

**SUPPORTING STATEMENT
FOR
Reporting and Recordkeeping For Electronic Products
Specific Product Requirements - 21 CFR 1020, 1030, 1040, and 1050
OMB No. 0910-0213**

A. JUSTIFICATION

The Radiation Control for Health and Safety Act (Public Law 90-602) became effective on October 18, 1968. When the Safe Medical Devices Act (Public Law 101-629) was signed into law on November 28, 1990, these electronic product radiation control provisions were transferred from the Public Health Service Act, Sections 354 - 360(F) [42 U.S.C. 263b- 263n], to the Federal Food, Drug, and Cosmetic Act, Chapter v, Subchapter C [21 U.S.C. 360(hh)-(ss)] (Attachment 1).

The purpose of this subchapter of the Act is to protect the public from unnecessary exposure to radiation from electronic products. Section 532 directs the Secretary of the Department of Health and Human Services to establish and carry out an electronic product radiation control program. Such a program shall include the development, promulgation and administration of performance standards to control the emission of electronic product radiation from electronic products. Section 534(g) directs the Secretary to review and evaluate industry testing programs on a continuing basis; and Sections 535(e) and (f) direct the Secretary to immediately notify manufacturers of, and assure correction of, radiation defects or noncompliances with performance standards. The authority for records and reports is contained in Sections 537(b)-(c) of the Act.

The regulations promulgated under these authorities are located in the Code of Federal Regulations (CFR), Title 21, Chapter 1, Subchapter J, Parts 1002 - 1050 (Attachment 2) and contain the specific product performance standards, which specify information to be supplied with the product or require specific reports. Subchapter A regulations 21 CFR 5.10(a) (3), 5.25(b), 5.35(a) (1), and 5.86 - 5.92 (Attachment 3), delegate administrative authorities to the Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH).

1. Circumstances Making the Collection of Information Necessary

FDA is requesting approval from the Office of Management and Budget (OMB) for the information collection requirements contained in 21 CFR, Parts 1020, 1030, 1040, and 1050 (see Attachment 2).

1020.20(c) (4) - Disclosure - Notification (Reporting):

Requires manufacturers of cold cathode tubes to provide safety instructions and specifications to users.

1020.30(d) (1)&(2) - Reporting:

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

***Form FDA 2579**, Report of Assembly of a Diagnostic X-ray System, is used to obtain the required information requested in 21 CFR 1020.30(d); therefore, FDA is also asking for reinstatement of approval of the form. There are no changes to the form since its last approval by OMB. (Attachment 5)

1020.30(g) - Disclosure - Notification (Reporting):

Requires manufacturers of diagnostic x-ray systems and their major components to provide assembly, installation, compatibility, and testing information to assemblers of such products, and others upon request.

1020.30(g) (2) (Recordkeeping):

Requires manufacturers of diagnostic x-ray systems and their major components to provide assemblers a statement of the maximum line current of the x-ray system based on the maximum input voltage and current characteristics of the tube housing assembly compatible with rated output voltage and rated output current characteristics of the x-ray control and associated high-voltage generator.

1020.30(h) (1)-(4) - Disclosure - Notification (Reporting):

Requires manufacturers of diagnostic x-ray systems and their major components to provide safety and technical information and instructions to the purchasers and users of such products, and others upon request.

1020.32 (a) (1) Disclosure - Notification (Reporting):

Requires manufacturers of fluoroscopic x-ray equipment to provide precautions and safety information to users. It is provided in the same manual as the information required in 1020.30(g).

1020.32 (g) Disclosure - Notification (Reporting):

Requires manufacturers of radiographic systems that contain Positive Beam Limitation (PBL) to provide precautions and safety information to users. It is provided in the same manual as the information required in 1020.30(g).

1020.33(c) - Disclosure - Notification (Reporting):

Requires manufacturers of Computed Tomography (CT) x-ray systems to provide technical and safety information to users. It is provided in the same manual as the information required in 1020.30(h), or in a separate manual devoted entirely to this information.

