CHAPTER 86 - MEDICAL AND RADIOLOGICAL DEVICE MONITORING AND QUALITY CONFORMANCE

SUBJECT:	IMPLEMENTATION DATE
Inspection and Field Testing of Radiation-Emitting Electronic Products	10/31/2007
	COMPLETION DATE 9/30/2010

DATA REPORTING

PRODUCT CODES	PRODUCT/ASSIGNMENT CODES
95RH-XXX (See Attachment B for detail)	86001
95RH-XXX (See Attachment C for detail)	86002
94RH-XXX (See Attachment D for detail)	86004

This compliance program consolidates and supersedes the following compliance programs:

- **7386.001 – Inspection of Manufacturers of Laser Products**
- **7386.002 – Field Implementation of the Sunlamp and Sunlamp Products Performance Standard As Amended**
- **7386.004 – Field Compliance Testing of Cabinet X-Ray Equipment**

FIELD REPORTING REQUIREMENTS

- Submit all Establishment Inspection Reports (EIRs) and field test reports, attachments, exhibits, correspondence between the district and firm, and other documentation to:

  Center for Devices and Radiological Health
  Office of Communication, Education and Radiation Programs
  ATTN: Electronic Products Branch (HFZ-240)
  1350 Piccard Dr.
  Rockville MD 20850.

- Copies of the EIRs and field test reports, attachments, exhibits, correspondence between the district and firm and other documentation should be routed to appropriate Radiological Health staff, as identified in Part VI of this program, to the accomplishing district and to the district where the firm is located (if located in a different district from the accomplishing district).

- All FACTS and PODS data should be entered by the accomplishing district where the operation was performed.

This document represents the agency's current thinking on the enforcement of the Federal Food Drug and Cosmetic Act Electronic Product Radiation Control provisions and related regulations. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

PART I - BACKGROUND

This compliance program provides guidance to FDA field and center staff for the inspection, field test and administrative/enforcement activities related to the Electronic Product Radiation Control (EPRC) provisions of the Federal Food Drug and Cosmetic Act (FFDCA, the Act) and regulations contained in Title 21 of the Code of Federal Regulations, Parts 1000 – 1050 (21 CFR 1000 – 1050). The intent of these requirements is to protect the public from unnecessary exposure to electronic products radiation. Manufacturers are responsible for producing products that do not emit hazardous or unnecessary radiation and that comply with all applicable radiation safety performance standards. All electronic product manufacturers must comply with applicable requirements in Title 21 CFR 1000, 1002, 1003, 1004 and 1005. If a mandatory radiation safety performance standard applies to a manufacturer's product, then the manufacturer must also comply with Title 21 CFR 1010 and the product must comply with the requirements of the specific standard found in 21 CFR 1020 – 1050. Manufacturers are required to self-certify their own products to be compliant with an applicable standard, based on a quality control testing program as described in 21 CFR 1010.2. The purpose of EPRC inspections and field tests are to verify that products comply with performance standards, and that the manufacturer's quality control testing program ensures such product compliance and radiation safety.

This program applies to certain electronic products subject to radiation safety performance standards described in 21 CFR 1010 – 1040, including:

- 21 CFR 1020.10 Television Receivers
- 21 CFR 1020.40 Cabinet X-Ray Systems
- 21 CFR 1030.10 Microwave Ovens
- 21 CFR 1040.10 Lasers and Laser Systems
- 21 CFR 1040.11 Specific Purpose Laser Products
- 21 CFR 1040.20 Sunlamps and Sunlamp Products

Diagnostic x-ray inspection and testing is conducted under Compliance Program 7386.001. Products and manufacturers subject to standards contained in 21 CFR 1020 – 1050, but are not listed above, will be subject to inspection or test on a for-cause basis only at the direction of CDRH.

The body of this program contains basic instructions for inspection, field test and administrative/enforcement activities applicable to all electronic products. Inspection and field test checklists, and additional considerations and instructions for specific products, such as laser, sunlamp, cabinet x-ray, television and microwave oven products, are covered in ATTACHMENTS B - F.

Medical devices that emit electronic product radiation are subject to EPRC requirements as well as Medical Device provisions of the Act and related regulations. Medical device inspection and enforcement activities described in Compliance Program 7382.845, Inspection of Medical Device Manufacturers, may be conducted jointly with this program at CDRH and district discretion. Examples of radiation-emitting medical devices include medical laser and sunlamp products, which could be covered by a joint EPRC/medical device inspection.

PART II – PROGRAM/IMPLEMENTATION

A. OBJECTIVES

This is a continuing, non-statistical compliance program intended:

1. To evaluate an electronic product manufacturer's quality control testing program for its ability to ensure such product compliance and radiation safety.

2. To identify certified electronic products which fail to comply with the requirements of applicable performance standards

3. To obtain correction of deficient quality control testing programs and noncompliant products identified by initiating appropriate administrative/regulatory action.

4. To provide guidance to manufacturers regarding compliance with the laws and regulations administered by FDA.

B. PROGRAM MANAGEMENT INSTRUCTIONS

1. Planning Instructions

   a. The role of the individual investigator and field radiological health specialists is a critical factor for the effective implementation of this program. Field specialists such as Electro-Optics Specialists (EOS) and Regional Radiological Health Representatives have been specifically trained in general EPRC requirements and may have specialized training in one or more performance standards.

      Only individuals trained in EPRC requirements should perform these inspections and field tests. Contact CDRH/OCER Electronic Products Branch (HFZ-240) and DFI (HFC-130) should the need for expertise, not otherwise available in the District, become apparent. At the discretion of CDRH and the district, radiological health specialists may be used to accompany a medical device investigator to conduct joint EPRC/medical device inspections. If an individual has training in both EPRC and medical device inspections, a single individual may conduct both portions of the inspection.

   b. Field radiological health specialists, their particular area of expertise, physical location and primary geographical areas of responsibility are listed in Part VI of this program.

   c. Based on the resources in the current FY workplan, field radiological health specialists will develop assignments for their organization. The assignments will be reviewed by his or her supervisor, entered into FACTS and transmitted to the affected field staff, Districts, HFC-l32 and HFZ-240. Workplans should include district inspections, field tests, and known CDRH assignments. The establishment inventory and guidance from CDRH should be used to determine inspection and field test locations.

2. Pre-announcement of Inspections
   Pre-announcement of EPRC inspections conducted under this compliance program is not mandatory, although it is recommended to facilitate the inspection. Pre-announcement ensures the firm is producing electronic products for the US market on the day of inspection, gives the firm time to collect all necessary procedures and records, and ensures appropriate individuals are available during the inspection. Section 537 of the Act permits inspection of any manufacturer for good cause, grounds for which may include introduction of any noncompliant product into US commerce, failure to comply with EPRC reporting requirements, or for purposes of suspected problems with a manufacturer's quality control testing program and product conformance with performance standards.

   Inspections of radiation-emitting medical device manufacturers must be pre-announced if the inspection will cover medical device Quality Systems Regulation compliance. Refer to instructions provided in the Guide to Inspections of Quality Systems, August 1999, and IOM Section 5.2.1.1, Pre-Announcements.

3. Pre-announcement of Field Tests
   Schedule an appointment with the user prior to the field test. Tell the user that the purpose of the visit is to conduct a survey of an electronic product to determine compliance with FDA's Federal radiation safety performance standards.

   Request that persons familiar with the operation of the electronic product to be tested be available to assist in the operation of the equipment.

4. Inspections and Field Test Priorities
   Inspections and field testing of electronic product manufacturers should be prioritized using the following criteria:

   a. Manufacturers and products posing a potential risk to public health or with great public health impact. High-risk products may be identified by additional product-specific guidance provided in Attachments B – F, direction provided from CDRH, level of radiation emissions accessible to the public or volume of products on the US market.

   b. Manufacturers or products with known compliance problems discovered through field testing, report review, complaints or other reason.

   c. New manufacturers that have not yet been inspected

   d. Products incorporating technology new to the US market or a major change in existing product.

5. Resource Instructions

   a. Field personnel may require personal radiation monitors, such as thermal luminescent dosimeter badges, when performing tests under this program. Dosimeters must be worn when performing inspections of cabinet x-ray manufacturers, cabinet x-ray field tests,

and other products that can emit x radiation. These monitors are available from the Winchester Engineering and Analytical Center (WEAC) Radiation Safety Officer. Part VI of this program contains the current list of contacts for WEAC.

b. Field personnel are responsible for contacting OCER and OSEL to arrange to have their radiation measurement equipment re-calibrated annually. Any personnel that do not have the appropriate radiation meters may request that equipment be loaned by another district or by CDRH, if available.

   CDRH will be phasing out calibration services currently provided for a number of instruments in the field, and alternate sources of equipment maintenance and calibration services will be identified. CDRH will assist in identifying sources for these services, and will maintain an inventory of equipment that may be available for use by field staff on loan.

PART III - INSPECTIONAL

A. OPERATIONS

1. Inspectional Strategy

   The purpose of electronic product manufacturer inspections is to evaluate the firm's quality control testing program to ensure product compliance with applicable performance standards and radiation safety. The inspection should also verify that EPRC requirements for reporting and recordkeeping are met by the firm.

2. Electronic Product Radiation Control Inspection

   a. Items to cover

      i. The firm's product(s) comply with the applicable requirements of the standard to the extent that:
         - The product has the applicable performance features, labels, and instructions for operation, maintenance and service
         - The product emissions are properly characterized. If appropriate, request to make measurements during the inspection using available FDA or manufacturer instruments to confirm emission specifications are below any established limits. Otherwise, witness the measurements performed by the manufacturer to confirm.
         - The brochures, catalogs and other promotional material contain any required warnings or label reproductions

      ii. The firm has procedures and documents for control of the manufacturing process appropriate to the product type and production volume including:
         - Stock and inventory control
         - Bills of materials
         - Control drawings and procedures that are authenticated and current
         - Incoming inspection, criteria for acceptance/rejection, and segregation of accepted from rejected parts
         - Disposition of rejected parts
         - Finished goods storage and inventory

      iii. The firm has quality control testing procedures and records to cover:
         - In-production tests to verify product compliance during production
         - Final test and inspection of finished products
         - Maintenance and calibration of test equipment

      iv. The firm maintains records required by the electronic product radiation control regulations:
         - Distribution to first purchasers or distributors
         - Safety related complaints, inquiries
         - Real or alleged injuries
         - Remedial actions taken for reports of non-compliant products, complaints, injuries
         - Reports submitted to CDRH

Specific product inspection and field test checklists or forms, if available, are included in ATTACHMENTS B – F. These checklists should be used in conjunction with the above guidance to record inspection and test observations.

b. Records to collect
   i. Organization chart identifying key individuals responsible for product design, manufacturing and quality control
   ii. Copies of testing procedures and where possible photographic evidence showing that testing does not ensure product safety or compliance with applicable standards
   iii. Samples of violative labels
   iv. Copies of manuals, in part or whole, that fail to contain required materials
   v. Copies of brochures and catalogs that fail to contain required warning or label reproductions
   vi. Distribution records for any violative products

c. Foreign inspections
   All foreign inspections should be conducted using this guide, and any special instructions contained in the inspection assignment. The failure of any foreign manufacturer to comply with these requirements may result in detention upon entry.

   Foreign inspections are subject to scheduling and time constraints as several manufacturers will be inspected in a single trip. Early planning is critical to conducting foreign inspections. Firms inspected must be notified as early as possible to ensure the firm will be producing for the US on the day of inspection, to give the firm time to collect all necessary procedures and records, prepare translations of needed documents, and make arrangements to have a translator available if needed.

   Any investigator with appropriate training may conduct foreign EPRC or joint EPRC/medical device inspections. For example, field specialists such as Electro Optics Specialists (EOS) and Regional Radiological Health Representatives have been trained in general EPRC requirements and may have specialized training in one or more performance standards.

d. Medical Device Inspections
   Radiation-emitting medical devices are subject to both electronic product radiation control requirements and medical device requirements including the Quality System, Medical Device Reporting (MDR), Medical device Tracking, Corrections and Removal, and Registration and Listing regulations.

   Based on district concurrence, a joint EPRC/medical device inspection covering the firm's compliance with both sets of requirements may be conducted under this compliance program and Compliance Program 7382.845 for Inspection of Medical Device Manufacturers.
   - The EPRC portion of the inspection should follow the instructions provided specifically in this program to determine the firm's compliance with electronic product radiation control requirements for reporting and recordkeeping,

certification to applicable performance standards, and a quality control testing program that ensures product compliance and radiation safety. Report EPRC time under the appropriate PAC identified in this program.

- The medical device portion of the inspection should follow instructions provided in the medical device inspection compliance program to assess the firm's quality system. Manufacturers of devices subject to radiation safety performance standards contained in 21 CFR Parts 1020 – 1050 should include in their device master and history records those procedures and records demonstrating compliance with the applicable standard, self-certification (21 CFR 1010), and reporting (21CFR 1002 – 1005). Report medical device time under the appropriate medical device PAC identified in Compliance Program 7382.845.

e. For-Cause Directed inspections
For-cause inspections are conducted in response to specific information that raises questions, concerns, or problems associated with the electronic product. Information can come from a variety of sources including:

- Sample analysis results
- Prior inspectional observations
- Questionable information in product reports
- Reports of injuries related to the firm's products
- Consumer or trade complaints about the firm.

For cause inspections are usually initiated at the request of CDRH. For-cause inspections will generally follow instructions provided in this compliance program, with additional questions and issues to cover provided in the assignment.

f. Inspectional Observations Review
Review inspectional observations with the most responsible individual and other technical experts at the firm prior to concluding the inspection. Record EPRC observations on the Form FDA-483. This compliance program provides guidance concerning severity of violations observed to identify major deficiencies. Deficiencies should be noted on Form FDA-483 in order of descending importance (i.e. most serious first). If both EPRC and medical device observations are noted, they should be grouped separately on the form.

The district has discretion to offer annotation of the FDA 483 for an EPRC inspection, if the investigator and firm believe annotation will facilitate the inspection process. An offer to annotate the FDA 483 should be extended for all joint EPRC/medical device inspections. When a FDA 483 is annotated, it should be done in accordance with the IOM Chapter 5 (Section 5.2.3).

The following statement should be included on each FDA 483:

> "This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations and do not represent a final Agency determination regarding your compliance. If you have an

objection regarding an observation, or have implemented, or plan to implement, corrective actions in response to an observation, you may discuss the objection or action with FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above."

For all medical device inspections the FDA 483 should contain the following additional statement:

"The observations noted in this form FDA 483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self audits to identify and correct any and all violations of the quality system requirements."

3. Electronic Product Radiation Control Field Tests

Field tests are examinations of installed electronic products and may be conducted at trade shows, manufacturing facilities or other sites where products are in use. Field tests assess the individual product's compliance with applicable performance standard requirements alone. It can not be expected that there will be staff on site with expert knowledge of the product being field tested or that it will be possible to evaluate all aspects of product compliance.

a. Items to cover:
   i. Product emissions are properly characterized. If possible, confirm by direct measurement using FDA or available instrumentation on-site documenting all maintenance and calibration information. At a minimum, document claimed product emissions based on product labeling review.
   ii. Product incorporates required performance features
   iii. Product displays the labels with required contents

   If the product becomes damaged during a field test, the owner, investigator, and supervisor should complete the appropriate sections of the form FDA 2766 entitled, Claim for Damages to an Electronic Product. Instructions for completion are on the back of the form, which is available from the FDA Forms Catalog (see FDA intranet home page under "forms" section).

b. Records to collect:

   i. Purchase information documenting the manufacturer and distributor of the product
   ii. Supporting documents or photographic evidence for questionable items, including noncompliant user and service manuals, inadequate protective housing, lack of interlocks, or lack of required labeling
   iii. Copy of promotional literature to show product specifications and intended use
   iv. Samples of violative labels
   v. Copies of manuals (or manual sections) that fail to contain required materials

c. Field test observations review

Review field test observations with the most responsible individual at the location and with other appropriate staff after completing the field test. Deficiencies should be noted in order of descending importance (i.e. most serious first) on the field test record form. If a field test is conducted as part of an inspection, field test results should be noted on the FDA-483 along with inspectional observations.

Share observations by providing a copy of the FDA- 483 and/or field test checklist or form.

Indicate that FDA will follow up with the manufacturer and take action to correct deficiencies, as appropriate. In the event of a Class A hazard, recommend the product should not be used until corrected. This compliance program provides guidance concerning severity of violations observed to identify major deficiencies in ATTACHMENTS A – F.

4. Investigations:
   Investigations are to be made to determine whether a suspected firm is in fact a manufacturer of one or more electronic products. The investigation may be initiated in preparation for a possible inspection, as a result of trade complaints, or from discovery via the Internet or printed materials of promotion of products that may not comply with EPRC requirements.

5. Physical and Documentary Samples:
   Physical samples of products are generally not collected under this compliance program. Samples are not required to support a letter issued to the firm or further action to include program disapproval or legal action. However, samples can be useful to support inspectional observations to demonstrate inadequacy of the quality control testing program or product noncompliance. The investigator should consult district management and CDRH to determine whether collecting physical samples would support any subsequent letter or action initiated. Documentary samples may be collected when collecting an actual physical sample is not practical and the evidence is necessary to support inspectional observations.

   Collect samples according to procedures defined in the Investigations Operations Manual, Chapter 4, and coordinate any sample collection activity with CDRH and WEAC to ensure proper procedures are followed and chain of custody is observed to maintain sample integrity.

PART IV - ANALYTICAL

No laboratory testing will be done under this program. CDRH or WEAC testing may be required on special assignments under Compliance Program for Lab Testing CP 7386.006 or as indicated in Part III.A.5 of this program.

PART V - REGULATORY/ADMINISTRATIVE FOLLOW-UP

A. REGULATORY PHILOSOPHY AND STRATEGY

CDRH is generally responsible for the final review of inspections and field tests made under this program and for the issuance of letters resulting from inspections and field tests performed by field radiological health staff. Exceptions where the district has direct reference authority are noted below under section C, Regulatory Action. The intent of this program is to follow up on problems that pose a radiation safety hazard or are a flagrant violation of EPRC requirements.

