CHAPTER 86 - MEDICAL AND RADIOLOGICAL DEVICE MONITORING AND QUALITY CONFORMANCE

SUBJECT:	IMPLEMENTATION DATE
INSPECTION OF DOMESTIC AND FOREIGN MANUFACTURERS OF DIAGNOSTIC X-RAY EQUIPMENT	10/01/2020
	COMPLETION DATE 08/28/2020

DATA REPORTING

PRODUCT CODES	PROGRAM ASSIGNMENT CODES
See Attachment B	86003

Previous editions obsolete

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Attachments

FIELD REPORTING REQUIREMENTS

Please submit copies of all Establishment Inspection Reports (EIRs), attachments, exhibits, correspondence between the Division and firm, and other documentation in accordance with the current Division policy.

When an inspection has been conducted under both Medical Device and Radiological Health Authorities, also follow the SOP for submission of Medical Device EIRs.

Original documents, such as EIRs, attachments, exhibits, and correspondence between the firm and Division should be maintained in approproriate electronic systems according to current ORA policy.

All inspection data should be entered by the accomplishing Division where the operation was performed.

- Comprehensive inspections are reported for manufacturing plants producing certified diagnostic radiation-emitting electronic products on a recurring basis.

- If the firm is not manufacturing or has not introduced any products into commerce, this time should be reported as investigations. Report all time spent for telephone calls and reviewing documentation that do not lead to on-site inspections under Operations Code 13 "Domestic investigations". Please contact CDRH about reporting any potential “Foreign investigations”.

- Report time spent on operations leading to on-site inspections of manufacturers as below:
  - Domestic inspections – use OP Code 12
  - Foreign inspections – use OP Code 11

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PART I

BACKGROUND

This compliance program provides procedures for Food and Drug Administration (FDA) field and Center staff to follow for the inspection, 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). Manufacturers are responsible for producing products that do not emit unnecessary hazardous radiation and that comply with all applicable radiation safety performance standards. All electronic product manufacturers must comply with applicable requirements in 21 CFR 1000, 1002, 1003, 1004 and 1005. If a mandatory radiation safety performance standard applies to a manufacturer's product, then the manufacturer must also comply with Title 21 CFR 1010 and the product must comply with the requirements of the specific standard found in 21 CFR 1020 – 1050. Manufacturers are required to self-certify their own products to be compliant with an applicable standard, based on a quality control testing program as described in 21 CFR 1010.2. The purpose of EPRC inspections are to verify that products comply with performance standards, and that the manufacturer's quality control (QC) testing program ensures such product compliance and radiation safety.

FDA is authorized to "review and evaluate" testing programs carried out by the industry to assure that the products minimize the delivery of unnecessary radiation to patients and to meet the standards issued regarding such products. Manufacturer compliance has been monitored through several mechanisms. The Center for Devices and Radiological Health (CDRH) and/or FDA's Office of Regulatory Affairs (ORA) reviews and evaluates manufacturer radiation safety reports, conducts field tests of products that have been installed and are in use, conducts laboratory testing of selected products, and inspects manufacturer sites to assess the adequacy of the QC testing and record keeping programs established by the manufacturer.

The focus of this compliance program will be the inspection of x-ray products that have been designed and manufactured for human use. The specific performance standards for diagnostic x-ray systems and their major components are contained in 21 CFR 1020.30 through 1020.33. Since manufacturers frequently claim voluntary conformance to applicable International Electrotechnical Commission (IEC) standards, Attachment A identifies applicable IEC standards, which cover radiation safety and other aspects of essential safety and performance.

A. International Electrotechnical Commission (IEC) Standards

International standards development organizations such as the IEC develop standards for diagnostic x-ray systems that address many aspects of device safety and performance. The IEC publishes safety and essential performance criteria for various types of x-ray equipment as particular standards. These particular standards build on a general standard for medical electrical equipment safety and essential performance and collateral standards that cover topics such as electromagnetic and radiation safety. The IEC standards are consensus standards, with a large international group of stakeholders participating in their development including industry,

academia, end users and often FDA. IEC standards are also periodically reviewed to determine if updates are necessary.

IEC standards are currently used in the regulatory framework of the FDA and European Medical Device Authorities. FDA incorporates standards into the US regulatory framework through a standards recognition program. Once a consensus standard has been published, it can be recognized in whole or in part by FDA. Conformance to an FDA-recognized standard can then be used by a manufacturer voluntarily to streamline regulatory review for medical device premarket submissions. As part of this program, FDA staff participate in the development of relevant IEC standards. In other markets such as the European Union and China, medical device manufacturers are required to manufacture their devices so that they conform to relevant IEC standards. Therefore, most diagnostic x-ray imaging devices conform to IEC standards.