1020.33(d) - Disclosure - Notification (Reporting):

Requires manufacturers of CT systems to provide quality assurance information to users. It is provided in a separate section in the same manual as the information required in 1020.30(h).

1020.33(g) (4) - Disclosure - Notification (Reporting):

Requires manufacturers of certain CT systems to provide alignment instructions to users. It is provided in the same manual as the information required in 1020.30(h).

1020.33(j) (1)&(2) - Disclosure - Notification (Reporting):

Requires manufacturers of CT x-ray systems to provide specific, technical instructions concerning the use of the method provided for calculation of the CT number mean and standard deviation to users. The information provided according to 21 CFR 1020.30(h) should be in the same manual as the information required in 1020.30(h).

1020.40(c) (9) (i)&(ii) - Disclosure - Notification (Reporting):

Requires manufacturers of cabinet x-ray systems to provide technical, safety, maintenance, and assembly information to purchasers.

1030.10(c) (4) Disclosure - Notification (Reporting):

Requires manufacturers of microwave ovens to provide legible radiation safety instructions to users. This information should be contained in a separate section and should be an integral part of requirements supplied in an enclosed cookbook or users manual.

1030.10(c) (5) (i-iv) - Disclosure - Notification (Reporting):

Requires manufacturers of microwave ovens to provide safety information and adequate instructions to service dealers and distributors and others upon request.

1030.10(c) (6) (iii) - (Reporting):

Describes warning labels on Microwave Ovens. In the history of this performance standard, the Director for the Center for Devices and Radiological Health has never determined that a specific warning is required for a microwave oven manufacturer. Therefore, this citation has been added to the burden chart with a minimal burden.

1030.10(c) (6) (iv) - (Reporting):

Specifies the information to be provided to FDA when a manufacturer of microwave ovens requests an exemption from required user warning labels.

1040.10 (a) (3) (i) (Reporting):

Requires manufacturers of laser products sold for use as a component or replacement to register with FDA and provide a listing by type of product in lieu of the reporting required by 1002.10 (OMB 0910-0025).

1040.10 (a) (3) (ii) - (Recordkeeping):

Requires manufacturers of laser products sold for use as a component or replacement to maintain distribution records in accordance with 1002.31 (OMB 0910-0025).

1040.10(h) (1) (i)-(vi) - Disclosure - Notification (Reporting):

Requires manufacturers of laser products to provide assembly, operation and maintenance instructions, technical information, legible reproductions of all label and hazard warnings, and a listing of all controls, adjustments, and procedures for operations and maintenance to users- The FDA is considering an amendment to simplify the information and harmonize with the international standards.

1040.10(h) (2) (i)-(ii) - Disclosure - Notification (Reporting):

Requires manufacturers of laser products to provide service information to dealers and distributors and to others upon request. It is provided in the same manual, as information required in 1040.10(h)(1).

1040.10(i) - (Reporting):

Requires manufacturers of laser products to recertify and reidentify the product in accordance with 1010.2 and 1010.3. Thus, the firm is required to report compliance information to FDA as required by 1002.10 (burden documented in OMB 0910-0025).

1040.11 (a) (2) - Disclosure - Notification (Reporting):

Requires manufacturers of certain medical laser products to provide instructions and a schedule for calibration with each product. It is provided in the same manual, as information required in 1040.11(A)(1).

1040.20 (d) & (e) (1)&(2) - Disclosure - Notification (Reporting):

Requires manufacturers of sunlamps or ultraviolet lamps to provide warning labels, use instructions, and technical and safety information to users.

1040.30 (c) (1) - Disclosure - Notification (Reporting):

Describes the general regulations for high intensity, mercury vapor discharge lamps, specifically the labeling of these lamps. Burden in this area is considered negligible, as the imprinting of the lamps has become industry standard. Industry also has said that if this requirement were eliminated, they would continue the practice because of the cost implications of retooling all manufacturing of mercury vapor lamps.