Violations of EPRC requirements may include:

- Failure to comply with an applicable performance standard
- Failure to establish and conduct an adequate quality control testing program
- Failure to submit required reports, including initial, model change, annual or accidental radiation occurrence reports

Appropriate regulatory or administrative actions include issuance of a notification of defect or non-compliance letter (warning or untitled letter), requiring repurchase, repair or replacement of product under an approved corrective action plan, or imposition of civil penalties and/or injunction. Appropriate follow-up actions should be determined by CDRH or in consultation with CDRH to ensure consistency in how EPRC requirements are enforced.

CDRH has classified several potential items of non-compliance that might be observed during an inspection or field test and classified those items in terms of health hazard and regulatory action. Tables are provided in Attachments A – F to provide guidance for use during the inspection or field test, while preparing FDA-483 and EIR or field test reports, and in classifying the inspection or field test and recommending follow-up.

B. DISTRICT RESPONSIBILITIES

1. Reporting inspection and test findings

   a. Inspection reports
   Provide a copy of the completed inspection and test record used during the inspection along with the Establishment Inspection Report (EIR) and exhibits. Refer to the IOM for EIR formats, and clearly indicate the scope of the inspection in the EIR. Document any corrections performed during the inspection or corrections promised with the timeframe for completion.

   b. Field test reports
   Provide a copy of the completed field test record along with a summary of findings.

2. Recommending Action
   A table of violations and their health and safety risk as well as the nature of the regulatory response has been provided for each product area.

   a. Hazard Class for Non-Compliance

Class A, B, C, and D refer to the hazard class of the observations, related to the severity of the threat to health and safety posed by a particular non-compliant product or practice.

- Class A: Conditions that pose an immediate radiation hazard to health and safety. Notify CDRH/OCER contacts identified in Part VI of this program immediately to discuss appropriate action to stop production or product use until corrective action has been taken. Consider contacting State Health Department or other local contacts to assist in addressing problems with product use, if warranted.

- Class B: Conditions that include radiation safety defects or items of noncompliance with the standard which, without corrective action, could pose a radiation hazard if the non-compliance or defect is not addressed.

- Class C: Labeling or user information fails to comply with a standard.

- Class D: No problems found.

b. Regulatory Response to Non-Compliance
The designations of a violation as Major, Minor, or Concern refer to the level of regulatory response required to correct deficiencies.

- Major: Non-compliance with a standard that always warrants regulatory action such as a warning letter.

- Minor: Non-compliance with a standard about which a manufacturer should be informed but is not severe enough to warrant a warning letter.

- Concern: Non-compliance which is not severe enough to mention unless also informing a manufacturer about a Major or Minor item.

c. Inspection Classification
Based on inspectional findings, the district will classify the inspection as OAI, VAI or NAI for further action.

If any major EPRC deficiencies exist, the district is expected to classify the inspection as OAI and recommend further regulatory action. Examples of findings that would result in an OAI classification include:

- Total failure to establish a quality control testing program capable of ensuring radiation safety of the product or compliance with applicable performance standards.

- Any single observation of a major deficiency listed in the specific product non-compliance tables contained in Attachments A – F of this program

- Several observations consisting of minor deficiencies listed in Attachments A – F of this program

The inspection may be classified VAI for a limited number of minor deficiencies listed in Attachments A – F and further regulatory action will be pursued at the discretion of the district and CDRH.

If it is determined that the EPRC deficiencies are of a quantity and type to conclude there is minimal probability that the firm will produce unsafe or noncompliant products, the inspection will be classified NAI and Form FDA-483 will serve to inform the firm of any objectionable findings. Deficiencies identified as violations of concern will generally not require additional follow-up but should be discussed with the firm.

Consult CDRH if additional guidance is required to classify inspection and test observations. If the inspection also covered firm compliance with medical device Quality Systems requirements, Compliance Program 7382.845, Part V, Quality System/GMP Regulatory/Administrative Follow-Up, should be consulted for appropriate regulatory and administrative follow-up.

C. REGULATORY ACTION

In determining appropriate regulatory action based on inspection and test findings, the district and CDRH should consider the significance of the product, the firm's history, whether the problem is widespread and continuing. Actions which may be considered include notification of noncompliance letters (warning and untitled letters), product repurchase, repair or replacement (recall), civil penalties and injunctions, and seizures (for radiation-emitting medical devices).

1. Notification of noncompliance letters (Warning and Untitled Letters)
   The Electronic Product Radiation Control provisions of the Federal Food Drug and Cosmetic Act (Section 535) and related regulations (21 CFR 1003) require the Agency to notify manufacturers in writing when product noncompliance with a standard is found. Manufacturers may also be advised in writing of a failure to comply with reporting and recordkeeping requirements (21 CFR 1002.31). A table classifying the severity of items of noncompliance with reporting and recordkeeping, and performance standard requirements is included in Attachments A – F.

   Issuance of all letters should follow Chapter 4 of the Regulatory Procedures Manual (RPM) http://www.fda.gov/ora/compliance_ref/rpm/. Consult the Office of Enforcement's (OE) Warning Letter page on ORA's intranet for current instructions for obtaining Office of Chief Counsel (OCC) clearance and for current approved Warning Letter templates. Letter templates must be used to satisfy Agency notification requirements in 21 CFR 1003.11. Where approved OCC templates are not available, consult CDRH for the current version of letter templates.

   Districts have DIRECT REFERENCE AUTHORITY for EPRC letters in certain areas which are described in Chapter 4 of the RPM. For example, districts have direct reference authority to issue sunlamp product warning and untitled letters, to grant exemption from notification, and approve manufacturer corrective action plans, which are further described in Attachment C of this program. CDRH is available for consult in assessing product noncompliance or

developing regulatory and enforcement strategy.

For the majority of cases, where districts DO NOT have direct reference authority to issue EPRC letters, forward the report with exhibits and recommended action to CDRH for review and follow-up. CDRH will copy the accomplishing district on any letters issued and consult on regulatory and enforcement strategy when needed.

a. Major Notification of Noncompliance Letter (Warning Letter)
This letter notifies the firm of major items of noncompliance and requires the firm to further notify purchasers and recall products. The firm is required to address all items in the letter, and submit a corrective action plan for CDRH approval.

Issue a major notification (warning) letter when the violation of the standard requires further regulatory action.
- All major violations must be addressed in a warning letter.
- Firms and products with several minor violations may also be issued a major notification letter, depending on the public health significance of the violation(s) and the number of products involved.
- Violations of concern may also be included in a major notification (warning) letter, but would not warrant issuance of a major notification (warning) letter on their own merit.

The firm's quality control testing program may be also be disapproved upon issuance of a major notification letter, when the Agency believes that the manufacturer's quality control and testing program is not following good manufacturing practices. A program disapproval orders the manufacturer to cease certification of products (i.e. stop production and testing) until the program disapproval is rescinded, and places the firm's products on automatic import detention without prior examination, under authority of Section 534(h) of the Act and 21 CFR1010.2 of the regulations. A program disapproval may be issued only by CDRH.

b. Minor Notification of Noncompliance Letter (Untitled Letter)
This letter notifies the firm of minor items of noncompliance and exempts the firm from further notifying purchasers and recalling products. The firm is instructed to address all items in the letter and make appropriate corrections for future production.

Issue a minor notification (untitled) letter when the violation of the standard does not justify further regulatory action at the time.
- Firms and products with a limited number of minor violations may be issued a minor notification letter, depending on the public health significance of the violation(s) and the number of products involved.
- Violations of concern may also be included in an untitled letter, but would not warrant issuance of an untitled letter on their own merit.

2. Repurchase, Repair, or Replacement of Electronic Products (Recall)
The Electronic Product Radiation Control provisions of the Federal Food Drug and Cosmetic

Act (Section 535) and related regulations (21 CFR 1004) also provide for manufacturer repurchase, repair or replacement of the noncompliant electronic products.

Every major notification of noncompliance letter issued as a result of a major violation or several minor violations requires manufacturer repurchase, repair or replacement of the affected electronic products at no cost to the purchaser. The firm is required to address all items in the letter, and submit a corrective action plan for CDRH approval. Refer to RPM Chapter 7, Attachment E for approval of manufacturer's corrective action plans.

3. Refutation or Exemption from Notification or Correction Requests
   Manufacturers can refute the noncompliance or be granted an exemption, by making a written request to CDRH. The exemption can be granted upon request by the manufacturer or by the Agency at its own initiative, and must show that the noncompliance does not create a significant risk of injury.

   Within 15 days after notification of the noncompliance/defect by FDA, a manufacturer may refute the alleged noncompliance under 21 CFR 1003.11(a)(3) or request an exemption from purchaser notification and correction as specified under 21 CFR 1003.30. If a manufacturer refutes the alleged noncompliance, or requests an exemption, the evidence presented by the manufacturer is evaluated by CDRH before granting or denying the request for exemption or responding to the refutation. Refer to RPM Chapter 7, Attachment E for information on responding to exemption requests and refutations.

4. Timeframes for action
   Immediately notify CDRH and State and local health authorities (through RRHR) for any Class A hazard.

   For all inspections and tests that may require issuance of a letter, the EIR should be provided to CDRH or the district compliance officer to allow sufficient time to review, draft, and secure approval for the letter. Timeframes for clearance of letters are provided in Chapter 4 of the RPM.

5. Civil Penalties/Injunctions
   Civil penalties should be recommended for violations of Subchapter C of the Act after other actions have failed to achieve compliance, or for knowing and willful violations. More severe civil penalty assessments may be sought under Section 303(f). See CPG Sec. 390.300 and RPM Chapter 6, Civil Penalties - Electronic Product Radiation Control. Informal consultation with the Center at an early stage in the development of a regulatory action is encouraged in order to facilitate timely implementation of the action; contact Electronic Products Branch Chief or Lead CSO at (240) 276-3332.

   If an establishment has a continuing pattern of significant deviations in spite of past warnings, injunction will usually be the recommended action of choice. If a serious health hazard exists, the recommendation should include a request for a temporary restraining order (TRO) to prevent the distribution of products that have been manufactured under the violative conditions documented by the inspection report per the instructions in Chapter 6 of

the RPM. Civil penalties and injunctions may be recommended concurrently.

6. Detention/Seizure
   Use administrative detention and recommend seizure of a defective or noncompliant radiation-emitting medical device if all three conditions below apply:
   - There is a Class A health hazard
   - The owner/operator refuses to remove the product from service or returns the product to use before the Class A hazard is corrected
   - The EPRC provisions are ineffective in achieving timely correction by the manufacturer

   Informal consultation with the Center at an early stage in the development of a regulatory action is encouraged; contact Electronic Products Branch Chief or Lead CSO at (240) 276-3332.

D. FEDERAL/STATE RELATIONS

Some states have Radiation Control Programs within the State Health Department or Department of Environmental Health, which may have adopted portions of the EPRC requirements into their radiation safety regulations.

Districts should use all reasonable means available to encourage voluntary conformance of products with the performance standard regardless of the date of manufacture. It is recommended that the districts coordinate regulatory activity with appropriate state representatives through the RRHR and DFSR, particularly where local authority may assist in achieving correction of a deficiency. This may be particularly useful to address issues related to product use where the State may have regulatory authority, which extends beyond FDA authority to regulate the design, production or manufacture of the product.

E. MEDICAL DEVICE REGULATORY/ADMINISTRATIVE FOLLOW-UP

Regulatory follow-up for joint EPRC/quality systems inspections can be handled separately or in combination at the discretion of the district and CDRH. Refer to Part V in Compliance Program 7382.845, Quality System/GMP Regulatory/Administrative Follow-Up, for guidance on regulatory actions related to radiation-emitting medical devices. Enforcement actions on radiation emitting medical device firms, which also include EPRC violations, require CDRH concurrence before implementation by the field. Contact CDRH for consultation when both EPRC and quality systems violations are noted during an inspection or field test.

PART VI - REFERENCES, ATTACHMENTS AND PROGRAM CONTACTS

A. REFERENCES

1. Law
   Federal Food, Drug, and Cosmetic Act, As Amended
   Electronic Product Radiation Control Provisions (formerly known as the Radiation Control for Health and Safety Act of 1968, Public Law 90-602, 0ctober 18, 1968)
   http://www.fda.gov/opacom/laws/fdcact/fdctoc.htm

2. Regulations
   21 CFR 1000 – 1005, General Requirements for All Electronic Products which Emit Radiation
   http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPartFrom=1000&CFRPartTo=1005

   21 CFR 1010, Performance Standards for Electronic Products: General
   http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=1010

   21 CFR 1020 – 1050, Specific Performance Standards for Electronic Products
   http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPartFrom=1020&CFRPartTo=1050

3. Regulatory Procedures Manual (RPM)
   http://www.fda.gov/ora/compliance_ref/rpm/default.htm

4. Investigations Operations Manual (IOM) - Chapter 5
   http://www.fda.gov/ora/inspect_ref/iom/default.htm

5. FDA Web Sites

   FDA home page
   http://www.fda.gov

   ORA home page
   http://www.fda.gov/ora/

   CDRH home page
   http://www.fda.gov/cdrh/

   Field Accomplishments and Compliance Tracking System (FACTS)
   (visit ORA's home page, then click the FACTS icon.)

   Electronic Product Radiation Control home page
   http://www.fda.gov/cdrh/radhealth

Product Code Classification Database (searchable)
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/pcdsimplesearch.cfm

Good Guidance Practices Database (searchable)
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfggp/search.cfm

B. ATTACHMENTS

1. Attachment A – Classification table for reporting and quality control testing program Non-Compliant Items (common to all EPRC inspections and field tests)

2. Attachment B – Specific Instructions for Laser Product Inspections and Tests

3. Attachment C – Specific Instructions for Sunlamp Product Inspections and Tests

4. Attachment D – Specific Instructions for Cabinet X-Ray Product Inspections and Tests

5. Attachment E – Specific Instructions for Television Product Inspections and Tests

6. Attachment F – Specific Instructions for Microwave Oven Product Inspections and Tests

C. PROGRAM CONTACTS

Center for Devices and Radiological Health

Office of Communication, Education and Radiation Programs, Division of Mammography Quality and Radiation Programs (DMQRP)

Contact for support in planning and executing inspections and field tests, classification of items of non-compliance, and for interpretation and current policy on EPRC requirements. Send all inspection and test reports to Chief, Electronic Products Branch, FDA/CDRH Office of Communication, Education and Radiation Programs (HFZ-240), 1350 Piccard Drive, Rockville, MD 20850.

Name	Phone	Email	Mail Stop	Position/Expertise
Sean Boyd	(240) 276-3287	sean.boyd@fda.hhs.gov	HFZ-240	Chief, Diagnostic Devices Branch
Dr. Helen Barr	(240) 276-3275	helen.barr@fda.hhs.gov	HFZ-240	Director, DMQRP
Thomas Ohlhaber	(240) 276-3274	thomas.ohlhaber@fda.hhs.gov	HFZ-240	Deputy Director, DMQRP
Jerome Dennis	(240) 276-3330	jerome.dennis@fda.hhs.gov	HFZ-240	Consumer Safety Officer, laser expert
Daniel Hewett	(240) 276-3268	daniel.hewett@fda.hhs.gov	HFZ-240	Consumer Safety Officer, laser products
Dan Kassiday	(240) 276-3280	daniel.kassiday@fda.hhs.gov	HFZ-240	Engineer, cabinet, industrial, analytical, security x-ray products

George Kraus	(240) 276-3298	george.kraus@fda.hhs.gov	HFZ-240	Consumer Safety Officer, TV and microwave oven products, imports
Frank Mackison	(240) 276-3264	frank.mackison@fda.hhs.gov	HFZ-240	Consumer Safety Officer, laser products
L. Dale Smith	(240) 276-3295	l.smith@fda.hhs.gov	HFZ-240	Consumer Safety Officer, laser light show products
Cory Tylka	(240) 276-3257	corinne.tylka@fda.hhs.gov	HFZ-240	Consumer Safety Officer, medical laser products
Varsha Savalia	(240) 276-3324	varsha.savalia@fda.hhs.gov	HFZ-240	Consumer Safety Officer, sunlamp and UV and laser products

Office of Science and Engineering Laboratories

Contact for assistance with identifying appropriate instrumentation for use in measuring electronic product radiation emissions.

Name	Phone	Email	Mail Stop	Position
Robert Faaland	(301) 827-4683	robert.faaland@fda.hhs.gov	HFZ-130	Engineer, laser expert
Sharon Miller	(301) 827-4692	sharona.miller@fda.hhs.gov	HFZ-130	Engineer, UV expert
Mary Walker	(301) 796-2558	mary.walker@fda.hhs.gov	TBD	X-ray instrumentation and calibration

Office of Regulatory Affairs

Field Regional Radiological Health Representatives

Name	Phone	Email	Mail Stop	Position
Mike Leal	(508) 793-0422	michael.leal@fda.hhs.gov	HFR-NE2570	NE RRHR
Tom Trout	(615) 366-7817	ralph.trout@fda.hhs.gov	HFR-SE300	SE RRHR
Rachel Evans	(312) 596-6518	rachel.evans@fda.hhs.gov	HFR-CE25	CE RRHR
Scotty Hargrave	(214) 253-4930	scotty.hargrave@fda.hhs.gov	HFR-SW19	SW RRHR
Suzie Kent	(208) 334-1054	suzie.kent@fda.hhs.gov	HFR-PA3505	PA RRHR

Field Electro-Optics Specialists and laser product contacts

Name	Phone	Email	Mail Stop	Position
Emir Galevi	(781) 729-5700 x724	emir.galevi@fda.hhs.gov	HFR-NE480	Engineer, WEAC
Leo Lagrotte	(813) 228-2671 x35	leo.lagrotte@fda.hhs.gov	HFR-SE2585	Electro-Optics Specialist, SER
James E. Frye	(513) 684-2700 x149	james.frye@fda.hhs.gov	HFR-CE400	Electro-Optics Specialist, CER
Don Leeseberg	(210) 541-9450	don.leeseberg@fda.hhs.gov	HFR-SW1545	Consumer Safety Officer, SWR
Gary L. Zahaek	(408) 291-7548 x103	gary.zaharek@fda.hhs.gov	HFR-PA1530	Electro-Optics Specialist, PAR

Frank J. Eng	(408) 291-7548 x105	frank.eng@fda.hhs.gov	HFR-PA1530	Electro-Optics Specialist, PAR

Winchester Engineering and Analytical Center contacts

Name	**Phone**	**Email**	**Mail Stop**	**Position**
John Marzilli	(781) 729-5700 x749	john.marzilli@fda.hhs.gov	HFR-NE400	WEAC Director
Jim Cherniak	(781) 729-5700	james.cherniack@fda.hhs.gov	HFR-NE400	Radiation Safety Officer
Vacant	Vacant	Vacant	HFR-NE400	Engineering Branch Director, WEAC
Jane Driscoll	(781) 729-5700 x716	jane.driscoll@fda.hhs.gov	HFR-NE480	Metrology Supervisor
Joe Matrisciano	(781) 729-5700 x736	joseph.matrisciano@fda.hhs.gov	HFR-NE480	Engineering Supervisor

Headquarters contacts

Name	Phone	Email	Mail Stop	Position
April Kidd	(301) 827-2913	april.kidd@fda.hhs.gov	HFC-150	ORO, DFSR

Classification table for reporting and quality control testing program Non-Compliant Items

The following items are common to all EPRC inspections and field tests, and may be cited for any product subject to the below reporting or certification requirements. Products subject to reporting are listed in Table 1 of 1002.1, and certification requirements are applicable to all products subject to a performance standard.

