§ 21.6 Posting requirements.

(a) (1) Each individual, partnership, corporation, dedicating entity, or other entity subject to the regulations in this part shall post current copies of—

(i) The regulations in this part;

(ii) Section 206 of the Energy Reorganization Act of 1974; and

(iii) Procedures adopted pursuant to the regulations in this part.

(2) These documents must be posted in a conspicuous position on any premises within the United States where the activities subject to this part are conducted.

* * * * *

4. In § 21.21, the introductory text of paragraph (a) is revised, paragraphs (c) and (d) are redesignated as paragraphs (d) and (e), and a new paragraph (c) is added to read as follows:

§ 21.21 Notification of failure to comply or existence of a defect and its evaluation.

(a) Each individual, corporation, partnership, dedicating entity, or other entity subject to the regulations in this part shall adopt appropriate procedures to—

* * * * *

(c) A dedicating entity is responsible for—

(1) Identifying and evaluating deviations and reporting defects and failures to comply associated with substantial safety hazards for dedicated items; and

(2) Maintaining auditable records for the dedication process.

* * * * *

5. Section 21.31 is revised to read as follows:

§ 21.31 Procurement documents.

Each individual, corporation, partnership, dedicating entity, or other entity subject to the regulations in this part shall ensure that each procurement document for a facility, or a basic component issued by him, her or it on or after January 6, 1978, specifies, when applicable, that the provisions of 10 CFR Part 21 apply.

6. Section 21.41 is revised to read as follows:

§ 21.41 Inspections.

Each individual, corporation, partnership, dedicating entity, or other entity subject to the regulations in this part shall permit the Commission to inspect records, premises, activities, and basic components as necessary to accomplish the purposes of this part.

7. In § 21.51 the introductory text of paragraph (a) and paragraph (b) are revised to read as follows:

§ 21.51 Maintenance and inspection of records.

(a) Each individual, corporation, partnership, dedicating entity, or other entity subject to the regulations in this part shall prepare and maintain records necessary to accomplish the purposes of this part, specifically—

* * * * *

(b) Each individual, corporation, partnership, dedicating entity, or other entity subject to the regulations in this part shall permit the Commission the opportunity to inspect records pertaining to basic components that relate to the identification and evaluation of deviations, and the reporting of defects and failures to comply, including any advice given to purchasers or licensees on the placement, erection, installation, operation, maintenance, modification, or inspection of a basic component.

8. Section 21.61 is revised to read as follows:

§ 21.61 Failure to notify.

(a) Any director or responsible officer of an entity (including dedicating entity) that is not otherwise subject to the deliberate misconduct provisions of this chapter but is subject to the regulations in this part who knowingly and consciously fails to provide the notice required as by § 21.21 shall be subject to a civil penalty equal to the amount provided by section 234 of the Atomic Energy Act of 1954, as amended.

(b) Any NRC licensee subject to the regulations in this part who fails to provide the notice required by § 21.21 or otherwise fails to comply with the applicable requirements of this part shall be subject to a civil penalty as provided by section 234 of the Atomic Energy Act of 1954, as amended.

(c) The dedicating entity, pursuant to § 21.21(c) of this part, is responsible for identifying and evaluating deviations, reporting defects and failures to comply for the dedicated item, and maintaining auditable records of the dedication process. NRC enforcement action can be taken for failure to identify and evaluate deviations, failure to report defects and failures to comply, or failure to maintain auditable records.

Dated at Rockville, Maryland, this 8th day of September 1995.

For the Nuclear Regulatory Commission.

James M. Taylor,

Executive Director for Operations.

[FR Doc. 95–23179 Filed 9–18–95; 8:45 am]

BILLING CODE 7590–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1000 and 1002

[Docket No. 82N–0273]

RIN 0905–AD78

Records and Reports Regulations for Radiation Emitting Electronic Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations regarding the requirements for recordkeeping and reporting of adverse experiences and other information relating to radiation emitting electronic products. This rule reduces recordkeeping and reporting requirements for some products, requires only abbreviated reporting for other products, and clarifies certain requirements. The timing and content of certain reports will be revised to enhance the usefulness of the information. These amendments will improve protection of the public health while reducing regulatory burdens on manufacturers, dealers, and distributors of radiation emitting electronic products.

EFFECTIVE DATE: October 19, 1995.

FOR FURTHER INFORMATION CONTACT: Joanne Barron, Center for Devices and Radiological Health (HFZ–300), Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850, 301–594–4654.

SUPPLEMENTARY INFORMATION:

I. Background

The Regulatory Flexibility Act (5 U.S.C. 601) and Executive Order 12866 require FDA to periodically conduct a comprehensive review of existing regulations. This review is to analyze alternative regulatory approaches and to identify regulations that need to be revised or revoked because they impose an unnecessary burden on specific segments of the public, such as manufacturers, dealers, small businesses, or the general public. In the Federal Register of July 2, 1982 (47 FR 29004), FDA announced its plan to review the records and reports regulations in part 1002 (21 CFR part 1002). FDA recognized that, although part 1002 does not appear to have a major impact on the overall radiation emitting electronic products industry, its impact on small manufacturers

should not be overly burdensome and should be determined.

FDA recognizes that, for some products, meeting the full recordkeeping and reporting requirements is not necessary to protect the public health. Therefore, in the final rule, FDA has reduced the recordkeeping and reporting requirements for some products and determined that an abbreviated report is sufficient regulatory monitoring for other products. FDA also recognizes that some sections of the regulations need additional clarification to be more meaningful and reduce regulatory burdens. Thus, FDA has adopted certain amendments to clarify its regulations.

On October 25, 1990, FDA published in the Federal Register (55 FR 43066) a proposed rule amending its regulations regarding the requirements for recordkeeping, reporting, and other information relating to radiation emitting electronic products. FDA invited interested parties to comment on the proposed rule by January 22, 1991. The comment period was later extended until March 25, 1991 (56 FR 7316). FDA received 11 comments. A summary of these comments and FDA's responses to them are set forth below. FDA is finalizing the proposed rule at this time and incorporating changes that are the result of the agency's review of the comments.

