Submission Report

Section: Main Menu

Welcome

Welcome to the CDRH Electronic Submissions Software (CeSub)

This software application is intended to automate the current paper submission process. This software contains a number of data capturing tools and helpful dialog boxes to reduce redundant responses for you, and to allow us to capture data in a more useful, structured format. These benefits will enable CDRH to improve our review process and reduce lengthy review times.

For your convenience, an email account has been established to support any questions that you may have regarding the use of this software. Please email any questions or comments to the CeSub team at: **cdrhesub@cdrh.fda.gov.** Please be sure to include your name, company name and contact information in the email.

Thank you again for using our electronic product reporting software. We look forward to hearing from you soon.

What type of product is this submission referring to? *
Radiation Emitting Product (OMB No. 0910-0025; Expiration Date: December 31, 2006)

Welcome (Cont.)

Department of Health and Human Services
Food and Drug Administration

Form Approved:
OMB Number 0910-0025
Expiration Date: December 31, 2006

Section: eRadHealth Menu

Role

What is your role? *	Manufacturer

Submission Information

What Type of Submission is this? (Supplements should be submitted selecting the same document type as the original report.) *
Annual Report
What Type of Product is this Annual Report about? *
Television Receivers, Television Projectors, Video and Computer Monitors containing Cathode Ray Tubes (CRT)
What Type of Correspondence is this?
What Type of Product is this Radiation Safety Report about?
What Type of Product is this Variance Request about?
What Laser Light Show Documents are you filing?

Section: Manufacturer Data

Introduction

Electronic Product Radiation Safety Reporting Form

This software application is intended to automate the hard copy product reporting forms in the effort of the Center for Devices and Radiological Health (CDRH) to become capable of accepting electronic submissions from industry and to improve our review process. This CDRH Electronic Submission (CeSub) software is the next version of the application the CDRH is developing to allow us to accept all Radiological Health reports and other submissions electronically and improve the ability of CDRH to accomplish its mandated product and industry evaluations in a timely and efficient manner.

We have already received many electronic submissions and are looking forward to receiving more in the future. With this new release of the software we have updated our procedures for packaging a submission to make this a smoother process for all. All electronic reports (your new CD-ROMs) and any other documents you are submitting in hard copy because they cannot be provided in an acceptable electronic format must be mailed to CDRH. A signed hard copy of the submittal letter generated by the submission software, should be printed out and included with your electronic submission. This printed documentation will provide the Document Control Room with enough information to log the submission. The electronic submissions should be sent directly to the Document Control room, which is the same process for the standard paper

submission.

The submission must be addressed to:

Electronic Product Document Control (HFZ-309), Attn: CeSub Team, Center for Devices and Radiological Health, 2094 Gaither Road, Rockville, MD 20850

After sending your submission to the Document Control Room, please send an email to the cdrhesub@cdrh.fda.gov email account so we will know that your submission is forthcoming. Please remember that all correspondence concerning your submission MUST be sent to the Electronic Product Document Control (HFZ-309), at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official notification submission. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html. You should also be familiar with the regulatory requirements for radiological products at www.fda.gov/cdrh/comp/eprc.html and medical devices available at Device Advice www.fda.gov/cdrh/devadvice/.

If you have specific questions regarding the software, please contact the CeSub team by email at: **cdrhesub@cdrh.fda.gov**.

Thank you for using our electronic product reporting software. Please communicate your comments and criticisms to the CeSub team as often as you like.

Thank you for your continued support of the CDRH eSubmission Pilot Program.

General Information

General Information for Radiological Health Products

Manufacturers of products subject to performance standards under the Federal Food, Drug, and Cosmetic Act (FFDCA), Chapter V, Subchapter C - Electronic Product Radiation Control are required to furnish various reports to the Center for Devices and Radiological Health (CDRH).