Reporting requirements			
1002.1	No product report	Minor	Class B
1002.11	No supplemental report	Minor	Class B
1002.13	No annual report	Minor	Class B
1002.2	No accidental radiation occurrence report	Minor	Class B
Certification requirements			
1010.2	No certification label	Minor	Class B
1010.2	Inadequate or lack of testing program	Major	Class A
1010.2	Incomplete testing---program exists but lacks record	Minor	Class B
1010.2	Incomplete testing with minor deficiencies	Concern	Class C
1010.2	Reference to DHEW or BRH	Concern	Class C
1010.3	No identification label	Concern	Class C
1010.3	Coded or abbreviated date	Minor	Class B
1010.3	Month & year in serial number on non-consumer product	Concern	Class C
1010.3	No manufacturer address	Concern	Class C
1010.3	Incomplete address	Concern	Class C

Specific Instructions for Laser Product Inspections and Tests

Background

The Laser Products Performance Standard (the standard), promulgated in August 1976, was designed to protect the public from unnecessary radiation hazards associated with the use of these products. The radiation emitted from these laser products can pose varying degrees of hazards depending upon the type, magnitude, and accessibility of the radiation and upon the particular functions or operations they perform. The standard was last amended in 1985. Since then, the CDRH has intended to harmonize the requirements of the standard with those of the international standard IEC 60825-1: 2001. As an interim step the CDRH published its Laser Notice 50 in 2001 stating that it would not object to compliance with specified requirements of the international standards in lieu of comparable requirements of the CDRH standard.

Specific Instructions

High-risk laser products and their manufacturers should be inspected or tested as a priority. Examples of high-risk laser products and manufacturers include:

- Class IIIb and IV medical lasers (e.g. surgical)
- Class IIIb and IV industrial lasers used in material processing
- Class IIIb and IV lasers used in law enforcement or military applications
- Manufacturers with known or suspected problems based on previous inspection, field tests or complaints
- New manufacturers not yet inspected
- Manufacturers introducing new technology to the US market
- Manufacturers with a large potion of the US market share for any laser product. Class I low risk laser products, such as optical disk drives or laser printers, should not be inspected or tested.

Electro-optics specialists have been specifically trained in general EPRC requirements and also have specialized training in the laser product performance standards. EOS's should perform these inspections and field tests, and may train additional field staff or accompany a medical device investigator to conduct joint EPRC/medical device inspections. If an EOS has training in both EPRC and QSIT inspections, a single EOS may conduct both portions of the inspection.

CDRH is responsible for review of laser manufacturer inspection and product field test observations and initiating administrative or regulatory follow-up.

References

Frequently Asked Questions about Lasers.

http://www.fda.gov/cdrh/radhealth/products/laserfaq.html

Performance Standard-Lasers and Products Incorporating Lasers
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?FR=1040.10

Performance Standard-Specific Laser Products (Includes Display, Survey, and Medical Laser Products)
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?FR=1040.11

Laser Compliance Guide
http://www.fda.gov/cdrh/radhlth/pdf/lasgde01.pdf

Reporting Guide-Radiation Safety Product Report for Laser Products
http://www.fda.gov/cdrh/radhlth/pdf/lasrpt0p.pdf

Reporting Guide-Radiation Safety Product Report for Laser Light Shows/Displays
http://www.fda.gov/cdrh/radhlth/pdf/llsrpt01.pdf

Laser Quality Control Guide
http://www.fda.gov/cdrh/radhlth/pdf/lasgdeqc.pdf

Refer to the laser products main page for guidance documents and additional information:
http://www.fda.gov/cdrh/radhealth/products/lasers.html.

Laser Product Codes

Translation of 2-Digit Code	Product Name	Product Code		CFR	Definition
Other Laser Products	Automotive Accessory, Automobile or Transport Vehicle, Laser	95	RDV	1040.10	A laser product or product containing a laser that is an automotive or other transport vehicle accessory.
Other Laser Products	General Purpose Laser Products, Non-Medical	95	RDW	1040.10	Product, laser, general, emit beam; A laser or product containing a laser that is intended for general purpose use with no medical claims.
Other Laser Products	Other	95	RZZ	Unk	A laser or product containing a laser for which its intended use is not previously defined.
Laser Light Show/Display Products	Low-Power Laser Light Show Projector	95	RDZ	1040.10; 1040.11	Product, laser, demo, projector, laser light show/display, Class IIIa/3R and lower; Laser projection system that incorporates a laser having a maximum radiation output of less than 5mw.
Laser Light Show/Display Products	High-Power Laser Light Show Projector (Output > 5mW)	95	REA	1040.10; 1040.11	Product, laser, demo, projector, laser light show/display, Class IIIb/IV/3B/4; Laser projection system that incorporates a laser having a maximum radiation output power greater than 5mw.
Laser Light Show/Display Products	High-Power Laser Light Show	95	REB	1040.10; 1040.11	Product, laser, demo, laser light show/display, Class IIIb/IV/3B/4; Laser light show or demonstration using laser projection equipment having an output that exceeds 5mW
Laser Light Show/Display Products	Laser Video Projector	95	REC	1040.10; 1040.11	Product, laser, demo, projector, display, video; A laser used in conjunction or incorporated in a video display system or projector.
Laser Light Show/Display Products	Laser Advertising Display System	95	RED	1040.10; 1040.11	Product, laser, demo, system, display, advertising
Laser Light Show/Display Products	Laser Visual Display - Display Retinal Image, Non-Medical Display Product	95	REE	1040.10; 1040.11	Product, laser, display, system, images, direct to retina
Laser Light Show/Display Products	Other	95	RZZ	Unk	Other laser products used in light shows or demonstrations that are not otherwise defined.
Medical Laser Products	Laser, Ophthalmic	86	HQF	1040.10; 1040.11	
Medical Laser Products	Laser Instrument, Surgical, Powered	79	GEX	1040.10; 1040.11	
Medical Laser Products	Laser, Surgical, Gynecologic	85	HHR	1040.10; 1040.11	
Medical Laser Products	Laser, ENT Microsurgical Carbon-Dioxide	77	EWG	1040.10; 1040.11	
Medical Laser Products	Photocoagulator and Accessories	86	HQB	1040.10; 1040.11	
Medical Laser Products	Lens, Surgical, Laser, Accessory, Ophthalmic Laser	86	LQJ	1040.10; 1040.11	

Medical Laser Products	Laser, Neurosurgical	84	LKW	1040.10; 1040.11	
Medical Laser Products	Laser, Neurosurgical, Argon	84	LLF	1040.10; 1040.11	
Medical Laser Products	Laser, Neodymium: YAG, Pulmonary Surgery	73	LLO	1040.10; 1040.11	
Medical Laser Products	Laser, Neodymium: YAG, for Gynecologic Use	85	LLW	1040.10; 1040.11	
Medical Laser Products	Laser, Neodymium: YAG, Ophthalmic for Uses Other than Posterior Capsulotomy and Cutting Pupil	86	LXS	1040.10; 1040.11	
Medical Laser Products	Laser, Neodymium: YAG, Ophthalmic for Uses Other than Posterior Capsulotomy	86	LOI	1040.10; 1040.11	
Medical Laser Products	Laser, Neodymium: YAG, Optical, Pumped Parametric Oscillator	86	MVQ	1040.10; 1040.11	
Medical Laser Products	Laser, Microsurgical Argon, for Use in Otology	77	LXR	1040.10; 1040.11	
Medical Laser Products	Laser, Microsurgical Argon, for Uses Other Than Otology	77	LMS	1040.10; 1040.11	
Medical Laser Products	Laser for Gastro-Urology Use	78	LNK	1040.10; 1040.11	
Medical Laser Products	Device, Angioplasty, Laser, Coronary	74	LPC	1040.10; 1040.11	
Medical Laser Products	Device, Laser Peripheral Angioplasty	74	LWX	1040.10; 1040.11	
Medical Laser Products	Catheter, Coronary Laser Myoplasty	74	MGC	1040.10; 1040.11	
Medical Laser Products	System, Laser, Transmyocardial	74	MNO	1040.10; 1040.11	

	Revascularization				
Medical Laser Products	Instrument, Visual Field, Laser	86	HPJ	1040.10; 1040.11	
Medical Laser Products	Laser for Pain Therapy	84	LLP	1040.10; 1040.11	
Medical Laser Products	Laser, System, Excimer	86	LZS	1040.10; 1040.11	
Medical Laser Products	Laser, Dental	76	LYB	1040.10; 1040.11	
Medical Laser Products	Photodynamic Therapy (PDT)	79	MVF	1040.10; 1040.11	
Medical Laser Products	Photodynamic Therapy (PDT), Fiber Optic	79	MVG	1040.10; 1040.11	
Medical Laser Products	Laser, Fluorescence Caries Detection	76	NBL	1040.10; 1040.11	
Medical Laser Products	Laser for Wound Healing	79	LXU	1040.10; 1040.11	
Medical Laser Products	Ophthalmoscope, Laser Scanner	86	MYC	1040.10; 1040.11	
Medical Laser Products	Laser, Phacolysis	86	MXO	1040.10; 1040.11	
Medical Laser Products	Caries Detector, Laser, Light, Transmission	76	NTK	1040.10; 1040.11	
Medical Laser Products	Other	95	RZZ	Unk	A laser or laser product intended for medical treatment or other uses on humans, not previously defined.
Other Demonstration Laser Products	Laser Science Education Products	95	REI	1040.10; 1040.11	Product, laser, demo, education, illustrate science principles
Other Demonstration Laser Products	Other	95	RZZ	Unk	Laser products used for demonstrations that are not otherwise defined.
Toy, Novelty, Play Laser Products	Toy, Novelty, Play Laser Product	95	REJ	1040.10; 1040.11	Product, laser, toy/novelty
Research, Scientific, Laboratory Laser Products	Research Laser, Scientific, Laboratory Laser Products	95	REK	1040.10	Product, laser, research/laboratory; A laser under development in and of itself. A laser used for conducting research during development of new data or to improve a process would not be considered a research laser although it is being used in research.
Research, Scientific, Laboratory Laser Products	Guide-Star Laser System, Research, Scientific, Laboratory Laser Products	95	REL	1040.10	Product, laser, adaptive-optics telescope focusing accessory, generate artificial star; A laser used for alignment of optical telescopes.
Research, Scientific, Laboratory Laser Products	Spectroscopy Instrument, Laser, Research, Scientific,	95	REM	1040.10	Product, laser, instrument, spectroscopy; An instrument incorporating a laser for spectroscopic testing or examination with no medical claims.

	Laboratory Laser Products				
Research, Scientific, Laboratory Laser Products	Particle-Size Measuring Instrument, Laser, Scientific, Laboratory Laser Products	95	REN	1040.10	Product, laser, instrument, particle size measurement; An instrument or system incorporating a laser for determining the size or number of particles of particles a test sample.
Research, Scientific, Laboratory Laser Products	Analytical Measuring and Detection, Research, Scientific, Laboratory Laser Products	95	REO	1040.10	Product, laser, instrument, analyze/detect chemical species
Research, Scientific, Laboratory Laser Products	Other	95	RZZ	Unk	Laser products used in scientific and laboratory applications that are not otherwise defined.
Surveying, Leveling, Alignment Laser Products	Surveying Laser Product, Leveling, Alignment Laser Products	95	REP	1040.10	Product, laser, surveying, instrument, determine position by measurement of angles
Surveying, Leveling, Alignment Laser Products	Ranging (Geodimeter) Laser Products	95	REQ	1040.10	Product, laser, ranging, instrument, measure distance by time-of-flight
Surveying, Leveling, Alignment Laser Products	Alignment Laser Product, Surveying, Leveling, Alignment Laser Products	95	RER	1040.10; 1040.11	Product, laser, alignment, aid positioning or adjusting parts in relation to each other
Surveying, Leveling, Alignment Laser Products	Laser Pointer, Surveying, Leveling, Alignment Laser Products	95	RES	1040.10; 1040.11	Product, laser, pointer, indicate point of interest; A laser product intended specifically to define a spot or surface for drawing attention to a viewer.
Surveying, Leveling, Alignment Laser Products	Laser Target Designator, Surveying, Leveling, Alignment Laser Products	95	RET	1040.10	Product, laser, target designator; An optical devices, using a visible beam of laser light that permits the alignment of a gun, cannon or rocket system with its target.
Surveying, Leveling, Alignment Laser Products	Laser Aiming Product, Visible, Surveying, Leveling, Alignment Laser Products	95	REU	1040.10; 1040.11	Product, laser, aiming, visible, attached to weapon; An optical devices, using a visible beam of laser light that permits the alignment of a gun, cannon or rocket system with its target

Surveying, Leveling, Alignment Laser Products	Laser Aiming Product, Non-Visible, Surveying, Leveling, Alignment Laser Products	95	REV	1040.10; 1040.11	Product, laser, aiming, infrared, attached to weapon, viewed with night-vision equipment; An optical devices, using an invisible beam of laser light that permits the alignment of a gun, cannon or rocket system with its target.
Surveying, Leveling, Alignment Laser Products	Other	95	RZZ	Unk	Other laser products used for surveying, leveling and alignment that are not otherwise defined.
Safety, Security, Surveillance Laser Products	IR Laser Illuminator with Alignment Aid/Night Vision System, Safety, Security, Surveillance Laser Products	95	REW	1040.10; 1040.11	Product, laser, infrared, illuminator with alignment aid, viewed through night-vision equipment
Safety, Security, Surveillance Laser Products	IR Laser Illuminator Only/Night Vision System, Safety, Security, Surveillance Laser Products	95	REX	1040.10	Product, laser, infrared, illuminator only, viewed through night-vision equipment
Safety, Security, Surveillance Laser Products	Collision-Avoidance Laser System, Safety, Security, Surveillance Laser Products	95	REY	1040.10	Product, laser, infrared, collision-avoidance system
Safety, Security, Surveillance Laser Products	Laser Traffic Signal, Safety, Security, Surveillance Laser Products	95	REZ	1040.10	Product, laser, traffic signal/control
Safety, Security, Surveillance Laser Products	Laser Automotive Lighting & Signals, Safety, Security, Surveillance Laser Products	95	RFA	1040.10	Product, laser, automotive, lighting/signals
Safety, Security, Surveillance Laser Products	IR Laser Intrusion Detection/Securit y System, Safety, Security, Surveillance Laser Products	95	RFB	1040.10	Product, laser, infrared, intrusion detecting, security system
Safety, Security, Surveillance Laser Products	Laser Radar (Lidar) or Speed Measurement, Safety, Security, Surveillance Laser Products	95	RFC	1040.10	Product, laser, infrared, Doppler or time-of-flight speed measurement

Safety, Security, Surveillance Laser Products	Other	95	RZZ	Unk	Laser products used in safety, security, surveillance applications not otherwise defined
Safety, Security, Surveillance Laser Products	Laser Weapon (Military or Police), Safety, Security, Surveillance Laser Products	95	RFD	1040.10	Product, laser, weapon (military/police)
Material Processing Laser Products	Laser Cutter, Material Processing Laser Products	95	RFE	1040.10	A high power laser intended to cut or drill a variety of materials in an industrial or commercial environment.
Material Processing Laser Products	Laser Welder, Material Processing Laser Products	95	RFF	1040.10	A high power laser intended to weld (join) materials in an industrial or commercial environment.
Material Processing Laser Products	Microelectronic Mask or Chip Checking/Repair, Material Processing Laser Products	95	RFG	1040.10	A laser intended to inspect and/or repair microelectronic components in an industrial or commercial environment.
Material Processing Laser Products	UV Curing, Material Processing Laser Products	95	RFH	1040.10	An ultraviolet wavelength laser used to illuminate a material of a certain composition such that the laser "cures" or causes a chemical reaction to change the material in a desired fashion with no medical claims. Typical materials are adhesives, plastics, potting compounds, etc.
Material Processing Laser Products	Print Industry Plate Maker, Material Processing Laser Products	95	RFI	1040.10	A laser intended to etch, engrave or otherwise create printer's plates used in an industrial or commercial environment.
Material Processing Laser Products	Process Control, Material Processing Laser Products	95	RFJ	1040.10	A laser used for inspection, counting, or other application intended to monitor a part of the manufacturing process in an industrial or commercial environment. Often incorporated in an automated process system.
Material Processing Laser Products	Laser Vision, Material Processing	95	RFK	1040.10	A laser used for positioning, focusing, inspection, counting, or other application in an industrial or commercial environment. Often incorporated in an automated assembly line system.
Material Processing Laser Products	Laser Micrometer, Material Processing	95	RFL	1040.10	A laser used in high precision dimensional measurements in materials processing.
Material Processing Laser Products	Laser-Based Material Positioning System	95	RFM	1040.10	A laser used in precision positioning of materials in manufacturing in an industrial or commercial environment.
Material Processing Laser Products	Other	95	RZZ	Unk	A laser used in materials processing not otherwise defined.