There are several ways in which conformance to relevant IEC standards can offer improvements in safety and performance as compared to FDA EPRC performance standards. For example, the IEC standards are more comprehensive than the FDA performance standards. While the FDA performance standards focus on radiation safety, the IEC standards for diagnostic x-ray devices also include other aspects of device safety and performance, including protection against mechanical, electrical and thermal hazards. The IEC standards are also updated more frequently than the FDA performance standards. The higher frequency of updates to the IEC standards enables them to address advances in technology and features that are not included in previous editions relatively quickly. This results in a standard that is more up-to-date than the FDA performance standards in many aspects.

While conformance to IEC standards for x-ray imaging devices is voluntary in the U.S., once a manufacturer declares conformance, they accept the requirements of radiation-related clauses of those standards as design specification. Per 21 CFR 1003.2(b)(1), an electronic product shall be considered to have a defect when a product which utilizes electronic product radiation to accomplish its primary purpose and from which such emissions are intended, and as a result of its design, production or assembly, fails to conform to its design specifications relating to the emission of electronic product radiation. Therefore if a manufacturer fails to meet a radiation-related clause or requirement of an IEC standard, it is considered a defect.

B. Applicability

Firms covered under this program may produce either a complete x-ray system or individual components that are designed to be compatible with components produced by other manufacturers and assembled into a complete system at the final user location. Since manufacturers of such x-ray components may not produce complete systems, inspections under this program can be complex. Because of this complexity, investigators conducting inspections under this program must have knowledge of the EPRC provisions of the FFDCA, specific IEC standards, and familiarity with radiation measurement techniques and instrumentation in addition to an understanding of medical device quality control processes.

Medical devices that emit electronic product radiation, such as diagnostic x-ray systems and their

major components, are subject to both EPRC and Medical Device provisions of the Act. There are specific IEC standards that cover these products that many manufacturers conform to as well. When possible, medical device inspection and enforcement activities described in Compliance Program 7382.845, Inspection of Medical Device Manufacturers, should be conducted jointly with this Compliance Program.

The EPRC provisions of the FFDCA mandate self-certification by manufacturers that their products meet the requirements of the regulations. Each manufacturer must determine the applicable requirements of the regulations and institute a program that assures the performance of their product. Prior to introduction into commerce, manufacturers are required to report this information to CDRH and properly label their products. To aid in this process, CDRH has published guidance in the form of reporting guides. The focus of these guides is to identify the pertinent information required for the specified certifiable components and to present an outline for a manufacturer to follow in preparing required information for certifiable components subject to the EPRC Performance Standards under 21 CFR 1020.30, 1020.31, and 1020.32. The reporting guides represent a mapping of the evaluation and self-certification of the conformance of diagnostic x-ray components to the applicable EPRC regulations. The guides have been created as a step-by-step process to lead manufacturers through the regulations and outline an acceptable format to establish and document programs leading to compliance for each type of regulated product. Please see Part VI References, Attachments, and Program Contacts for the reporting guides.

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PART II

PROGRAM/IMPLEMENTATION

A. OBJECTIVES

1. To ensure that the regulated products and manufacturer quality control testing programs conform to EPRC regulations;

2. To identify diagnostic x-ray products which fail to comply with the applicable performance standard;

3. To obtain correction of noncompliant products identified in l and 2 above by initiating appropriate administrative and/or regulatory action when necessary;

4. To provide guidance to manufacturers regarding compliance with applicable EPRC laws and regulations, and applicable IEC standards' requirements, recognized by FDA; and

5. Provide guidance for joint QS/EPRC inspection approach, and underscore that it is preferable to combine QS and EPRC inspections to conserve agency resources.

B. PROGRAM MANAGEMENT INSTRUCTIONS

1. Planning Instructions

a. For the effective implementation of this program, individuals trained in EPRC requirements should perform these inspections. Field specialists within ORA/OMDRHO have been specifically trained in general EPRC requirements and may have specialized training in the diagnostic x-ray performance standards.