The Radiological Health staff, CDRH developed this software application for the Product and Annual reports. This application will assist manufacturers of electronic products that emit radiation in providing adequate reporting of radiation safety testing and compliance with federal performance standards. Title 21 of the Code of Federal Regulations (CFR), Parts 1002 and 1003 specify Reporting and Notification requirements 1,2,3.

Reports submitted on radiation safety of electronic products must follow the appropriate

form (21 CFR 1002.7). This software application serves the same report responsibility, so long as the submitter or manufacturer prints out the cover letter and sends it in along with the CD containing the report files. The submitter of the report will receive an acknowledgment letter (or email message) with the accession number that CDRH assigns to the report. Please reference this accession number in the future when providing additional information about this model family in either a supplement or the annual report. If a report is incomplete or inadequate CDRH may reject it and return it for completion. CDRH will not enter a rejected report into our database.

CDRH DOES NOT APPROVE THESE REPORTS OR THE PRODUCTS BEING REPORTED. It is the manufacturer's responsibility to certify that their products comply with all applicable standards (21 CFR 1010 - 1050), based on a testing program in accordance with good manufacturing practices. Prior to the shipment of products in interstate commerce, 21 CFR 1002 requires the manufacturer to submit the product and Annual Reports and to comply with all applicable importation requirements (21CFR 1005). If there are deficiencies, CDRH may disapprove the firm's quality control and testing program, determine that the product contains a radiation defect, or determine that the product fails to comply with a standard. CDRH will notify the manufacturer if we make such a determination. CDRH may require the manufacturer to cease introduction into U.S. commerce until deficiencies are corrected, and to initiate a corrective action program (21CFR 1003 - 1004) for products already introduced into commerce.

CDRH can now accept and process 'CeSub' electronic submissions at this time, if all attachments are PDF files only, and the cover letter is printed out and included with a real signature. Translate any text that appears in a language other than English into English in a complete and accurate manner. Keep a copy (save a copy to your hard drive) of the completed report in your records.

We are providing our new software applications for the old reporting forms upon request during this beta testing period of development in Spring, 2005. Other regulatory information is still available on the Internet under http://www.fda.gov/cdrh/comp/eprc.html. No copyright exists for these forms.

Reproduce these forms as needed. If you would like to comment on the reporting forms, website, or future electronic submissions, you may direct the comments to the address below.

A complete Product Report is required for each product model or model family. Product Reports are now more generally referred to as Radiation Safety Reports to distinguish the Radiological Health submissions from medical device submissions. CDRH suggests that a complete report on one model of a family be submitted, with a separate Supplemental Report for each of the other models in the family. The Supplemental Report should respond in detail to the parts of the form where there are differences to report, referencing the number of the affected item. Items that are unchanged will still appear in the supplement from the original report.

When new models of a product are introduced, if the models satisfy the criteria for an established reporting exemption or if the new models do not involve changes in radiation emission or performance requirements, then the manufacturer need not report the models prior to introduction into commerce. Rather, the manufacturer is only required to identify them in the annual report, or in quarterly updates to the annual report. Quarterly updates to annual reports may be submitted using the Annual Report software included in this application. [See 21 CFR 1002.13(c).]

All symbols, units, and unusual terms in the report must be adequately defined and consistently used. Please use the terms as defined in Section 1040.10(b) and in the IEEE Standard Dictionary of Electrical and Electronic Terms (IEEE Std. 1001972 and ANSI C42.1001972).

Definitions

Definitions for Rad Health Products

Manufacturers

Manufacturer is any person or organization engaged in the business of manufacturing, assembling, or importing of electronic products (21 CFR1000.3(n)). Manufacturers of electronic products subject to 21CFR1000-1050 must:

- Design and manufacture their products to be in compliance with applicable performance standards;
- Test their products to assure compliance;
- Certify compliance of their products;
- Maintain test and distribution records and a file of correspondence concerning radiation safety, safety complaints, and inquiries;
- Use the published reporting forms or electronic software application to submit reports to CDRH, including Product reports describing the manner of compliance of the product design and testing program and Annual Reports summarizing their compliance testing;
- Report accidental radiation occurrences (i.e., possible, suspected,or known exposures);
- Report any radiation defects or noncompliances; and
- Recall (i.e., repair, replace, or refund the purchase price of) defective or noncompliant products.