1040.30 (c) (2) - Disclosure - Notification (Recordkeeping):

Describes labeling of mercury vapor discharge lamps in lieu of permanently affixing or inscribing tabs or labels on the product as required by §§ 1010.2(b) and 1010.3(a). The manufacturer of any high intensity mercury vapor discharge lamp may permanently affix or inscribe such required tags or labels on the lamp packaging uniquely associated with the applicable lamp.

1050.10(f) (1) - Disclosure - Notification (Reporting):

Requires manufacturers of ultrasonic therapy products to provide service information to dealers and distributors and others upon request. Also provides user instructions concerning safety and precaution, adequate description of the spatial distance of the ultrasonic radiation field, and adequate description of the uncertainties of magnitude.

1050.10(f) (2) (i)-(iii) Disclosure - Notification (Reporting):

Requires manufacturers of ultrasonic therapy products to provide safety and technical information to users. It is provided in the same manual as information required in 1050.10(f) (1).

2. **Purpose and Use of Information**

The information collections are either specifically called for in the Act or were developed to aid the Agency in performing its obligations under the Act. These requirements are placed upon manufacturers, importers, and assemblers of electronic products. Not all of the requirements are placed on all of these groups.

The data reported to FDA and the records that are maintained are used by FDA and the industry to make decisions and take actions, which protect the public from radiation hazards presented by electronic products. This information refers to the identification, location, operational characteristics, quality assurance programs for, and problem identification and correction of electronic products. The data provided to users and others are intended to encourage actions to reduce or eliminate radiation exposures.

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

3. **Use of Information Technology and Burden Reduction**

The electronic product radiation performance standards reduce reporting burden by providing a consistent set of rules, that, when met, allow the respondent to minimize testing of electronic products. In addition, the Agency makes every effort to provide guidance in the submission of information, and forms when appropriate, so that extraneous information is not included. For example, the Form FDA 2579 simplifies and combines the information that would otherwise be required by 1002.10 (OMB 0910-0025), which has an hourly burden 10 times greater.

The FDA is investigating several improved information technologies and methods to reduce the burden placed on manufacturers and assemblers, such as electronic transfer and optical storage. The CDRH is currently investigating the usefulness and appropriateness of a more expedient means of processing the data from Form FDA 2579. These methods will be incorporated when they satisfy technical and legal requirements such as data integrity for a regulated industry and comparability of data.

Utilization of computers and word processors has greatly reduced the time needed to compile, submit and maintain the required documents. The use of the Center's optical scanning and retrieval system, IMAGE, is being tested for use in reviewing submissions, such as Investigational Device Exemption (IDE) applications, and receipt of documents on IMAGE may be a future option. Utilization of word processing equipment has greatly reduced the amount of time needed to compile and arrange documents for submissions to FDA and has expanded our capability to digest and analyze that information. The Act and the IDE regulation limit further reduction in burden.

4. **Efforts to Identify Duplication and Use of Similar Information**

The FDA is the only authorized Agency to control the radiation of electronic products. Therefore, the activities are not duplicated anywhere else. Those electronic products that are medical devices are subject to additional FDA regulations. There is very little duplication of information and where there is, exemptions have been granted so that the medical device reporting has precedence. Often, the documentation submitted to describe how radiation safety is provided through compliance with mandatory performance standards satisfies both requirements simultaneously.

There is no other similar information collected that can be used to carry out the enforcement of these regulations.

5. **Impact on Small Businesses or Other Small Entities**

Small businesses are not exempt from the information collection. These regulations apply to all firms, institutions, or individuals involved in conducting clinical investigations of medical devices, regardless of the size of the organization. However, protection of the public health is necessary regardless of the size of a company. Therefore, efforts have been made to require the minimum amount of information possible for the Agency to make decisions and take actions to protect the public from radiation hazards presented by electronic products. In addition, the Division of Small Manufacturers Assistance (DSMA), CDRH, provides assistance to small businesses in carrying out the reporting requirements. Many of the FDA's recordkeeping requirements are part of normal records necessary for any business practice, and the disclosure information is typically part of the manuals that are provided with any manufactured product.