FDA is also amending references to statutory citations to reflect changes in the law. On November 28, 1990, the President signed into law the Safe Medical Devices Act of 1990 (the SMDA), which amended the Federal Food, Drug, and Cosmetic Act (the act). Section 19 of the SMDA transferred the Radiation Control for Health and Safety Act of 1968 from the Public Health Service Act (the PHS Act) into the act as subchapter C. Thus, all references to the PHS Act in parts 1000 and 1002 (21 CFR parts 1000 and 1002) are being revised to reflect this change. Additionally, the agency is changing all references to the ''Office of Compliance and Surveillance'' throughout parts 1000 and 1002 to the ''Office of Compliance'' to reflect an organizational change within the Center for Devices and Radiological Health (CDRH). The agency is also changing references to ''the Secretary'' and to ''the Director'' of CDRH in order to reflect the delegation of the Secretary's authority in accordance with 21 CFR 5.90.

II. Highlights of the Final Rule

To reduce the regulatory burden on the industry, FDA is amending regulations regarding the recordkeeping and reporting requirements for certain radiation emitting electronic products.

First, the reporting requirements in § 1002.12 (reports of model changes) have been consolidated with the requirements of § 1002.10 (initial reports), and the name ''initial report'' has been changed to ''product report.''

Second, FDA has developed two new categories of reports, ''supplemental reports'' in § 1002.11, and ''abbreviated reports'' in § 1002.12. New § 1002.11 (supplemental reports), which requires manufacturers to provide information on product safety and testing, applies to a smaller subset of manufacturers, and reduces the number of required reports by approximately 40 percent. New § 1002.12 (abbreviated reports) requires manufacturers to report abbreviated information on product safety and testing and replaces the existing requirements for many initial reports and model change reports. Although the total combined number of product reports and abbreviated reports will remain about the same as the former initial reports and model change reports, the time necessary to complete the reports will be reduced by approximately 60 percent.

Finally, FDA has limited the applicability of the records requirements in §§ 1002.30 and 1002.40. These changes have reduced the number of records to be maintained by manufacturers and by dealers/distributors by 50 percent and 99 percent, respectively.

Overall, this final rule will reduce the annual reporting and recordkeeping burden hours on the industry by 81 percent, without reducing public health protection.

III. Comments

The following is a summary of the comments and the agency's responses to them.

A. Reporting Requirements

1. One comment stated that there are no relevant changes in the content or format of the initial report to warrant a name change to ''product report.'' The comment states that the name change would result in unnecessary additional costs because personnel, particularly nonregulatory staff, who are familiar with the term initial report, would need to be reeducated.

FDA recognizes that, as with any new requirement, the affected parties may need some training in order to appreciate and understand the changes. In this case, the change is intended to lessen the burden of this requirement by clearly describing the reports that are required, and the filing and content requirements of such reports. For example, FDA has deleted the reference to a 90-day due date for filing an initial report (see revised § 1002.10) because that requirement was applicable only to newly listed products. FDA believes that the long-term benefits of such changes—clearer regulatory requirements, a reduced regulatory burden on industry, and improved cost effectiveness and efficiency—outweigh its short-term training costs. Because FDA and the industry have used the previous term for 20 years, it is expected that there will be a period of transition to the new term over the next year for both the industry and FDA personnel.

2. One comment stated that industrial x-ray systems should not be included in the list of products for which abbreviated reports, rather than initial reports (to be called ''product reports''), are required. The comment expressed the belief that industrial x-ray systems should follow the same reporting requirements as diagnostic x-ray and other x-ray systems.

FDA included analytical and industrial x-ray equipment in the list of products for which abbreviated reports are required because there is no FDA radiation performance standard for these products and, unlike diagnostic x-ray systems, any exposure of people to radiation would be unintentional. In addition, the users of such equipment are trained to be more aware of precautions necessary to reduce or eliminate exposures. In the event that a public health concern arises, however, the regulation would permit FDA to request additional safety information from the manufacturer.

3. One comment asked whether FDA will exempt linear accelerators and low-energy therapy x-ray devices from annual reporting requirements.

Linear accelerators and low-energy therapy x-ray equipment are included in § 1002.1, Table 1, under the category of ''Products Intended to Produce Particulate Radiation or X-rays Other Than Diagnostic or Cabinet X-ray.'' The format of Table 1 has been modified to make clear that the requirements are the same for all medical, analytical, and industrial systems that fall within this product category. Specifically, manufacturers are required to submit abbreviated and annual reports and to maintain test and distribution records for these products.

4. One comment expressed the concern that, unlike television receivers, video display terminals (VDT's) are not specifically delineated by FDA under the reporting and recordkeeping provisions of the regulations. The comment stated that there is little

difference between television receivers and VDT screens and monitors and, therefore, these products should be treated similarly in these provisions. The comment stated that recent investigations of VDT use have shown that low levels of electromagnetic radiation are emitted from certain brands and models. The comment stated that the health and safety effects of these emissions are unknown, but the nature of most VDT work suggests that the effects may be detrimental. Given the health concerns, and the fact that such emissions have generally not been examined, the comment recommended that manufacturers be required to provide product reports, supplemental reports, annual reports, and test records to VDT purchasers, who in turn should be required to relay such information to their employees and representatives. The comment suggested that the hazard communication standard under the Occupational Safety and Health Act (29 CFR 1910.1200) would provide a model for FDA in constructing radiation recordkeeping requirements for VDT's.

FDA has used the designation ''television products'' in § 1002.1, Table 1, to reflect the scope of the product category that is the subject of the performance standard for television receivers at 21 CFR 1020.10. The intent of that standard has been to reduce unnecessary x-ray exposure to persons from any electronic product that can display a viewable picture on a cathode ray tube (CRT). FDA agrees that there are a number of clarifications that need to be made regarding this category of products. FDA anticipates issuing a notice of proposed rulemaking to amend the television receiver standard to address the issues raised in this comment and other issues concerning VDT's. FDA will propose the appropriate changes to part 1002 when the performance standard for television receivers is amended.

With respect to the suggestion that manufacturers be required to provide reports and records to users of VDT's, amended § 1002.3 will provide the mechanism for FDA to require manufacturers to provide the ultimate purchaser of the product with necessary performance and technical data.

5. One comment stated that a 25 kilovolt (kV) criterion should be established for television receivers to differentiate between television receivers that will be subject to relatively moderate reporting requirements (abbreviated reports and annual reports) and those that will be subject to more substantial reporting requirements (product reports, supplemental reports, and annual reports).

FDA agrees with this comment and adopted a 25 kV criterion in the rule. See § 1002.1, Table 1.

6. One comment stated that television receivers with less than 25 kV and less than 0.1 milliroentgen per hour (mR/hr) should be relieved of the annual report requirement of 1002.13 and the preservation and inspection of records provisions of § 1002.31. The comment asserted that exemptions from these provisions already apply to receivers with less than 25 kV pursuant to a 1987 letter to industry which stated that only status identification is required for annual reports on these products.

