CHAPTER 86 - MEDICAL AND RADIOLOGICAL DEVICE MONITORING AND QUALITY CONFORMANCE

SUBJECT:	IMPLEMENTATION DATE
Inspection and Field Testing of Radiation-Emitting Electronic Products	01/01/2023
	COMPLETION DATE
	01/01/2023

DATA REPORTING

PRODUCT CODES	PRODUCT ASSIGNMENT CODES (PAC)
See Product Codes Search Engine for All Radiation-emitting Electronic Products: http://www.fda.gov/Radiation-EmittingProducts/ElectronicProductRadiationControlProgram/GettingaProducttoMarket/PerformanceStandards/ucm135508.htm	86001 INSPECTION OF MFRS OF LASER PRODUCTS 86002 FIELD IMPLEMENTATION OF SUNLAMP REGS 86004 FIELD TEST OF CABINET X-RAY 86006 FOREIGN PL 90-602 STANDARD INSPECTIONS 86006A CMPL TEST OF MICROWAVE OVENS – WEAC
Product Code Builder: https://www.accessdata.fda.gov/scripts/ora/pcb/index.cfm	

Table of Contents for Compliance Program 7386.001

Coversheet: Field Reporting Requirements

- Follow the Office of Regulatory Affairs (ORA) electronic submission procedures (e.g. eNSpect) for Establishment Inspection Reports (EIRs) including attachments, exhibits, correspondence between the ORA Division and firm, and other documentation.

- Submit standalone field test reports to RadHealthCustomerService@fda.hhs.gov. Field tests conducted as a part of inspection are processed consistent with ORA and CDRH current inspection procedures.

All joint Electronic Product Radiation Control (EPRC) and Quality System (QS) EIRs, which are classified Voluntary Action Indicated (VAI) or Offical Action Indicated (OAI) for EPRC by ORA, are sent to Center for Devices and Radiological Health (CDRH), in accordance with CDRH's process for EIR intake for review.

PART I - BACKGROUND

This compliance program provides instruction to FDA field and center staffs 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 health from electronic product radiation. FDA is to accomplish this goal by minimizing the emissions of the exposure of people to unnecessary electronic product radiation. Manufacturers are responsible for producing products that comply with all applicable mandatory radiation safety performance standards and which do not have defects affecting the safety of their use related to the emission of electronic product radiation. All electronic product manufacturers must comply with applicable requirements in Title 21 CFR 1000, 1002, 1003, 1004 and 1005.25. If a specific mandatory radiation safety performance standard applies to a manufacturer's product, then the manufacturer must also comply with Title 21 CFR 1005 (importation) and 1010 (the general performance standard) as well as assuring its product complies with the requirements of the applicable specific standard found in 21 CFR 1020 – 1050. It's worthwhile to note that per CDRH's guidance document, Medical X-Ray Imaging Devices Conformance with IEC standards, certain reporting requirements are exempted to reduce industry burden. For example, FDA does not object to the absence of reports for certain medical devices if the devices have been cleared through via a 510(k) premarket notification. Manufacturers are required to self-certify their own products to be compliant with applicable standards, based on a quality control testing program as described in 21 CFR 1010.2. The purpose of EPRC inspections and field tests is to verify that products comply with performance standards, and that the manufacturer's quality control testing program documents and ensures such product compliance and radiation safety.

This program applies to certain electronic products subject to specific radiation safety performance standards described in 21 CFR 1020 – 1040, including:

- 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

EPRC-only inspections and testing are scheduled for good cause based on various factors, including product risk, compliance history, and import/distribution volume. Manufacturers of electronic products not listed above, will also be subject to inspection or test for cause such as directed inspections from CDRH or the ORA Division having obtained information regarding a possible radiation hazard. Such for-cause is most easily assessed when a specific performance standard applies but there may be rare occasions where a manufacturer of an electronic product not subject to a specific performance standard (21 CFR 1020 - 1050) should be inspected. During a Quality Systems inspection, if EPRC failures to comply are identified, EPRC observations can be included in the FDA-483 and EIR. Diagnostic X-ray systems inspection and testing is conducted according to Compliance Program Guidance Manual 7386.003a.

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

Medical devices that are also electronic products 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 the discretion of CDRH and ORA Division. Examples of electronic products that are also 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

1. To evaluate an electronic product manufacturer's quality control and testing program for its ability to document and ensure product compliance with applicable performance standards and radiation safety.

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

3. To obtain correction of deficient quality control and 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. Only individuals trained in EPRC requirements should perform these inspections and field tests. Contact CDRH at RadHealth@fda.hhs.gov (see the CDRH management directory for specific staff contacts: https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHOffices/ucm127854.htm) should the need for expertise, not otherwise available in the ORA Division, become apparent. At the discretion of CDRH and the ORA Division, radiological health specialists or a CDRH SME (subject matter expert) may 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. Workplans should include ORA Division inspections and known CDRH assignments. The establishment inventory and guidance from CDRH should be used to assist in determining inspection and field test locations.

2. Pre-announcement of Inspections
   If the inspection is intended to cover medical device Quality System regulation (e.g. sunlamp devices), the inspection must be pre-announced according to medical device inspection procedure. Otherwise, pre-announcement of EPRC inspections conducted under EPRC 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 and testing program and product conformance with performance standards.

Inspections of manufacturers of electronic products that are also medical devices must be pre-announced unless the inspection is considered a for-cause inspection (See section 702 of the FDA Reauthorization Act).

3. Pre-announcement of Field Tests
Unless there is a basis for no pre-announcement of field tests, schedule an appointment with the electronic product's 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
Planned 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 – E, 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 or user facilities (e.g. retail tanning salons) that have not yet been inspected and /or the products introduced by those manufacturers.

   d. Products incorporating technology new to the US market or a major change in existing product and/or the manufacturers introducing those new products.

5. Investigator Safety
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 contacts for WEAC.

PART III - INSPECTIONAL

A. INSPECTIONAL STRATEGY

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

B. ELECTRONIC PRODUCT RADIATION CONTROL INSPECTION

1. Items to cover
   a. The firm's product(s) comply with the requirements of the applicable specific performance standard and the general performance standard to the extent that:
      i. The product has required performance features, labels, and instructions for operation, maintenance and service.
      ii. Review the manufacturer's justification for its measurement procedures. Include in your evaluation justification for use of the procedure, acceptance criteria for its tests, instrument choice, and calibration. If there are concerns, collect and submit relevant documented procedures and test results for further review.
      iii. The product emissions are properly characterized. Witness the measurements performed by the manufacturer. Confirm they are made according to the manufacturer's procedures. Assess if the procedures appear to be adequate to ensure compliance with performance standards. Also verify results are recorded appropriately.
      iv. The brochures, catalogs, websites, and other promotional material contain any required warnings or label reproductions if required by the applicable specific performance standard.
   b. The firm has procedures and documents for control of the manufacturing process appropriate to the product type and production volume including:
      i. Stock and inventory control
      ii. Bills of materials
      iii. Controlled drawings and procedures that are authenticated and current
      iv. Incoming inspection, criteria for acceptance/rejection, disposition of rejected parts, and segregation of accepted from rejected parts
      v. Finished goods storage and inventory
   c. The firm has quality control and testing procedures and records to cover:
      i. In-production tests to verify product compliance during production
      ii. Final test and inspection of finished products
      iii. Maintenance and calibration of test equipment
      iv. Submission of required reports such as product and annual reports, accidental radiation occurrence (ARO) reports, and notification of non-compliance or defect reports. For electronic products that are also medical devices, the firm's

procedure should include instructions and criteria for submitting ARO vs. medical device reports (MDR). Please note that an ARO may be required when a MDR is not required, for example when service personnel are exposed to radiation. Additionally, be aware that while the Quality Systems regulations requires a procedure for evaluating MDRs, there is no such requirement for ARO evaluations. 21 CFR 1002.20 simply requires that when the manufacturer determines there was such an event, it must be reported to FDA.

d. The firm maintains records required by the electronic product radiation control regulations:
    i. Distribution to purchasers or distributors
    ii. Radiation safety related communications, complaints, and inquiries
    iii. Real or alleged injuries and any subsequent investigation
    iv. Remedial actions taken for reports of non-compliant products, products with defects, radiation safety complaints, or injuries
    v. Reports submitted to CDRH

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

2. Records to collect
    a. Organization chart identifying key individuals responsible for product design, manufacturing and quality control
    b. Testing procedures and where possible photographic evidence showing that testing does not ensure product safety or compliance with applicable standards
    c. Samples of all labels, as practicable
    d. Manuals, in part or whole, that fail to contain required materials
    e. Brochures and catalogs that fail to contain required warning or label reproductions
    f. Distribution records for any violative products
    g. Document evaluation justifications for use of the procedure, acceptance criteria for its tests, instrument choice, and calibration, if there are concerns.

