AROs that are not associated with a death or serious injury (§ 1002.20). The proposed amendment will allow manufacturers of a radiation emitting electronic product to submit quarterly summary reports of AROs that are not associated with a death or serious injury and not required to be reported under the medical device reporting regulations (§ 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 proposing to amend 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 proposing to amend the reports of assembly requirements for major components of diagnostic x-ray systems to no longer require assemblers who install certified components to submit a report of assemblies, Form FDA 2579, to CDRH (§ 1020.30(d)(1)) (Ref. 22). FDA also proposes to withdraw the language to require submission to ''the Director'' in this subsection, but will still publish a PDF form online for assemblers to download, complete, and provide to applicable States and purchasers as required. We have moved the corresponding information collection burden estimate from reporting to third-party disclosure burden and revised Form FDA 2579.

FDA is proposing to amend the laser products regulation to add an exception to the applicability of the laser product performance standards (see §§ 1040.10 and 1040.11) to a manufacturer who incorporates an unmodified laser product into another product when such laser product is not intended for use as a component or replacement and such laser product is certified by the

manufacturer of such laser product, subject to certain conditions (§ 1040.10(a)). We have reduced the number of respondents in our burden estimate to reflect the amendment.

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

To ensure that comments on information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB (see **ADDRESSES**). All comments should be identified with the title of the information collection.

In compliance with the PRA (44 U.S.C. 3407(d)), the Agency has submitted the information collection provisions of this proposed rule to OMB for review. These revisions will not be effective until FDA obtains OMB approval. FDA will publish a notice concerning OMB approval of these revisions in the **Federal Register**.

X. Federalism

We have analyzed this proposed rule in accordance with the principles set forth in E.O. 13132. We have determined that this proposed 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 Executive Order 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 (21 U.S.C. 360ss). 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 proposed rule does not impose any new performance standard requirements. This proposed rule prescribes more defined exceptions from the applicability of Federal standards (under proposed amendments to § 1040.10(a)) and a reduction in Federal standards (through repeal of § 1050.10) pursuant to section 534 of the FD&C Act. To the extent that the proposed rule, if finalized, removes or excludes applicability of certain Federal standards, any State issued performance standards are no longer preempted.

XI. Consultation and Coordination With Indian Tribal Governments

We have analyzed this proposed rule in accordance with the principles set forth in E.O. 13175. We have tentatively 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. The Agency solicits comments from tribal officials on any potential impact on Indian Tribes from this proposed action.

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. E.O. 13771 (January 30, 2017), available at *https://www.federalregister.gov/documents/2017/02/03/2017-02451/reducing-regulation-and-controlling-regulatory-costs.*

*2. E.O. 13777 (February 24, 2017), available at *https://www.federalregister.gov/documents/2017/03/01/2017-04107/enforcing-the-regulatory-reform-agenda.*

*3. 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.*

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

*5. American Dental Association and FDA, ''Dental Radiographic Examinations: Recommendations for Patient Selection and Limiting Radiation Exposure,'' Revised: 2012, available at *http://www.ada.org/~/media/ADA/Member%20Center/FIles/Dental_Radiographic_Examinations_2012.pdf.*

*6. CRCPD, ''Part F-Medical Diagnostic and Interventional X-ray Imaging and Systems,'' available at *https://c.ymcdn.com/sites/www.crcpd.org/resource/resmgr/docs/SSRCRs/F_Part_2015.pdf.*

*7. 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.*

*8. Department of Health and Human Services, FDA, Charter for Technical Electronic Product Radiation Safety Standards Committee, available at *https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Radiation-EmittingProducts/TechnicalElectronicProductRadiationSafetyStandardsCommittee/UCM537440.pdf.*

*9. 2016 TEPRSSC Meeting, October 25–26, 2016, available at *https://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Radiation-EmittingProducts/TechnicalElectronicProductRadiationSafetyStandardsCommittee/ucm526004.htm.*

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

*11. ICRP, ''Radiological Protection in Medicine.'' Publication 105. Ann ICRP. 2007;37(6): 1–63, available at *http://www.icrp.org/publication.asp?id=ICRP%20Publication%20105.*

12. NCRP, Reference levels and achievable doses in medical and dental imaging: recommendations for the United States, Report No. 172, 2012, available at

https://ncrponline.org/publications/reports/ncrp-report-172/.