Consistent with the November 16, 1987, letter to manufacturers of television receiver products from the Director of CDRH (Ref. 1), television receivers which, when tested under phase III conditions, will not equal or exceed 25 kV and for which the chassis power curve will not reach or exceed the 0.1 mR/hr isoexposure rate limit curve (IRLC) are relieved of the annual report requirement of § 1002.13 and the preservation and inspection of records provisions of § 1002.31. Section 1002.1, Table 1, has been revised accordingly.

7. One comment noted discrepancies between the preamble language and Table 1 of the proposed rule. The preamble states that abbreviated reports will replace initial and supplemental reports for ''certain television products.'' The text further states that product reports, but not supplemental reports, will be required for television receivers emitting less than 0.1 mR/hr. However, Table 1 of the proposed rule states that television receivers with less than 25 kV and less than 0.1 mR/hr will require abbreviated reports and television receivers emitting greater than 0.1 mR/hr will require only product reports (not supplemental reports). The comment supports the requirements as set forth in Table 1, but recommends, consistent with the preamble, that the requirement for supplemental reports be deleted for television receivers with greater than 25 kV and less than 0.1 mR/hr.

FDA has corrected the errors appearing in Table 1. Since November 16, 1987, the policy at CDRH has been that certain categories of television products may be exempt from some of the reporting and recordkeeping requirements, depending on the maximum high voltage on the picture tube and the possibility of emission of x-rays at or above 0.1 mR/hr. Manufacturers were given the responsibility to conduct phase III tests and inform CDRH, through annual reports, which models qualify for such exemptions. The agency's intention was to maintain the same level of requirements under the amended reporting and recordkeeping regulations that has previously been in effect for products that may operate at or above 25 kV and products that may emit x-rays at a rate of 0.1 mR/hr or above. The agency believes that these products represent different levels of risks and that different levels of recordkeeping and reporting requirements continue to be appropriate for each category.

Therefore, any television product that contains a CRT or other component capable of producing x-rays, and which, when tested under phase III conditions, will not equal or exceed 25 kV and for which the chassis power curve will not reach or exceed the 0.1 mR/hr IRLC, will require only abbreviated reports. A television product containing a CRT, which, when tested under phase III conditions, may equal or exceed 25 kV but for which the chassis power curve does not reach or exceed the 0.1 mR/hr IRLC, will require product reports, supplemental reports, and annual reports. A television product containing a CRT, for which, when tested under phase III conditions, the chassis power curve reaches or exceeds the 0.1 mR/hr IRLC, will require product reports, supplemental reports, annual reports, and maintenance of the records of test results and distribution of products for 5 years.

Manufacturers must continue to conduct an adequate quality control and testing program to ensure continued compliance of all models with the performance standard. Products for which there is no requirement that test results be kept for 5 years must, nevertheless, be tested adequately and the results should be reviewed by a quality control manager. These products should be rejected at a maximum limit of 0.1 mR/hr when tested under phase III conditions.

The agency retains the authority to inspect all documents supporting the adequacy of the manufacturer's quality control and testing program, including programs for these products for which it is not necessary to retain test results for 5 years. The final rule has added a footnote to Table 1 (footnote 1) to clarify this point.

8. One comment stated that FDA should codify its existing practice concerning importation of products for compliance testing and other related purposes to reduce the potential for confusion about the precise terms and conditions surrounding these activities. The comment stated that bulletins sent by FDA to the industry have stated, at

least with respect to television receivers and laser products, that FDA performance standards do not apply to products ''that are imported for purpose of research, investigations, studies, demonstrations, or training, and that consist of 10 or fewer units per shipment,'' so long as certain administrative safeguards are observed.

The scope of this rule is limited to the reporting andrecordkeeping requirements in part 1002 and is not intended to amend FDA practices and regulations regarding the scope of the applicability of performance standards. Under current policies, FDA allows exemptions from performance standards for 10 or fewer units of certain products (i.e., television products, microwave ovens, and certain laser products), that are imported for test and evaluation and remain under the importer's control, if such products are properly labeled. These exemptions are referenced in FDA Compliance Program 7382.007 which is available from the Division of Small Manufacturers Assistance, Center for Devices and Radiological Health (HFZ–220), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 800–638–2041 or 301–443–6597. These policies will be continued but this rule does not expand the scope of that exemption to all products. However, the rule codifies procedures that allow manufacturers to apply for special exemptions from the reporting and recordkeeping requirements of part 1002 or the Director of CDRH to grant such exemptions on his or her own. See §§ 1002.50(a)(3) and 1002.50(b).

9. One comment requested that FDA clarify the distinctionbetween television receivers and CRT's and explain whether there are differences in the regulations that apply to the products that fall within these two categories. The comment noted that the majority of television receivers use CRT's to display video images (a small minority of receivers use liquid crystal displays), and the comment was uncertain why television receivers remain subject to various reporting requirements while CRT's will be generally exempt from reporting requirements, with the exception of § 1002.20. The comment further stated that FDA's distinction apparently depends on whether a device is limited by design to display only alphanumeric characters (CRT) or whether it can also display other video images (television receiver). The comment stated that FDA's distinction does not appear to be based on public health considerations, and that confusion and potential compliance problems would be avoided by adopting a definition of television that is more consistent with that of the affected industry. The comment suggests that FDA consider adopting the definition used by the FCC, which defines television receiver as a ''device designed to receive television pictures that are broadcast simultaneously with sound on the television channels authorized under part 73 of the FCC's rules.'' (See 47 CFR 15.3(w)(1990)).

Previously, the regulations required manufacturers to submit initial, model change, and annual reports for television receivers and to submit initial and model change reports for CRT's. A CRT is an electronic product component and, as such, is subject to the general radiation safety requirements, but not subject to a performance standard. FDA has determined that the Joint Electron Device Engineering Council/Tube Engineering Panel Advisory Council (JEDEC/TEPAC) data on CRT's that is available from the Electronic Industries Association is sufficient for FDA to assess the potential radiation hazards for CRT's; therefore, any additional reports on the CRT's are not necessary. However, the monitors and video display products that contain the CRT's and associated electronics are subject to the television receiver standard. Accordingly, manufacturers are required to demonstrate that these products, including the CRT's contained in them, meet the standard and to report how the products are tested for compliance. FDA currently is reviewing whether to change the performance standard for television receivers to clarify the definitions of products to which the standard is applicable. This comment will be included in that review.