Note: Please see IOM section 5.3.8 – Records Obtained, for additional information and for collecting electronic records.

3. 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 it being added to an Import Alert and be subject to detention without physical exam (DWPE) upon attempted entry into the U.S. FDA's Import Alerts – such as 95-01 (sunlamp products), 95-04 (laser pointers, laser gunsights, laser light shows, and similar products), and 95-05 (electronic products) – are listed at:

https://www.accessdata.fda.gov/cms_ia/ialist.html

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 U.S. 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, investigators have been trained in general EPRC requirements and may have specialized training in one or more performance standards.

4. Medical device inspections
Radiation-emitting medical devices are subject to both electronic product radiation control requirements and medical device requirements including the Quality System (QS) regulation Medical Device Reporting (MDR), Medical Device Tracking, Corrections and Removals, and Registration and Listing, and Unique Device Identification (UDI) (21 CFR 830 and 21 CFR 801 Subpart B).

Based on ORA Division 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:

a. 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 record keeping, certification to applicable performance standards, and a quality control and testing program that ensures product compliance and radiation safety. Report EPRC time under the appropriate PAC identified in this program. EPRC reporting should comply with requirements defined in 21 CFR 1002 or notifications defined in 21 CFR 1003.
b. 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 specific 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 specific standard, and self-certification required by the general performance standard (21 CFR 1010). Report medical device time under the appropriate medical device PAC identified in Compliance Program 7382.845.

While it is preferable to perform joint QS and EPRC inspections to conserve agency resources, a joint QS and EPRC inspection is not applicable for some firms. FDA may conduct an EPRC-only inspection of a firm currently participating (active) in the Medical

Device Single Audit Program (MDSAP) when there is 'good cause'. In these circumstances, please see the following guidance:

a. The EPRC-only inspection should follow the instructions provided specifically in this program, which can follow the general flow of a Quality System Inspection Technique (QSIT) inspection. However, there are records which would not be appropriate to review during EPRC-only inspections and other documents which may be reviewed for limited purposes. For example, review of records covering complaints, equipment calibration, DMR, DHRs, non-conformance reports, and correction/removal fall within the scope of an EPRC-only inspection, so long as the focus of reviewing the records is to ensure conformance with applicable EPRC performance standards. The review of procedures covering complaint handling, MDR, and CAPA should not be carried out with the intention of identifying QS deficiencies, and no QS deficiencies should be cited on the FDA 483 for an EPRC-only inspection (any potential expansion in the scope of the inspection should be discussed with FDA/ORA management). Review of such procedures and records may be appropriate in an effort to identify concerns related to radiation emission and to determine if the firm took appropriate actions, such as a Notification of Defect or Failure to Comply, and Corrective Action Plan.
b. At the beginning of the inspection, the investigator should explain that the focus of the inspection is on emission of radiation, as measured by compliance with the EPRC regulations, and the extent to which corresponding test procedures are followed, as well as the extent to which the firm may use and fully implement a quality control testing program with associated requirements to define and implement production procedures.

5. 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:
   a. Sample analysis results
   b. Prior inspectional observations
   c. Questionable information in product reports
   d. Reports of injuries related to the firm's products
   e. Consumer or trade complaints/allegations about product, labeling or process problems at 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 coverage provided in the assignment.

6. Inspectional observations review
Discuss inspectional observations with the firm prior to concluding the inspection. Record EPRC observations on the Form FDA-483. This compliance program provides instruction concerning severity of violations observed to identify major deficiencies. If both EPRC and

medical device observations are noted, they should be grouped separately on the form using subheadings as needed.

The ORA Division has discretion to offer annotation of the FDA 483 if the investigator and firm believe annotation will facilitate the inspection process. When a FDA 483 is annotated, it should be done in accordance with the IOM Chapter 5 (Section 5.2.3.4).

C. ELECTRONIC PRODUCT RADIATION CONTROL FIELD TESTS

Field tests are examinations of installed electronic products, which have been introduced into commerce. Field tests may be conducted at trade shows, manufacturing facilities (e.g. laser welders or laser engravers used in production), or other sites where products are in use (e.g. tanning salons). 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. Manufacturer information (of the product being tested) is required for the field test, as it is needed in order to pursue compliance action.

1. Items to cover:
   a. 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.
   b. Product incorporates required performance features
   c. 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 (https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/MedicalDeviceQualityandCompliance/UCM261429.pdf).

2. Records to collect:

   a. Purchase information documenting the manufacturer and distributor of the product
   b. 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
   c. Promotional literature to show product specifications and intended use
   d. Samples of all labels, as practicable
   e. Manuals (or manual sections) that fail to contain required materials

Note: Please see IOM section 5.3.8 – Records Obtained, for additional information and for collecting electronic records.

3. Field test observations review

   Deficiencies identified during the field test may be shared with the facility management during a verbal discussion and/or by listing the deficiencies on a FDA-483, where appropriate.

   Discuss 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 on the field test record form. If a field test procedure is used as part of an inspection, results should be noted on the FDA-483 along with inspectional observations.

   When the field examination is carried out at a point of use, indicate that FDA may follow up with the manufacturer and take action to correct any deficiencies identified, as appropriate. If there is a product that poses an immediate radiation hazard to health and safety, recommend the product should not be used until corrected.

   Note the field test checklist is not a stand-alone document. Therefore, details of the product tested and the person providing the information may be needed in an EIR and/or internal memorandums.

D. 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 or consumer complaints, or from discovery via the Internet or printed materials of promotion of products that may have a defect or may not comply with applicable performance standards.

E. PHYSICAL AND DOCUMENTARY SAMPLES

Samples are not required to support a letter issued to the firm or further action to include program disapproval. 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 ORA Division management, ORA/WEAC, 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 such as photographs, labeling, actual product labels, packaging inserts, etc. Documentary samples are recommended when a Judicial Action is being considered, in order to fully substantiate interstate commerce.

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

Laboratory testing is not covered by this compliance program. CDRH or WEAC testing may be required on special assignments under CPGM 7386.006, Compliance Testing of Radiation Emitting Electronic Products, or as indicated in Part III.E of this program.

PART V - REGULATORY/ADMINISTRATIVE FOLLOW-UP

A. REGULATORY STRATEGY

The intent of this program is to identify and address problems that pose a radiation safety hazard or are a flagrant violation of EPRC requirements. 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. ORA Divisions only have direct reference authority for EPRC letters in certain areas. Those areas are described in Chapter 4 of the RPM. CDRH is available for consult in assessing product noncompliance or developing regulatory and enforcement strategy.

Actions that are unlawful under the EPRC provisions include, but are not limited to:

- Introduction into commerce of electronic products that fail to comply with an applicable FDA 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
- Failure to submit a notification of defect or noncompliance
- Failure to submit proposed corrective action plan (CAP)
- Failure to certify or false certification of an electronic product

See 21 USC Sec. 360oo - *Prohibited acts* for a complete list of unlawful actions. Note: The first prohibited act applies only to manufacturers but all of the other prohibited acts apply to any person.

Available regulatory enforcement actions for EPRC prohibited acts are:

- Issuance a notification of defect or non-compliance letter
- Imposition of civil penalties
- Injunction
- Seizure – Only for adulterated or misbranded medical devices that are also electronic products

These actions may be combined. Details regarding these enforcement actions are described below in Section C, Regulatory Action.

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 – E 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. ORA DIVISION RESPONSIBILITIES

1. Reporting inspection and test findings

   a. Inspection reports
   Completed inspection and test records used during the inspection should be documented

in an Establishment Inspection Report (EIR) and include appropriate attachments 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
Document field tests as Field Examinations/Tests and in memorandums which incorporate details relating to the site, personnel involved in significant discussions along with the field test records as attachments.

2. EPRC observations
Inspectional observations should be listed on the FDA-483.

a. Inspection classification
Based on inspectional EPRC findings, the ORA Division puts forward an initial classification of the inspection as OAI (Official Action Indicated), VAI (Voluntary Action Indicated), or NAI (No Action Indicated). CDRH provides the final classification for the EPRC findings after reviewing the EPRC observations in EIRs.

An OAI inspection classification occurs when significant objectionable conditions or practices were found and regulatory action is warranted to address the establishment's lack of compliance with statutes and regulations. Examples of findings that would result in an OAI classification include, but are not limited to:

- Total failure to establish a quality control and testing program capable of ensuring radiation safety of the product or compliance with applicable performance standards.
- Any single observation of a condition that poses an immediate radiation hazard to health and safety.
- Observations of any conditions that include radiation safety defects or failures to comply with applicable mandatory FDA radiation safety performance standards which, without correction, could pose a radiation hazard if the issue or defect is not addressed.