Material Processing Laser Products	General Industrial Use Material Processing Laser Products	95	RZN	1040.10	A laser used in industrial manufacturing or materials processing not otherwise defined.
Data Measurement, Transmit, Control Laser Products	Fiber Optic Communication and Data Transfer, Laser	95	RFN	1040.10	A laser used in fiber optic communications to transmit data and information.
Data Measurement, Transmit, Control Laser Products	IR Free-Space Data Transmit/Control, Laser	95	RFO	1040.10	A laser used in free space (open air) communications to transmit data and information.
Data Measurement, Transmit, Control Laser Products	Remote Controller, Laser, Data Measurement, Transmit	95	RFP	1040.10	A laser used to transmit signals and/or information in order to operate equipment or machinery remotely.
Data Measurement, Transmit, Control Laser Products	Interferometric Position Measuring Product, Laser	95	RFQ	1040.10	A laser used as an interferometer for high precision positioning and/or measurements.
Data Measurement, Transmit, Control Laser Products	Product Incorporating Certified Class 1 Laser Data Measurement, Transmit, Control	95	RFR	1040.10	A data measurement, data transmission, or remote control product that incorporates a certified Class 1 laser.
Data Measurement, Transmit, Control Laser Products	Other	95	RZZ	Unk	A data measurement, data transmission, or remote control product that incorporates a laser other than a certified Class 1 laser.
Utility/Peripheral Laser Products	Reprographics, Laser, Utility/Peripheral Laser Products	95	RFS	1040.10	A reprographics machine that incorporates a laser utilized to expose internal sensitive components or materials for photocopying text and graphics.
Utility/Peripheral Laser Products	Laser Printer, Utility/Peripheral Laser Products	95	RFT	1040.10	A printing machine that incorporates a laser utilized in printing images on paper with no medical claims.
Utility/Peripheral Laser Products	Laser FAX Machine, Utility/Peripheral Laser Products	95	RFU	1040.10	A printing machine that incorporates a laser utilized in printing facsimiles of images on paper.
Utility/Peripheral Laser Products	CD, CD-ROM Player, Laser Utility/Peripheral Laser Products	95	RFV	1040.10	A CD or CD-ROM player that utilizes a laser to read data on the compact disc.
Utility/Peripheral Laser Products	DVD, DVD-ROM Player, Laser Utility/Peripheral Laser Products	95	RFW	1040.10	A DVD or DVD-ROM player that utilizes a laser to read data on the digitally recorded video disc.

Utility/Peripheral Laser Products	CD-R, CD-RW Recorder, Utility/Peripheral Laser Products	95	RFX	1040.10	A CD-R or CD-RW recorder machine that utilizes a laser to read and/or write data on the compact disc.
Utility/Peripheral Laser Products	DVD-R, DVD+R, DVD-RAM, DVD+RW, DVD-RW Recorder, Utility/Peripheral Laser Products	95	RFY	1040.10	A DVD recorder machine that utilizes a laser to read and write or read, write, and erase data on a digitally recorded video disc in any of the data formats: DVD-R, DVD+R, DVD-RAM, DVD-RW, or DVD+RW.
Utility/Peripheral Laser Products	UPC Reader (Bar Code Reader), Utility/Peripheral Laser Products	95	RFZ	1040.10	A laser used to scan across a bar code to identify the product. Bar code readers can be hand-held accessories, under-counter components incorporated in store check-out systems, or laser scanner systems incorporated in assembly lines used for identification and inventory purposes in manufacturing facilities, warehouses and storage facilities, or other consumer, industrial, health care, or commercial locations.
Utility/Peripheral Laser Products	Home/Office Machine Incorporating Utility/Peripheral Laser	95	RZP	1040.10	A laser utilized in the home or office environment not otherwise defined.
Utility/Peripheral Laser Products	Product Incorporating Certified Class 1 Data Utility/Peripheral Laser Products	95	RGA	1040.10	A utility/peripheral laser product that incorporates a certified Class 1 laser.
Utility/Peripheral Laser Products	Other	95	RZZ	Unk	A utility/peripheral laser product that incorporates a laser other than a certified Class 1 laser.
In Vitro and Other Medical Laser Products	Veterinary Laser, In Vitro and Other Medical Laser Products	95	RGB	1040.10; 1040.11	A laser used for treatment of animals other than human
In Vitro and Other Medical Laser Products	Separator, Automated, Blood Cell, Diagnostic	81	GKT	1040.10	
In Vitro and Other Medical Laser Products	Automated Differential Cell Counter	81	GKZ	1040.10	
In Vitro and Other Medical Laser Products	Cell Particle Counter (Automated)	81	GKL	1040.10	
In Vitro and Other Medical Laser Products	Urine Particle Counter	88	LKM	1040.10	
In Vitro and Other Medical Laser Products	System, Separation, Hematopoietic Stem Cell	81	MZK	1040.10	
In Vitro and Other Medical Laser Products	Test, Urea (Breath or Blood) for H. Pylori Test	83	MSQ	1040.10	

In Vitro and Other Medical Laser Products	Multipurpose System for In-vitro Coagulation	81	JPA	1040.10	
In Vitro and Other Medical Laser Products	System, Laser Assisted Hatching	85	MRX	1040.10; 1040.11	
In Vitro and Other Medical Laser Products	Sorter, Cell	81	KEX	1040.10	
In Vitro and Other Medical Laser Products	Separator, Semi-Automated, Blood Component	81	MYY	1040.10	
In Vitro and Other Medical Laser Products	Other	95	RZZ	Unk	A laser used for in vitro applications or other medical applications that do not expose patients to the laser radiation.
Positioning Medical Laser Products	X-Ray Field Indicator Light (Laser), Positioning Medical Laser Products	95	RGC	1020.30; 1040.10; 1040.11	A laser incorporated in a diagnostic x-ray system that is irradiated onto the film screen area indicating the x-radiation area. The beam is usually scanned to show a rectangular region for patient placement.
Positioning Medical Laser Products	Monitor, Patient Position, Light Beam	90	IWE	1040.10; 1040.11	
Positioning Medical Laser Products	Positioning Medical Laser Product	95	RZS	1040.10; 1040.11	A laser used for positioning in medical applications not otherwise defined.

Classification of Non-compliant Items

Performance requirements			
1040.10(d)	Classified in higher class	Minor, Concern	Class B, C
1040.10(d)	Classified in lower class	Major	Class A
1040.10(f)(1)	Protective housing allows unnecessary body access to Class IV or high IIIb radiation	Major	Class A
1040.10(f)(1)	Protective housing allows unnecessary straight line access to interior Class IV or high IIIb radiation With high risk of exposure (IV or IIIb product) With low risk of exposure (IV or IIIb product) With any risk of exposure (I, IIa, II, or IIIa product)	 Major Minor Major	 Class A Class B Class A
1040.10(f)(1)	Protective housing allows unnecessary body access to low Class IIIb or IIIa radiation In a Class IV or IIIb product In a Class I, IIa, II, or IIIa product	 Minor Major	 Class B Class A
1040.10(f)(1)	Protective housing allows necessary body access to Class IIIa or IIIa radiation In a Class IV or IIIb product In a Class I, IIa, II, or IIIa product	 Concern Minor	 Class C Class B
1040.10(f)(1)	Protective housing allows unnecessary body access to Class II radiation In a Class II product In a Class I product	 Concern Minor	 Class C Class B
1040.10(f)(2)	Safety interlocks absent when required	Major	Class A
1040.10(f)(2)	Single safety interlock when redundant required	Major	Class A
1040.10(f)(2)	Single component with multiple contacts when redundant required	Minor	Class B
1040.10(f)(2)	Defeatable safety interlocks lacks indication	Minor	Class B
1040.10(f)(2)	Defeatable safety interlocks fails to prevent replacement of protective housing during defeat	Minor	Class B
1040.10(f)(3)	No remote interlock connector	Major	Class A
1040.10(f)(4)	No key control	Major	Class A
1040.10(f)(4)	Key control removable when on	Major	Class A
1040.10(f)(5)	No emission indicator	Major	Class A
1040.10(f)(5)	No delay preceding radiation emission	Minor	Class B
1040.10(f)(5)	Shorter delay than required	Minor	Class B
1040.10(f)(5)	Remote control lacks emission indicator	Major	Class A
1040.10(f)(6)	Beam attenuator without approvable alternate	Major	Class A
1040.10(f)(6)	Beam attenuator with approvable alternate	Concern	Class C
1040.10(f)(8)	Viewing optics Hazardous Non-hazardous for viewing period	 Major Concern	 Class A Class C
1040.10(f)(9)	No scanning guards	Major	Class A
1040.10(f)(10	No manual reset	Major	Class A
1040.10(g)(1), (2), and (3)	Warning logotype None Classification too low Classification too high	 Major Major Minor, Concern	 Class B Class B Class B

1040.10(g)(4)	Warning logotype output information	Minor	Class B
1040.10(g)(5)	No aperture label	Minor	Class B
1040.10(g)(5)	Aperture label not in close proximity to aperture	Minor	Class B
1040.10(g)(5)	Aperture label wording incorrect	Concern	Class C
1040.10(g)(6), (7)	No protective housing labels	Minor	Class B
1040.10(g)(6), (7)	Protective housing placement inappropriate	Minor	Class B
1040.10(g)(6), (7)	Protective housing wording wrong	Concern	Class C
1040.10(g)(8)	Invisible radiation warning on labels	Minor	Class B
1040.10(g)(9), (10)	Label positioning and legibility	Minor	Class B
1040.10(h)(1)	User instructions (i) Promoting unsafe practices Inadequate instructions to avoid exposure (ii) Inadequate radiometric specifications (iii) Inadequate reproductions and locations (iv) Inadequate listing of controls Inadequate caution statement	 Major Minor Minor Minor Minor Concern	 Class A Class B Class B Class B Class B Class C
1040.10(h)(2)(i)	Reproduction of warning logotype not in catalogs	Minor	Class B
1040.10(h)(2)(ii)	Service information inadequate	Minor	Class B
Specific product requirements			
1040.11(a)(1)	Means to measure medical laser output None Inaccurate	 Major Major	 Class A Class A
1040.11(a)(2)	Inadequate calibration procedure/schedule	Major	Class A
1040.11(a)(3)	Aperture label	Minor	Class B
1040.11(b)	Excessive output on surveying lasers	Major	Class A
1040.11(c)	No variance for demonstration Class IIIb or Class IV lasers	Major	Class A

Sample Laser Product Inspection and Field Test Checklist

LASER PRODUCT TEST RECORD

MANUFACTURER_____ CLASS_____

MODEL_____ SERIAL NUMBER_____

Status of Unit Examined (Circle one): Prototype/Production unit

Status of Assembly (circle one): Complete/Incomplete

Manufactured Date:_____

A. Product Description: (Include basic configuration and size of product, reference to photos and/or diagrams, basic functions to be performed during operation and during maintenance.)

_____

_____

_____

_____

_____

_____

_____

_____

Product Report: Has the product been reported to CDRH?

Yes_____ No_____

If yes, what is the Accession Number? _____

Summary of Product Evaluation:

C. Certification/Identification Requirements. If possible, obtain a sample of each required label and attach it to this report. Otherwise, quote pertinent information, especially any noncompliant items.

1. Certification label (1010.2)

a. Is the label permanently affixed? Yes___ No___ ND___ NA___

b. Is the Label readily viewable? Yes___ No___ ND___ NA___

Location:_____

c. Is the label properly stated? Yes___ No___ ND___ NA___

(Note: Products under variance require modified certification labels 1010.4(d))

d. Remarks: _____

_____

2. Identification label (1010.3)

a. Is the label permanently affixed? Yes___ No___ ND___ NA___

b. Is the label readily viewable? Yes___ No___ ND___ NA___

Location: _____

c. Does the label contain the full name and address?

Yes___ No___ ND___ NA___

d. Does the label contain the place of manufacture (in full or in code)?

Yes___ No___ ND___ NA___

e. If coded, has CDRH been provided the code?

Yes___ No___ ND___ NA___

f. Are the month and year of manufacture stated in full?*

Yes___ No___ ND___ NA___

Month and year: _____

g. Remarks:_____

_____

*Note: Serialization is acceptable in lieu of month and year for consumer electronic products.

D. Special Purpose Products (1040.11)

1. Is the product a medical laser product?

Yes___ No___ ND___ NA___

Note: In inspecting manufacturers of not only medical laser products but also laser products that are medical devices, verify compliance with other applicable requirements including but not limited to current registration and listing, 510k market clearances, device master record or quality system, current complaint and service records, etc.

a. Does the product include a means of measurement of levels of radiation intended for irradiation of the human body?

Yes___ No___ ND___ NA___

b. How is this accomplished? Measure beam prior to delivery system and determine output levels via calibration constant _____;
Measure output of delivery system _____;
Other _____.

c. Indication: power _____; energy_____; time _____.

d. Type of indicator: energy/power select switch ___; "Test shot" display (remains constant until next best shot) ___; Real time display (displays level at all times) ___; Other ___.

e. If test shot is available only at initiation of procedure or if a select switch is used, does the product have an internal monitoring system capable of maintaining output levels to within ± 20% of displayed value?

Yes ___ No___

f. Is display analog ____; or digital ____? If digital, are there sufficient significant digits to allow ± 20% accuracy?

Yes ___ No ___

g. Is the total measurement error within ± 20% (see Attachment G)

Yes___ No___ ND___ NA___

h. Is there a laser aiming beam? Yes ___ No ___. Is there a means to measure the level of the aiming beam if the product is ophthalmic and the aiming beam may exceed 1 mW or if the product is not ophthalmic but the aiming beam may exceed 5 mW?

Yes ___ No ___

i. Remarks: _____

_____

2. Is the product a surveying, leveling, and alignment product?

Yes___ No___ ND___ NA___

a. Is access prevented for wavelengths of 400 nm to 710 nm to radiation power in excess of 5.0 mW for any duration greater than 3.8×10^{-4} seconds?

b. Is access prevented to radiation levels in excess of Class I limits for any other combination of emission Duration and wave length range?

Yes___ No___ ND___ NA___

c. Remarks: _____

_____

3. Is the product a demonstration laser product?

Yes___ No___ ND___ NA___

a. Does the product prevent human access to radiation in excess of the Class IIIa (3R) limit?

Yes___ No___ ND___ NA___

b. Remarks: _____

_____

E. Label Requirements. See instruction in paragraph B.

1. Warning logotypes* (1040.10(g)(1),(2),(3),(4),(5),(9), and (10)

a. Is the logotype the correct logotype?

Yes___ No___ ND___ NA___

b. Is the label properly worded for its class designation?

Yes___ No___ ND___ NA___

c. Does the label have the proper color?

Yes___ No___ ND___ NA___

d. Is the output information present and correct?

(Maximum output stated _____.) Yes___ No___ ND___ NA___

e. Is the media or wavelength information present and correct?

Yes___ No___ ND___ NA___

f. Is the label permanently affixed and clearly visible during operation, maintenance, and service?

Yes___ No___ ND___ NA___

g. Is the label positioned so as to make exposure unnecessary during reading?

Yes___ No___ ND___ NA___

Location: _____

h. Does the label include a warning for "invisible" or "invisible and/or visible" radiation?

Yes___ No___ ND___ NA___

i. Remarks: _____

_____

_____

Note: Warning labels in accordance with IEC 60825-1 including product classification are acceptable.

2. Aperture label (for Classes II, IIIa, IIIb, IV, 3R, 3B and 4) 1040.10(g)(5),(8),(9), and (10)

a. Is a label present and in proximity to each aperture?

Yes___ No___ ND___ NA___

b. Is the label properly worded? Yes___ No___ ND___ NA___

c. Is the label permanently affixed and clearly visible?

Yes___ No___ ND___ NA___

d. Is the label positioned so as to make exposure unnecessary during reading?

Yes___ No___ ND___ NA___

(Location: _____)

e. Does the label include a warning for "invisible" or "invisible and/or visible" radiation?

Yes___ No___ ND___ NA___

f. Remarks: _____

_____

_____

3. Noninterlocked protective housing label (1040.10(g)(6),(8),(9), and (10)

a. Are the labels on or near all appropriate panels or covers which are removed for operation, maintenance, or service?

Yes___ No___ ND___ NA___

b. Are all labels visible prior to removal of such portions of the protective housing?
Yes___ No___ ND___ NA___

c. Are all labels visible after opening?
Yes___ No___ ND___ NA___

d. Are all labels correctly worded? Yes___ No___ ND___ NA___

e. Are all labels permanently affixed and clearly visible?

Yes___ No___ ND___ NA___

f. Do all labels contain a warning for "invisible" or "invisible and/or visible" radiation?
Yes___ No___ ND___ NA___

g. Remarks: _____

_____

_____

4. Defeatably interlocked housing labels 1040.l0(g)(7),(8),(9), and (10)

a. Are labels provided for each defeatably interlocked panel or cover which is removed for operation, maintenance, or service?

Yes___ No___ ND___ NA___

b. Are all labels visible prior to interlock defeat?

Yes___ No___ ND___ NA___

c. Are all labels visible during interlock defeat?

Yes___ No___ ND___ NA___

d. Are all labels correctly worded?

Yes___ No___ ND___ NA___

e. Are all labels permanently affixed and clearly visible?

Yes___ No___ ND___ NA___

f. Do all labels contain a warning for "invisible" or invisible and/or visible" radiation?

Yes___ No___ ND___ NA___

g. Remarks: _____

_____

F. Performance Requirements (1040.l0(f)):

1. Protective Housing (1040.l0(f)(l))

a. Does the housing prevent access at all times to laser radiation above Class I not necessary for operation of the product?

Yes___ No___ ND___ NA___

b. Does the housing prevent access at all times to collateral optical radiation above Class I not necessary for operation of the product?

Yes___ No___ ND___ NA___

c. Has x-radiation been evaluated?

Yes___ No___ ND___ NA___

d. Does the housing prevent access to x-radiation levels in excess of 0.5 mR/hr at all times during operation of the product?

Yes___ No___ ND___ NA___

e. Remarks: _____

_____

2. Safety Interlocks (1040.10(f)(2)) (Complete for each interlock. Identify the portion of removable or displaceable housing and interlock described.)

a. Do operation or maintenance functions require moving portions of the housing which could allow access to radiation?

Yes___ No___ ND___ NA___

Describe: _____

_____

b. Class of radiation to which access could be gained?
Class _____.

c. Is a fail safe or multiple interlock required (including 1040.l(f)(2)(iii)?