Subject Matter Experts (SME)
Contact CDRH and ORA/OMDRHO if expertise is needed outside the Division. Investigators are encouraged to contact CDRH prior to the inspection to gather useful information that may not be found through database searches, such as CDRH review of premarket submissions and complaints, and clarification on any regulation. CDRH contacts have been identified in Part VI of this CPGM. At the discretion of CDRH, radiological health specialists or CDRH SMEs 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. As part of the inspectional preparation, generate a total product life cycle (TPLC) report and review data from other databases such as Center Tracking System (CTS), as indicated in section 5.6.2.1 of the Investigation Operations Manual (IOM) Pre Inspectional Activities. If you need access to other databases such as CTS, please inform

the CDRH contacts identified in Part VI of the CPGM. It is recommended that the investigator contact CDRH to determine the need for a teleconference to address specific areas to be inspected at the facility. These calls are beneficial since TPLC reports and database searches may not capture all concerns or potential deficiencies that have been received by CDRH. For instance, in previous years, deficiencies and concerns observed during premarket reviews and complaints received by CDRH were discussed with investigators and helped FDA determine the firm's compliance with the QS and radiological health regulations.

To schedule the teleconference, contact CDRH's RadHealth mailbox at RadHealth@fda.hhs.gov. Additionally, management contact information can be obtained at the following link: CDRH Management Directory.

2. Pre-announcement of Inspections

Because these inspections are intended to cover EPRC compliance and the medical device Quality System Regulations, these inspections must be pre-announced according to 7382.845, Inspection of Medical Device Manufacturers, and section 704(h)(1) of the FD&C Act (not applicable to for-cause inspections). Refer to instructions provided IOM Section 5.2.1.1, Pre-Announcements. For joint QS/EPRC inspections, ~~the~~ the firm should be informed that EPRC requirements will be evaluated during the inspection. The investigator can provide pre-inspectional information to the firm during the pre-announcement telephone call (if the firm is eligible for pre-announcement). When an inspection covers only EPRC regulations, such as when the firm's Quality System has been adequately evaluated under Medical Device Single Audit Program (MDSAP), pre-announcement should be considered and is at the discretion of the performing Division, unless identified as a for-cause inspection. Such EPRC-only inspections are scheduled for good cause based on various factors, including product risk, compliance history, and import/distribution volume.

For foreign inspections, pre-announcement will always occur. Pre-announcement aims to ensure the firm will have the appropriate knowledge and procedures to produce 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.

3. Inspection Priorities

These are the criteria for prioritizing inspections of electronic product manufacturers:

a. Manufacturers of products posing a potential risk to public health or with great public health impact. Such products may be identified by direction provided from CDRH, based on their potential level of radiation emission, volume in US commerce, etc.

b. Manufactures of products with identified issues. For example: concerns raised during premarket notification [510(k)] reviews; known or suspected compliance problems

discovered through complaints; problems reported under Medical Device Reports (MDRs), Accidental Radiation Occurences (AROs) or Corrective Action Plans (CAPs).

c. Products incorporating a major change to the existing product or incorporating a technology that is new to the US market.

d. New manufacturers that have never been inspected.

4. Resource Instructions

Dosimeters must be worn when performing inspections of diagnostic x-ray manufacturers. These monitors are available from the Winchester Engineering and Analytical Center (WEAC) Radiation Safety Officer. Part VI of this program contains the current list of contacts for WEAC.

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PART III

INSPECTIONAL

OPERATIONS

A. EPRC Inspectional Strategy

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

ORA's Office of Training and Educational Development (OTED) and CDRH have been training investigators on assessing compliance to EPRC requirements while conducting a Quality System inspection. Please see Section 2 below; and Attachments A, C, D, and E for details and tips on the joint inspectional approach.

ORA has created District Use Codes for radiological health products that are used to help identify firms in our Official Establishment Inventory (OEI) with EPRC requirements. These codes should be reviewed prior to an inspection and updated after an inspection or investigation as appropriate.

a. Foreign inspections:

All foreign inspections should be conducted using this Compliance Program, and any special instructions contained in the inspection assignment. The failure of any foreign manufacturer to comply with these requirements may result in the article being refused at entry into the United States.