A VAI inspection classification occurs when objectionable conditions or practices were found that do not meet the threshold of regulatory significance or do not pose an immediate radiation hazard to health and safety.

A NAI inspection classification occurs when no objectionable conditions or practices were found during the inspection or the significance of the documented objectionable conditions found does not justify further regulatory actions.

Consult CDRH if additional guidance is needed. 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

To determine the appropriate regulatory action the ORA Division (Direct Reference only) and CDRH should consider inspection and test findings; the public health significance of objectionable conditions; the firm's history; the firm's responsiveness to observations; and whether the problem is widespread and continuing. Available actions include notification letters (21 CFR § 1003.11 - a notification letter often results in a mandatory corrective action (21 CFR part 1004)), civil penalties, injunctions, and seizures. Informal consultation with the Center at an early stage in the development of a regulatory action is encouraged; contact CDRH at RadHealth@fda.hhs.gov.

1. Timeframes for action
   Immediately notify CDRH and State and local health authorities about any product that poses an immediate radiation hazard to health and safety because of a defect or failure to comply. State and Local health authorities should be notified through a Radiological Health Representative (RHR).

   For all inspections and field tests that may require issuance of a notification letter, the EIR should be provided to CDRH through the ORA Division compliance officer to allow sufficient time to review, draft, and secure approval for the letter. The recommended timeframes for clearance of letters are provided in Chapter 4 of the Regulatory Procedures Manual (RPM): https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-manuals/regulatory-procedures-manual.

2. Notification letters
   The Electronic Product Radiation Control provisions of the Federal Food Drug and Cosmetic Act (Section 535) and related regulations (21 CFR 1003.11) require the Agency to immediately notify manufacturers in writing upon determining that an electronic product fails to comply with an applicable performance standard or has a defect (21 CFR 1003.2). If the notified manufacturer does not submit a refutation (21 CFR 1003.11(a)(3)) or request an exemption from notification (21 CFR 1003.30(a)) or if the refutation or exemption request are denied by CDRH, then the notification will result in a mandatory corrective action (21 CFR 1004) for products which have left the place of manufacturer. Also, manufacturers should be made aware that they may not initiate any entries into commerce of electronic products that have known failures to comply. Issuance of all letters should follow Chapter 4 of the RPM. For electronic products that are also medical devices, notification letters may incorporate verbiage from Warning/Untitled Letters (and vice versa), in circumstances where there are both failures to comply with EPRC regulations as well as violations of medical device statutes.

   CDRH has direct reference authority to issue most EPRC letters. When there are FDA-483 observations and/or "Discussion with Management" items involving the EPRC regulations, ORA forwards the report with exhibits and recommended action to CDRH for review and follow-up. CDRH copies the accomplishing ORA Division on any letters issued and consults

on regulatory and enforcement strategy when needed.

a. Notification – Options and Details
Notifications must include at least one defect (21 CFR 1003.2) or one failure to comply with applicable performance standards. The applicable performance standards are the general performance standard (21 CFR 1010) and at least one specific performance standard (21 CFR 1020 – 1050). The general performance standard only applies to electronic products subject to a specific performance standard. Defects may be cited for products subject to performance standards but only if the safety issue of concern is not also a failure to comply with those standards. If no specific performance standard applies then defect is the only option available to cite in a notification letter.

A manufacturer's failure to fulfill applicable reporting and record keeping requirements (21 CFR 1002) is unlawful; however, it is not a failure to comply with a performance standard. Failures related to reports and record keeping may be included as additional violations that the manufacturer must correct in addition to other actions and responses required by the notification letter.

A manufacturer that discovers, or is notified of, a failure to comply with a performance standard must immediately cease entry into commerce of affected electronic products. It is unlawful for a manufacturer to introduce an electronic product into commerce if it fails to comply with applicable performance standards. Before resuming entry into commerce a manufacturer must: 1) correct the design, manufacturing, or assembly issue that caused the failures to comply; 2) if there are any affected products that have not left the place of manufacture they must be modified to assure they fully comply with the performance standards; and 3) submit any required radiation safety reports, or report supplements, that document the changes made to assure new products will fully comply with the performance standards. The above actions are independent of a manufacturer's corrective action plan for affected electronic products that have left the place of manufacture.

If there are indications (evidence, compliance history, lack of any written procedures, etc.) that a manufacturer is unlikely to correct root causes of its products' failures to comply, then a quality control and testing program disapproval should be considered (21 CFR 1010.2). Manufacturers are usually informed of program disapproval in a notification letter. A manufacturer's quality control and testing program can be disapproved if that program cannot assure that electronic products comply with applicable performance standards before introduction into commerce. A manufacturer may request that CDRH rescind a program disapproval after the manufacturer has submitted evidence that they have implemented necessary changes to assure new electronic products will comply with the applicable standards. If CDRH concurs that the evidence shows that a valid quality control and testing program has been established, then the program disapproval will be rescinded. In extreme cases a follow up inspection may be required to verify that an adequate quality control and testing program has been

established. Until CDRH rescinds a program disapproval the affected manufacturer is prohibited from certifying electronic products. It is unlawful to enter electronic products subject to performance standards into commerce without certification or with false certification.

If a manufacturer has submitted a complete notification (21 CFR 1003.20) to the Agency there is no need to issue a notification letter for the defects and failures to comply identified in that notification. Manufacturers are required to notify the Agency if they discover a failure to comply or defect (21 CFR 1003.10 & 1003.20).

The exemption criteria in the regulations (21 CFR 1003.31(c)) should be considered when defects and failures to comply present a minor risk. If the defect or failure to comply does not create a significant risk of injury, including genetic injury, to any person, then it may be appropriate to include an approved exemption from notification of dealers, distributors, and purchasers with the notification sent to the manufacturer. The result of this option is that the manufacturer must correct only its undistributed electronic products and future production.

b. Manufacturers' options to Refute or Request Exemption
Within 15 days of receipt of FDA's notification of defect or failure(s) to comply with performance standards, a manufacturer may refute the existence of the alleged noncompliance(s) (21 CFR 1003.11(a)(3)) or request an exemption from purchaser notification (21 CFR 1003.30). When a manufacturer refutes the alleged noncompliance, or requests an exemption, the manufacturer must submit written evidence and views to CDRH. CDRH will evaluate the manufacturer's views and evidence and issue a response to the manufacturer regarding its request for exemption or refutation. The criteria for granting exemption is that the defect or failure to comply does not create a significant risk of injury, including genetic injury, to any person (21 CFR 1003.31(c)). If an exemption from notification is granted the manufacturer is no longer required to submit and implement a corrective action plan (21 CFR 1004.1(a)) for products that have left the place of manufacture. Refer to RPM Chapter 7, Attachment E for information on responding to exemption requests and refutations. Approvals can include additional conditions.

c. Manufacturers required to Notify Dealers, Distributors, and Purchasers
When a manufacturer who has received a notification letter is not granted an exemption or does not successfully refute all charges, then the manufacturer is required (21 CFR 1003.11(c)) to furnish a notification to Dealers, Distributors, and Purchasers (21 CFR 1003.10(b)) in the manner specified in the regulations (21 CFR 1003.21) within 14 days of receipt of a letter denying a refutation / a request for exemption or the notification letter if no refutation or exemption request was submitted. Additionally, repurchase, repairs, or replacement of affected electronic products is required in accordance with a corrective action plan (21 CFR 1004).

If repurchase, repairs, or replacement (corrective action) is required, then the manufacturer must submit a corrective action plan to CDRH for approval. The manufacturer is not required to wait for approval before implementing a corrective action plan; however, CDRH can require more or different actions if we do not approve the submitted corrective action plan or if the corrective action proves to be inadequate to correct the electronic products. Corrective action plan approvals may also include conditions set by CDRH. Manufacturers are required implement corrective actions without any charge to the purchaser. Refer to RPM Chapter 7, Attachment E for approval of manufacturer's corrective action plans. Note: If a correction takes place in accordance with an approved corrective action plan (21 CFR 1004) then a manufacturer of an electronic product that is also a device does not need to also submit a notice of correction and removal (21 CFR 806.10(f)).

3. Civil Penalties/Injunctions see 21 USC Sec. 360pp – Enforcement
   Civil penalties should be recommended for actions prohibited under 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 CDRH at RadHealth@fda.hhs.gov or refer to CDRH Management Directory (https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHOffices/ucm127854.htm).