CDRH has established DSMA as required by the 1976 Amendments to the Act. DSMA's staff provides technical and other nonfinancial assistance to small firms, expressly to aid them in complying with the requirements of the Act. DSMA participates in and presents conferences, workshops, and seminars on the application and interpretation of relevant regulations. They also consult with individual firms/sponsors, and develop and disseminate educational materials. Staff are always available to respond to questions and a toll free telephone number was established to facilitate this communication link.

6. **Consequences of Collecting the Information Less Frequently**

The frequency of the collection requirements depends on the device's date of introduction into commerce decided by the firm. In the event that device information was not provided to FDA shortly after introduction into commerce, a hazard could go undetected and the risk to the public from unnecessary radiation would be increased significantly. If information was not provided to users, distributors, or assemblers at the time of possession of the product they may be unable to make rational decisions and take actions relating to safety. Because the report required by 1040.10 (a) (3) (I) is only submitted once by each firm, the chance of public health risk increases as the length of time extends from the date of introduction of the device.

If the information were obtained less frequently, it would not be possible to assure protection of the public health from significant risk devices.

7. **Special Circumstances relating to the Guidelines of 5 CFR 1320.5**

One of the collection requirements in this request is inconsistent with that outlined in 5 CFR 1320.5. Section 1020.30(d) requires the assembler of a diagnostic x-ray system to submit a report of assembly within two weeks of installation. This response time was agreed upon jointly by FDA and the manufacturers. It was felt that the two-week period was sufficient time to fill out and submit the Form FDA 2579 after completion of the assembly.

If FDA did not possess this information, equipment could not be located quickly when a particular system is suspected of causing harm. If an entire model line is defective, FDA also must be able to locate other installations of the defective components to eliminate additional hazards.

The collection of information under the IDE regulation is consistent with 5 CFR 1320.5.

8. **Consultations with Persons Outside FDA**

In accordance with 5 CFR 1320.8(d) on June 22, 1998 in volume # 63, No. 119, pages 33933 to 33934, a 60-day notice for public comment (Attachment 4) was published in the Federal Register.

FDA consulted with the organizations listed below. All agree that although the IDE regulation presents a burden for those who are complying, it is reasonable within the context of protecting public health.

The Agency consults with members of industry, government and the public through the Technical Electronic Product Radiation Safety Standards Committee (TEPRSSC) and the Radiologic Devices Panel (RDP). They are permanent advisory committees established under Sections 534(f) and 513(b) of the Act. The CDRH is required to consult with the TEPRSSC before establishment of or changes to standards. The RDP advises CDRH on use of radiation in the healing arts. In addition, proposals of new or changed rules, including performance standards, are published in the Federal Register so that interested persons may submit comments.

During the proposal phase of the amendments to the Performance Standard for Diagnostic X-Ray Systems, the FDA received 78 comments from manufacturers, professional and trade organizations, State and local health agencies, and individuals. In addition, a meeting of TEPRSSC was held on November 14-15, 1990. The most recent industry representatives on the TEPRSSC committee included:

Neal W. Hursh, Product Safety Administrator
Thomson Consumer Electronics
600 North Sherman Drive, Indianapolis, IN 46201

John E. Olsson
Manager of Safety & Regulatory Engineering
General Electric Medical Systems Group

P.O. Box 414; Mail Code W-709
Milwaukee, WI 53210

George W. Clark
Lighting Consultant
18 Washington Street
Topsfield, MA 01983

Toni Honkisz
Quality Administrator
Phillips Lighting Company
200 Franklin Square Drive
Somerset, NJ 08775

The committee members and most of the commentors favored the concept of reducing the information collection burden, although not the approach of reducing some technical safety requirements to achieve that end. No comments have been received from assemblers indicating a change in the hourly burden is necessary for the Form FDA 2579.