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

Any investigator with appropriate training may conduct foreign EPRC or joint EPRC/medical device inspections.

b. EPRC Directed Inspections:

EPRC Directed Inspections are conducted in response to specific information that raises questions, concerns, or problems associated with the electronic product. Information can come from a variety of sources including:

- Sample analysis results
- Prior inspectional observations
- Questionable information in EPRC reporting

- Reports of injuries related to the firm's products
- Consumer or trade complaints about the firm

EPRC Directed inspections are usually initiated at the request of CDRH. These inspections will generally follow instructions provided in this compliance program; additional instructions will be provided in the assignment.

c. Inspectional Observations Review:
Review inspectional observations with the most responsible individual and other technical experts at the firm, as they arise and prior to concluding the inspection. Record EPRC observations on the Form FDA 483. This compliance program provides procedures concerning severity of violations observed in order to identify major deficiencies. Deficiencies should be noted on Form FDA 483 in order of descending significance (i.e. most serious first). If both EPRC and medical device observations are noted, they should be grouped separately on the form, using identical text headings from eNspect.

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

The following statement should be included on each FDA 483:

> "This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective actions in response to an observation, you may discuss the objection or action with FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above."

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

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

B. Joint QS/EPRC Inspection
Radiation-emitting medical devices are subject to both electronic product radiation control requirements (Subchapter J) and medical device requirements including the Quality System Regulation, Medical Device Reporting (MDR), Medical Device Tracking, Corrections and

Removal, and Registration and Listing regulations covered in Compliance Programs 7382.845 Inspection of Medical Device Manufacturers and 7386.003a Inspection of Domestic and Foreign Manufacturers of Diagnostic X-Ray Equipment.

Pre-Inspection Preparation

For firms that meet the eligibility requirements for pre-announcement, this inspection should be pre-announced according to Investigation Operations Manual (IOM) 5.2.1.1. The pre-announcement telephone call should include informing the firm that the inspection will cover the medical device regulations and will also cover the firm's compliance with applicable EPRC reporting and performance standard requirements. Consider specifically listing examples of items which may be covered under EPRC, such as testing for characterization of emissions, labeling content, and submission of required reports which may include accidental radiation occurences and notifications of product defects (see 21 CFR 1002.1 Table 1 for record and reporting requirements by product).

Pre-inspection preparation should be performed and include review of Total Product Life Cycle (TPLC) and OSAR Firm 360 reports, registration and listing, MDRs, complaints reported to FDA, and recalls. Additionally, pre-inspection preparation should include review of EPRC reports available in the Center Tracking System (CTS), including Accidental Radiation Occurrence (ARO) reports and Notice of Defect/Failure to Comply reports.

Refer to IOM 5.6.2.1 – Pre Inspectional Activities for instructions on how to run TPLC reports.

Pre-inspection preparation should also include review and familiarization with the performance standards that are specific to diagnostic x-ray systems, under the following Parts of Title 21 of the Code of Federal Regulations: 1020.30 (Diagnostic x-ray systems and their major components); 1020.31 (Radiographic); 1020.32 (Fluoroscopic); and 1020.33 (Computed Tomography).

Contact CDRH for a pre-inspection meeting if required by the assignment or if there is a need for additional assignment clarification, explanation of specific EPRC performance standards, history of firm compliance, or specific product performance information.

For level 1 and 2 inspections of medical, diagnostic x-ray devices, the Quality System Inspection Technique (QSIT) should be followed as appropriate. However, there are EPRC requirements that should be inspected in tandem with medical device requirements.

QS/EPRC Requirements

Information provided in this section is intended to define an inspectional approach for conducting combined medical device and EPRC inspections by simultaneously covering the Quality System regulations as well as the EPRC performance standards and reporting requirements. Specifically, EPRC inspections can follow QSIT and be integrated into the Quality System inspection.

a. Management Controls Subsystem
   - Management must ensure that the Quality Control Testing Program is adequate to support the Certification Statement
   - Management must ensure all EPRC reporting requirements are met: Notice of Defect/Failure to Comply and AROs

b. Design Controls Subsystem
   - Design specifications should address the quality, quantity, and controlled direction of radiation
   - Design Inputs should include applicable Performance Standards requirements
   - Design Outputs should conform to features and/or values required by the applicable Performance Standards
   - Design Verification should demonstrate that design outputs meet applicable performance standard requirements
   - Design changes should be validated or where appropriate verified prior to implementation
   - The product has the applicable performance features, labels, and instructions for operation, maintenance and service
   - EPRC reporting may be required for design changes to the quality or direction of emission, in the case that the original design did not meet design specifications or did not fully meet performance standard requirements (Notice of Defect or Failure to Comply)
   - Risk analysis should include the risks associated with the emission of radiation, such as the risk associated with over exposure, rescan, image quality, etc.
   - Instructions for Assemblers and Users should meet performance standard requirements and may require validation to ensure the instructions are understood