Accidental Radiation Occurrences

An 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.

Importers

Importer is any person of organization engaged in the business of importing electronic products. An importer is considered to be a manufacturer. The requirements for Manufacturers given above also apply to importers if the requirements have not been done by the foreign manufacturer.

United States Agent for Foreign Manufacturers

Every manufacturer of electronic products, prior to offering such product for importation into the United States, shall designate a permanent resident of the United States as the manufacturer`s agent upon whom service of all processes, notices, orders, decisions, and requirements may be made for and on behalf of the manufacturer as provided in section 536(d) of the Radiation Control for Health and Safety Act of 1968 (21U.S.C. 360mm(d)) and this section. The agent maybe an individual, a firm, or a domestic corporation. For purposes of this section, any number of manufacturers may designate the same agent.

From The Federal Food, Drug, and Cosmetic Act

Sec 536 [21 U.S.C. 360mm](d) Designation of agent for purposes of service

It shall be the duty of every manufacturer offering an electronic product for importation into the United States to designate in writing an agent upon whom service of all administrative and judicial processes, notices, orders, decisions, and requirements may be made for and on behalf of said manufacturer, and to file such designation with the Secretary, which designation may from time to time be changed by like writing, similarly filed. Service of all administrative and judicial processes, notices, orders, decisions, and requirements may be made upon said manufacturer by service upon such designated agent at his office or usual place of residence with like effect as if made personally upon said manufacturer, and in default of such designation of such agent, service of process, notice, order, requirement, or decision in any proceeding before the Secretary or in any judicial proceeding for enforcement of this part or any standards prescribed pursuant to this part may be made by posting such process, notice, order, requirement, or decision in the Office of the Secretary or in a place designated by him by regulation.

Sec. 531 [21 U.S.C. 360hh] (1) the term **''electronic product radiation''**means:

(A) any ionizing or non-ionizing electromagnetic or particulate radiation, or

(B) any sonic, infrasonic, or ultrasonic wave, which is emitted from an electronic product as the result of the operation of an electronic circuit in such product.

Sec. 531 [21 U.S.C. 360hh](2) the term **''electronic product''**means:

(A) 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

(B) any manufactured or assembled article which is intended for use as a component, part, or accessory of a product described in clause (A) and which when in operation emits (or in the absence of effective shielding or other controls would emit) such radiation.

Burden to Industry

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 26 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, completing, and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Food and Drug Administration CDRH (HFZ-240)
1350 Piccard Drive Rockville, MD 20850

Please DO NOT RETURN this application to this address.

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Manufacturer Responsible for Product Compliance

Note:	*This is the firm that takes responsibility for certification that the product meets the performance standard. This firm develops and maintains the quality control and testing program that is the basis for the certification of this product. Additionally, this firm usually is the owner of the product design and manufacturing process design.*

Copy from the establishment address book *	
Establishment Information:	
Establishment Name	
Division Name	
Home Page	
Physical Location:	
Address	
Telephone Number	

Fax Number	
Mailing Location:	
Address	

Responsible Individual

Note:	*The responsible individual is the highest level and most responsible individual affiliated with this establishment.*

Copy from contact address book *	
Contact Information:	
Contact Name	
Occupation Title	
Email Address	
Establishment Information:	
Establishment Name	
Division Name	
Physical Location:	
Address	
Telephone Number	
Fax Number	
Mailing Location:	
Address	

Manufacturer's Reporting Official

Note:	*This is the person at the manufacturing facility that is knowledgeable and responsible for addressing all aspects of the testing and quality control procedures for certification as reported to FDA in the product report. Documentation of changes intesting and quality control procedures submitted to FDA must be signed by this individual.*