Yes___ No___ ND___ NA___

Where? _____

_____

d. Are safety interlock(s) present? where?_____

1. TYPE: Microswitch____; Mercury switch____; male-female plug____; mechanical shutter____; other____.

Describe: _____

e. Method of limiting access: directly interrupts primary laser power____; interrupts primary laser power through relay, contactor, switching tube or transistor____; spoils the cavity____; shutter beam via solenoid____; other____.

f. Is there a multiple or fail safe interlock on each housing for which an interlock is required?

Yes___ No___ ND___ NA___

g. Is the interlock defeatable? Yes___ No___ ND___ NA___

h. Is there an indication of defeat? Yes___ No___ ND___ NA___

Describe: _____

i. Does the interlock preclude replacement of the housing while the interlock is defeated?

Yes___ No___ ND___ NA___

j. Are non-safety interlocks present? Where?_____

Yes___ No___ ND___ NA___

k. Remarks: _____

_____

3. Remote Interlock Connector (1040.l0(f)(3), Class IIIb or IV systems only)

a. Is a remote control connector present?

Yes___ No___ ND___ NA___

b. Type? Describe: _____

c. Is the voltage across the connector less than 130 volts RMS?

Yes___ No___ ND___ NA___

d. Is the access to laser and collateral radiation prevented when the terminals are not joined?

Yes___ No___ ND___ NA___

e. Method of operation: Directly interrupts laser power____; interrupts laser power through relay, etc.____; shutters beam or interrupts cavity____.

f. Does the emission delay reactivate when the remote control circuit is interrupted?

Yes___ No___ ND___ NA___

g. Must the emission be manually restarted following interruption via the remote interlock connector?

Yes___ No___ ND___ NA___

h. Remarks: _____

_____

4. Key Control (1040.10(f)(4), Class IIIb, IV, 3B, or 4 systems only)

a. Is a key control present? Yes___ No___ ND___ NA___

Describe: _____

_____

b. Is a key removable in the "on" position?

Yes___ No___ ND___ NA___

c. Is operation prevented when the key is removed?

Yes___ No___ ND___ NA___

d. How? _____

_____

e. Remarks: _____

_____

5. Beam Attenuator (1040.l0(f)(6), Class IIIb, IV, 3B or 4 systems only)

a. Is a beam attenuator present? Yes___ No___ ND___ NA___

b. Type: mechanically operated shutter____; electrically operated____; aperture cap or cover____; other____.

Describe: _____

_____

c. Is the attenuator permanently attached?

Yes___ No___ ND___ NA___

d. Does the attenuator prevent access by any part of the body to radiation in excess of Class I limits?

Yes___ No___ ND___ NA___

e. If there is no beam attenuator, has the manufacturer requested and obtained approval of an alternate means of safety?

Yes___ No___ ND___ NA___

f. Remarks: _____

_____

6. Emission Indicator (1040.10(f)(5), Class, IIIb, IV, 3B or 4 Systems only)

a. Is an emission indicator present on the laser product?

Yes___ No___ ND___ NA___

Where? _____

b. Type: tungsten lamp(s)____; neon lamp(s)____; LED(s)____; other____.

Describe: _____

_____

c. If the indicator is visible, is it visible through the protective eyewear that is normally supplied or recommended?

Yes___ No___ ND___ NA___

d. Can the indicator be viewed without exposure to radiation in excess of Class I limits?

Yes___ No___ ND___ NA___

e. Is there a delay between an indication of emission and the beginning of emission?
Yes___ No___ ND___ NA___

f. How is emission delay achieved? Thermal relay___; inherent in the lasing process___; delay circuit___; other___.

Describe: _____

_____

g. Length of delay? _____

h. Is the power source or operation control separable from the laser by greater than 2 meters when assembled for use?

Yes___ No___ ND___ NA___

i. If separated greater than 2 meters, is an emission indicator present on the energy source or controller?

Yes___ No___ ND___ NA___

Where? _____

j. Type: Tungsten lamp(s)___; neon lamp(s)___; LED(s)___; bell or buzzer___; meter or display___; mechanical flag___; other___.

Describe: _____

_____

k. Is there a delay between an indication of emission and the beginning of emission?
Yes___ No___ ND___ NA___

l. How is emission delay achieved? Thermal relay___; inherent in the lasing process___; delay circuit___; other___.

Describe: _____

_____

m. Length of delay? _____

n. Remarks: _____

_____

_____

6. Location of Controls (1040.10(f)(7))

a. Are the controls located so that exposure is unnecessary for operation or adjustments?
Yes___ No___ ND___ NA___

b. Remarks: _____

_____

_____

7. Viewing optics (1040.l0(f)(8))

a. Are viewing optics or viewports present?

Yes___ No___ ND___ NA___

b. Type: microscope___; telescope___; viewport___; display screen___; other___.

Describe: _____

_____

_____

c. Where? _____

_____

d. Do the viewing optics attenuate radiation at all times during operation or maintenance to levels less than Class I limits?

Yes___ No___ ND___ NA___

e. Do the viewing optics employ a shutter or variable attenuator?

Yes___ No___ ND___ NA___

f. Upon failure of the shutter of the variable attenuator is access to radiation levels greater than the Class I limits prevented?

Yes___ No___ ND___ NA___

g. Remarks: _____

_____

_____

8. Scanning Safeguard (1040.10(f)(9))

a. Is the radiation emitted by the product scanned?

Yes___ No___ ND___ NA___

b. Is the classification of the product based on the level of scanned radiation?

Yes___ No___ ND___ NA___

c. In the event of scan failure, is human access to laser radiation in excess of the product class prevented?

Yes___ No___ ND___ NA___

d. Remarks: _____

_____

9. Manual Reset Mechanism (1040.l0(f)(l0) Class IV laser systems)

Describe the operation of the Manual Reset. _____

_____

How is it achieved? (latching relay, etc.) _____

_____

10. Removable laser system (1040.10(c)(2))

a. Does the product incorporate a laser system?

Yes___ No___ ND___ NA___

b. Is the laser system removable?

Yes___ No___ ND___ NA___

c. If removable, is the laser system independently certified?

Yes___ No___ ND___ NA___

d. If not removable, specify how removability is prevented: hard wiring___; modified connector___; assembled internally from components___; other (specify).
_____

e. Remarks: _____

_____

_____

G. Laser Product Measurements

Model # _____ Serial # _____

Manufacturer's Claimed Classification: _____

Brief description of product: _____

_____

_____

Test Instrument(s) Used: _____

_____

Circle radiometric quantity tested and specify units below (Radiance (W cm^{-2} sr^{-1}), Radiant Energy (J), Power (W), etc.)

Measurement No.	Wavelength (nm)	Instrument reading, R (units _____)	Calibration factor, K (units _____)	Corrected value, R*K (units _____)

Calculations (as needed):

_____

_____

H. Results of FDA measurements: _____

I. Compliance with other requirements (e.g., conditions of a variance, labeling for medical devices, etc.)

_____

_____

_____

J. Information requirements (Directions: Complete this section only if the information and requirements are reviewed during the inspection).

1. User Information (1040.l0(h)(l))

a. Does the manual contain adequate instructions for assembly, operation, and maintenance? Yes___ No___ ND___ NA___

b. Does it contain clear warnings to avoid exposure?

Yes___ No___ ND___ NA___

c. Does it contain a statement of output parameters?

Yes___ No___ ND___ NA___

d. Does it contain legible reproductions of all labels and hazard warnings?

Yes___ No___ ND___ NA___

e. Does it include the corresponding position of each label on the product?

Yes___ No___ ND___ NA___

f. Does it contain listing of controls, adjustments, and procedures for operation and maintenance?

Yes___ No___ ND___ NA___

g. Does it contain a schedule of maintenance?

Yes___ No___ ND___ NA___

h. Does it contain the "Caution - use of controls..." warning?

Yes___ No___ ND___ NA___

i. Does it contain a compatibility statement (laser source or laser system not supplied with the product?

Yes___ No___ ND___ NA___

j. Does it contain a calibration schedule (medical laser product)?

Yes___ No___ ND___ NA___

k. Does it include a warning not to point the laser radiation at the audience (especially Class IIIa demonstration laser products)?

Yes___ No___ ND___ NA___

l. Does it include information to determine nominal hazard zone(class IV multi-axis workstations)?

Yes___ No___ ND___ NA___

m. Remarks: _____

_____

_____

2. Purchasing Information (1040.10(h)(2))

a. Are legible reproductions of the logotype required to be affixed to the product (including information required for positions 1, 2, and 3) contained in catalogues, specification sheets, and descriptive brochures?

Yes___ No___ ND___ NA___

3. Servicing Information (1040.l0(h)(2))

a. Are adequate instructions for service adjustments and service procedures available?

Yes___ No___ ND___ NA___

b. Are clear warnings and precautions to avoid possible exposure included?

Yes___ No___ ND___ NA___

c. Is a schedule of maintenance necessary to keep the product in compliance included?

Yes___ No___ ND___ NA___

d. Are controls and procedures which would he used by reasons other than the manufacturer or his agent to increase accessible emission levels listed?

Yes___ No___ ND___ NA___

e. Is a clear description of the locations of displaceable portions of the protective housing provided?

Yes___ No___ ND___ NA___

f. Do these instructions provide legible reproductions of required labels and hazard warnings?

Yes___ No___ ND___ NA___

g. Do these instructions include protective procedures for service personnel?
Yes___ No___ ND___ NA___

h. Remarks: _____

_____

_____

Specific Instructions for Sunlamp Product Inspections and Tests

Background

A sunlamp product is an electronic product designed to use one or more ultraviolet lamp(s) and is intended for irradiation of any part of the living human body by ultraviolet radiation within a specified range of wavelengths to induce skin tanning. The ultraviolet lamps, subject to the performance standard, produce radiation within a prescribed range of wavelengths and are intended for use in sunlamp products.

Sunlamp products include portable home units, table top models, tanning beds and tanning booths. These units may incorporate different types of fluorescent lamps, reflector spot (RS) or High Intensity Discharge (HID) with different levels of energy output and radiation at different wavelengths.

Since sunlamp products are radiation-emitting electronic products as defined by Section 531 of Subchapter C- Electronic Product Radiation Control (EPRC) formerly the Radiation Control for Health and Safety Act (RCHSA) and medical devices as defined by Section 201(h)(3) of the Federal Food, Drug, and Cosmetic Act (FFDCA, the Act), they are regulated under both laws.

Under authority of Section 534 of the (EPRC), a performance standard for sunlamp products and ultraviolet lamps intended for use in these products was promulgated effective May 7, 1980 (21 CFR 1040.20). The standard was intended to reduce sunlamp related injuries by reducing unnecessary exposure and overexposure to sunlamp radiation by: (1) limiting shorter wavelength emissions that are not necessary and pose unreasonable risk, (2) providing for adequate warning label and user instructions containing safety information, and (3) requiring special lamp bases, protective eyewear, timers, and controls to help users limit the duration and amount of exposure.

This performance standard was promulgated when the common sunlamp product was a table-top, home portable unit incorporating one or two RS lamps having a large part of their radiation output in the wavelength range of 260 to 320 nanometers (UVB). In 1979-80, a new-wave of sunlamp products came onto the market. These products, commonly referred to as Tanning Booths, usually measured 3'x3'x7' and contained one or two fluorescent ultraviolet lamps in each corner. These products also had relatively high UVB output.

Around early 1983, another product in the shape of a bed and/or canopy entered the market with fluorescent lamps that emit radiation mainly in the 320-400 nanometer range (UVA), with usually less than 5% in-the UVB range. This type of product requires longer exposure times to achieve its intended purpose and the risk of chronic sunburn is reduced relative to the older type of products. Most manufacturers requested variance under 21 CFR 1010.4 to equip the products with timers which would allow exposure in excess of ten minutes. Since the products usually required 30 minutes to achieve their intended result, the variances were granted with two conditions: (1) the maximum timer interval shall not exceed the maximum recommended exposure time specified in the required product label, and (2) the UVB to UVA ratio shall not exceed .05 (no more than 5% UVB). The manufacturers are required to specify the variance number and effective date on the product).

Some of these products incorporate High Intensity Discharge (HID) lamps. These lamps are usually used for facial tanning, although some whole body exposure systems use such lamps exclusively. In

most cases, however, these lamps are used in conjunction with ultraviolet fluorescent lamps. The HID lamps are much smaller than fluorescent lamps, (usually about 1/2" in diameter by 3" in length) and they usually incorporate an outer, clear, glass envelope.

On September 6, 1985, amendments to the performance standard were published and became effective in September 8, 1986. The purpose of the amendments is to accommodate new products employing design concepts significantly different from those for which the original standard was developed. Also, FDA experience in applying the original standard indicated that some requirements were either inappropriate for or not applicable to some products. The amendments are intended to establish a standard that is appropriate for the present technology of tanning and new sunlamp product designs. This revised program offers guidance for testing products against the original standard or revised standard, as appropriate.

Specific Instructions

Some electro-optics specialists, x-ray auditors and other radiological health specialists have been trained in general EPRC requirements and also may have specialized training in the sunlamp product performance standards. Only trained individuals should perform these inspections and field tests and may train additional field staff or accompany a medical device investigator to conduct joint EPRC/medical device inspections. If an EOS has training in both EPRC and QSIT inspections, a single EOS may conduct both portions of the inspection.

The District Offices have the authority (delegated under 21 CFR 5.37 and 5.89) to make declarations of noncompliance and/or defect for sunlamp products. The field also has the authority to approve sunlamp manufacturer corrective action plans under 21 CFR 1004 and to grant exemptions (from notification and product repair) in accordance with 21 CFR 1003.31. Consult CDRH for assistance in determining appropriate enforcement action or other support. A copy of any letter issued to a manufacturer must be sent to HFZ-240.

References

Sunlamp Products, Performance Standard – 21 CFR 1040.20.
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?FR=1040.20

Quality Control Guide for Sunlamp Products. (Publication; FDA 84-8234)
http://www.fda.gov/cdrh/radhlth/pdf/SUNQCG.pdf

Policy on Warning Label Required on Sunlamp Products (6/25/85)
http://www.fda.gov/cdrh/radhlth/pdf/sunpol01.pdf

Policy on Maximum Timer Interval and Exposure Schedule for Sunlamp Products (8/21/86)
http://www.fda.gov/cdrh/radhlth/pdf/sunpol01.pdf

Policy on Lamp Compatibility (9/2/86).
http://www.fda.gov/cdrh/radhlth/pdf/sunpollc.pdf

Sunlamp Products Reporting Guide, (dated September, 1995).

http://www.fda.gov/cdrh/radhlth/pdf/sunrpt0p.pdf

Refer to the sunlamp products main page for additional information:
http://www.fda.gov/cdrh/radhealth/products/sunlamps.html

Sunlamp Product Codes

Translation of 2-Digit Code	Product Name	Product Code		CFR	Definition
Sunlamp Products (Certified)	Suntan Booth	79	LEJ	1040.20	
Sunlamp Products (Certified)	Suntan Bed, Sunlamp Products (Certified), Non-Medical	95	REF	1040.20	A bed or other platform that is designed to incorporate one or more ultraviolet lamps and intended for irradiation of any part of the human body, by ultraviolet radiation with wavelengths in air between 200 and 400 nanometers, to induce skin tanning with no medical claims.
Sunlamp Products (Certified)	Suntan Lamp, Sunlamp Products (Certified), Non-Medical	95	REG	1040.20	A lamp that produces ultraviolet radiation in the wavelength range of 200 to 400 nanometers in air and that is intended for use in any sunlamp product or fixture with no medical claims.
Sunlamp Products (Certified)	Tabletop Sunlamp System (Certified), Non-Medical	95	REH	1040.20	A sunlamp system that sits on a table, primarily intended to tan the face by ultraviolet radiation with wavelengths in air between 200 and 400 nanometers with no medical claims.
Sunlamp Products (Certified)	Other	95	RZZ	Unk	Sunlamp product means any electronic product designed to incorporate one or more ultraviolet lamps and intended for irradiation of any part of the human body, by ultraviolet radiation with wavelengths in air between 200 and 400 nanometers, to induce skin tanning.