c. Corrective and Preventive Actions (CAPA) Subsystem
   - When reviewing the Satellite Program Areas, records being reviewed should be evaluated to determine if the issues relate to the emission of radiation or a potential failure to comply with a Performance Standard
   - Ensure that Defects/Failures to Comply are appropriately routed through the CAPA system, with documentation of investigation of the root cause(s), identification of corrective action(s) addressing root cause(s), and verification/validation of corrective action(s) to ensure such action(s) is/are effective and there is no adverse effect on finished device.
   - In addition to MDR and Reports of Corrections & Removals, Accidental Radiation Occurrences (ARO) and Notifications of Defect/Failures to Comply must be reported upon discovery.
   - Defects/Failures to Comply may be inappropriately reported as Corrections & Removals or not reported at all with justification documented. While this may be acceptable for Corrections & Removals, there are no exemptions for reporting Defects/Failures to Comply (i.e., all Defects/ Failures to Comply must be reported to the FDA).

- Issues which may indicate failures to comply include: over exposure, rescan, image quality etc.
- A radiation-related event reported as an MDR is exempted from reporting as an ARO. Such MDRs are also exempted from reporting as a Defect/Failure to Comply but not exempted from notifying customers, and implementing a Corrective Action Plan that has been approved by the Secretary. NOTE: Only MDRs that result in an EPRC violation require a Corrective Action Plan.
- Safety related complaints, inquiries
- Real or alleged injuries
- Remedial actions taken for reports of non-compliant products, complaints, injuries

d. Production and Process Controls (P&PC) Subsystem
   - Certification of compliance with applicable performance standards must be based upon a test
   - Device history records must be maintained and include the test results demonstrating compliance with the performance standards
     - Firms must maintain records defining the test methods and describing the rationale for how their method ensures conformance if/when the product is tested in accordance with the method described under the performance standard. NOTE: The firm is not required to adopt the method described in the perfornance standard. Questions about the test instruments, equipment, and methods can be forwarded to the Center.
     - Example: leakage radiation from the diagnostic source assembly must be evaluated at leakage technique factors and by actually measuring emission at a distance of 1 meter in every direction [21 CFR 1020.30(k)]. The firm must select a method to test for leakage radiation, the method must be valid to demonstrate the leakage radiation would not exceed 0.88 mGy/hr if tested at 1 meter in any direction, and the method of validation must be documented.
   - Device Master Records must be maintained and include the methods, procedures as well as the basis for selecting those methods, and equipment needed for certification.
   - Device history records must contain or refer to the location of required labels and labeling. Manufacturers of Electronic Products must also maintain certification tag(s), identification tag(s), and any warning labels or other information required to be provided to assemblers and users per the performance standard.
   - Purchasing Controls: A manufacturer may produce and certify components themselves or receive components that have been certified by a supplier. If the system manufacturer purchases certified components, the manufacturer must include this requirement in the receiving acceptance criteria. The manufacturer should also verify that the components are of the appropriate type/model. The identification of the appropriate type/model or specifications would be provided by the certifying supplier as part of the Information to be Provided to Assemblers (21 CFR 1020.30(g)). If purchasing certified components from a supplier, a system manufacturer may, at their discretion, choose to re-certify the components with their own labels or certify the system as a whole after which they assume full responsibility for the compliance of those components or the system. NOTE: Manufacturers must certify that each

component or system complies with the relevant performance standards (21 CFR 1020.30(c)).

- In-process tests may be used to verify product compliance during production
- Final test and inspection of finished products
- Maintenance and calibration of test equipment
- Test results and data supporting product compliance with FDA performance standards. The firm may also voluntarily claim conformance to applicable IEC standards. If the firm states conformance to IEC standards, they should also document tests results and data supporting product compliance with those standards.
- The brochures, catalogs and other promotional material contain any required warnings or label reproductions
- Distribution records to first purchasers or distributors. (Note: dealers and distributors of certifiable products valued at $50 or above are required to maintain detailed distribution records of the product(s). The distributor/dealer has the option to retain those records or to forward them to the original manufacturer. Determine if the manufacturer is receiving such records and if so, is maintaining them in a retrievable manner.)