B. Exemptions

10. One comment proposed that manufacturers of products forwhich there is no applicable performance standard under 21 CFR part 1020 and for which a 510(k) premarket notification (510(k)) has been submitted and cleared in accordance with part 807, subpart E, be exempt from submitting all reports listed in Table 1 of proposed § 1002.1. The comment believes it would be appropriate to include manufacturers of these products in the exemption under proposed § 1002.50(e), because sufficient information regarding safety and effectiveness has been obtained through FDA review of the 510(k) submission. Alternatively, the comment suggests that the fact that any particular electronic product is also a medical device subject to 510(k) notifications should be included among the criteria for considering a special exemption under proposed § 1002.50(a).

Generally, a 510(k) notice on a medical device is submitted to FDA to demonstrate that a design specification is substantially equivalent to the specifications of a predicate device. The radiation safety reporting required by this part of the regulations is intended to provide information on actual production testing and quality control and on the actual product design as produced. If the two are redundant in any particular circumstance, the Director of CDRH can issue exemptions from the reporting and recordkeeping requirements in accordance with § 1002.50(b). FDA does not believe a general exemption from the reporting requirement is in the interest of public health.

11. One comment objected to the exemption of distributors and dealers from the recordkeeping requirement for microwave ovens. The comment states that if such an exemption is granted, these products would be much more difficult to locate to ensure their safety. The comment notes that customer warranty registrations are not sufficient to locate products because such registrations are returned by the customers at such a low rate. The comment states that if the dealer/distributor records are no longer required, the burden of locating the microwave oven shifts to the manufacturer who would have no other alternative but to launch an advertising campaign that would be more expensive, less effective, and slower than any recordkeeping on the part of distributors or dealers.

It has been FDA's experience that dealer and distributor records are rarely needed for the intended purpose of notifying purchasers of product noncompliance. In light of the fact that there have been limited recalls of microwave ovens in the past 10 years (due in part to prototype examinations by FDA), FDA believes that it would be overly burdensome to require distributors and dealers to comply with the recordkeeping requirement. When recalls are necessary, FDA believes that purchasers can be notified by other means, such as general media announcements.

12. One comment recommended that FDA exempt televisionreceivers whose voltage on the CRT is less than 5 kV at zero beam current from the recordkeeping and reporting requirements of part 1002, with the exception of § 1002.20. The comment stated that there is no evidence to suggest that products with such a low voltage (generally, videocamera

viewfinders and televisions with 2 or 3 inch screens) are capable of generating x-rays, which is the primary concern in part 1002. Another comment contended that it would be inappropriate to impose testing and reporting requirements on television receivers with less than 5 kV on the CRT, while CRT's with comparable or even greater voltages are exempted.

Under the amended reporting and recordkeeping requirements, television products whose voltage on the CRT is less than 5 kV will require only abbreviated reports and annual reports, and manufacturers may apply for special exemption from these requirements under the new regulations in § 1002.50. FDA will include these comments in the agency's review of possible amendments to the television performance standard.

13. One comment noted that the preamble to the proposed rule states that television receivers emitting less than 0.1 mR/hr will be exempt from the requirements of maintaining manufacturer's testing and distribution records. The preamble also notes that other products, including ''television receivers,'' are already exempt from these requirements. In comparison, Table 1 of the proposed rule exempts all television receivers from the requirements to maintain manufacturer testing and distribution records. The comment supports the exemption for all television receivers as reflected in Table 1.

A similar concern about the discrepancy between the preamble and Table 1 was addressed above in comment 7. There was an error in the printing of Table 1 of the proposed rule. For television receivers for which the chassis power curve reaches or exceeds the 0.1 mR/hr IRLC, there should have been an X in the following columns: Supplemental reports, Test records, and Manufacturer distribution records. These reports and records are important for FDA to monitor the safety of those products which, by design, can emit radiation levels above background. Table 1 has been amended accordingly.

14. One comment noted an inadvertent error with respect tomanufacturer distribution recordkeeping requirements under § 1002.30(b). The comment stated that FDA has eliminated these requirements for class I lasers and products containing such lasers. Proposed Table 1 to § 1002.1, however, appears to state that class I lasers and products containing class I lasers will be subject to manufacturer distribution recordkeeping requirements under § 1002.30(b). The comment requested FDA to clarify, by amendment of proposed Table 1, that class I lasers and products containing such lasers will retain the exemptions that already apply, including the exemption for manufacturer's distribution records.

Table 1 has been amended to clarify that the exemption for these products from certain reporting requirements remains in effect. FDA has added to Table 1 a category for ''Class I lasers and laser products containing such lasers,'' that will have X's in the columns for Product Reports, Annual Reports, Manufacturer's Test Records, but not for Supplemental Reports, Abbreviated Reports, Manufacturer's Distribution Records, or Dealer/Distributor Distribution Records.

FDA will determine which reporting category is applicable to a product that may have more than one class of laser on the basis of the worst-case hazard in the product. Thus, a class I laser product containing a class IV laser and a class II alignment laser will fall in the category ''Class IIIb and IV lasers and products containing such lasers,'' because this represents the worst-case hazard within the product. Table 1 has been supplemented with a footnote to explain this policy (footnote 7).

15. One set of comments supported the agency's efforts to minimize the reporting and recordkeeping requirements for radiation emitting electronic products. Another comment disagreed with the intent to eliminate initial reports for diagnostic ultrasound equipment. Instead, that comment proposed that diagnostic ultrasound equipment be added to the category of products for which an abbreviated report is required, and that such products be exempt from annual reports. The comment stated that this proposal would reduce the burden on the industry from the medical device premarket clearance process.

Currently, diagnostic ultrasound devices are subject to initial reports but not annual reports. However, in a letter to all manufacturers of diagnostic ultrasound products from the CDRH Director dated February 24, 1986 (Ref. 2), these devices were exempted from the initial reports as long as a 510(k) was filed. CDRH issued this letter to reduce the burden and duplication of paperwork on the industry. The agency recognizes the increase in the timeframe necessary to gather all the information that must be submitted in the 510(k) notification, including production test information that otherwise would be contained in the initial report. Therefore, FDA has amended Table 1 to include abbreviated reports for diagnostic ultrasound equipment in order to retain its ability to obtain production test information about these products. However, CDRH intends to continue to exempt these products from the abbreviated (formerly initial) report requirement until documentation submitted for premarket clearance or for special controls is no longer duplicative of information that would be contained in the abbreviated report.

IV. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(8) 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.

V. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96–354). Executive Order 12866 directs agencies 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). The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the final rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the provisions of the final rule reduce or simplify the records and reporting requirements for manufacturers, dealers, and distributors of radiation emitting electronic products, the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required. A copy of the document supporting this determination, ''Report of the CDRH Task Force for Retrospective Review of the Recordkeeping and Reporting Requirements of 21 CFR 1002,'' is on file at the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, and may be seen by interested persons in

that office between 9 a.m. and 4 p.m., Monday through Friday.

VI. Paperwork Reduction Act of 1980

This final rule contains information collections which are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1980 (44 U.S.C. Chapter 35). The title, description, and respondent description of the information collection are shown below with an estimate of the annual reporting and recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Title: Reporting and Recordkeeping Requirements for Electronic Products Under Pub. L. 90–602—General Requirements.

Description: The Food and Drug Administration is amending its regulations regarding the requirements for recordkeeping, reporting, and other information relating to radiation emitting electronic products. The timing and content of certain reports will be revised to enhance the usefulness of the information. The purpose of these changes is to improve the protection of the public health while also reducing the regulatory burden on manufacturers, dealers, and distributors of radiation emitting electronic products.

Description of Respondents: Businesses or other for profit organizations.

Estimated annual reporting and recordkeeping burden

Section	Annual number of reports and records	Average burden per response (hours)	Annual burden (hours)
1002.10, 1002.12			
Existing:			
Initial	320	34	10,880
Model Change	725	42	30,450
Supplements	2,520	0.5	1,260
Subtotal	3,565	avg 11.9	42,590
Amended:			
Product	850	24	20,400
Supplements	1,500	0.5	750
Abbreviated	150	5	750
Subtotal	2,500	avg 8.8	21,900
Total Reports Reduction			20,690
1002.30			
Existing:	4,000,000	0.12	480,000
Amended:	1,904,000	0.12	480,000
Reduction:			251,520
1002.40			
Existing:	17,000,000	0.048	816,000
Amended:	145,000	0.048	6,960
Reduction:			809,040
Total Records Reduction			1,060,560
Total existing annual burden hours			1,338,590
Total amended annual burden hours			257,340
Total difference in annual burden hours			1,081,250
			(81% reduction)

As required by section 3504(h) of the Paperwork Reduction Act of 1980, FDA has submitted a copy of this rule to OMB for its review of these information collection requirements. Other organizations and individuals desiring to submit comments regarding this burden estimate or any aspects of these information collection requirements, including suggestions for reducing the burden, should direct them to FDA's Dockets Management Branch (address above) and to the Office of Information and Regulatory Affairs, OMB, rm. 3208, New Executive Office Bldg., Washington, DC 20503, Attn: Desk Officer for FDA.

VII. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Director, CDRH, FDA, letter to manufacturers of television receiver products, dated November 16, 1987.

2. Director, CDRH, FDA, letter to manufacturers of ultrasound products, dated February 24, 1986.

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.

Therefore, under the Federal Food, Drug, and Cosmetic Act, the Radiation Control for Health and Safety Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 1000 and 1002 are amended as follows:

PART 1000—GENERAL

1. The authority citation for 21 CFR part 1000 is revised to read as follows:

Authority: Secs. 530–542 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360hh–360ss).

2. Section 1000.3 is revised to read as follows:

§ 1000.3 Definitions.

As used in this Subchapter J:

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

(b) Act means the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360hh–360ss).

(c) Chassis family means a group of one or more models with all of the following common characteristics:

(1) The same circuitry in the high voltage, horizontal oscillator, and power supply sections;

(2) The same worst component failures;

(3) The same type of high voltage hold-down or safety circuits; and

(4) The same design and installation.

(d) Commerce means:

(1) Commerce between any place in any State and any place outside thereof, and

(2) Commerce wholly within the District of Columbia.

(e) Component, for the purposes of this part, means an essential functional part of a subassembly or of an assembled electronic product, and which may affect the quantity, quality, direction, or radiation emission of the finished product.

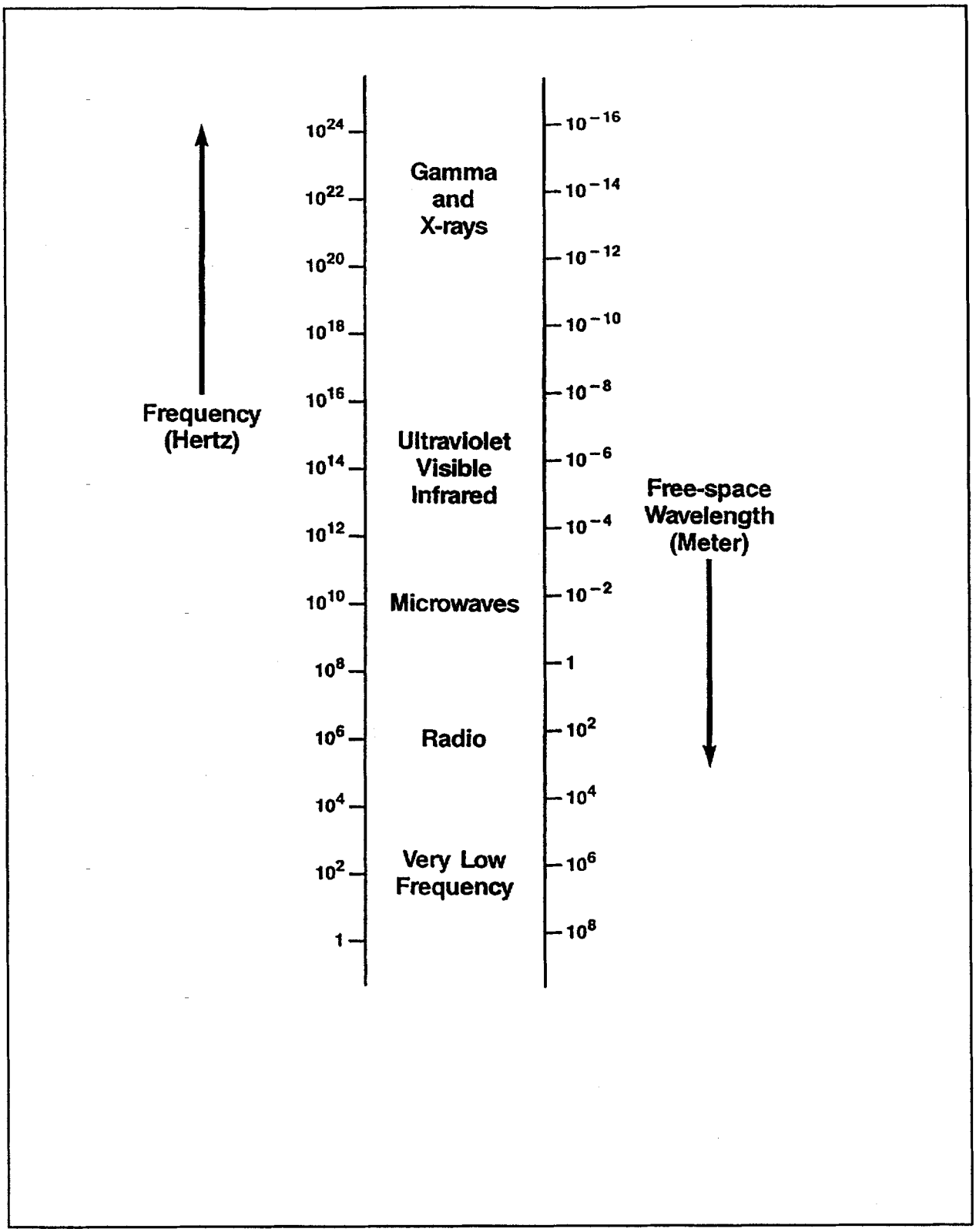
(f) Dealer means a person engaged in the business of offering electronic products for sale to purchasers, without regard to whether such person is or has been primarily engaged in such business, and includes persons who offer such products for lease or as prizes or awards.