Classification of Non-compliant Items

Performance Requirements			
1040.20(c)(1)	Fails to comply with the irradiance ratio limits for UVC over UVB cannot exceed 0.003	Minor	Class B
1040.20(c)(2)(i)	Fails to incorporate a timer system with multiple timer settings adequate for recommended exposure time intervals	Major	Class A
1040.20(c)(2)(ii)	Maximum timer interval(s) is more than 3 times greater than the manufacturer's recommended maximum exposure time(s) as indicated on label	Major	Class A
1040.20(c)(2)(ii)	Maximum timer interval(s) is 2 – 3 times greater than the manufacturer's recommended maximum exposure time(s) as indicated on label	Minor	Class B
1040.20(c)(2)(ii)	Maximum timer interval(s) is less than 2 times greater than the manufacturer's recommended maximum exposure time(s) as indicated on label	Concern	Class C
1040.20(c)(2)(iii)	Maximum timer interval error > 30 percent	Major	Class A
1040.20(c)(2)(iii)	Maximum timer interval error > 20 and < 30 percent	Minor	Class B
1040.20(c)(2)(iii)	Maximum timer interval error > 10 and < 20 percent	Concern	Class C
1040.20(c)(2)(iv)	Timer automatically resets and causes radiation to resume.	Major	Class A
1040.20(c)(3)	Fails to incorporate a control for termination of radiation emission (at minimum a timer system)	Major	Class A
1040.20(c)(4)(i)	Fails to have protective eyewear	Minor	Class B
1040.20(c)(4)(ii)	Spectral transmittance of the protective eyewear exceeds a value of 0.001 over the wavelength UVC and UVB(200nm to 320nm)	Minor	Class B
1040.20(c)(4)(ii)	Spectral transmittance of the protective eyewear exceeds a value of 0.01 over the wavelength UVA (>320nm to 400nm)	Minor	Class B
1040.20(c)(4)(ii)	Spectral transmittance (>400nm) of protective eyewear does not allow user to clearly see to reset the timer	Minor	Class B
1040.20(c)(5)	UV lamp capable of insertion and operation in either the "single-contact medium screw" or the "double-contact medium screw" lamp holders.	Major	Class A
Label Requirements for Sunlamp Products			
1040.20(d)(1)(i)	Fails to have warning statement "Danger UV radiation…"	Minor	Class B
1040.20(d)(1)(ii)	Fails to have recommended exposure position(s)	Minor	Class B
1040.20(d)(1)(iii)	Fails to have directions for recommended exposure position(s) and warning other positions may result in overexposure	Minor	Class B
1040.20(d)(1)(iv)	Fails to have recommended exposure schedule	Minor	Class B
1040.20(d)(1)(v)	Fails to have time before expected results statement	Concern	Class C
1040.20(d)(1)(vi)	Fails to have ultraviolet lamp designation	Minor	Class B
Label Requirements for Ultraviolet Lamps			
1040.20(d)(2)(i)	Fails to have "Sunlamp-DANGER-Ultraviolet radiation. Follow Instructions"	Minor	Class B
1040.20(d)(2)(ii)	Fails to have model identification	Minor	Class B
1040.20(d)(2)(iii)	Fails to have "Use ONLY in fixture equipped with timer"	Minor	Class B
Label Specifications for Sunlamp Products and Ultraviolet Lamps			

1040.20(d)(3)(i)	Fails to be permanently affixed or inscribed on the exterior surface of sunlamp product when fully assembled for use so as to be legible and readily accessible to view by person being exposed immediately before use of product	Minor	Class B
1040.20(d)(3)(ii)	Fails to be permanently affixed or inscribed on the ultraviolet lamp so as to be legible or readily accessible to view	Minor	Class B
1040.20(d)(3)(iv)	Fails to have identification and certification labels on shelf package of ultraviolet lamps and coded mfr name and date of mfr on ultraviolet lamp	Minor	Class B
1040.20(d)(3)(v)	Labels contain statements or illustrations that are false or misleading, diminish the impact of the required statements, or are prohibited by this chapter.	Major	Class A
Instructions to be provided to users of Sunlamp Products			
1040.20(e)	Inadequate instructions for use to avoid or minimize potential injury provided to purchaser	Minor	Class B
1040.20(e)(1)(i)	Failed to have reproduction of "Danger Ultraviolet Radiation warning statement…"	Minor	Class B
1040.20(e)(1)(ii)	Failed to have a statement of the maximum number of users and warning that only that number of protective eyewear was provided	Concern	Class C
1040.20(e)(1)(iii)	Failed to have instructions on the proper operations of the product including function, use, and setting of the timer and other controls , and use of the protective eyewear	Minor	Class B
1040.20(e)(1)(iv)	Failed to have instructions determining the correct exposure time and schedule for persons according to skin type.	Minor	Class B
1040.20(e)(1)(v)	Failed to have instructions for obtaining repairs and recommended replacement components and accessories which are compatible with the product, including compatible protective eyewear, ultraviolet lamps, timers, reflectors, and filters, if installed or used as instructed would result in continued compliance with the standard.	Minor	Class B
1040.20(e)(2)(i)	User instructions for ultraviolet lamps not sold with sunlamp products failed to have a reproduction of the "Danger Ultraviolet Radiations…warning statement and the "Sunlamp-DANGER Ultraviolet radiation. Follow Instructions" and "Use ONLY in a fixture equipped with a timer" label	Minor	Class B
1040.20(e)(2)(ii)	User instructions for ultraviolet lamps not sold with sunlamp products failed to have a warning that instructions should be followed to avoid or minimize potential injury	Minor	Class B
1040.20(e)(2)(iii)	User instructions for ultraviolet lamps not sold with sunlamp products failed to have a clear identification by brand and model designation of all lamps models for which replacement lamps are promoted	Minor	Class B
Tests for Determination of Compliance			
1040.20(f)	Fail to account for all errors and statistical uncertainties in the process for changes in radiation emission or degradation in radiation safety with age of the product.	Minor	Class B

1040.20(f)	Fail to make measurements for certification under operational conditions as recommended by the manufacturer.	Minor	Class B
1040.20(f)	Fail to position measuring instrument at recommended exposure position and oriented to result in maximum detection of the radiation	Minor	Class B

Sample Sunlamp Product Inspection and Field Test Checklist

INSPECTIONAL FIELD TEST CHECKLIST REPORT FOR SUNLAMP PRODUCTS MANUFACTURED AFTER SEPTEMBER 8, 1986

(Including Pertinent Parts of the Regulation)

FACILITY NAME: _____

ADDRESS: _____

_____

PERSON INTERVIEWED: _____

TELEPHONE NUMBER _____

FIELD TEST DATE _____

WARNING LABEL [21 CFR 1040.20(d)(1)]

Accessible To View: Yes / No Legible From One Meter: Yes / No Exposure Position:Yes / No "DANGER" Statement:: Yes / No

If "NO" to any of the above,
Explain:_____

Exposure Schedule times: Minimum ____min. / Maximum ____min. Warning Label Location:_____

List All Lamp Types Designated On Unit Labeling:_____

CERTIFICATION LABEL [21 CFR 1040.20(d) & 21 CFR 1010.2]

Adequate Certification: Yes / No Written In English: Yes / No Legible: Yes / No

If "NO" to any of the above,
Explain:_____

IDENTIFICATION LABEL [21 CFR 1040.20(d) & 21 CFR 1010.3] (AS APPEARS ON LABEL)

Name & Address of Manufacturer:_____

Model #:_____ Serial #:_____ Date of Manufacture:_____

PROTECTIVE EYEWEAR [21 CFR 1040.20(C) (4)]

Maximum Number of Users for Sunlamp Product:_____

Number of pairs:_____ Model Type:_____
Manufacture:_____

Number of pairs:_____ Model Type:_____
Manufacture:_____

LAMPS IN UNIT [21 CFR 1040.20(d) (1) & (d) (2)] & LAMP COMPATIBLITY [21 CFR 1040.20 (e) 2 (iii)]

Total Number of Lamps in Unit:_____ Lamp Compatibility Information : YES / NO / N/A

Lamp Model Designation:_____ Number of Lamps: _____
Manufacture:_____

Lamp Model Designation:_____ Number of Lamps: _____
Manufacture:_____

Facilities Lamp Supplier(s) (name, address, fax & phone #):_____

TIMER [21 CFR 1040.20 (C)(2)]

Type of Timer: Digital / Electro-mechanical / Spring Wound / Token / Other:_____

Timer Capabilities:_____(Minimum Time) _____(Maximum Time) Timer Interval (i.e. 1min increments): _____

Timer Interval Compatible with Exposure Schedule: YES / NO, If "NO", Explain:_____

Timer Manufacturer Name and Address:_____

Timer Accuracy: 10%: _____min _____sec, 50%: _____min _____sec, 100%:_____min _____sec

(Note: Record Timer Accuracy in minutes and seconds for 10%, 50% and 100% of Maximum Timer Capability for the Sunlamp Product. Remote timers are acceptable provided all other requirements of (C)(2)/(3) are maintained.)

TERMINATION CONTROL [21 CFR 1040.20 (C)(3)]

Presence: YES / NO Description: Toggle / Push Pull / Push Button / Other:_____

How is exposure re-initiated:_____

USER INSTRUCTIONS [21 CFR 1040.20 (e) (1)] (i.e. owner manual / operator manual)

Provided by the Manufacturer: YES /NO, Available to Patrons: YES / NO, Contains Instructions To Determine Exposure Schedule and Skin Types: YES / NO, Contains Reproduction of "WARNING LABEL" :YES / NO, Contains Instructions for Obtaining Replacement

Parts and Repairs: YES / NO, If "NO" to any, Explain:_____

_____ _____

INSPECTING DISTRICT NAME OF PERSON AND TITLE

INSPECTIONAL CHECKLIST REPORT

FOR SUNLAMP PRODUCTS MANUFACTURED PRIOR TO SEPTEMBER 8, 1986
(Including Pertinent Parts of the Regulation)

Facility Name: _____ Person Interviewed _____

Address: _____ Telephone (_____) _____

_____ Field Test Date _____

Mfr. Name _____ Address: _____

Home District_____ CFN/FEI_____Product Type:_____

Model_____Serial Number Date_____ Manufactured _____ / _____ / _____

Lamps: UV-A_____UV-B _____HID _____Properly labeled _____Mfr/Model:_____

Max Timer Setting _____Gradations_____Consistent w/exposure schedule:_____

Timer Exceed Max. Recom. Exp._____Accuracy @ 10%_____ 50%_____ 100%_____

Type of Timer_____ (e.g. Token) Mfr. of Timer_____How can user terminate exposure? _____

How is exposure re-initiated? _____
Eyewear_____Sufficient #_____

Labeling visible w/eyewear ____ Eyewear Mfr. and Model_____

Certification Label: _____ (Va_____)Permanently affixed_____ Viewable_____

Location_____ Properly Worded____ Mfr. I.D. Label_____ Viewable_____

Full Name/Address_____ Date Mfrd._____ Place Mfrd._____

Warning Label: Readily Viewable_____ Location_____ Danger Statement _____

Lamp Type_____ Min. exposure distance_____ How measured _____Warning: Min. exposure distance_____

Warning: Protective Eyewear _____ Warning: Max. exposure time_____ Exposure Schedule _____

Time before results can be expected_____ Any misleading statements?_____

User's Instructions: Provided by the Mfr. _____ Available to patrons _____

Contains copy of warning label_____ Instructions for replacement parts _____ Statement of # of people/eyewear _____

Equipment Recommendations: User position indicated _____ Timer error less than 10% _____ Temperature Control _____

Electrical Safety_____ Mechanical Safety_____ Protection from Lamps_____ Access and Support _____

_____ _____

Name and Title Inspecting District

Specific Instructions for Cabinet X-Ray Product Inspections and Tests

Purpose

The Radiation Safety Performance Standard for Cabinet X-ray Systems [Title 21 CFR § 1020.40] (performance standard) was designed to protect the public and system operators from unnecessary radiation hazards associated with the use of cabinet x-ray systems. The performance standard sets an exposure emission limit of 0.5 milliRoentgen (mR) in one hour for radiation emitted from a cabinet x-ray system. Additional required safety features include interlocks, indicator lights, and warning labels. The performance standard applies to all cabinet x-ray systems manufactured or assembled on or after April 10, 1975. Requirements regarding x-ray systems designed primarily for the inspection of carry-on airline baggage apply to systems manufactured or assembled on or after April 25, 1974.

Specific Instructions

The potential risk from a cabinet x-ray system is dependent on the maximum power that can be delivered to the x-ray tube and the environment in which the system is used. A cabinet x-ray system that can operate at higher peak tube potential and tube current will present a greater potential risk when compared with a lower power cabinet x-ray system. The following is an example of how the use environment affects the potential risk: a cabinet x-ray system used for checking circuit board quality is integrated into an automated production line and very rarely approached by anyone poses a lower potential risk than a carry on baggage security x-ray system which is loaded by members of the public and always has an operator present in close proximity.

Follow the general guidance on inspection, investigation, and field test priorities provided in section II.B.3 above and use your discretion based on the preceding discussion of potential risk. An example inspection checklist of cabinet x-ray specific issues has been included. For further guidance on compliance with specific requirements of the performance standard see the Cabinet X-Ray Compliance Guide (see reference below).

Radiological Health Specialists have been specifically trained in general EPRC requirements and also have specialized training in the cabinet x-ray product performance standards. These specialists should perform cabinet x-ray inspections and field tests, and may train additional field staff or accompany a medical device investigator to conduct joint EPRC/medical device inspections.

When conducting a cabinet x-ray system manufacturer inspection or field test all FDA personnel are required to wear a personal radiation monitor. If you do not have a personal radiation monitor badge, follow the instructions as noted in Part II of this program.

CDRH is responsible for all administrative/regulatory action, regulatory follow-up, and for the issuance of all notices of violations to manufacturers of cabinet x-ray systems.

Field Test Instructions

Generally cabinet x-ray field tests should be performed when requested by CDRH, in response to requests from other federal agencies, to check the validity of a trade or consumer complaint, or when it is necessary for confirmation that a manufacturer's testing program or corrective action plan is adequate.

When performing a cabinet x-ray field test collect data in accordance with the written procedures prescribed in "Routine Compliance Testing for Cabinet X-ray Systems to which 21 CFR Subchapter J is

applicable, Dated March 1985" (see reference below). If it is determined that the written procedures cannot be followed, describe in detail the variance from the prescribed procedure in the comments section of the test form.

Field Test Equipment: MDH meters are not sufficiently sensitive to detect radiation emissions from a cabinet x-ray system. Use only the meters identified in the field test procedure identified below.

NOTE: Cabinet X-Ray Systems installed at airports are not to be field tested except as requested by CDRH, Transportation Security Administration (TSA), Customs and Border Protection (CBP), or Department of Agriculture (USDA). Usually there will be a manager from the relevant agency at the facility containing the system to be tested. Coordinate the test with the appropriate agency on-site manager. Where the national radiation safety contacts are known they should also be contacted. The national contacts for TSA and CBP are included below:

Contacts for Radiation Safety at other Federal Agencies

Name	Phone	Email	Position
Jill Segraves	(571) 227-2292	Jill.Segraves@dhs.gov	Radiation Safety Program Manager, Transportation Security Administration
Richard Whitman	(317)614-4843	richard.t.whitman@dhs.gov	Radiation Safety Officer, Customs and Border Protection

Results for all field tests of TSA or CBP cabinet x-ray systems should be sent CDRH, the appropriate contact listed above, and the on-site manager.

References

Frequently Asked Questions on Cabinet X-ray Systems (March 24, 2003)
http://www.fda.gov/cdrh/radhealth/products/cabinetxrayfaq.html

Compliance Guide for Cabinet X-Ray Systems: Coming soon to the web

Routine Compliance Testing for Cabinet X-ray Systems to which 21 CFR Subchapter J is applicable, Dated March 1985
http://www.fda.gov/cdrh/radhlth/pdf/cabgdeft.pdf

Refer to the Cabinet X-Ray Systems main page for additional information:
http://www.fda.gov/cdrh/radhealth/products/cabinetxray.html

Cabinet X-Ray Product Codes

Translation of 2-Digit Code	Product Name	Product Code		CFR	Definition
Cabinet X-Ray Systems, Non-Medical	Cabinet X-Ray, Industrial, Non-Medical	94	RCE	1020.40	A cabinet x-ray system used for quality control, non-destructive testing, or some other industrial purpose.
Cabinet X-Ray Systems, Non-Medical	Explosive Detection Systems, Cabinet X-Ray Systems, Non-Medical	94	RCF	1020.40	A cabinet x-ray system used for detection of explosives in closed containers such as airline baggage. Usually these systems use a non-standard x-ray mode to perform this function such as computed tomography.
Cabinet X-Ray Systems, Non-Medical	Security X-Ray (includes Baggage X-Ray), Cabinet X-Ray Systems, Non-Medical	94	RCG	1020.40	A cabinet x-ray system used to examine the contents of containers such as airline baggage, brief cases, and purses to detect weapons or other contraband.
Cabinet X-Ray Systems, Non-Medical	Cargo X-Ray, Cabinet X-Ray Systems, Non-Medical	94	RCH	1020.40	A large cabinet x-ray system used to examine pallets full of cargo to find weapons or other contraband.
Cabinet X-Ray Systems, Non-Medical	Other	94	RZZ	1020.40	A cabinet x-ray system used for an unlisted specific purpose.

Classification of Non-compliant Items

Emission Limit			
1020.40(c)(1)(i)	**Exceeds emission limit**		
1020.40(c)(1)(i)	Radiation emission > 10mR in one hour	Major	Class A
1020.40(c)(1)(i)	Radiation emission rate ≤ 10 mR in one hour and > 0.5 mR in one hour	Major	Class B
1020.40(c)(1)(ii)	Emission limit requirements – measurement inadequate	Major	See (c)(1)(i)
Floors			
1020.40(c)(2)	Floor fails to adequately attenuate radiation emission into occupied area underneath x-ray system	Major	See (c)(1)(i)
Ports and Apertures			
1020.40(c)(3)(i)	**It is possible to reach the primary beam through a port**		
	Primary beam greater than 10 R per hour and beam is easy to access	Major	Class A
	Primary beam greater than 10 R per hour and beam is possible but difficult to access inadvertently	Major	Class B
	Primary beam less than 10 R per hour and greater than 5 R per hour	Minor	Class B
	Primary beam less than 5 R per hour	Concern	Class C
1020.40(c)(3)(ii)	**Aperture allows human access to interior of cabinet**		
	Radiation exposure rate in accessed area greater than 5 R per hour	Major	Class B
	Radiation exposure rate in accessed area less than 5 R per hour	Minor	Class C
Safety Interlocks			
1020.40(c)(4)(i)	Safety interlock - door does not have any interlock and emission rate with door open is > 10mR in one hour	Major	Class A
1020.40(c)(4)(i)	Safety interlock - door does not have multiple interlocks	Major	Class B
1020.40(c)(4)(i)	**Neither door safety interlock causes physical disconnect**		
1020.40(c)(4)(i)	Radiation emission rate with interlock failure and door open > 2 mR per hour	Major	Class B
1020.40(c)(4)(i)	Radiation emission rate with interlock failure and door open ≤ 2 mR per hour and > 0.5 mR in any one hour	Minor	Class B
1020.40(c)(4)(i)	**Safety interlocks - disconnect based on movement other than door**		
1020.40(c)(4)(i)	Radiation emission rate with interlock failure and door open > 2 mR per hour	Major	Class B
1020.40(c)(4)(i)	Radiation emission rate with interlock failure and door open ≤ 2 mR per hour and > 0.5 mR in any one hour	Minor	Class B
1020.40(c)(4)(ii)	Lack of safety interlock - access panel and emission rate with access panel open is > 10 mR in one	Major	Class B
1020.40(c)(4)(iii)	Safety interlocks - after an interruption reset of the interlock results in resumption of x-ray production	Major	Class B
1020.40(c)(4)(iv)	Safety interlocks - single component failure disables more than one interlock	Major	Class B
Ground fault			
1020.40(c)(5)	Ground fault can result in x-ray initiation	Major	Class A
Controls and Indicators			
1020.40(c)(6)(i)	Key control - not provided	Major	Class B
1020.40(c)(6)(i)	Key control - not functional	Major	Class B
1020.40(c)(6)(ii)	Controls to initiate and terminate x-rays other than interlocks or power control are not present	Major	Class B