NOTE: There are many references to test methods used to determine compliance with the performance standards: 1020.30(k), (l), (m)(3), (n), 1020.31(b)(2), (c)(3), (d)(2)(iii), (e)(4), (g)(3), (h)(2), (l), (m)(3), 1020.32((a)(2), (b)(1),(d)(3). These methods are NOT prescriptive for the manufacturer to use as part of their Quality Control Testing Program but rather are declarations of how FDA determines compliance with the performance standards when performing testing under 21 CFR 1005.1. A manufacturer may use these testing methods directly but is also free to choose alternative testing methods. They remain responsible for ensuring that, after assembly into a finished x-ray system, their products will comply with all applicable performance standards when tested using the test methods provided in the performance standards. A manufacturer is also required to maintain records of the basis for selecting the methods, devices, and procedures used to ensure electronic product radiation safety [21 CFR 1002.30(a)(2)].

Requirements that may be inspected in tandem:
The following tables list common medical device requirements and any analogous EPRC requirements. In order to maximize investigational efficiency, the inspectional techniques for EPRC requirements should be similar as the inspectional techniques for the analgous medical device requirements.

I. Reporting requirements

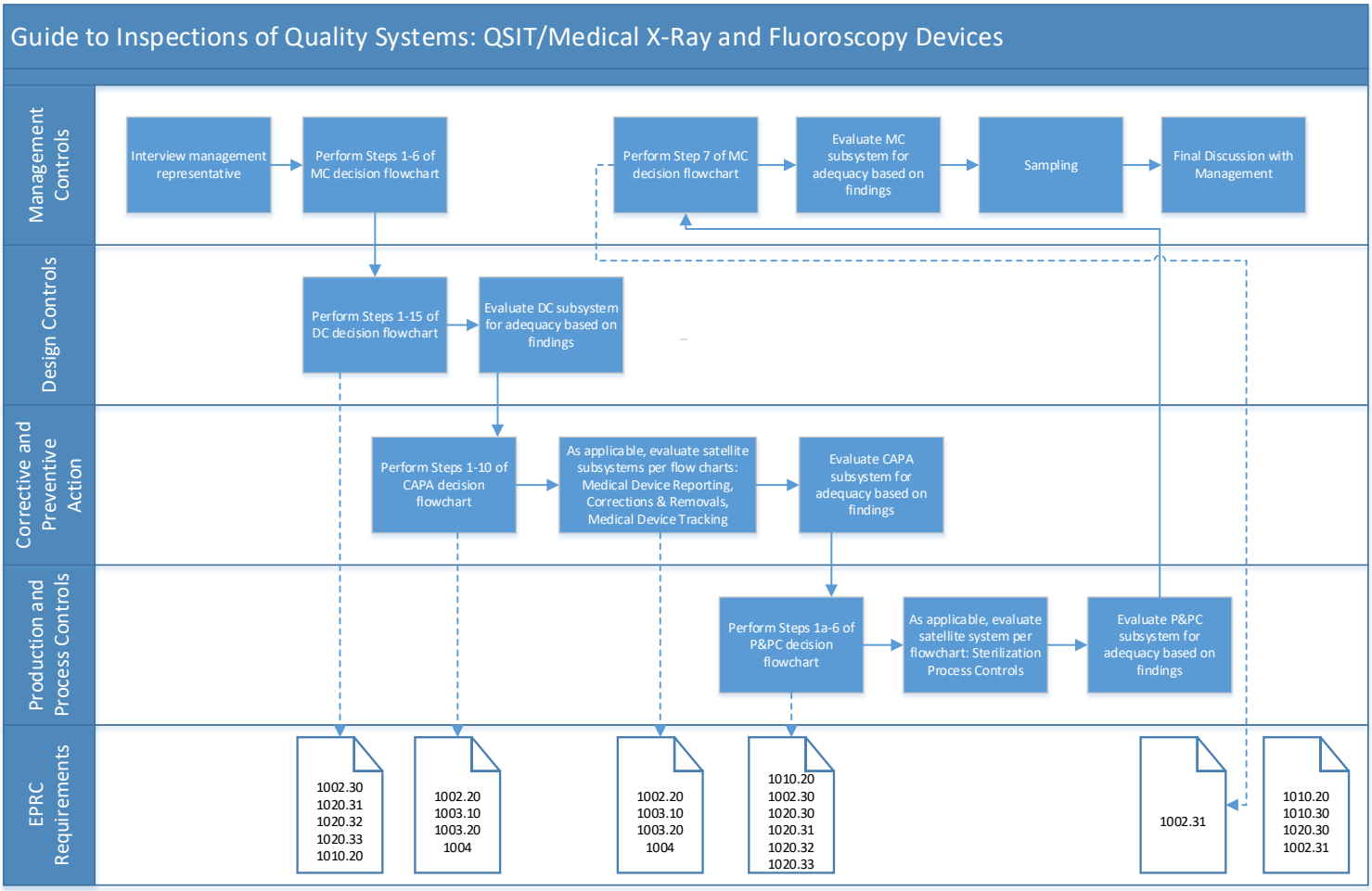
Medical Device Requirements	**EPRC Requirements**
21 CFR 803 Medical Device Reporting	1002.20 Reporting of accidental radiation occurrences Note: If a manufacturer is required to report per 1002.20 and also is required to report under 21 CFR 803, the manufacturer shall report in accordance with part 803. A separate report under 1002.20 is not required. However, if a manufacturer is required to notify FDA per 1002.20 and is not required to report to the FDA under 21 CFR 803, the manufacturer shall notify FDA in accordance with 1002.20. Also, some manufacturers may participate in ARO summary reporting (on a quarterly basis) instead of submitting individual ARO reports.
21 CFR 806 Reports of Corrections and Removals	1003.10, 1003.20 Discovery of defect or failure of compliance by manufacturer; notice requirements Note: If a manufacturer is required to notify FDA per 1003.10 and also is required to report under 21 CFR 803, the manufacturer shall report in accordance with part 803. A separate report under 1002.20 is not required. However, if a manufacturer is required to notify FDA per 1003.10 and is not required to report to the Food and Drug Administration under part 803, the manufacturer shall notify FDA in accordance with 1003.10. 1004 Repurchase, Repairs, or Replacements of Electronic Products, in accordance with an approved CAP