(g) Director means the Director of the Center for Devices and Radioloical Health.

(h) Distributor means a person engaged in the business of offering electronic products for sale to dealers, without regard to whether such person is or has been primarily or customarily engaged in such business.

(i) Electromagnetic radiation includes the entire electromagnetic spectrum of radiation of any wavelength. The electromagnetic spectrum illustrated in Figure 1 includes, but is not limited to, gamma rays, x-rays, ultra-violet, visible, infrared, microwave, radiowave, and low frequency radiation.

Figure 1



BILLING CODE 4160–01–C

(j) Electronic product means:

(1) Any manufactured or assembled 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

(2) Any manufactured or assembled article that is intended for use as a component, part, or accessory of a product described in paragraph (j)(1) of this section and which, when in operation, emits (or in the absence of effective shielding or other controls would emit) such radiation.

(k) Electronic product radiation means:

(1) Any ionizing or nonionizing electromagnetic or particulate radiation, or

(2) Any sonic, infrasonic, or ultrasonic wave that is emitted from an electronic product as the result of the operation of an electronic circuit in such product.

(l) Federal standard means a performance standard issued pursuant to section 534 of the Federal Food, Drug, and Cosmetic Act.

(m) Infrasonic, sonic (or audible) and ultrasonic waves refer to energy transmitted as an alteration (pressure, particle displacement or density) in a property of an elastic medium (gas, liquid or solid) that can be detected by an instrument or listener.

(n) Manufacturer means any person engaged in the business of manufacturing, assembling, or importing electronic products.

(o) Model means any identifiable, unique electronic product design, and refers to products having the same structural and electrical design characteristics and to which the manufacturer has assigned a specific designation to differentiate between it and other products produced by that manufacturer.

(p) Model family means products having similar design and radiation characteristics but different manufacturer model numbers.

(q) Modified model means a product that is redesigned so that actual or potential radiation emission, the manner of compliance with a standard, or the manner of radiation safety testing is affected.

(r) Particulate radiation is defined as:

(1) Charged particles, such as protons, electrons, alpha particles, or heavy particles, which have sufficient kinetic energy to produce ionization or atomic or electron excitation by collision, electrical attractions or electrical repulsion; or

(2) Uncharged particles, such as neutrons, which can initiate a nuclear transformation or liberate charged particles having sufficient kinetic energy to produce ionization or atomic or electron excitation.

(s) Phototherapy product means any ultraviolet lamp, or product containing such lamp, that is intended for irradiation of any part of the living human body by light in the wavelength range of 200 to 400 nanometers, in order to perform a therapeutic function.

(t) Purchaser means the first person who, for value, or as an award or prize, acquires an electronic product for purposes other than resale, and includes a person who leases an electronic product for purposes other than subleasing.

(u) State means a State, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, and American Samoa.

PART 1002—RECORDS AND REPORTS

3. The authority citation for 21 CFR part 1002 is revised to read as follows:

Authority: Secs. 502, 510, 519, 520, 531–542, 701, 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352, 360, 360i, 360j, 360hh–360ss, 371, 374).

4. Section 1002.1 is revised to read as follows:

§ 1002.1 Applicability.

The provisions of this part are applicable as follows:

(a) All manufacturers of electronic products are subject to § 1002.20.

(b) Manufacturers, dealers, and distributors of electronic products are subject to the provisions of part 1002 as set forth in Table 1 of this section, unless excluded by paragraph (c) of this section, or unless an exemption has been granted under § 1002.50 or § 1002.51.

(c) The requirements of part 1002 as specified in Table 1 of this section are not applicable to:

(1) Manufacturers of electronic products intended solely for export if such product is labeled or tagged to show that the product meets all the applicable requirements of the country to which such product is intended for export.

(2) Manufacturers of electronic products listed in Table 1of this section if such product is sold exclusively to other manufacturers for use as components of electronic products to be sold to purchasers, with the exception that the provisions are applicable to those manufacturers certifying components of diagnostic x-ray systems pursuant to provisions of § 1020.30(c) of this chapter.

(3) Manufacturers of electronic products that are intended for use by the U.S. Government and whose function or design cannot be divulged by the manufacturer for reasons of national security, as evidenced by government security classification.

(4) Assemblers of diagnostic x-ray equipment subject to the provisions of § 1020.30(d) of this chapter, provided the assembler has submitted the report required by § 1020.30(d)(1) or (d)(2) of this chapter and retains a copy of such report for a period of 5 years from its date.