*13. FDA, CDRH Health, Initiative to Reduce Unnecessary Radiation Exposure from Medical Imaging (2010), available at *https://www.fda.gov/Radiation-EmittingProducts/RadiationSafety/RadiationDoseReduction/ucm2007191.htm.*

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

*15. NCRP, ''Ionizing Radiation Exposure of the Population of the United States,'' Report No. 160, 2009, available at *https://ncrponline.org/publications/reports/ncrp-report-160-2/.*

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

*17. CRCPD, Suggested State Regulations for Control of Radiation, available at *https://www.crcpd.org/page/ssrcrs.*

*18. Centers for Medicare & Medicaid Services, Accreditation of Advanced Diagnostic Imaging Suppliers, available at *https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Accreditation-of-Advanced-Diagnostic-Imaging-Suppliers.html.*

*19. FDA, ''Laser Notice No. 42—Clarification of Compliance Requirements for Certain Manufacturers Who Incorporate Certified Class I Laser Products Into Their Products,'' December 18, 1989, available at *https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM095307.pdf.*

*20. FDA, ''Policy Clarification and Premarket Notification [510(k)] Submissions for Ultrasonic Diathermy Devices; Final Guidance for Industry and Food and Drug Administration Staff,'' available at *https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM573663.pdf.*

*21. FDA, Report of Assembly of Diagnostic X-ray System, Form FDA 2579, available at *https://www.fda.gov/ForIndustry/FDAeSubmitter/ucm107879.htm.*

*22. FDA eSubmitter, available at *https://www.fda.gov/forindustry/fdaesubmitter/default.htm.*

*23. Preliminary 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 Part 1000

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

21 CFR Part 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 1040

Electronic products, Labeling, Lasers, Medical devices, Radiation protection, Reporting and recordkeeping requirements.

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, we propose that 21 CFR parts 1000, 1002, 1010, 1020, 1040, and 1050 be 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.

§ 1000.3 [Amended]

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

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:

§ 1002.1 Applicability.

* * * * *

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Table 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
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
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]	X [8]			X	X		

Manufacturer							Dealer & Distributor
Products	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
Class I laser products containing class IIa, II, IIIa, lasers [7]	X			X	X	X	
Class IIa, II, IIIa lasers and products other than class I products containing such lasers [7]	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 Class I laser products that do not by virtue of their design allow human access to laser radiation in excess of the accessible emission limits of Class I specified in § 1040.10(d) of this chapter, as determined in accordance with § 1040.10(e), under any condition of operation, maintenance, service, or failure (e.g., Class I optical disc products, laser printers).

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§ 1002.2 [Removed]

■ 6. Remove reserved § 1002.2.

§ 1002.13 [Amended]

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

■ 8. 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 electronically through Center for Devices and Radiological Health eSubmitter or addressed to 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. 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

■ 9. 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.

■ 10. Section 1010.4 is amended by revising paragraph (b) 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, you must submit an original copy by mail to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Applications for variance can also be submitted electronically through the *Regulations.gov* website under Docket Number FDA–2013–S–0610 as a new comment with an upload of the variance application materials.

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PART 1020—PERFORMANCE STANDARDS FOR IONIZING RADIATION EMITTING PRODUCTS

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

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

■ 12. Section 1020.30 is amended by revising paragraph (d)(1) 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 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.

* * * * *

PART 1040—PERFORMANCE STANDARDS FOR LIGHT-EMITTING PRODUCTS

■ 13. The authority citation for part 1040 continues to read as follows:

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

■ 14. Section 1040.10 is amended by revising paragraph (a) to read as follows:

§ 1040.10 Laser products.