II. Current Good Manufacturing Practice Requirements

Medical Device Requirements 21 CFR 820	**EPRC Requirements**
820.30 Design Controls	1002.30(a)(1) Description of the quality control procedures with respect to electronic product radiation safety1020.30(h) Labeling requirements NOTE: Performance standard requirements would also be included in design inputs and design verification, and design validation. These inputs must ensure that devices meet the user needs and intended uses, as it relates to emission of radiation.
820.50 Purchasing Controls	1020.30(a) Applicability 1002.1 Applicability 1000.3(j) Electronic product
820.70 Production and Process Controls 820.80 Acceptance Activities 820.181 Device Master Records 820.184 Device History Records	1010.2 Products are certified based on a quality control testing program in accordance with GMP 1010.2(c) Certification 1002.30(a)(1) Description of the quality control procedures with respect to electronic product radiation safety 1002.30(a)(2) Records of the results of tests for electronic product radiation safety, including the control of unnecessary, secondary or leakage electronic product radiation, the methods, devices, and procedures used in such tests, and the basis for selecting such methods, devices, and procedures. 1020.30(m)(1) Half-value layer 1020.31(a)(4) Accuracy of Technique **Fluoroscopy:** 1020.32(b) X-ray Field & image Receptor Alignment 1020.32(d) Air Kerma Rate 1020.32(g) Source-Skin Distance 1020.32(j) Last-image-hold 1020.32(k) AKR & Cumulative Air Kerma **Computed Tomography** 1020.33(c)(1) Conditions of operation 1020.33(c)(2) CT dose index 1020.33(c)(3) Imaging Performance 1020.33(d) Quality Assurance 1020.33(f) Control and indication of conditions of operation
820.90 Nonconforming Product; 820.100 Corrective and Preventive Actions; 820.198 Complaint Files	1002.20 Reporting of accidental radiation occurrences 1003.10, 1003.20 Discovery of defect or failure of compliance by manufacturer; notice requirements 1004 Repurchase, Repairs, or Replacements of Electronic Products
801 Labeling*; 820.120 Device Labeling	1010.2(b) Certification 1010.3 Identification 1020.30(g) Information to be provided to assemblers 1020.30(h) Information to be provided to users 1020.33(c) Information to be provided for users 1020.33(d)(2)&(3) Quality assurance
820.160 Distribution	1002.30(b) Distribution Records
820.170 Installation	1020.30(g) Instructions for assembly, installation and adjustment
820.200 Servicing	1020.30(h)(1)(ii) Maintenance schedule
820.180 Recordkeeping	1002.31 Preservation and inspection of records

*Note: The formatting of the Unique Device Identifier (UDI) expiration date is not applicable to devices subject to EPRC performance standards, per 21 CFR 801.18(b)(2).