Table 1.—Record and Reporting Requirements By Product

	Manufacturer						
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 § 1002.309(b)[2]	Dealer Distributor—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-ray table or cradle			X		X	X	X
X-ray film changer			X		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	
CABINET X RAY (§ 1020.40)							
Baggage inspection	X	X		X	X	X	X
Other	X	X		X	X	X	

Table 1.—Record and Reporting Requirements By Product

	Manufacturer						
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 § 1002.309(b)[2]	Dealer Distributor—Distribution records §§ 1002.40 and 1002.41
PRODUCTS INTENDED TO PRODUCE PARTICULATE RADIATION OR X-RAYS OTHER THAN DIAGNOSTIC OR CABINET 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 millroentgen per hour (mR/hr IRLC[1,2]			X	X[6]			
≤=24kV and <0.1mR/hr IRLC[5]	X	X		X	X	X	
≤=0.1mR/hr IRLC[5]	X	X		X	X	X	
MICROWAVE/RF							
MW ovens (§ 1030.10)	X	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[2]	X			X	X		
Class I laser products containing class IIa, II, IIIa, lasers[7]	X			X	X	X	

Table 1.—Record and Reporting Requirements By Product

Products	Manufacturer						
	Product reports § 1002.10	Supplemental reports § 1002.11	Abbreviated reports § 1002.12	Annual reports § 1002.13	Test records § 1002.30(a)[1]	Distribution records § 1002.309(b)[2]	Dealer Distributor—Distribution records §§ 1002.40 and 1002.41
Class IIa, II, IIIa lasers and products other than class I products containing such lasers[7]DX	X		X	X	X	X	
Class IIIb and IV lasers and products containg such lasers[7]	X	X		X	X	X	X
Sunlamp products (§ 1040.20)							
Lamp only	X						
Sunlamp products	X	X		X	X	X	X
Mercury vapor lamps (§ 1040.30)							
T lamps	X	X		X			
R lamps			X				
ACOUSTIC							
Ultrasonic therapy (1050.10)	X	X		X	X	X	X
Diagnostic ultrasound			X				
Medical ultrasound othe 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 21 CFR 1020.30(d)(1) through (d)(3).
[4]Systems records and reports are required if a manufacturer exercises the option and certifies the system as permitted in 21 CFR 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.

§ 1002.2 [Removed]

5. Section 1002.2 Definitions is removed from subpart A.

6. Section 1002.3 is revised to read as follows:

§ 1002.3 Notification to user of performance and technical data.

As authorized by § 5.90 of this chapter, the Director and Deputy Director of the Center for Devices and Radiological Health may require a manufacturer of a radiation emitting electronic product, to provide to the ultimate purchaser at the time of original purchase, such performance data and other technical data related to safety of the product as the Director or Deputy Director finds necessary.

7. Section 1002.7 is amended by adding a new sentenceto the end of the introductory text, by revising the first sentence in paragraph (b), and by adding new paragraph (c) to read as follows:

§ 1002.7 Submission of data and reports.

* * * The submissions required by this part shall be addressed to the Center for Devices and Radiological Health, Electronic Product Reports, Office of Compliance (HFZ–307), 2098 Gaither Rd., Rockville, MD 20850.

* * * * *

(b) Where guides or instructions have been issued by the Director for the submission of material required by this part, such as test data, product reports, abbreviated reports, supplemental reports, and annual reports, the material submitted shall conform to the applicable reporting guides or instructions.

* * *

(c) Where the submission of quality control and testing information is common to more than one model, or model family of the same product

category, a ''common aspects report'' consolidating similar information may be provided, if applicable.

8. Subpart B, consisting of §§ 1002.10 through 1002.13, is revised to read as follows:

Subpart B—Required Manufacturers' Reports for Listed Electronic Products

Sec.
1002.10 Product reports.
1002.11 Supplemental reports.
1002.12 Abbreviated reports.
1002.13 Annual reports.

Subpart B—Required Manufacturers' Reports for Listed Electronic Products

§ 1002.10 Product reports.

Every manufacturer of a product or component requiring aproduct report as set forth in Table 1 of § 1002.1 shall submit a product report to the Center for Devices and Radiological Health, Electronic Product Reports, Office of Compliance (HFZ–307), 2098 Gaither Rd., Rockville, MD 20850, prior to the introduction of such product into commerce. The report shall be distinctly marked ''Radiation Safety Product Report of (name of manufacturer)'' and shall:

(a) Identify which listed product is being reported.

(b) Identify each model of the listed product together with sufficient information concerning the manufacturer's code or other system of labeling to enable the Director to determine the place of manufacture.

(c) Include information on all components and accessories provided in, on, or with the listed product that may affect the quantity, quality, or direction of the radiation emissions.

(d) Describe the function, operational characteristics affecting radiation emissions, and intended and known uses of each model of the listed product.

(e) State the standard or design specifications, if any, for each model with respect to electronic product radiation safety. Reference may be made to a Federal standard, if applicable.

(f) For each model, describe the physical or electrical characteristics, such as shielding or electronic circuitry, incorporated into the product in order to meet the standards or specifications reported pursuant to paragraph (e) of this section.

(g) Describe the methods and procedures employed, if any, in testing and measuring each model with respect to electronic product radiation safety, including the control of unnecessary, secondary, or leakage electronic product radiation, the applicable quality control procedures used for each model, and the basis for selecting such testing and quality control procedures.

(h) For those products which may produce increased radiation with aging, describe the methods and procedures used, and frequency of testing of each model for durability and stability with respect to electronic product radiation safety. Include the basis for selecting such methods and procedures, or for determining that such testing and quality control procedures are not necessary.

(i) Provide sufficient results of the testing, measuring, and quality control procedures described in accordance with paragraphs (g) and (h) of this section to enable the Director to determine the effectiveness of those test methods and procedures.

(j) Report for each model all warning signs, labels, and instructions for installation, operation, and use that relate to electronic product radiation safety.

(k) Provide, upon request, such other information as the Director may reasonably require to enable him/her to determine whether the manufacturer has acted or is acting in compliance with the Act and any standards prescribed thereunder, and to enable the Director to carry out the purposes of the Act.

§ 1002.11 Supplemental reports.

Prior to the introduction into commerce of a new or modified model within a model or chassis family of a product listed in Table 1 of § 1002.1 for which a report under § 1002.10 is required, each manufacturer shall submit a report with respect to such new or modified model describing any changes in the information previously submitted in the product report. Reports will be required for changes that:

(a) Affect actual or potential radiation emission.

(b) Affect the manner of compliance with a standard or manner of testing for radiation safety.

§ 1002.12 Abbreviated reports.

Manufacturers of products requiring abbreviated reports as specified in Table 1 of § 1002.1 shall submit, prior to the introduction of such product, a report distinctly marked ''Radiation Safety Abbreviated Report'' which shall include:

(a) Firm and model identification.

(b) A brief description of operational characteristics that affect radiation emissions, transmission, or leakage or that control exposure.

(c) A list of applications or uses.

(d) Radiation emission, transmission, or leakage levels.

(e) If necessary, additional information as may be requested to determine compliance with the Act and this part.