1020.40(c)(6)(iii)	Two independent means of Exposure indication at initiation are not present	Major	Class B
1020.40(c)(6)(iii)	Exposure indication - other than milliammeter is not present	Major	Class B
1020.40(c)(6)(iii)	Exposure indication at initiation – is not visible from control	Major	Class B
1020.40(c)(6)(iii)	Multiple failures of exposure indication caused by a single failure	Major	Class B
1020.40(c)(6)(iii)	Exposure indication - labeling - X-RAY ON is not present	Concern	Class C
1020.40(c)(6)(iii)	Exposure indication - labeling - x-ray tube current is not present	Concern	Class C
1020.40(c)(6)(iv)	Exposure indication required to be visible from a door, panel, or port and is not present	Major	Class B
1020.40(c)(6)(iv)	Exposure indication not visible from each door, panel, or port	Major	Class B
1020.40(c)(6)(iv)	Exposure indication at door, panel, or port is not labeled - X-RAY ON	Concern	Class C
Additional controls and indicators for systems designed to admit humans			
1020.40(c)(7)(i)	No means for preventing and terminating x-rays from within	Major	Class A
1020.40(c)(7)(ii)	X-rays can be initiated from within the cabinet	Major	Class A
1020.40(c)(7)(iii)	No Pre-exposure warning within cabinet	Major	Class A
1020.40(c)(7)(iii)	Pre-exposure warning within cabinet – Warning did not activate at least 10 seconds prior to exposure	Major	Class A
1020.40(c)(7)(iii)	Pre-exposure warning within cabinet - a single failure causes both audible and visual warnings to fail	Major	Class A
1020.40(c)(7)(iv)	No exposure warning within cabinet	Major	Class A
1020.40(c)(7)(v)	Lack of signs giving meaning of warning signals	Major	Class B
1020.40(c)(7)(v)	Lack of signs giving instructions for use of controls to terminate	Major	Class B
1020.40(c)(7)(v)	Signs are not legible, accessible, illuminated	Major	Class B
Warning Labels			
1020.40(c)(8)(i)	Lack of Warning labels - X-rays Produced	Concern	Class C
1020.40(c)(8)(ii)	Lack of Warning labels - Human Access	Concern	Class C
Information to be provided			
1020.40(c)(9)(i)	Instruction manuals - not provided	Minor	Class C
1020.40(c)(9)(i)	Instruction manuals - inadequate technical & safety information	Minor	Class C
1020.40(c)(9)(i)	Assembly instructions - required and not provided	Major	Class B
1020.40(c)(9)(i)	Assembly instructions - not adequate for compliance	Major	Class B
Additional requirements for systems loaded by the public (e.g. Baggage inspection)			
1020.40(c)(10)	X-ray baggage inspection systems (public area) - No means to assure operator presence	Major	Class A
1020.40(c)(10)(i)	No means to terminate exposure	Major	Class B
1020.40(c)(10)(ii)	No means to terminate an exposure sequence	Major	Class B
Modification of a certified system			
1020.40(d)	Modification – failure to re-certify and re-identify	Major	Class B

Cabinet X-Ray Product Inspection Guidance and Field Test Form

Cabinet X-ray inspection checklist.

This guidance is in addition to the instruction provided in Part III.A.2 of this program. Refer to the *Compliance Guide for Cabinet X-Ray Systems* (referenced above) for a detailed discussion of the cabinet x-ray system performance standard.

I. Record Firm Identification, Location, and Contact information

II. Models
   a. What models does the manufacturer produce?
   b. What models are available for observation of certification testing?

III. Performance Requirements
   a. Radiation Emission Limit
      Unlike lasers, the "characterization" of the radiation emitted from a cabinet x-ray system is not relevant. The amount of x radiation emitted is critical. **Note:** The emission limit in the cabinet x-ray standard is for the amount of exposure (less than 0.5 mR) in one hour. It is not a limit on the instantaneous rate of radiation emission.
      i. Is there a written procedure for emission testing?
      ii. Are numerical values recorded for the worst case emission from each system?
      iii. What instruments are used during emission testing? (Record the model and manufacturer of each radiation meter)
         1. Identify the type of each meter (ideally the mfr. should know the type). A few possible types are: ion chamber, Geiger-Mueller (GM), plastic scintillators.
         2. What is the response time for each meter?
         3. Can the x-ray system produce a beam for longer than the meter's response time? Does the procedure specify that x-ray will be produced for longer than the meter's response time?
         4. Is the meter held still at various positions around the x-ray system or is it moved slowly around the system?
            a. If the meter is in motion during an exposure is there a maximum scan speed noted in the procedure?
            b. During the test, is the meter moved slowly enough so that its response time is not a factor?
            c. Is the scan speed limit adhered to by the person performing the test?
            d. Are all the likely points of excess emission checked? If there are emission issues they usually occur at the ports, seems, corners, access panels, and doors.
         5. If the x-ray beam can not be produced continuously can the radiation meter measure an integrated dose?
         6. Does the meter used for the quantitative measurement have a current calibration? What energy was the meter calibrated at? What is the peak tube potential of the cabinet x-ray system?
         7. Does the meter produce a linear response for the expected energy range of emission from the product?
         8. Is the meter sufficiently sensitive in the relevant energy range that it

responds to radiation emission from the product?

iv. If there are calculations involved in determining the total amount of exposure in anyone hour are all the steps clearly identified and justified?

v. What is the rejection limit set by the manufacturer for emissions? If the rejection limit is the same as the limit in the performance standard how is the inherent experimental error in measuring radiation emission from the system accounted for? If less than the limit in the performance standard is it sufficiently restrictive to account for experimental error?

vi. Based on the answers above and observation of the emission test procedure, is the emission testing conducted by the manufacturer sufficient to assure that the product will comply with the performance standard?

b. Are items placed into the cabinet through a port or through a door?

i. If items are placed into the cabinet through a port is it necessary for someone to hold the item while it is being exposed to radiation? If so can any part of the body reach the primary beam through the port?

ii. If items are moved into the system on a conveyor belt will any part of the body reach the primary beam during normal operation? (Crawling into the system is not considered normal operations)

iii. If it appears that it is possible to reach the primary beam inadvertently ask the manufacturer for the exposure rate in the primary beam per hour.

c. If the system has a door does it have a minimum of two interlocks? **Note:** A door is used to put a sample into the cabinet. If a part of the shielding is opened for maintenance it is an access panel not a door.

i. Is at least one of the interlocks designed so that door opening results in <u>physical</u> disconnection of the energy supply circuit to the high-voltage generator? Occasionally a system may have a "shutter" so that when either the shutter or the door is closed energy continues to be supplied to the high-voltage generator and if both were to open simultaneously then the power would be cut.

ii. Is the disconnection <u>dependent upon any moving part</u> other than the door? In most cases the secondary physical disconnect interlock will be visible when the door is open. Relays and magnetic switches contain moving parts and do not meet this requirement.

iii. Will closing the door cause the automatic resumption of x-ray production or is it necessary for an operator to re-initiate x-ray production by taking some action?

d. Does the system have an access panel?

i. Do all access panels that allow access to the interior of the cabinet require a tool to open?

ii. Do all access panels have an interlock that prevents production of x-ray when the panel is open?

iii. Will closing an access panel cause the automatic resumption of x-ray production or is it necessary for an operator to re-initiate x-ray production by taking some action?

e. Has the manufacturer performed a ground fault analysis? Can the product fail via a ground fault in such a way that x-ray production is initiated?

f. Is there a capture key control? Can the key be removed when in a position that allows the production of x-ray?

g. Is there a control to initiate and stop x-ray production other than the power key?
h. Are there at least 2 independent means that indicate when and only when x-ray is being produced? Are they labeled "x-ray on"?
i. Can an x-ray on indicator be seen from any position that a port, access panel, or door can be operated? Is the indicator labeled "x-ray on"?
j. Is the system designed to admit humans? Is the system so large that it would be easy for a human to walk into the cabinet?
    i. Is there a control inside the cabinet for terminating x-ray generation?
    ii. Can x-ray generation be initiated from within the cabinet?
    iii. Are there audible and visible warning signals within the cabinet that are actuated for at least 10 seconds prior to the first x-ray generation after closing any door designed to admit humans?
    iv. Visible warning signal within the cabinet that is illuminated when and only when x-rays are being generated?
    v. Signs that indicate the meaning of the warning signals provided to meet the other requirements of this section?
k. Warning labels
    i. At the location of any controls that can be used to initiate x-rays is there a label that says: **Caution: X-Rays Produced When Energized**
    ii. Is there a label at every port that says: Caution: **Do Not Insert Any Part of the Body When System is Energized--X-ray Hazard**
l. Are user instructions provided to purchasers?
    i. Do the instructions include: Potential, current, and duty cycle ratings of the x-ray generation equipment; and adequate instructions concerning any radiological safety procedures and precautions which may be necessary because of unique features of the system?
    ii. Do the instructions include a schedule of maintenance necessary to keep the system in compliance with this section?
m. Does the product require the customer or a third party to be assembled? If so are there adequate assembly instructions provided by the manufacturer?
n. Is the product used for security screening of items placed on it by members of the public?
    i. Are there means provided to assure that the operator is present at the control area and in a position that permits surveillance of the ports and doors during generation of x-radiation?
    ii. Are there means provided to assure that the operator can terminate an exposure?
o. Is the manufacturer modifying a previously certified system? If so have they re-labeled the system and re-identified and recertified that the modified product meets the requirements of the performance standard?

Field Test Form

The cabinet x-ray field test procedure uses an official form to record the data. This form, FDA 2903 entitled, Cabinet X-Ray Systems Field Test Record can be found at the FDA Forms Catalog (see the FDA intranet home page under Medical Devices).

Specific Instructions for Television Product Inspections

Background

The Television Product Performance Standard (the standard) was designed to protect the public from x-radiation hazards associated with early cathode-ray-tube (CRT) television sets. The radiation emitted from these products has been dramatically reduced over the years as a result of the standard, and by improvements in technology and design. The hazards of x-ray emissions from CRT televisions and video monitors are further diminished because of a well-established and conscientious industry and the increasing market for flat panel LCD and plasma displays that do not pose a radiation hazard. A minimal, but risk-based and continued presence by FDA is needed in the television industry to ensure continued compliance with radiation safety standards so long as there is a market for CRT products. This presence is limited to for-cause manufacturer inspection and laboratory inspection. No field tests are conducted on television products.

Specific Instructions

Television product manufacturers should be inspected or tested at CDRH direction. Television product manufacturers are all located overseas, and all inspections will require foreign travel. Reasons for manufacturer inspection include:

- Manufacturers with known or suspected problems based on previous inspection or complaints
- New manufacturers not yet inspected
- Manufacturers introducing new CRT-based technology to the US market
- Manufacturers with a large potion of the US market share.

WEAC laboratory analysts have knowledge of general EPRC requirements and also have specialized training in the television product performance standard. These analysts have experience planning and conducting foreign television manufacturer inspections. WEAC analysts should perform these inspections and field tests and may train additional field staff.

CDRH is responsible for review of television manufacturer inspection observations and initiating administrative or regulatory follow-up.

References

Performance Standard-Television Products
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?FR=1020.10

Reporting and Compliance Guide for Television Products
http://www.fda.gov/cdrh/radhlth/pdf/tvvrptgd.pdf

Refer to the television products main page for guidance documents and additional information:
http://www.fda.gov/cdrh/radhealth/products/tvvdt.html

Television Product Codes

Translation of 2-Digit Code	Product Name	Product Code		CFR	Definition
TV Receivers & Products Containing Same	Oscilloscope (Exempted), TV Receivers & Products, Non-Medical	94	RAY	1020.10	A device that depicts on a screen periodic changes in an electric quantity, as voltage or current, using a cathode ray tube and is not used in a medical application
TV Receivers & Products Containing Same	Television Receiver, Medical Imaging, Color	94	RAZ	1020.10	A television receiver using a color cathode ray tube to display medical images in colors.
TV Receivers & Products Containing Same	Television Receiver, Medical Imaging, Monochrome	94	RBA	1020.10	A television receiver using a monochrome cathode ray tube to display medical images in black and white with shades of gray or in different shades of one color.
TV Receivers & Products Containing Same	Television Receiver, General Purpose, Color, Non-Medical	94	RBB	1020.10	An electronic product with no medical claims designed to receive and, using a color cathode ray tube, to display a television picture in colors from broadcast, cable, video disk player, video recorder, computer or closed circuit television signals.
TV Receivers & Products Containing Same	Television Receiver, General Purpose, Monochrome, Non-Medical	94	RBC	1020.10	An electronic product with no medical claims designed to receive and, using a monochrome cathode ray tube, to display a television picture in black and white with shades of gray or in different shades of one color from broadcast, cable, video disk player, video recorder, computer or closed circuit television signals.
TV Receivers & Products Containing Same	Video Monitor, Medical Imaging, Color	94	RBD	1020.10	An electronic product using a color cathode ray tube to display medical images in colors from signals from a computer or electronic medical device.
TV Receivers & Products Containing Same	Video Monitor, General Purpose, Color	94	RBE	1020.10	An electronic product using a color cathode ray tube to display general images in colors from signals from a computer or electronic medical device.
TV Receivers & Products Containing Same	Video Monitor, Medical Imaging, Monochrome	94	RBF	1020.10	An electronic product using a monochrome cathode ray tube to display medical images in black and white with shades of gray or in different shades of one color from signals from a computer or electronic medical device.
TV Receivers & Products Containing Same	Video Monitor, General Purpose, Monochrome	94	RBG	1020.10	An electronic product using a monochrome cathode ray tube to display general images in black and white with shades of gray or in different shades of one color from signals from a computer or electronic medical device.
TV Receivers & Products Containing Same	Projector, TV Receivers & Products	94	RBH	1020.10	Electronic products that use a cathode ray tube or several cathode ray tubes to generate television images which are projected on a screen either from the front or from the rear.

TV Receivers & Products Containing Same	TV View Finder, TV Receivers and Products	94	RBI	1020.10	An electronic product using a cathode ray tube to display the image seen through the lens of a camcorder. To be exempt the cathode ray tube must operate under 5 kilovolts under the test conditions in the standard (Phase III).
TV Receivers & Products Containing Same	Camera, Television, Surgical, Without Audio	79	FWB	1020.10	
TV Receivers & Products Containing Same	Camera, Television, Surgical, With Audio	79	FWC	1020.10	
TV Receivers & Products Containing Same	Camera, Television, Microsurgical, Without Audio	79	FWD	1020.10	
TV Receivers & Products Containing Same	Camera, Television, Microsurgical, With Audio	79	FWE	1020.10	
TV Receivers & Products Containing Same	Camera, Television, Endoscopic, Without Audio	79	FWF	1020.10	
TV Receivers & Products Containing Same	Camera, Televsion, Endoscopic, With Audio	79	FWG	1020.10	
TV Receivers & Products Containing Same	System, Reading, Television, Closed-Circuit	79	HJG	1020.10	
TV Receivers & Products Containing Same	Other	94	RZZ	Unknown	Other electronic products using cathode ray tubes to display television images from broadcast, cable, video disk player, video recorder, computer or closed circuit television signals.

Classification of Non-compliant Items

Emission Limit			
1020.10(c)	**Exceeds exposure rate limit**		
1020.10(c)(1)	Radiation emission > 10mR in one hour	Major	Class A
1020.10(c)(3)	Test conditions are not in accordance with requirements	Minor	Class B
1020.10(c)(4)	Critical component warning label missing or inadequate	Minor	Class B

Sample Television Product Inspection Checklist

Manufacturer Identification

Manufacturer Name : _____

Plant Location: _____

Date(s) of Visit: _____

FDA Personnel

Name	Title	Organization

Manufacturer Personnel

Name	Title	Name	Title

LIST OF EXHIBITS

	Organization Chart		Sampling Procedures		Engineering Test Plan		Service Manual(s)
	Incoming Q. C. Test Procedures		Reaction Plan Procedures		Engineering Test Records		Mfr's Agent agreement (21 CFR 1005.25)
	Instrument Calibration Control Log		Labels (ID, Cert. and Crit. Comp.)		Vendor Test Data		Other:
	X-Radiation Test Record		Production Line Procedures		Manufacturer Distribution Records		

GENERAL EVALUATION OF THE SPECIFIC AREAS INSPECTED

Specific Area Inspected	Gen. Eval.*	See Attach.	Details on Page	Specific Area Inspected	Gen. Eval.*	See Attach.	Details on Page
General Organization							
Engineering Test Plan							
Incoming Materials Testing Program							
Written Comm. Concerning Radiation							
Manufacturer Distribution Records							
Instrument Calibration							

***Legend for Evaluation:** **A -** Satisfactory **B -** Questionable **C -** Unsatisfactory

NARRATIVE DESCRIPTION OF FINDINGS

1. PRODUCTION SUMMARY

MAXIMUM NUMBER OF PRODUCTION

Line Name	Model No.	Brand	Rate (Sets/day)	Meets Abbr. Rep. Criteria?	Line Name	Model No.	Brand	Rate (Sets/day)	Meets Abbr. Rep. Criteria?

2. GENERAL ORGANIZATION

1.	Flowchart of company functions and organization available?										
		Yes		No	See Exhibit:						
2.	Corresponding official is :										
	Q.A.		Q.C.		Product Safety		Engineering				
	Production		Sales		Other:						
3.	Is the Compliance Testing Program separate from Production?						Yes		No		
4.	(Foreign companies only) Does the company have a Manufacture's Agent who lives in the U.S.? (21 CFR 1005.25)										
	Yes		No								

3. ENGINEERING

1.	**Test Plan**					
a)	The receiver selected for the Engineering Analysis is a:					
	Prototype		Preproduction		Other:	
b)	The engineering x-radiation testing is performed by:					
	Q.C.		Engineering		Other:	
c)	The acceptance/rejection criteria for new design is:					
d)	The A/R decision is made by:					
e)	Life test prior to mass production?		Yes		No	

3. ENGINEERING (Cont.)

2.	**Engineering Test Records**						
a)	Are records kept?						
		Yes, where?					
		No (Explain)					
b)	Type of information kept on record:						
c)	Is the worst tolerance chassis retained for further testing?		Yes		No		

4. INCOMING TESTS FOR CRITICAL COMPONENTS

1. Test Summary

Components	Test Performed		Sampling Plan	Rejection Criteria	Test Method
	Yes	No			
CRTs					
Capacitors					
H.V. Transformers					
Yoke					
Others					

		Yes	No
2.	Incoming test records on file?		
3.	CRTS tested In-House?		
	If yes, Registered at TEPAC?		

a) Explain the CRT test procedure:

b) X-Radiation Instrumentation used:

Model	Cal. Date

4.	If CRT□s are tested by vendor does the vendor provide:		
	a) test data for each lot?		
	b) general guarantee of Engineering X-Radiation specifications		

5. INCOMING CHECK OF REQUIRED LABELS

1.	Are the labels, which are received at the incoming area, checked for compliance with 21 CFR 1010?		
2.	If yes, are the labels compared with approved labels on file?		