   If an establishment has a continuing pattern of significant deviations in spite of past warnings, injunction will usually be the appropriate action. If a serious health hazard exists, the recommendation should include a request for a temporary restraining order (TRO) to restrain manufacturers, dealers and distributors of electronic products from selling or otherwise disposing of electronic products which do not conform to an applicable standard except when such products are disposed of by returning them to the distributor or manufacturer from whom they were obtained. Document the failure(s) to comply with applicable performance standards in the inspection report per the instructions in Chapter 6 of the RPM. Civil penalties and injunctions may be recommended concurrently. Note: the Civil Penalty amounts for EPRC violations are lower than those for devices.

4. Detention/Seizure
   Use administrative detention and recommend seizure of a defective or noncompliant electronic product that is also a medical device only if all three conditions below apply:
   a. There are conditions that pose an immediate radiation hazard to health and safety
   b. The owner/operator refuses to remove the product from service or returns the device to use before the severe radiation hazard to health and safety is corrected
   c. The EPRC provisions were ineffective in achieving timely correction by the manufacturer

Note: Seizure only may be applied to electronic products that are also adulterated or misbranded medical devices.

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.

ORA Divisions 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 ORA Divisions coordinate regulatory activity with appropriate state representatives through the RHR (Radiological Health Representative) and OP (Office of Partnerships) 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 ORA Division 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)
   https://www.fda.gov/regulatoryinformation/lawsenforcedbyfda/federalfooddrugandcosmeticactfdcact/default.htm

2. Regulations
   21 CFR 1000 – 1005, General Requirements for All Electronic Products which Emit Radiation
   https://www.ecfr.gov/cgi-bin/text-idx?SID=dfc9b20669f30a419ea8ef757673de0c&mc=true&node=pt21.8.1000&rgn=div5

   21 CFR 1010, Performance Standards for Electronic Products: General
   https://www.ecfr.gov/cgi-bin/text-idx?SID=dfc9b20669f30a419ea8ef757673de0c&mc=true&node=pt21.8.1010&rgn=div5

   21 CFR 1020 – 1050, Specific Performance Standards for Electronic Products
   https://www.ecfr.gov/current/title-21/chapter-I/subchapter-J/part-1020?toc=1
   Ionizing Radiation Emitting Products
   https://www.ecfr.gov/cgi-bin/text-idx?SID=dfc9b20669f30a419ea8ef757673de0c&mc=true&tpl=/ecfrbrowse/Title21/21cfr1020_main_02.tpl

   Microwave and Radio Frequency Emitting Products
   https://www.ecfr.gov/cgi-bin/text-idx?SID=dfc9b20669f30a419ea8ef757673de0c&mc=true&node=pt21.8.1030&rgn=div5

   Light-Emitting Products
   https://www.ecfr.gov/cgi-bin/text-idx?SID=dfc9b20669f30a419ea8ef757673de0c&mc=true&node=pt21.8.1040&rgn=div5

   Sonic, Infrasonic, and Ultrasonic Radiation-emitting Products
   https://www.ecfr.gov/cgi-bin/text-idx?SID=dfc9b20669f30a419ea8ef757673de0c&mc=true&tpl=/ecfrbrowse/Title21/21cfr1050_main_02.tpl

3. Regulatory Procedures Manual (RPM)
   https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-manuals/regulatory-procedures-manual

4. Investigations Operations Manual (IOM) - Chapter 5
   https://www.fda.gov/media/76769/download

5. FDA Web Sites

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

   ORA home page
   https://www.fda.gov/about-fda/office-global-regulatory-operations-and-policy/office-regulatory-affairs

   CDRH home page
   https://www.fda.gov/MedicalDevices/default.htm

   Electronic Product Radiation Control home page
   https://www.fda.gov/Radiation-EmittingProducts/default.htm

   Product Code Classification Database (searchable)
   https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm

   FDA Guidance Documents for Medical Devices and Radiation-Emitting Products (searchable)
   http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfggp/search.cfm

B. ATTACHMENTS

Attachment A – Examples of Non-Compliant reporting and quality control testing program Items

Attachment B – Specific Instructions for Laser Product Inspections and Tests

Attachment C – Specific Instructions for Sunlamp Product Inspections and Tests

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

Attachment E – Specific Instructions for Microwave Oven Product Inspections and Tests

C. PROGRAM CONTACTS

CDRH Management Directory by Organization

Submit additional evidence from inspections and/or all required reports to CDRH at RadHealthCustomerService@fda.hhs.gov

Submit any questions related to CDRH's policies and procedures at RadHealth@fda.hhs.gov.

For CDRH staff contacts, see:
https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHOffices/ucm127854.htm

Office of Regulatory Affairs (ORA)

See ORA Directory for contact information for ORA Headquarters and Field Offices:
https://www.fda.gov/aboutfda/centersoffices/officeofglobalregulatoryoperationsandpolicy/ora/contactora/default.htm

U.S. Food & Drug Administration
Winchester Engineering & Analytical Center (WEAC)
109 Holton St.
Winchester, MA 01890
E-mail: ORAWEACMNGTTM@fda.hhs.gov
Phone: (781)756-9700
Fax: (781)756-9757

PART VII - CENTER RESPONSIBILITIES

CDRH is responsible for the final review and classification of inspections made under this program, as well as the issuance of any follow-up letters. Exceptions where the ORA Division has direct reference authority are noted above in Part V, 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.

ATTACHMENTS

ATTACHMENT A: REPORTING, CERTIFICATION, AND QUALITY CONTROL

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.

The ORA's electronic system, eNSpect, has the complete list of cites and all the relevant options. The following list should be considered only as limited examples of non-compliant items.

Reporting

1002.10	No product report
	Never submit any reports to FDA
	Miss one product report but has reports on file
1002.11	No supplemental report
	Never submit any supplemental reports to FDA
	Miss one supplemental report but has others on file
1002.13	No annual report
1002.20	No accidental radiation occurrence report

Certification and Identification

1010.2	No certification label
1010.3	No identification label on the product
	If any information of the manufacturer is not found in any labeling
	If any information of of the manufacturer is available in user's manual
1010.3	Coded or abbreviated date
1010.3	Month & year in serial number on non-consumer product
1010.3	No manufacturer address
1010.3	Incomplete address
1010.3	Label not legible (English), viewable, or permanent

Quality Control

1010.2(c)	Program does not assure adequacy of safeguards against hazardous radiation and/or does not assure compliance with standard
1030.10(c)(3)	No measurements/tests done for certification
	Measurement uncertainties not included
	Incomplete measurements/testing, program exists but lacks record
1030.10(c)(4), (5), (6)	No inspection of labels or manuals

ATTACHMENT B: LASER PRODUCT INSPECTIONS AND TESTS

Background

The Laser Product 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, and updated in 2007 to include IEC 60825-1:2007 and IEC 60601-2-22, stating that it would not object to compliance with specified requirements of the international standards in lieu of comparable requirements of the CDRH standard. Additionally, CDRH has published Laser Notices 56 in May of 2019, in which CDRH has intended to harmonize requirements of the standard those of IEC 60825-1: 2014. Check the list of Notices to the Laser Industry for any updates: https://www.fda.gov/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/HomeBusinessandEntertainment/LaserProductsandInstruments/ucm116422.htm.

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/3B and IV/4 medical lasers (e.g. surgical laser)
- Class IIIb/3B and IV/4 industrial lasers used in material processing
- Class IIIb/3B and IV/4 lasers used in law enforcement or military applications
- Manufacturers with known or suspected problems based on previous inspection, field tests or complaints
- Manufacturers introducing new technology to the US market (The firm's website or CDRH staff may identify a new product as featuring a breakthrough in technology)
- Manufacturers with a large portion of the US market share for any laser product. However, manufacturers of Class I low risk laser products, such as optical disk drives or laser printers, should not be inspected or tested. Class I industrial products with high-power embedded lasers are made in small quantities and can be considered high risk.
- New manufacturers not yet inspected

Many FDA investigators have been specifically trained in general EPRC requirements and also have specialized training in the laser product performance standards. They should perform these inspections

and field exams and may train additional field staff or accompany a medical device investigator to conduct joint EPRC/medical device inspections. If an investigator has training in both EPRC and QSIT inspections, a single Investigator 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 EPRC
https://www.fda.gov/Radiation-EmittingProducts/ElectronicProductRadiationControlProgram/GettingaProducttoMarket/default.htm

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
https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM095304.pdf

Reporting Guide-Radiation Safety Product Report for Laser Products
https://www.fda.gov/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/HomeBusinessandEntertainment/LaserProductsandInstruments/default.htm

Reporting Guide-Radiation Safety Product Report for Laser Light Shows/Displays
https://www.fda.gov/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/HomeBusinessandEntertainment/ucm118907.htm

Laser Quality Control Guide
https://www.fda.gov/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/HomeBusinessandEntertainment/LaserProductsandInstruments/default.htm

Refer to the laser products main page for guidance documents and additional information:
https://www.fda.gov/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/HomeBusinessandEntertainment/LaserProductsandInstruments/default.htm

Laser Notices to Industry:
https://www.fda.gov/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/HomeBusinessandEntertainment/LaserProductsandInstruments/ucm116422.htm

Laser Product Codes

Laser product codes can be searched in FDA Radiation Emitting Electronic Product Codes database: **https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD_RH/classification.cfm.**

For example, under "Product Description" section, you can choose the following categories if you want to find a filtered list of codes.