(a) *Applicability.* The provisions of this section and § 1040.11, are applicable to all laser products, except when:

(1) Incorporation of an uncertified laser product intended to be used as a component or replacement for an electronic product—The provisions of this section and § 1040.11 are not applicable to an uncertified laser product that is incorporated into an electronic product that is then certified by the manufacturer of such finished electronic product in accordance with § 1010.2 of this chapter, when:

(i) Such a laser product is either sold to a manufacturer of an electronic product for use as a component (or replacement) in such electronic product, or

(ii) Sold by or for such a manufacturer of an electronic product for use as a component (or replacement) in such electronic product, provided that such laser product:

(A) Is accompanied by a general warning notice that adequate instructions for the safe installation of the laser product are provided in servicing information available from the complete laser product manufacturer under paragraph (h)(2)(ii) of this section, and should be followed,

(B) Is labeled with a statement that it is designated for use solely as a component of such electronic product and therefore does not comply with the appropriate requirements of this section and § 1040.11 for complete laser products, and

(C) Is not a removable laser system as described in paragraph (c)(2) of this section; and

(iii) The manufacturer of such a laser product, if manufactured after August 20, 1986:

(A) Registers, and provides a listing by type of such laser products manufactured that includes the product name, model number and laser medium or emitted wavelength(s), and the name and address of the manufacturer. The manufacturer must submit the registration and listing to the Director, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G609, Silver Spring, MD 20993–0002. Alternatively, reports may be submitted electronically through Center for Devices and Radiological Health eSubmitter.

(B) Maintains and allows access to any sales, shipping, or distribution records that identify the purchaser of such a laser product by name and address, the product by type, the number of units sold, and the date of sale (shipment). These records shall be maintained and made available as specified in § 1002.31 of this chapter.

(2) Incorporation of a certified laser product into another product—The provisions of this section and § 1040.11 are applicable to a manufacturer of a laser product and are not applicable as specified to a manufacturer who incorporates such laser product manufactured or assembled after August 1, 1976, into another product, when:

(i) The manufacturer of such incorporated laser product is not a laser product intended for use as a component or replacement as described in paragraphs (a)(1)(i) and (ii) of this section,

(ii) The manufacturer of the incorporated laser product certifies such a laser product under § 1010.2 of this chapter,

(iii) The incorporated laser product is not modified as defined in paragraph (i) of this section,

(iv) The incorporated laser product is installed in accordance with the instructions for the incorporated laser product as provided by the manufacturer of the incorporated laser product,

(v) The manufacturer of the incorporating product provides with the incorporating product the user information required under paragraph (h) of this section,

(vi) The labeling requirements of §§ 1010.3 of this chapter and 1040.10(g) for the incorporated laser product would be met when the incorporated laser product is removed from the incorporating product,

(vii) The labeling requirements of § 1040.10(g) for the incorporated laser product would be met in any service configuration of the incorporated laser product, even when that incorporated laser product could be serviced without removal from the incorporating product, and

(viii) The manufacturer of the incorporating product otherwise meets the requirements under this subchapter applicable to distributors of laser products (§§ 1002.40 and 1002.41 of this chapter).

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PART 1050—[REMOVED AND RESERVED]

■ 15. Remove and reserve part 1050.

Dated: March 19, 2019.

Scott Gottlieb,

Commissioner of Food and Drugs.

[FR Doc. 2019–05822 Filed 3–29–19; 8:45 am]

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG–124627–11]

RIN 1545–BK43

Corporate Reorganizations; Guidance on the Measurement of Continuity of Interest

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Withdrawal of notice of proposed rulemaking.

SUMMARY: This document withdraws a notice of proposed rulemaking that would have provided guidance on how to determine whether certain transactions satisfy the continuity of interest (COI) requirement under § 1.368–1(e), applicable to certain corporate reorganizations described in section 368 of the Internal Revenue Code of 1986 (Code). The proposed regulations being withdrawn would have affected corporations and their shareholders.

DATES: As of April 1, 2019, the proposed amendment to § 1.368–1 in the notice of proposed rulemaking (REG–124627–11) that was published in the **Federal Register** (76 FR 78591) on December 19, 2011, is withdrawn.

FOR FURTHER INFORMATION CONTACT: Jean R. Broderick at (202) 317–6848 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

The provisions of subchapter C, chapter 1, of the Code generally provide nonrecognition treatment for corporate transactions that are described as reorganizations in section 368. The COI requirement is one of a number of requirements that a transaction must satisfy in order to qualify as a reorganization. The COI requirement