§ 1002.13 Annual reports.

(a) Every manufacturer of products requiring an annual report as specified in Table 1 of § 1002.1 shall submit an annual report summarizing the contents of the records required to be maintained by § 1002.30(a) and providing the volume of products produced, sold, or installed.

(b) Reports are due annually by September 1. Such reports shall cover the 12-month period ending on June 30 preceding the due date of the report.

(c) New models of a model family that do not involve changes in radiation emission or requirements of a performance standard do not require supplemental reports prior to introduction into commerce. These model numbers should be reported in quarterly updates to the annual report.

9. Section 1002.20 is amended by adding a sentence at the end of paragraph (c) to read as follows:

§ 1002.20 Reporting of accidental radiation occurrences.

* * * * *

(c) * * * 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.

10. Section 1002.30 is amended in the first sentence of paragraph (a) introductory text, by removing ''paragraphs (b) and (c) of § 1002.61'' and adding in its place ''Table 1 of § 1002.1''; and adding new paragraph (a)(5) to read as follows:

§ 1002.30 Records to be maintained by manufacturers.

(a) * * *

(5) Data on production and sales volume levels if available.

* * * * *

§ 1002.31 [Amended]

11. Section 1002.31 Preservation and inspection of records is amended in paragraph (c) by removing ''paragraph (c) of § 1002.61'' and adding in its place ''Table 1 of § 1002.1''.

12. Section 1002.40 is amended by revising paragraph (a) to read as follows:

§ 1002.40 Records to be obtained by dealers and distributors.

(a) Dealers and distributors of electronic products for which there are performance standards and for which

the retail price is $50 or more shall obtain such information as is necessary to identify and locate first purchasers if the product is subject to this section by virtue of Table 1 of § 1002.1.

* * * * *

13. Section 1002.50 is revised to read as follows:

§ 1002.50 Special exemptions.

(a) Manufacturers of electronic products may submit to the Director a request, together with accompanying justification, for exemption from any requirements listed in Table 1 of § 1002.1. The request must specify each requirement from which an exemption is requested. In addition to other information that is required, the justification must contain documented evidence showing that the product or product type for which the exemption is requested does not pose a public health risk and meets at least one of the following criteria:

(1) The products cannot emit electronic product radiation in sufficient intensity or of such quality, under any conditions of operation, maintenance, service, or product failure, to be hazardous;

(2) The products are produced in small quantities;

(3) The products are used by trained individuals and are to be used by the same manufacturing corporation or for research, investigation, or training.

(4) The products are custom designed and used by trained individuals knowledgeable of the hazards; or

(5) The products are produced in such a way that the requirements are inappropriate or unnecessary.

(b) The Director may, subject to any conditions that the Director deems necessary to protect the public health, exempt manufacturers from all or part of the record and reporting requirements of this part on the basis of information submitted in accordance with paragraph (a) of this section or such other information which the Director may possess if the Director determines that such exemption is in keeping with the purposes of the Act.

(c) The Director will provide written notification of the reason for any denial. If the exemption is granted, the Director will provide written notification of:

(1) The electronic product or products for which the exemption has been granted;

(2) The requirements from which the product is exempted; and

(3) Such conditions as are deemed necessary to protect the public health and safety. Copies of exemptions shall be available upon request from the Office of Compliance (HFZ–307), Center for Devices and Radiological Health, 2098 Gaither Rd., Rockville, MD 20850.

(d) The Director may, on the Director's own motion, exempt certain classes of products from the reporting requirements listed in Table 1 of § 1002.1, provided that the Director finds that such exemption is in keeping with the purposes of the act.

(e) Manufacturers of products for which there is no applicable performance standard under parts 1020 through 1050 of this chapter and for which an investigational device exemption has been approved under § 812.30 of this chapter or for which a premarket approval application has been approved in accordance with § 814.44(d) of this chapter are exempt from submitting all reports listed in Table 1 of § 1002.1.

Subpart G—[Removed]

14. Subpart G, consisting of § 1002.61 *List of specific product groups*, is removed.

Dated: September 11, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 95–23130 Filed 9–18–95; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 1

RIN 2900–AG75

Organizational Contact for Missing Children Official Mail Program

AGENCY: Department of Veterans Affairs.

ACTION: Final rule.

SUMMARY: This final rule amends the Department of Veterans Affairs (VA) regulations concerning the use of official mail in the location and recovery of missing children. This rule updates the Departmental contact person and organizational units, reflects current practices, and clarifies provisions.

EFFECTIVE DATE: This amendment is effective September 19, 1995.

FOR FURTHER INFORMATION CONTACT: Mrs. Roslynd R. Stewart, Information Management Service (045A4), Office of Policy and Program Assistance, Office of Information Resources Management, Office of Management, Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420–0001, (202) 565–8949.

SUPPLEMENTARY INFORMATION:

Administrative Procedure Act

The changes made by this final rule constitute rules of agency organization. The remainder of the changes made by this final rule are nonsubstantive and there is good cause for concluding that notice and public procedure thereon are unnecessary and contrary to the public interest. Accordingly, pursuant to 5 U.S.C. 553, we are dispensing with prior notice and comment and with a 30-day delay of the effective date.

Regulatory Flexibility Act

The Secretary certifies that this final rule will not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act, 5 U.S.C. 601–612. The amendments made by this final rule will not have a substantial effect on any individuals or entities. Therefore, pursuant to 5 U.S.C. 605(b), this amendment is exempt from the initial and final regulatory flexibility analysis requirements of sections 603 and 604.

The Catalog of Federal Domestic Assistance number is 16.543.

List of Subjects in 38 CFR Part 1

Administrative practice and procedure, Archives and records, Cemeteries, Claims, Courts, Flags, Freedom of information, Government contracts, Government employees, Government property, Infants and children, Inventions and patents, Investigations, Parking, Penalties, Postal Service, Privacy, Reporting and recordkeeping requirements, Seals and insignia, Security measures, Veterans Affairs Department, Wages.

Approved: September 8, 1995.

Jesse Brown,

Secretary of Veterans Affairs.

For the reasons set out in the preamble, 38 CFR part 1 is amended as follows:

PART 1—GENERAL PROVISIONS

1. The authority citation following the table of contents for part 1 is revised to read as follows:

Authority: 38 U.S.C. 501, except as otherwise noted.

2. Section 1.700 is revised to read as follows:

§ 1.700 Purpose.

Sections 1.700 through 1.705 of this title provide a Missing Children Official Mail Program in the Department of Veterans Affairs.