- Data measurement/transmit/control laser products
- In Vitro and other medical laser products
- Laser light show/display products
- Laser products (pre-standard)
- Material processing laser products
- Medical laser products
- Other demonstration laser products
- Other laser products
- Positioning medical laser products
- Research/scientific/laboratory laser products
- Safety/Security/Surveillance laser products
- Surveying/leveling/alignment laser products
- Toy/novelty/play laser products
- Utility/peripheral laser products

Please note that Laser Products (pre-standard) refers to any laser products that were manufactured prior to August 2, 1976, when the FDA laser product performance standard went into effect.

If you want all laser codes, then selecting the applicable performance standard will return all the codes.

The ORA's electronic system, eNSpect, has the complete list of cites and all the relevant options. The following list should be considered only as limited examples of non-compliant items.

1040.10(d)	Classified in higher class
1040.10(d)	Classified in lower class
1040.10(f)(1)	Protective housing allows unnecessary body access to Class IV or high IIIb radiation
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)
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
1040.10(f)(1)	Protective housing allows unnecessary body access to Class IIa or IIIa radiation In a Class IV or IIIb product In a Class I, IIa, II, or IIIa product
1040.10(f)(1)	Protective housing allows unnecessary body access to Class II radiation In a Class II product In a Class I product
1040.10(f)(2)	Safety interlocks absent when required
1040.10(f)(2)	Single safety interlock when redundant required
1040.10(f)(2)	Single component with multiple contacts when redundant required
1040.10(f)(2)	Defeatable safety interlock lacks indication
1040.10(f)(2)	Defeatable safety interlock fails to prevent replacement of protective housing during defeat
1040.10(f)(3)	No remote interlock connector, or interlock connection occupied by another required control/feature
1040.10(f)(4)	No key control
1040.10(f)(4)	Key control removable when on
1040.10(f)(5)	No emission indicator
1040.10(f)(5)	No delay preceding radiation emission
1040.10(f)(5)	Remote control lacks emission indicator
1040.10(f)(6)	Beam attenuator without approvable alternate
1040.10(f)(6)	Beam attenuator absent but product has approvable alternate
1040.10(f)(7)	One or more controls are located in an area where laser exposure (> Class I) can occur: Class II, IIa, IIIa Class IIIb, Class IV
1040.10(f)(8)	Viewing optics Hazardous Non-hazardous for viewing period
1040.10(f)(9)	No scanning safeguards

1040.10(f)(10)	No manual reset
1040.10(g)(1), (2), and (3)	Warning logotype None Classification too low Classification too high
1040.10(g)(4)	Warning logotype output information incorrect For Class IIIb and IV products For Class I, II, and IIIa products
1040.10(g)(5)	No aperture label
1040.10(g)(5)	Aperture label not in close proximity to aperture
1040.10(g)(5)	Aperture label wording incorrect
1040.10(g)(6), (7)	No protective housing labels
1040.10(g)(6), (7)	Protective housing placement inappropriate
1040.10(g)(6), (7)	Protective housing wording wrong
1040.10(g)(8)	Invisible radiation warning on labels
1040.10(g)(9), (10)	Label positioning and legibility
1040.10(h)(1)(i)	User instructions promote unsafe practices User instructions not adequate to avoid exposure Not in English
1040.10(h)(1)(ii)	User instructions have incorrect/incomplete radiometric specifications
1040.10(h)(1)(iii)	User instruction have inadequate label reproductions or description of locations of labels
1040.10(h)(1)(iv)	User instruction have inadequate listing of controls Inadequate caution statement
1040.10(h)(2)(i)	Reproduction of warning logotype not in catalogs
1040.10(h)(2)(ii)	Service information inadequate
1040.11(a)(1)	Means to measure medical laser output None Inaccurate
1040.11(a)(2)	Inadequate/missing calibration procedure/schedule
1040.11(a)(3)	Aperture label
1040.11(b)	Excessive output on surveying lasers
1040.11(c)	No variance for demonstration Class IIIb or Class IV lasers

Sample Laser Product Inspection or Field Test Record

LASER PRODUCT TEST RECORD

Date of Examination:
Name of Investigator:

Facility Visited (Name, address and FEI if applicable)
Person Interviewed:
Manufacturer (*Required*): _____
Manufacturer FEI: _____

Note: Laser Notice 50 and 56 refer to conformance to IEC standards, see: https://www.fda.gov/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/HomeBusinessandEntertainment/LaserProductsandInstruments/ucm116422.htm

Model:_____ Serial Number:_____

Class: Either IEC 60825-1 or FDA/CDRH laser performance standard class _____

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:

B. 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.

NA = Not applicable, ND = Not determined

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 an approved variance, and approved exemption, or Laser Notice 50 or 56 (or other Laser Notices) require modified certification labels 1010.4(d)

   d. Does the manufacturer conform to parts of the IEC Laser standards, pursuant to a Laser Notice? Yes___ No___

      Note: Laser Notice 53 refers to label placement alternatives, see: https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm094371.htm

      Note: Laser Notices 15, 25, and 52 refer to exemption options, see: https://www.fda.gov/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/HomeBusinessandEntertainment/LaserProductsandInstruments/ucm116422.htm

   e. 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___

      Note: Laser Notice 48 refers to the manufacturer's address being encoded, see:

https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM095208.pdf

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: _____
(Month should be spelled out and year shown as a four-digit number)

g. Remarks: _____

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

C. 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. If the product emits a Class III/IV (3/4) beam, 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_____; exposed 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%? 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 exceeds 1 mW? Is the product not ophthalmic but with an aiming beam that exceeds 5 mW?

Yes ___ No ___

i. Remarks: _____

Note: Laser Notices 31, 34, and 44 refers to medical laser products, see: https://www.fda.gov/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/HomeBusinessandEntertainment/LaserProductsandInstruments/ucm116422.htm

2. Is the product a surveying, leveling, and alignment product, such as a laser pointer?

Yes___ No___ ND___ NA___

a. Is access prevented for wavelengths of 400 nm to 700 nm to radiation power in excess of 5.0 mW (Class IIIa)?

Yes___ No___ ND___ NA___

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

Yes___ No___ ND___ NA___

c. Remarks: _____

3. Is the product a demonstration laser product?

Yes___ No___ ND___ NA___

Note: Laser Notices 22, 40, 46, 47, 51, and 55 refer to laser light show projectors and shows, see: https://www.fda.gov/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/HomeBusinessandEntertainment/LaserProductsandInstruments/ucm116422.htm

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

Yes___ No___ ND___ NA___

b. Remarks (what is the internal beam output level, describe how a higher power beam is attenuated down to at or below IIIa/3R, such as protective housing, interlocks, scanning, etc.):

_____

D. Label Requirements

Note: if the product conforms with the IEC laser standard(s), the labels will likely not look exactly like the labels in 21 CFR 1040.10(g) and 1040.11(a)(3) but the information should be very similar. Taking photos and adding them to this document would be very helpful. Please ensure the labels match the printed labels in the user manual.

Note: Laser Notice 53 refers to label placement alternatives, see: https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm094371.htm

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 laser type, laser medium, 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?
   Location: _____

   Yes___ No___ ND___ NA___

   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 if the certification refers to the applicable Laser Notice.

2. Aperture label (for Classes II, IIIa, IIIb, IV, 3R, 3B and 4) 1040.10(g)(5),(8),(9), and (10), and 1040.11(a)(3) for medical laser products.

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? (Location: _____)

Yes___ No___ ND___ NA___

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)). If there are panels or doors that would not be opened for any operation or maintenance procedures, then a noninterlocked protective housing label would be required.

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 the opening created by removal or displacement 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", “invisible and visible” or "invisible and/or visible" radiation per 1040.10(g)(8)?