Copy from contact address book *	
Contact Information:	
Contact Name	
Occupation Title	
Email Address	
Establishment Information:	
Establishment Name	
Division Name	
Physical Location:	
Address	
Telephone Number	
Fax Number	
Mailing Location:	
Address	

Electronic Signature

Electronic signature (not available in this release of the software)	
File Attachment	

Report Submitter

Note:	*The submittermaybe a consulting individual or firm providing assistance in report preparation and maintenance. All documents prepared by the submitter must have the manufacturer's reporting official signature for authenticity of submitted documentation.*
Copy from contact address list *	
Contact Information:	
Contact Name	
Occupation Title	
Email Address	
Establishment Information:	
Establishment Name	
Division Name	
Physical Location:	
Address	
Telephone Number	
Fax Number	
Mailing Location:	
Address	

Parent Establishment

Is there a parent establishment? *	
Copy from contact address book	
Contact Information:	
Contact Name	
Occupation Title	
Email Address	
Establishment Information:	
Establishment Name	
Division Name	
Physical Location:	
Address	
Telephone Number	
Fax Number	
Mailing Location:	

Address	

Manufacturer Designated United States Agent

Note:	*Manufacturers exporting to the U.S. must designate a U.S. agent, see 21 CFR 1005.25.*
Is there a United States agent that has been designated by the manufacturer? *	

Section: Product Data

Product Type Reported

What product type is being reported? *Please note that this list of 66 product types are grouped according to their radiation type and applicable regulations (e.g., laser products, microwave products, ionizing products, etc.) *

Report Information

Is this submission a supplement to an Annual Report submitted previously for the same reporting year? *	
Provide the Accession Number of the report for which this is a supplement (Do not enter any Device Premarket Application or Notification document number here, such as PMAs, 510(k)s, IDEs, etc.):	
Are you requesting a new variance, a renewal, extension or amendment to a previous variance? *	
If you are requesting a renewal, extension, or amendment, please provide the variance number that was issued by CDRH.	
Error:	*If you are requesting a new variance, renewal, extension, or amendment, you must file a Variance Request separate from this report. To do this, open a new report (File > New) and select either "Laser Light Show Variance Request" or "Variance Request, Other" as your Type of Submission in the Submission Information Screen. If you select "Variance Request, Other" you must select the product for which you are requesting a variance at the end of the screen.*

Noncompliances or Defects

Does this document or any of its attachments contain:	
A self-declaration or notification of noncompliance or defect? *	
Provide an explanation:	

Responses to Noncompliances or Defects

Does this documentor any of its attachments contain:	
A refutation of noncompliances? *	
A request for an exemption from notification and corrective action? *	
Information on corrective actions you may be conducting? *	
A description of any design changes for future production? *	

Provide an explanation:

Exemption Requests

Does this document or any of its attachments contain:		
Exemption of a product for government use from a standard (1010.5)?	*	
Exemption for products for government use from reporting and recordkeeping (1002.51)?	*	
Special exemption of products from reporting and/or recordkeeping (1002.50)?	*	
Request for approval of alternate labeling?	*	
Application for alternate test procedures (1010.13)?	*	

Provide an explanation:
Attach any necessary files.

File Attachment	

Variance Requests

This submission includes an application for a variance from certain requirements.	
Item	
Provide an explanation and attach supporting files, if necessary. Click on the Add... button below to attach files.	
Details	
File Attachment	
Error:	*In addition to the electronic copy of this submission, please be sure to submit one hard-copy of the signed variance request document to the following address:* *Division of Dockets Management (HFA-305)* *Food and Drug Administration* *Rm 1061, 5630 Fishers Lane* *Rockville, MD 20852*

Responses to Communications from FDA

Does this document or any of its attachments contain:		
A response to an inspection?	*	
What was the date of the inspection?		
A response to a warning letter from the Food and Drug Administration (FDA)?	*	
What was the date of the Warning Letter?		
A response to a report review inquiry from the Center for Devices and Radiological Health (CDRH) (the inquiry may have been in the form of a letter, email, or phone call)?	*	
What was the date of the inquiry?		