9. **Explanation of Any Payment or Gift to Respondents**

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

10. **Assurance of Confidentiality Provided to Respondents**

Section 537 of the Act states that the Secretary shall not disclose any information that contains or relates to a trade secret or other matter referred to in Section 1905 of Title 18 of the United States Code. Information provided under this collection is handled in a manner to comply with this requirement and the FDA regulations on public information, 21 CFR Part 20.

The information received in an IDE application will be kept confidential in accordance with 18 U.S.C. 1905 and 21 U.S.C. 331(j), Sections 301(j) and 520(g) of the Act.

11. **Justification for Sensitive Questions**

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

12. **Estimates of Hour Burden Including Annualized Hourly Costs**

The estimated annual cost to the industry is \$963,438 as presented in The Estimated Annual Reporting and Recordkeeping Burden Tables. This amount is derived from the total burden (39,324 hours) multiplied by an average cost of \$24.50 per hour (\$51,000 per staff year of 2080 hours) This average hourly cost includes overhead, technical staff, support staff, etc.

The total estimated reporting and recordkeeping burden for this information collection is 39,324 hours as presented in separate reporting and recordkeeping tables (below). (When information is generally provided to users, assemblers or dealers in the same manual, they have been grouped together in the Estimated Annual Reporting Table).

The approximate burden for disclosure is 32,672 hours and for reports is 6,551 hours, totaling 39,223 hours for reporting. This burden affects 3,606 firms, and requires an average of 1.71 hours per firm annually; the Form FDA 2579 specifically affects 2,345 firms, for an average of 0.30 hours, each totaling 6,300 hours. The frequency of reporting is on occasion, as a manufacturer introduces a new model into commerce or assembles a diagnostic x-ray system.

The estimated burden for recordkeeping is 101 hours. This burden affects 112 recordkeepers, and requires an average of 0.90 hours per firm annually. Records are required to be maintained for 5 years in accordance with 1002.30 - 1002.41 for traceability during a product safety concern. Since most of the burden is in generating rather than maintaining records, CDRH anticipates reducing the number of some records rather than the maintenance time (see OMB 0910-0025)

The burden estimates were derived by consultation with FDA and industry personnel. An evaluation of the type and scope of information requested was also used to derive some time estimates. For example, disclosure information primarily requires time only to update and maintain existing manuals. Initial development of manuals has been performed except for new firms entering the industry.

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

Table 1--Estimated Annual Reporting Burden

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
1020.20(c)(4)	1	1	1	1	1
1020.30(g)	200	1.33	265	35	9,275
1020.30(h)(1) through (h)(4) and 1020.32(a)(1) and (g)\2*	200	1.33	265	35	9,275
1020.32(g) and 1020.33(c), (d), (g)(4), (j)(1), and (j)(2)\2*	9	1.00	9	40	360
1020.40(c)(9)(I) and (c)(9)(ii)	8	1.00	8	40	320
1030.10(c)(4)	41	1.61	66	20	1,320
1030.10(c)(5)(I) through (c)(5)(iv)\2*	41	1.61	66	20	1,320
1040.10(h)(1)(I) through (h)(1)(iv)	805	1.00	805	8	6,440
1040.10(h)(2)(I) and (h)(2)(ii)\2*	100	1.00	100	8	800
1040.11(a)(2)\2*	190	1.00	190	10	1,900
1040.20(d)(1), (d)(2), (e)(1), and (e)(2)	110	1.00	110	10	1,100
1040.30(c)(1)	1	1.00	1	1	1
1040.30(c)(2)	7	1	7	1	7
1050.10(f)(1) and (f)(2)(I) through (f)(2)(iii)	10	1.00	10	56	560
Disclosure Subtotal	1,176		1,186		32,679
1020.30(d)(1) and (d)(2) and Form FDA 2579	2,345	8.96	21,000	.30	6,300

1030.10(c)(6)(iii) and (c)(6)(iv)	1	1.00	1	1	1
1030.10(c)(6)(iv)	1	1.00	1	1	1
1040.10(a)(3)(I)	83	1.00	83	3	249
1040.10(I)--burden in 1002.10 (0910-0025)	0		0	0	0
Reports Subtotal	2,430		21,085		6,551
Total Annual Reporting Burden	3,606	6.37	22,981	1.71	39,230

\1\There are no capital costs or operating and maintenance costs associated with this collection of information.