Yes___ No___ ND___ NA___

- Note: For visible laser radiation only, the phrase “laser light” may replace the phrase “laser radiation”.

g. Remarks: _____

4. Defeatably interlocked housing labels (1040.10(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 visible prior to the opening created by removal or displacement of such portions of the protective housing per 1040.10(g)(7)?

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

f. Are all labels permanently affixed and clearly visible? Yes___ No___ ND___ NA___

g. Do all labels contain a warning for "invisible", “invisible and visible” or invisible and/or visible" radiation?

Yes___ No___ ND___ NA___

- Note: For visible laser radiation only, the phrase “laser light” may replace the phrase “laser radiation”.

h. Remarks: _____

E. Performance Requirements (1040.10(f))

1. Protective Housing (1040.10(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 ultraviolet or infrared radiation been evaluated? Note that certain types of lasers may emit more than a single wavelength, due to frequency doubling or some other technology. An example is green laser pointers that also emit infrared wavelengths which must be filtered down to a Class I/1 level.

Yes___ No___ ND___ NA___

d. Does the housing prevent access to UV or IR collateral radiation levels in excess of 0.5 mR/hr at all times during operation of the product (See Table VI in 1040)?

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. Does opening or removing portions of the housing, which could allow access to radiation, permitted during operation or maintenance? These would be doors or panels intended to be opened during operation or maintenance. Consider if a work piece is loaded into an enclosed area for lasing, does the operator have or need access to a high power or aiming beam.

Yes___ No___ ND___ NA___

Describe: _____

Note: Laser Notice 34 refers to interlocks, see: https://www.fda.gov/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/HomeBusinessandEntertainment/LaserProductsandInstruments/ucm116422.htm

b. Class of radiation to which access could be gained inside a laser product? Class _____.

c. If failure of a single interlock would allow (a) human access to laser radiation beyond Class IIIa/3R or (b) laser radiation beyond Class II from displacement of the interlocked portion of the protective housing, are fail safe or multiple interlocks incorporated with visible or audible indication (e.g. internal levels) (see 21 CFR 1040.10(f)(2)(iii))?

Yes___ No___ ND___ NA___

Where? _____

d. Are safety interlock(s) present? A safety interlock is a type of electronic or mechanical interlock that, if it were to fail, one could not open the interlocked door or panel. _____ If so, where?_____

Type: (This could take the form of a single, safety-rated switch with dual internal contacts wired in series. Otherwise, look for two single-contact switches or some other redundancy.)
Microswitch____;
Mercury switch____;
Magnetic reed switch_____;
male-female plug____;
mechanical shutter____;
Safety-rated switch____.

Describe: _____

e. Method of limiting access to the laser beam:
Directly interrupt primary laser power____;
Interrupt primary laser power through relay, contactor, electronic cutoff____;
Shutter beam via solenoid____;
Other____.

f. Is there a fail safe or multiple interlocks 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. Remarks: _____

3. Remote Interlock Connector (1040.10(f)(3), Class IIIb/3B or IV/4 systems only)

a. Is a remote interlock connector present? Yes___ No___ ND___ NA___

b. Type? Describe: _____

Note: Laser Notice 11 refers to remote interlock connectors, see: https://www.fda.gov/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/HomeBusinessandEntertainment/LaserProductsandInstruments/ucm116422.htm

c. Is the voltage across the connector less than 130 RMS volts?
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 interrupt laser power____;
Interrupt laser power through relay, etc.____;
Shutter beam or interrupt 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). This feature can be software password entry or other security controls.

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___

How? _____

_____

d. Remarks: _____

5. Beam Attenuator (1040.10(f)(6), Class IIIb, IV, 3B or 4 systems only). This is a mechanism for blocking the beam temporarily without turning the machine off.

   Note: Laser Notices 43 and 49 refer to beam attenuators, see: https://www.fda.gov/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/HomeBusinessandEntertainment/LaserProductsandInstruments/ucm116422.htm

   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/3B and IV/4 or Systems only)

   Note: Laser Notices 43, and 49 refer to emission indicators, see: https://www.fda.gov/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/HomeBusinessandEntertainment/LaserProductsandInstruments/ucm116422.htm

   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 (required for Class IIIb and IV)?

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 for the second emission indicator (required for Class IIIb and IV)?

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: _____

7. 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: _____

8. Viewing optics (1040.10(f)(8))

Note: Laser Notice 8 refers to Viewing Optics (e.g. window), see:
https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM095367.pdf

a. Are viewing optics or viewports present? Yes___ No___ ND___ NA___

b. Type:
Microscope___;
Telescope___;
Window___;
Display screen___;

Other___.

Describe: _____

Where? _____

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

Yes___ No___ ND___ NA___

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

Yes___ No___ ND___ NA___

e. 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___

f. Remarks: _____

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

Note: Laser Notices 22, 40, 46, 47, 51, and 55 refer to laser light show projectors and shows, see: https://www.fda.gov/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/HomeBusinessandEntertainment/LaserProductsandInstruments/ucm116422.htm

a. Is the radiation emitted by the product scanned? Yes___ No___ ND___ NA___

If yes, please describe how it scans: _____

_____

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: _____

10. Manual Reset Mechanism (1040.10(f)(10) Class IV/4 laser systems) This can be any tool or software mechanism (e.g. stand-by mode) that blocks or otherwise resets the laser emission status after a power interrupt such that the user must consciously do something to achieve beam emission again.

    Describe the operation of the Manual Reset: _____

    _____

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

    _____

11. 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, meaning that it can be removed and operated by applying a power source, such as plugging it in?
    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: _____

    f. 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):

G. Results of measurements: _____

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

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

Note: Laser Notices 13, 30, 35, 39, and 44 refer to informational requirements, see: https://www.fda.gov/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/HomeBusinessandEntertainment/LaserProductsandInstruments/ucm116422.htm

1. User Information (1040.10(h)(l))

Note: Please check the labels on the products match with the labels in the user manual. If the labels are not consistent, please write the note in the inspection and inform it to the manufacturer.

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 (e.g., pulse duration(s), maximum radiant power, and wavelength(s)) for each laser? 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 required per 21 CFR 1040.10 and 1040.11?
Yes___ No___ ND___ NA___

h. Does it contain the "Caution - use of controls..." warning per 21 CFR 1040.10(h)(1)(iv)?
Yes___ No___ ND___ NA___

i. In the case of laser products other than laser systems, does it contain a statement of compatibility requirements for a laser source that will assure compliance of the laser product per 21 CFR 1040.10(h)(1)(v)?

Yes___ No___ ND___ NA___

j. Does it contain calibration procedures and a calibration schedule (required for Class IIIb and IV medical laser product) or calibration check procedures and schedule (required per IEC Standards for Class 3B and 4 medical laser product)?

Yes___ No___ ND___ NA___

k. Does it include a warning not to point the laser radiation at performers, employees, and the audience (for Class II/2, IIIa/3R, IIIb/3B, and IV/4 demonstration laser products)?

Yes___ No___ ND___ NA___

l. Does it include information to determine nominal hazard zone (Class IIIb/3B or IV/4 multi-axis workstations) per 21 CFR 1040.10(h)(1)(i)?

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, descriptive brochures, and firm's websites?

Yes___ No___ ND___ NA___

3. Servicing Information (1040.10(h)(2))

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

Yes___ No___ ND___ NA___

b. Are clear warnings and precautions to avoid possible exposure to laser emission 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 be used by persons other than the manufacturer or the manufacturer's agents (e.g., authorized service personnel) 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 allowing access to internal laser radiation 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: _____

ATTACHMENT C: 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. Their manufacturer must be in accord with the medical devices Quality System regulation (21 CFR 820) promulgated under the Act.

Under authority of Section 534 of the Act covering the EPRC program, 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. The intended purposes of a sunlamp product timer are to provide for reliable control of exposures and to limit acute (and delayed) damage from unintentionally long exposures. However, the maximum timer setting should also allow for selection of exposure times needed to build up and maintain a tan. The maximum timer interval is in no way to be considered as a safe limit; all ultraviolet radiation is potentially hazardous.

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

Many FDA investigators 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 investigator has training in both EPRC and QSIT inspections, a single investigator may conduct both portions of the inspection.