6. COMMUNICATIONS CONCERNING RADIATION SAFETY

1.	Are records kept?		
2.	Who responds to these questions?		

7. MANUFACTURER DISTRIBUTION RECORDS

1.	Are records kept? If Yes, where are they kept?:		
2.	Information kept on record:		
	Dealer/Distributor name and address?		
	Date distributed?		
	Model and serial No.?		
3.	Are records computerized?		
4.	Are dealers/distributors notified of their obligation to obtain and maintain purchaser records? (for non-exempt		
5.	Are dealers/distributors notified of the exempt products?		

8. INSTRUMENT CALIBRATION

1.	Is the qualitative meter given a periodic (30 day) check for proper operation?		
2.	Are the actual readings for each tube recorded?		

3.	The date of the CST-l source used for the thirty-day check is:		
4.	Is it adjusted?		
5.	Is the quantitative instrument checked to a source traceable to a NBS standard?		
6.	Is there a system for reminding personnel that an instrument is due to be calibrated?		
7.	Are there alternative x-radiation instruments available should the instruments in use require repair or		

9.	**SAMPLING PROCEDURES FOR PRODUCTION RADIATION TESTING**	**Yes**	**No**
1.	The samples for production testing are selected by:		
2.	From: Each production line?		
	Each shift?		
	Each model?		
	End of production line?		
	Warehouse?		
3.	Sample size:		
4.	Lot size:		
5.	How determined?		
6.	Normal amount of production:		
7.	Rejection criteria:		

Unit: _____ mR/hr Lot: _____ mR/hr

10. REACTION PLAN UPON REJECTION (review actual rejection cases)								
1.	Who is notified by the test technician?							
2.	Who examines the cause?							
3.	Disposition of the rejected lot while examining cause:							
4.	Who issues the order to stop shipment and/or production?							
5.	Are other lots (previous and/or subsequent) subjected to increased testing?							
6.	Have there been any failures?							
	If yes, was it documented ?							
7.	Does the Reaction plan appear to be adequate?							

1.	Where are records kept?					
2.	Are they maintained for five years?		Yes		No	
3.	How are they filed? (model, date, etc.)					

11. X-RADIATION TEST RECORDS

4. What information is recorded?

	Model/Chassis		Test Date		Technician		Beam Current		All Sides
	Serial #		Fault		High Voltage		X-Radiation		Background

5. Are any records in excess of the rejection limit?

	Yes, disposition of rejected units/lots:	
	No	

12. PRODUCTION LINE PROCEDURES	Yes	No
1. Shielding		
a) Is special shielding checked for proper placement?		
2. Sealed Controls		
a) Are they checked?		
b) Checking Method: ☐ Visual ☐ Mechanical		
c) Do seals appear to be permanent?		
3. Labels		
a) Is the presence of labels being checked on line?		
b) Are labels readily viewable?		
c) Are they permanently affixed?		

13. PRODUCTION LINE PROCEDURES AND OPERATIONAL SAFETY TESTS

1) Chassis Number						
	Yes	**No**	**Yes**	**No**	**Yes**	**No**
2) B+ measured?						
% Checked	%		%		%	
Meter Calibration Current?						
Instructions Available?						
3) H.V. measured?						
% Checked	%		%		%	
Meter Calibration Current?						
Instructions Available?						
4) Hold Down/Safety Circuit Subassembly						
Finished product						
Instructions available?						

Comments:

14. RADIATION TESTING PROGRAM FOR PRODUCTION SETS

1. Test Instrumentation

			Calibrated		Operational Checks	
Instruments	**Manufacturer**	**Model**	**Last**	**Due**	**Yes**	**No**
Qualitative	Johnson	TVX-1				
Quantitative	Victoreen	440 RF/C				
Voltmeter						
Ammeter						
H.V. Meter						

2. Demonstration Test Number 1

a) Identification of receiver tested:

Chassis No.				Color		Black and White
CRT No.			Model No.			
Serial No.						
Sample selected by:						
Sample selected from:						

b) Labeling Information:

Label	Viewable	Obscured	Missing	Adhesion
Certification				
Date of manufacturer.				
Place of Manufacturer.				
Critical Component Warning				

c) Test Conditions:

Input voltage: _____

User controls adjusted? ☐ Yes ☐ No

Service controls adjusted? ☐ Yes ☐ No

List adjusted controls: _____

Describe worst-case failure: _____

Usable Picture? ☐ Yes ☐ No _____

Test pattern: _____

d) Test Results:

Max. Qualitative: _____ counts/min at _____ kV and _____ □A

Location: _____ Background: _____ counts/min

Max. Quantitative: _____ mR/hr at _____ kV and _____ □A

Location: Scan Rate: inches/sec

Comments:

3. Demonstration Test Number 2

a) Identification of receiver tested:

Chassis No. _____ ☐ Color ☐ Black and White
CRT No. _____ Model No. _____
Serial No. _____
Sample selected by: _____
Sample selected from: _____

b) Labeling Information:

Label	Viewable	Obscured	Missing	Adhesion
Certification				
Date of manufacturer.				
Place of Manufacturer.				
Critical Component Warning				

c) Test Conditions:

Input voltage:									
User controls adjusted?			Yes		No				
Service controls adjusted?			Yes		No				
List adjusted controls:									
Describe worst-case failure:									
Usable Picture?		Yes		No					
Test pattern:									

d) Test Results:

Max. Qualitative:		counts/min at		kV and		mA
Location:		Background:			counts/min	
Max. Quantitative:		mR/hr at		kV and		mA
Location:		Scan Rate:			inches/sec	

Comments:

Specific Instructions for Microwave Oven Product Inspections

Background

The Microwave Oven Product Performance Standard (the standard) was designed to protect the public from unnecessary emissions from microwave ovens. A minimal, but risk-based and continued presence by FDA is needed in the microwave oven industry to ensure continued compliance with radiation safety standards. This presence is limited to for-cause manufacturer inspection and laboratory inspection. No field tests are conducted on microwave oven products.

Specific Instructions

Microwave oven product manufacturers should be inspected or tested at CDRH direction. Microwave oven product manufacturers are all located overseas, and all inspections will require foreign travel. Reasons for manufacturer inspection include:

- Manufacturers with known or suspected problems based on previous inspection or complaints
- New manufacturers not yet inspected
- Manufacturers introducing new technology to the US market
- Manufacturers with a large portion of the US market share.

WEAC laboratory analysts have knowledge of general EPRC requirements and also have specialized training in the microwave oven product performance standard. These analysts have experience planning and conducting foreign microwave oven manufacturer inspections. WEAC analysts should perform these inspections and field tests and may train additional field staff.

CDRH is responsible for review of microwave oven manufacturer inspection observations and initiating administrative or regulatory follow-up.

References

Performance Standard-Microwave Oven Products
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=1030&showFR=1

Guide for Preparing Reports on Radiation Safety of Microwave Ovens
http://www.fda.gov/cdrh/radhlth/pdf/mworptgd.pdf

Refer to the microwave oven products main page for guidance documents and additional information:
http://www.fda.gov/cdrh/radhealth/products/microwave.html

Microwave Oven Product Codes

Translation of 2-Digit Code	Product Name	Product Code		CFR	Definition
Microwave Ovens (Food Prep)	Microwave Oven, Consumer (Food Prep)	96	RCR	1030.10	A machine that utilizes microwave radiation for food preparation, designed for home use.
Microwave Ovens (Food Prep)	Microwave Oven, Commercial (Food Prep)	96	RCS	1030.10	A machine that utilizes microwave radiation for food preparation, designed for commercial establishments
Microwave Ovens (Food Prep)	Tunnel/Conveyor, Microwave Ovens (Food Prep)	96	RCT	1030.10	A machine that utilizes microwave radiation for food preparation using a conveyorized or tunnel microwave waveguide.
Microwave Ovens (Food Prep)	Vending Machine, Microwave Ovens (Food Prep)	96	RCU	1030.10	A machine that utilizes microwave radiation for dispensing heated foods in public areas.
Microwave Ovens (Food Prep)	Other	96	RZZ	Unknown	A machine that utilizes microwave radiation for food preparation not previously specified.

Classification of Non-compliant Items

Power density limit requirements			
1030.10(c)(1)	Leakage from door, vents, other seams > 6mW/cm^2	Major	Class A
1030.10(c)(1)	Leakage from door, vents, other seams >1.25mW/cm^2, < 6mW/cm^2	Minor	Class B
1030.10(c)(1)	Leakage from door, vents, etc. < 6mW/cm^2 after purchase	Concern	Class C
Safety interlocks			
1030.10(c)(2)(i), (iv)	Does not incorporate two (2) independent safety interlocks or monitor	Major	Class A
1030.10(c)(2)(i)	No concealed or inaccessible interlock	Major	Class A
1030.10(c)(2)(ii)	Single mechanical/electrical failure disables interlocks	Major	Class A
1030.10(c)(2)(iii)	Secondary interlock allows leakage > 6mW/cm^2	Major	Class A
1030.10(c)(2)(iii)	Primary interlock allows excess leakage > 6mW/cm^2		
1030.10(c)(2)(iv)	Insulating wire is accessible to energy-containing space Opening is obvious to user Opening is not obvious or readily accessible	Major Minor	Class A Class B
User instructions			
1030.10(c)(4)(ii)	Precaution statement unclear, not located to elicit attention, not legible or durable, etc.	Minor	Class B
1030.10(c)(4)(iii)	User manual or cookbook has no precaution statement	Minor	Class B
Service instructions			
1030.10(c)(5)(ii)	Safety information or precaution statement unclear, not located to elicit attention not legible or durable, etc.	Minor	Class B
1030.10(c)(5)(iii)	Service instructions have non precaution statement	Minor	Class B
1030.10(c)(5)(iv)	Service instructions have insufficient safety information	Major	Class A
Warning labels			
1030.10(c)(6)(i), (ii)	No user warning label or service caution label	Major	Class A

Sample Microwave Oven Product Inspection Checklist

Manufacturer Identification

Manufacturer Name : _____

Plant Location: _____

Date(s) of Visit: _____

F.D.A. Personnel

Name	Title	Organization

Manufacturer Personnel

Name	Title	Name	Title

LIST OF EXHIBITS

A	-	C	-	E	-	G	-
B	-	D	-	F	-		

GENERAL INSPECTION OVERVIEW

SUMMARY OF FINDINGS (See the FDA483 in Exhibit A)

HISTORY OF BUSINESS

PERSONS INTERVIEWED AND INDIVIDUAL RESPONSIBILITY

FIRM'S TRAINING PROGRAM

RAW MATERIALS AND COMPONENTS

MANUFACTURING PROCEDURES

SAMPLES COLLECTED

Y2K ISSUES

COMPLAINTS

REFUSALS

DISCUSSION WITH MANAGEMENT

1.0 ***Production Summary*** - Maximum number of production lines is:

Line Name	Model #	Brand	Type*	Rate	Shift/Hours	Comments

* **CTD** = Countertop/Domestic **CTC** = Countertop/Commercial **UTC** = Under-the-cabinet **WHO** = Wall hanging **COM** = Common cavity **MOD** = Module for High/Low **HLO** = High/Lo **BDO** = Built-in-double **BSO** = Built-in single

2.0 ***Component Inspection***

Components	Test Parameters*/Sampling Rate			
2.1 Cavities and Waveguides	___/_____	___/_____	___/_____	___/_____
2.2 Interlock & Monitor Switches	___/_____	___/_____	___/_____	___/_____
2.3 Wire Harnesses	___/_____	___/_____	___/_____	___/_____
2.4 Door Structure, Hinges, Latches	___/_____	___/_____	___/_____	___/_____
2.5 Door Chokes and Seals	___/_____	___/_____	___/_____	___/_____
2.6 Door Screen Perforations	___/_____	___/_____	___/_____	___/_____
2.7 Noncertified MWO Modules	___/_____	___/_____	___/_____	___/_____

*Test Parameter Keys: **D** = dimension check, **E** = electrical continuity or performance, **F** = function check, **RF** = RF emission check, **V** = visual inspection, **W** = weld integrity

3.0 ***Component Control***

3.1 Are the incoming components adequately controlled to prevent their use until quality control tests are completed and lot acceptability is determined?

____ Yes ____ No (Explain) _____

3.2 Are the rejected lots of components adequately marked or secured so the rejected parts are not used in production unless reworked?

____ Yes ____ No (Explain) _____

4.0 ***Production Line and Final Tests***

General Tests

	Line Names /All Lines			
Door installation & adjust. checks				
Safety interlocks & monitor continuity checks				
RF emission hazard waveguide, cavity seams, etc.				
Check door travel before sec. interlock actuation				
Open door (shut off-restart) operation test				
Presence and content of required labels				

RF Emission Tests

Door viewing screen				
Door perimeter				
Door perimeter ~ door pulled & all interlocks operating				
Door perimeter ~ door pulled & only Secondary interlock operating				
Door hinge				
Control panel				
Vents and Louvers				
Underneath the oven (bottomless or exposed cavity)				
Automated Microwave Scanner				

NP = Not performed, B = Before final assembly, A = After final assembly NA = Not applicable, ND = Not determined

4.1 Are the written procedures or diagrams available or posted in the working area for the operator performing Q.C. checks?

____ Yes ____ No (Explain) _____

4.2 Are repaired ovens returned to the assembly line at a point prior to the test that caused their rejection?

____ Yes ____ No (Explain) _____

4.3 Are all repaired ovens, regardless of the nature of the repair, returned to the assembly line for the open door operation test and final RF emission test?

____ Yes ____ No (Explain) _____

5.0 ***Final Test Records (Check information permanently retained)***

___ Final and highest RF value

___ Serial no.

___ Date of Test

___ Secondary Interlock Only RF

___ Safety Interlocks/Monitor Continuity

___ Label check

___ Scanner Start-up Test

___ Open Door (Shut Off - Restart) Test

6.0 ***Automated Microwave Oven Scanner***

Line Name	AMOS Brand/ Serial No.	Model Family	Model Exceptions	Qualified	RF Reject Limit

* User manual provided to person responsible for operation of AMOS?

___ Yes ___ No

* Maintenance record shows regular and adequate maintenance of the AMOS (cone checks, wires, RF absorbers, etc.)?

___ Yes ___ No

7.0 ***Microwave Emission - Final Test***

Line Name	Number of Testers	Scan Rate	Meter Type	Reject Limit	Comments on Scan Rate or Scan Pattern

general instrumentation :**warm-up, **reset zero, **dirty cones, **AC cover missing, **battery check, **voltage supply for AC powered meters, **barrel holding

8.0 ***Quality Audit***

General Tests **Line Names/ALL Lines/Lab Sampling Rate**

8.4 Life and Endurance Testing (Check items observed & fill in units)

Magnetron/weld RF hazard test				
Continuity check: interlocks, monitor, wiring				
Check door travel before sec. interlock actuation				
Open door (shut off-restart) operation test				
Presence and content of required labels				
Check for caution statements in User and Service manuals				
Insertion by finger or wire into concealed safety interlock(s) and cavity				

RF Emission Tests

Door viewing screen				
Door perimeter				
Door perimeter ~ door pulled & all interlocks operating				
Door perimeter ~ door pulled & only Secondary interlock operating				
Door hinge				
Control panel				
Vents and Louvers				
Underneath the oven (bottomless or exposed cavity)				
Automated Microwave Scanner (Audit rate - manual rescan)				

NP = Not performed, NA = Not applicable, ND = Not determined

8.1 Audit Test Records (Circle information permanently retained)

Final and Highest RF Value	Serial No.
Date of Test	Secondary Interlock Only RF
Safety Interlocks/Monitor Continuity	Label check
Daily Scanner Audit	Open Door (Shut Off - Restart) Test

8.2 Audit Size and Reaction Plan (review any actual instances of audit failures)

Critical Defects	**Reaction Plan**	**Failures?**	**Documented?**
Excess Emission	Test Entire Lot	Yes	Yes
Interlock/Monitor	Test Days Production	No	No
Open Door Operation	Tighten Sampling		
Missing Labels/statements			

8.3 Scanner Audit Reaction Plan

Has there been a failure in the scanner audit? (document adequate audit response)

No Yes (Explain) _____

9.3 Annual Calibration	Yes	No	Comments
Annual calibration of LCR is performed by:			
Absolute calibration of LCR is performed annually?			
Document shows annual calibration of LCR?			
All records restarted after annual calibration of LCR?			
Are they using JMI calibration data correctly?			
Do they perform absolute. cal. of survey meters every 3 yrs.?			

9.4 Repair	Yes	No	Comments
Disposition of defective instruments clearly documented?			
Are broken meters segregated and labeled?			
If the Narda probe is replaced, are the meter and new probe calibrated together?			

10.0 ***Record keeping***	Yes	No	Comments
Are the results of the quality control tests conducted on the production line kept for a minimum of 1 year after filing the annual report for these records?			
Are the quality control audit records, documentation of defective ovens found in audit, and results of audit reaction plan kept for a minimum of five years?			
Is a file maintained of all written communications from all sources concerning radiation safety including complaints, investigations, instructions, or explanations affecting the use, repair, adjustment, maintenance or testing?			
Is a file maintained of records necessary for the tracing of microwave ovens to distributors, dealers and purchasers?			
Have all the dealers and distributors been informed of their obligations to obtain the purchaser information?			

Manufacturer can trace shipment to dealers/distributors or purchasers by:

____ Model Number

____ Serial No.

____ Date of Manufacture

____ Other (Specify): _____