* The total number of respondents in the reporting burden table above include respondents who have already been included as a subset of another group in the table. The number of firms marked by an asterisk have been included and counted as a sub-set of the total firms subject to reporting burden. Therefore, the number of firms represented by an asterisk have not been added to the total number of respondents on the entry entitled "Disclosure Sub Total", and are not included in the total listed on the last entry of the reporting burden chart entitled "Total Annual Reporting Burden". However, any hours of burden generated by these firms were added to the total reporting burden hours on both the disclosure sub total and total lines of the reporting burden chart.

Estimated Annual Recordkeeping Burden					
21 CFR Section	No. of Recordkeepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
1020.30(g)(2)	22	1	22	0.5	11
1040.10(a)(3)(ii)	83	1	83	1.0	83
Totals	112		112	0.90	94

(Footnote) There are no capital costs or operating and maintenance costs associated with this collection.

Certain labeling requirements included in these regulations are either exempt from the definition of “collection of information” under 5 CFR § 1320.3(c)(2) because they are “public disclosure[s] of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public” or have negligible burden. For example, 21 CFR § 1040.10(g) states that “in addition to the requirements of §§ 1010.2 and 1010.3, each laser product shall be subject to the applicable labeling requirements of this paragraph.” The provision goes on to require several cautionary statements in the labeling of laser products approved under this regulation, and further specifies the exact wording, placement and label design of the required labeling. Because of the mandatory labeling statement wording and placement, this section is exempt under the provisions of the Paperwork Reduction Act of 1995.

Section 21 CFR 1020.10(c)(4), a critical component warning which must be attached to all television receivers, is an example of burden exempt from PRA 95. The manufacturer, in the normal course of business, must permanently affix a clearly legible warning label on all TV receivers, which could produce excess radiation exposure rates if they fail or are improperly adjusted. The label will indicate specific operating high voltage and directions for adjusting high voltage to specific voltages. Because the labels required under this section are used in the normal course of business, this section is therefore exempt from the Paperwork Reduction Act of 1995 burden requirements.

21 CFR Section 1030.10(c)(6)(iii) describes warning labels on Microwave Ovens, specifically with labels covered in 21 CFR Parts 1030.10 (c) (6) (I) & (ii) (i.e. warning labels for Microwave Ovens). This section covers specific radiation warnings other than in (I) and (ii), which are “necessary for particular oven designs or models, as determined by the Director, Center for Devices and Radiological Health or the manufacturer”. In the history of this performance standard there has not been a situation where the Director, Center for Devices and Radiological Health has determined that a specific radiation warning is required for a microwave oven manufacturer under 1030.10(c)(6)(iii). This citation has been added to the burden chart with a minimal burden of one hour.

21 CFR Section 1040.30 (c) (1) deals with general regulations of high intensity mercury vapor discharge lamps, specifically the labeling of these lamps. The lamps must “be permanently labeled or marked in such a manner that the name of the manufacturer and month and year of manufacture of the lamp can be determined on an intact lamp and after the other envelope of the lamp is broken or removed. The name of the manufacturer and month and year of manufacturer may be expressed in code or symbols, provided the manufacturer has previously supplied the Director, Center for Devices and Radiological Health, with the key to the code or symbols and the location of the coded information or symbols on the lamp.” In consultation with an industry representative (Toni Honkisz, Quality Administrator, Philips Lighting Company, 200 Franklin Square Drive, Somerset, New Jersey 08875) regarding the burden associated with 21 CFR 1040.30(C)(1), the burden is considered negligible. Imprinting/labeling of mercury vapor lamps with the information required by this section was implemented when the performance standard for mercury vapor lamps became effective on March 7, 1980 and has become an industry wide standard operating practice. Comments from the industry suggest that if the requirement was eliminated the practice would continue because retooling of existing manufacturing equipment to eliminate this step in the manufacturing process would result in no savings to the industry. Therefore, eliminating the labeling on mercury vapor lamps is not considered cost effective, and has been added to the burden chart with a minimal burden.