A response to any other communication from FDA? *	
What was the date of the communication?	
Provide an explanation:	

Use Environment

Who are the intended users?
[ ] Children and/or Youth [ ] Consumers [ ] Elderly [ ] Employees/Workers [ ] Engineers or Scientists [ ] General Public [ ] Medical Staff [ ] Patients [ ] Other
What is the use environment?
[ ] Consumer Home [ ] Hospital or Clinic [ ] Industrial Facility or Factory [ ] Office/Warehouse/Store [ ] Outdoors [ ] Public Arena [ ] Schools, Gymnasium/Auditorium [ ] Lab or Research Facility [ ] Transportation Facility [ ] Other
Please select the best match for the affected population:
[ ] Children and/or Youth [ ] Consumers [ ] Elderly [ ] Employees/Workers [ ] Engineers or Scientists [ ] General Public [ ] Medical Staff [ ] Patients [ ] Other

Additional Information

Is there any other relevant information or additional comments that would help expedite the review of this submission? Click the Add... button below to attach any supporting files.	
File Attachment	
Details	

Private Labeling

Is the product sold by other companies under different brand names? *	

Medical Devices

Provide the premarket 510(k), IDE, HDE, PDP, or PMA filing numbers related to this medical product, if one of these numbers has been assigned by FDA yet.
If it has not been assigned yet, provide an explanation and submit it as soon as you receive such a filing number.

Electromagnetic Compatibility and Interference

Electromagnetic Compatibility with other Products
Provide description of analysis and indicate any shielding you have for your product to protect other products from EMI:

Susceptibility to EMI from other Products
Provide description of analysis and indicate any protective shielding your product has to protect it from EMI:

Section: General Annual Report

Part 1 Report Identification

Message:	*This Annual Report is submitted in accordance with 21 CFR 1002.11 for the period:*	
-	From July 1, 20 _ _(Provide the last two digits of the year) *	
-	Through June 30, 20 _ _(Provide the last two digits of the year) *	

If your products meet other voluntary industry standards, provide below:			
Item	Standard Title and Reference Number	Category	Organization

If your product is designed to meet additional voluntary industry standards, list them in the table below.	
Item	

Part 2 Production Status

Production Status (Click on the right button and select the statement that applies to your firm and take the indicated action) *

Part 3 Current Production Tabulation

Item: 1

Model Family Designation:	
Model Designation (Name and/or Number): *	
Accession Number (For previously reported models, CDRH will have assigned this number and reported it to you) *	

Note:	*Each product that CDRH regulates is assigned a product code by CDRH.* *If you know the three letter code, enter it in the space provided.* *If you do not,* *- Click the filter search icon (next to the trash can). You will see a product code filter dialog box.* *- Enter a keyword to search the database. You will be provided a list of product codes from which to choose. (If you are not finding the correct product, try other words and/or variations of the keywords.)* *- Select the best match to your product.* *- The remaining fields will be filled in for you when you select your product code.* *- If you do not find the code that you are looking for, use RZZ (Other)*

Identify the product code.	
Product Code	
Device Class	
Classification Panel	
C.F.R. Section	

Number of Units Produced *	
Introduction Into Commerce (MM/DD/YYYY) *	
Is this model now discontinued but was produced during this reporting period? *	
If so, provide the date of discontinuation:	

Plant Location *	
Establishment Information:	
Establishment Name	
Division Name	
FDA Establishment Identifier (FEI)	
Central File Number (CFN)	
Registration Number	
Owner/Operator Number	
Home Page	
Physical Location:	
Address	
Telephone Number	
Fax Number	
Mailing Location:	
Address	

Provide any information that is needed for any of the items as an attachment.	
File Attachment	

Part 4 Procedures for Quality Control and Testing

Note:	*You are required by 21 CFR 1002.30 (a) (1) and (2) to maintain written procedures for quality control and testing. The procedures in use and those submitted in the Product Reports should be reviewed and updated. Compare your current procedures with those submitted in your Product Reports.*