References

Sunlamp Products, Performance Standard – 21 CFR 1040.20.
https://www.ecfr.gov/cgi-bin/text-idx?SID=10366eccc2983e3e1be447fb13c835aa&mc=true&node=se21.8.1040_120&rgn=div8

Quality Control Guide for Sunlamp Products. (Publication; FDA 84-8234)
https://www.fda.gov/regulatory-information/search-fda-guidance-documents/quality-control-guide-sunlamp-products-fda-88-8234

Policy on Warning Label Required on Sunlamp Products (08/24/2018)
https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-warning-label-required-sunlamp-products

Policy on Maximum Timer Interval and Exposure Schedule for Sunlamp Products (08/21/85)
https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-maximum-timer-interval-and-exposure-schedule-sunlamp-products

Policy on Lamp Compatibility (9/2/86).
https://www.fda.gov/media/74075/download

Sunlamp Products Reporting Guide (dated September, 1995).
https://www.fda.gov/media/72567/download

Specific Instructions for Sunlamp Product Inspections and Tests (05/23/2015)
https://www.fda.gov/regulatory-information/search-fda-guidance-documents/inspection-and-field-testing-radiation-emitting-electronic-products-attachment-c-specific

Refer to the sunlamp products main page for additional information:
https://www.fda.gov/radiation-emitting-products/home-business-and-entertainment-products/sunlamps-and-sunlamp-products-tanning-bedsbooths

Sunlamp Product Codes

Sunlamp product codes can be searched in FDA Radiation Emitting Electronic Product Codes database:

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD_RH/TextSearch.cfm

For example, under “Product Description” section, you can choose the following categories.

- Sunlamp products (certified)
- Sunlamp products (pre-standard)

Please note that “Sunlamp products (certified)” refers to most sunlamp products and indicates that the sunlamp product must be certified to comply with the 21 CFR 1040.20 Performance Standard.

Please note that “Sunlamp products (pre-standard)” refers to any sunlamp products that were manufactured prior to May 7, 1980, when the FDA sunlamp product performance standard went into effect.

If you want all sunlamp codes, then selecting the applicable performance standard will return all the codes.

The ORA's electronic submission system, eNSpect, has the complete list of cites and all the relevant options. The following list should be considered only as limited examples of non-compliant items.

Performance Requirements

1040.20(c)(1)	Fails to comply with the irradiance ratio limits for 200 to 260 nm wavelength range over 260 to 320 nm wavelength range cannot exceed 0.003
1040.20(c)(2)(i)	Fails to incorporate a timer system with multiple timer settings adequate for recommended exposure time intervals
1040.20(c)(2)(ii)	Maximum timer interval(s) exceeds the manufacturer's recommended maximum exposure time(s) as indicated on label
1040.20(c)(2)(iii)	Maximum timer interval error >10 percent
1040.20(c)(2)(iv)	Timer automatically resets and causes radiation to resume.
1040.20(c)(3)	Fails to incorporate a control for termination of radiation emission (at minimum a timer system)
1040.20(c)(4)(i)	Fails to have protective eyewear
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)
1040.20(c)(4)(ii)	Spectral transmittance of the protective eyewear exceeds a value of 0.01 over the wavelength UVA (>320nm to 400nm)
1040.20(c)(4)(ii)	Spectral transmittance (>400nm) of protective eyewear does not allow user to clearly see to reset the timer
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.

Label Requirements for Sunlamp Products

1040.20(d)(1)(i)	Fails to have warning statement "Danger UV radiation…"
1040.20(d)(1)(ii)	Fails to have recommended exposure position(s)
1040.20(d)(1)(iii)	Fails to have directions for recommended exposure position(s) and warning other positions may result in overexposure
1040.20(d)(1)(iv)	Fails to have recommended exposure schedule
1040.20(d)(1)(v)	Fails to have time before expected results statement
1040.20(d)(1)(vi)	Fails to have ultraviolet lamp designation

Label Requirements for Ultraviolet Lamps

1040.20(d)(2)(i)	Fails to have "Sunlamp-DANGER-Ultraviolet radiation. Follow Instructions"
1040.20(d)(2)(ii)	Fails to have model identification
1040.20(d)(2)(iii)	Fails to have "Use ONLY in fixture equipped with timer"

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
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

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 manufacture on ultraviolet lamp
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.

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
1040.20(e)(1)(i)	Failed to have reproduction of "Danger Ultraviolet Radiation warning statement…"
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
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
1040.20(e)(1)(iv)	Failed to have instructions determining the correct exposure time and schedule for persons according to skin type.
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.
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
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
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

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

Sample Sunlamp Product Inspection or Field Test Record

INSPECTIONAL FIELD TEST RECORD FOR SUNLAMP PRODUCTS MANUFACTURED AFTER SEPTEMBER 8, 1986
(Including Pertinent Parts of the Regulation)

DATE OF EXAMINATION:
NAME OF INVESTIGATOR:
FACILITY VISITED (name address and FEI if applicable)
PERSON INTERVIEWED:
MANUFACTURER (*required*): _____
MANUFACTURER FEI: _____

WARNING LABEL [21 CFR 1040.20(d)(1)]
(i) A warning statement with the words "DANGER—Ultraviolet radiation. Follow instructions. Avoid overexposure. As with natural sunlight, overexposure can cause eye and skin injury and allergic reactions. Repeated exposure may cause premature aging of the skin and skin cancer. WEAR PROTECTIVE EYEWEAR; FAILURE TO MAY RESULT IN SEVERE BURNS OR LONG-TERM INJURY TO THE EYES. Medications or cosmetics may increase your sensitivity to the ultraviolet radiation. Consult physician before using sunlamp if you are using medications or have a history of skin problems or believe yourself especially sensitive to sunlight. If you do not tan in the sun, you are unlikely to tan from the use of this product."

Warning label accessible to view: YES / NO
Legible from one meter: YES / NO
"DANGER" statement: YES / NO
Recommended exposure position: YES / NO
Directions for achieving the recommended exposure position(s) and a warning that the use of other positions may result in overexposure: YES / NO
A statement of the time it may take before the expected results appear.: 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:_____

BLACK BOX WARNING LABEL REGARDING USE BY PERSONS UNDER THE AGE OF 18 YEARS [21 CFR 878.4635 (b)(6)(i)(A)]

Attention: This sunlamp product should not be used on persons under the age of 18 years.

Warning label in black box: YES / NO

Permanently affixed: YES / NO
Legible from one meter: YES / NO
Text at least 10 mm in height: YES / NO
Accessible to view when open or closed: YES / NO

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

INSTRUCTIONS ON CLEANING AND DISINFECTION BETWEEN USES [21 CFR 878.4635(b)(6)(i)(B)]

Provided by the Manufacturer: YES / NO

USER INSTRUCTIONS [21 CFR 878.4635(b)(6)(ii)(A) - (D)]
(A) "Contraindication: This product is contraindicated for use on persons under the age of 18 years."
(B) "Contraindication: This product must not be used if skin lesions or open wounds are present."
(C) "Warning: This product should not be used on individuals who have had skin cancer or have a family history of skin cancer."
(D) "Warning: Persons repeatedly exposed to UV radiation should be regularly evaluated for skin cancer."

Provided by the manufacturer: YES / NO
Available to patrons: YES / NO
"Contraindication" statements present: YES / NO
"Warning" statements present: YES / NO

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:_____
(Month should be spelled out and year is shown as a four-digit number)

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

Note: Each sunlamp product shall be accompanied by the number of sets of protective eyewear that is equal to the maximum number of persons who may be exposed to the product at the same time.

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., 1 min increments): _____

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

Timer Manufacturer:
Name: _____
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 ORA DIVISION	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: _____

ORA Division_____ Facility FEI_____

Product Type:_____

Manufacturer Name: _____

Model Name:_____

Serial Number _____

Manufactured Date _____ / _____ / _____Lamps: UV-A_____UV-B _____HID _____Properly labeled

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:

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

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

Location:_____

Identification label:

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 (Month should be spelled out and year is shown as a four-digit number):

_____

g. Remarks: _____

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

Warning Label: Readily viewable_____ Yes___ No___ ND___ NA___

Location_____

Danger Statement _____ Yes___ No___ ND___ NA___

Label for ultraviolote lamp type (how a salon determine a replacement lamp?)

_____

Label for Min. exposure distance with lamps _____

How measured _____Warning: Min. exposure distance_____

Warning: Protective eyewear _____ Warning: Max. exposure time_____

Exposure schedule including duration and spacing of sequential exposures and maximum exposure time(s) in minutes _____

Statement of the time it may take before the expected results appear (days or weeks)_____

Any misleading statements?_____

User's Instructions: Provided by the Mfr. _____ Yes___ No___ ND___ NA___

Available to patrons Yes___ No___ ND___ NA___

Contains copy of warning label Yes___ No___ ND___ NA___

Instructions for replacement parts (e.g. lamps, timer) _____

Protective eyewear:

Does a salon has protective eyewear equal to the maximum number of patrons at anytime?