21 CFR Sections 1050.10 (d) (1) lists labeling regulations of Ultrasonic Therapy Products, and the labeling of operation controls, service controls, generators, and applicators. These labels are required in the federal performance standard for ultrasound therapy product's operation controls, service controls, generators and applicators and are also required under the normal course of business and therefore exempt from the Paperwork Reduction Act of 1995.

Sections 21 CFR Parts 1040.30 (c) (1), 1050.10 (d) (1)-(5), and 1020.10 (c) (4) are labeling requirements, which are exempt from OMB's enforcement of respondent burden under the Paperwork Reduction Act of 1995.

The burden hour and cost estimates were derived by consultation with FDA and industry personnel. An evaluation of the type and scope of information requested was also used to derive some time estimates. For example, disclosure information primarily requires time only to update and maintain existing manuals. Initial development of manuals has been performed except for new firms entering the industry. When information is generally provided to users, assemblers, or dealers in the same manual, they have been grouped together in the "Estimated Annual Reporting Burden" table.

13. **Estimate of Other Total Annual Cost Burden to Respondents or Recordkeepers**

There is no other annual cost burden to respondents or recordkeepers

14. **Annualized Cost to the Federal Government**

FDA estimates that 58 professional and support staff years will be required to review IDE applications and supplements related to this information collection. This amounts to a yearly total of \$4,854,890 based on a cost of \$83,705 per staff person per year.

15. **Explanation for Program Changes or Adjustments**

The decrease in burden from the previous level of 48,783 hours annually to 39,324 hours has resulted primarily from a decrease in the number of assembly reports (Form FDA 2579) from firms. There were fewer reports because the amendments to the performance standard for diagnostic x-ray equipment, (dated May 3, 1993), deleted section 1020.30 (p) of the standard. Additional reductions are expected as other changes affecting Positive Beam Limiting (PBL) devices are implemented by the industry over the next few years and when the number of records to be maintained for 5 years is changed (See OMB 0910-0025).

There have also been some adjustments made from the previous burden statement. The number of total firms affected was reduced when it was discovered that there were duplicates. In addition, some of the number of firms and reports included in the previous burden duplicated some of the information contained in OMB 0910-00025, which is why the two statements are being consolidated. [Note: The citation of OMB 0910-0195 at the end of 1040.20 is outdated and will be corrected].

16. **Plans for Tabulation and Publication and Project Time Schedule**

The results of this collection will not be published for statistical use unless requested by Congress in accordance with Section 533 of the Act. Manufacturers or assemblers employ no statistical methods in obtaining the information.

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

Currently, CDRH is not requesting an exemption for display of the OMB expiration date.

18. **Exception to Certification for Paperwork Reduction Act Submissions**

Currently, CDRH is not requesting an exemption to Certification for the Paperwork Reduction Act Submissions.

List of Attachments to Supporting Statement

- Attachment 1 - The Federal Food, Drug, and Cosmetic Act, Chapter V, Subchapter C (former title: The Radiation Control for Health and Safety Act of 1968 (P.L. 90-602))
- Attachment 2 - Electronic Product Radiation Control Regulations (21 CFR Chapter I, Subchapter J, parts 1002, 1020, 1030, 1040, and 1050)
- Attachment 3 - Delegation of Authority Regulations (21 CFR Chapter I, Subchapter A, part 5)
- Attachment 4 - Federal Register document soliciting comments on " Reporting and Recordkeeping For Electronic Products Specific Product Requirements - 21 CFR 1020, 1030, 1040, and 1050", June 22, 1998, Pages 33933 - 33934, Docket No. 98N-0364.
- Attachment 5 - Form FDA 2579