The written procedures for assessing and controlling radiation safety have been reviewed. (These include prototype testing, incoming materials testing, assembly testing, retesting after repair, and service testing.) The procedures for maintaining quality control testing equipment have also been reviewed. All procedures are up-to-date, complete, and accurate. *	
The initial report(s) provided to CDRH for each model family currently in production have been reviewed and the procedures contained within are up-to-date, complete, and accurate. *	

4.1 Current Procedures

Item: 1

Provide the current procedures as a PDF file attachment here, identifying the model accession number or provide an explanation.	
File Attachment	
Details	
Model Accession Number:	

Part 6 Correspondence Concerning Radiation Safety

Note:	*You are required by 21 CFR 1002.30 (a) (4) to maintain copies of communications to or from dealers, distributors, and purchasers concerning radiation safety. Correspondence should be reviewed if it involves any of the following: complaints or concerns about radiation exposure; difficulties with safety components in use or servicing of the product; investigations made or instructions issued concerning use, adjustment, and repair.*

Specifiy the number of letters received from users,dealers, or others about possible radiation exposure during use of the product, defects or noncompliances. *	
Attach a copy of each letter. Click the Add... button below to attach any supporting files.	
File Attachment	

Indicate the number of letters received from dealers, distributors, or others concerning the need for repair, adjustment, or replacement of a part to maintain radiation safety of the product. *	
Attach a summary of correspondence or a sample. Identify any trends in failed components or adjustments needed during servicing. Click the Add... button below to attach any supporting files.	
File Attachment	

Indicate the number of notices or brochures sent to users, dealers, or service personnel regarding defects, noncompliances, or precautions and actions to be taken to maintain radiation safety of the product. *	
Attach a summary of correspondence or a sample. Click the Add... button below to attach the files.	
File Attachment	

Part 7 Distribution Records

Provide address of the Production facility that maintains shipping records *	
Establishment Information:	
Establishment Name	
Division Name	
FDA Establishment Identifier (FEI)	
Central File Number (CFN)	
Registration Number	
Owner/Operator Number	
Home Page	
Physical Location:	
Address	
Telephone Number	
Fax Number	
Mailing Location:	
Address	

Note:	*Indicate how the products can be traced from the records. Check all that apply.*	
By Model		[ ]
By Serial Number		[ ]
By Date of Manufacture		[ ]
Other		[ ]
If you selected the checkbox for Other, please specify		

Section: TV Annual Report

Summary of Test Results

The manufacturer certifies the following: *	
All of the model families listed in Part 3 (Current Production Tabulation) have been certified to comply with the U.S. Federal Performance Standard for Television Receivers, 21 CFR 1020.10, and other applicable regulations 21 CFR 1010.1 through 1010.3. The manufacturer has conducted a full engineering analysis of the Worst-Tolerance Chassis, Design-Center Chassis, with the Worst-Component Failure, under Phase III test condition, of each model family, prior to production. For models that qualify for Product Report, x-radiation emission levels were found to be under 0.5 milliroentgens (mR) per hour Isoexposure Rate Limit Curve (IRLC) at a distance of five (5) centimeters from the external surface of the receiver, as measured in accordance with sections 21 CFR 1020.10(c)(2) and (c)(3). For models that qualify for Abbreviated Report, the x-radiation emission level were found to be under 0.1 mR per hour (IRLC) and less than 25 kilovolts (kV). All of the models listed in Part 3 (Current Production Tabulation) have a certification and identification label as required by 21 CFR 1010.1 through 1010.3.	

Error:	*You have reached the end of this report. Please verify that all PDFs that are to be included in this submission are correctly attached to a specific file attachment question. Otherwise, they will not be packaged with your report. Check to make sure you have no missing data (select Missing Data Report from the Output menu). Once you have confirmed that there is no missing data and all your files are attached, click on the Package Submission icon on the tool bar.*
Message:	*FDA 3634 Television Products Annual Report (03/06)*