Yes___ No___ ND___ NA___

Equipment Recommendations: User position indicatedYes___ No___ ND___ NA___

Timer error less than 10%Yes___ No___ ND___ NA___

Temperature Control Yes___ No___ ND___ NA___

Protection from Lamps_____

Access and Support _____

Does a salon permit ultraviolet lamp therapy (different medical intended use) in the taining product(s)? Yes___ No___ ND___ NA___

Note: If yes, it requires a 510(k) submission for the medical product.

_____ _____

Name and Title	Inspecting ORA Division

ATTACHMENT D: 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).

Many FDA Investigators 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.

References

Frequently Asked Questions on Cabinet X-ray Systems (March 9, 2018)
https://www.fda.gov/radiation-emitting-products/security-systems/frequently-asked-questions-cabinet-x-ray-systems

Compliance Guide for Cabinet X-Ray Systems (September 19, 2007)
https://www.fda.gov/regulatory-information/search-fda-guidance-documents/compliance-guide-cabinet-x-ray-systems

Routine Compliance Testing for Cabinet X-ray Systems to which 21 CFR Subchapter J is applicable, Dated March 1985
https://www.fda.gov/media/76001/download

Refer to the Cabinet X-Ray Systems main page for additional information
https://www.fda.gov/radiation-emitting-products/security-systems/cabinet-x-ray-systems-closed-x-ray-systems

Cabinet X-Ray Product Codes

Cabinet X-ray product codes can be searched in FDA Radiation Emitting Electronic Product Codes database:
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD_RH/classification.cfm.

For example, under “Product Description” section, you can choose the following categories.

- Cabinet X-Ray Systems/Medical
- Cabinet X-Ray Systems/Non-Medical

The ORA's electronic submission system, eNSpect, has the complete list of cites and all the relevant options. The following list should be considered only as limited examples of non-compliant items.

Emission Limit

1020.40(c)(1)(i)	Radiation emission > 0.5 mR in one hour
1020.40(c)(1)(ii)	Emission limit requirements – measurement inadequate

Floors

1020.40(c)(2)	Floor fails to adequately attenuate radiation emission into occupied area underneath x-ray system. Emission is > 0.5 mR in one hour

Ports and Apertures

1020.40(c)(3)(i)	It is possible to reach the primary beam through a port Exposure to primary beam is likely to occur during routine use of the system because of system design or configuration Inadvertent exposure to primary beam could occur during routine use of the system.
1020.40(c)(3)(ii)	Aperture allows human access to interior of cabinet

Safety Interlocks

1020.40(c)(4)(i)	The door's safety interlocks fail to comply with requirements and emission rate with door open is > 0.5 mR in one hour. Failures include: no interlock, only one interlock, neither interlock results in disconnection of the power supply to the high voltage without reliance on a moving part other than the door, and all interlocks are of the physical disconnection type (There should be at least one of each type – traditional should be primary and physical disconnect should be secondary so that no current is going through it unless the primary interlock has failed).
1020.40(c)(4)(ii)	An access panel lacks a safety interlock and emission rate with access panel open is > 0.5 mR in one hour
1020.40(c)(4)(iii)	After a safety interlock interrupts x-ray generation reset of the interlock results in immediate resumption of x-ray production without an operator action to re-initiate x-ray generation.
1020.40(c)(4)(iv)	A single component failure disables more than one interlock

Ground fault

1020.40(c)(5)	Ground fault can result in x-ray initiation

Controls and Indicators

1020.40(c)(6)(i)	Key control - not provided or does not capture key when in the on position.
1020.40(c)(6)(ii)	Controls to initiate and terminate x-ray generation other than safety interlocks or system power control are not present
1020.40(c)(6)(iii)	Two independent means of exposure indication are not present and visible at any location from which x-ray generation can be initiated
1020.40(c)(6)(iii)	Exposure indication - other than milliammeter is not present
1020.40(c)(6)(iii)	Multiple failures of exposure indication caused by a single failure
1020.40(c)(6)(iii)	Exposure indication - labeling - X-RAY ON is not present
1020.40(c)(6)(iii)	Exposure indication - labeling - x-ray tube current is not present
1020.40(c)(6)(iv)	Exposure indication required to be visible from a door, panel, or port and is not present
1020.40(c)(6)(iv)	Exposure indication at door, panel, or port is not labeled - X-RAY ON

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
1020.40(c)(7)(ii)	X-rays can be initiated from within the cabinet
1020.40(c)(7)(iii)	No Pre-exposure warning within cabinet
1020.40(c)(7)(iii)	Pre-exposure warning within cabinet – Warning did not activate at least 10 seconds prior to exposure
1020.40(c)(7)(iii)	Pre-exposure warning within cabinet - a single failure causes both audible and visual warnings to fail
1020.40(c)(7)(iv)	No exposure warning within cabinet
1020.40(c)(7)(v)	Lack of signs giving meaning of warning signals
1020.40(c)(7)(v)	Lack of signs giving instructions for use of controls to terminate
1020.40(c)(7)(v)	Signs are not legible, accessible, illuminated

Warning Labels

1020.40(c)(8)(i)	Lack of Warning labels - X-rays Produced
1020.40(c)(8)(ii)	Lack of Warning labels - Human Access

Information to be provided

1020.40(c)(9)(i)	A schedule of maintenance required is not provided and such maintenance is necessary to assure continued compliance with the performance standard
1020.40(c)(9)(i)	Instruction manuals - inadequate technical & safety information or no manual provided
1020.40(c)(9)(i)	Assembly instructions - required and not provided
1020.40(c)(9)(i)	Assembly instructions - not adequate for compliance

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 Inadequate means provided to assure that an operator can monitor both input and output ports
1020.40(c)(10)(i)	No means to terminate exposure
1020.40(c)(10)(ii)	No means to terminate an exposure sequence

Modification of a certified system

1020.40(d)	Modification – failure to re-certify and re-identify

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).

ATTACHMENT E: 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. In 2022, 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 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
https://www.ecfr.gov/cgi-bin/text-idx?SID=214da7575b21b55ca3e1ef5ac2a39f3b&mc=true&node=pt21.8.1030&rgn=div5

Guide for Preparing Reports on Radiation Safety of Microwave Ovens
https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=&cad=rja&uact=8&ved=2ahUKEwj0samRnovyAhXhEVkFHS6DAmQQFjAAegQIAxAD&url=https%3A%2F%2Fwww.fda.gov%2Fmedia%2F124631%2Fdownload&usg=AOvVaw3E2qVKYYDv5hwU90l1smZw

Refer to the microwave oven products main page for guidance documents and additional information:
https://www.fda.gov/radiation-emitting-products/home-business-and-entertainment-products/microwave-ovens

Microwave Oven Product Codes

Microwave oven product codes can be searched in FDA Radiation Emitting Electronic Product Codes database:

https://www.fda.gov/radiation-emitting-products/performance-standards/product-codes-radiation-emitting-electronic-products

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD_RH/TextSearch.cfm

For example, under "Product Description" section, you can choose the following categories.

- Microwave Ovens (Food Prep)

The ORA's electronic submission system, eNSpect, has the complete list of cites and all the relevant options. The following list should be considered only as limited examples of non-compliant items.

Power density limit requirements	
1030.10(c)(1)	Leakage from door, vents, other seams exceed 1 mW/cm^2 prior to acquisition or 5 mW/cm^2 after purchase
Safety interlocks	
1030.10(c)(2)(i), (iv)	Does not incorporate two (2) independent safety interlocks or monitor
1030.10(c)(2)(i)	No concealed or inaccessible interlock
1030.10(c)(2)(ii)	Single mechanical/electrical failure disables interlocks
1030.10(c)(2)(iii)	Secondary interlock leakage exceeds $5mW/cm^2$
1030.10(c)(2)(iii)	Primary interlock leakage exceeds $5mW/cm^2$
1030.10(c)(2)(iv)	Insulated wire is accessible to energy-containing space and exceed the leakage described in (c)(1)
User instructions	
1030.10(c)(4)(ii)	Precaution statement unclear, not located to elicit attention, not legible or durable, etc.
1030.10(c)(4)(iii)	User manual or cookbook has no precaution statement
Service instructions	
1030.10(c)(5)(ii)	Safety information or precaution statement unclear, not located to elicit attention not legible or durable, etc.
1030.10(c)(5)(iii)	Service instructions have non-standard precaution statement
1030.10(c)(5)(iv)	Service instructions have insufficient safety information
Warning labels	
1030.10(c)(6)(i), (ii)	No user warning label or service caution label
	Safety information or precaution statement unclear, not located to elicit attention not legible or durable, easily peeled off, etc.

Sample Microwave Oven Product Inspection Checklist

Manufacturer Identification

Manufacturer Name : _____

Plant Location: _____

Manufacturer FEI: _____

Date(s) of Examination: _____

Name of Investigator

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): _____