The following process map is a visual representation of the information contained in the tables regarding the medical device and EPRC requirements that may be inspected in tandem for medical x-ray and fluoroscopy devices. This process map shows the systems in QSIT alongside possible corresponding EPRC requirements. The areas of commonality are shown in the blue boxes with white font. The additions to the process which are specific to EPRC performance standards are shown in white boxes with a dotted line to the applicable QSIT subsystem.



Other requirements
The firm's compliance with 510(k)/PMA should also be assessed and documented (e.g., modifications to a cleared device in technological characteristics and/or intended use).

Example of records to be reviewed and collected (not a comprehensive list):

- Organization chart identifying key individuals responsible for product design, manufacturing and quality control
- Copies of testing procedures and where possible, photographic evidence showing that testing does not ensure product safety or compliance with applicable standards
- Copies of device history records, including test records and labels, for a portion of devices that do not meet performance standard requirements
- Samples of violative labels
- Copies of manuals, in part or whole, that fail to contain required materials
- Specific to alignment/positioning lasers, warning/caution labeling is required to be reproduced in user manuals and marketing materials [21 CFR 1040.10 and 1040.11]
- Copies of brochures and catalogs that fail to contain required warning or label reproductions (example: label reproduction for alignment lasers)
- Distribution records for any violative products

C. EPRC-only Inspections

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. An inspection to assess compliance with EPRC regulations may have good cause in the case that a firm is currently participating (active) in the Medical Device Single Audit Program (MDSAP). In these circumstances, please see the following guidance:

An EPRC-only inspection can follow the general flow of a 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. 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.

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 utilize and fully implement a quality control testing

program with associated requirements to define and implement production procedures. The following describes an approach and includes examples of records to be reviewed:

- Ensure all performance standard features are tested
- Determine whether there is 100% testing of performance features:
    - Testing < 100% relies on a quality control testing program
        - Review production controls (limited to those bearing on performance standards) in P&PC procedures, which are required. Failures should be cited on an FDA 483 under 21 CFR 1002.30.
- Review the following to ensure that procedures are being followed and are consistent with the regulation:
    - Test procedures
    - Test records
    - Test method validation and rationale
    - Examination of the product (labeling and performance)
- Ensure that there is approved and documented justification (i.e., variance, exemption) for any differences from requirements of the EPRC regulations
- Review design records, where EPRC features are covered, in a limited fashion to identify whether there are any missing performance standard features, with follow-up review of the actual product, device master records, or device history records in order to verify the performance standard feature is missing. Review of design control SOPs is generally out of scope. The following represent potentially relevant components of such review:
    - Design output records, limited to identifying the firm's design requirements for radiation emission.
    - Design verification records, only if the firm achieves compliance to performance standards through design instead of testing/examination (Note: this may not be appropriate for all requirements but could be for some)
    - Design changes bearing on radiation emission or on performance standards
    - Design history file (DHF) in order to (a) determine the performance features, as they relate to emission of radiation, and (b) determine whether the firm meets a performance standard but fails to meet its own design specifications, which may then result in a Notice of Defect and CAP (21 CFR 1003/1004)
- Review may also include:
    - CAPAs bearing on radiation emission or on performance standards (unreported AROs, unreported notifications of failure to comply/defect)
    - Complaints related to radiation emission or performance standard features
    - EPRC Reporting: ARO, Notice of Defect/Failure to Comply
- FDA 483 citations should be limited to EPRC:
    - 21 CFR 1002 (Test Records/SOPs, ARO, etc.)
    - 21 CFR 1003 & 1004 (Notice of Defect/CAP)
    - 21 CFR 1010.2 & 1010.3 (Cert. & ID Tag)
    - Specific Performance Standard Deviations (1020.30/31/32/33)

- In the course of the inspection, if potential objectionable conditions are found pertaining to 21 CFR Part 820, they can be verbally discussed with the firm and documented in the EIR's "General Discussion With Management" section (and not listed on the FDA 483). Include a description in the EIR that clearly demonstrates how potential QS deficiencies were discovered during review of the EPRC documentation.

D. Investigations

Investigations are to be made to determine whether a suspected firm is in fact a manufacturer of one or more electronic products or to establish that their products are being offered for sale in the US. The investigation may be initiated in preparation for a possible inspection, as a result of trade complaints, or from discovery via the internet or printed materials of promotion of products that may not comply with EPRC requirements or identified defects related to IEC standards.

E. Physical and Documentary Samples

Under this program, physical samples will be collected only upon CDRH approval or under special request from CDRH. Documentary samples will be collected as necessary to document conditions of noncompliance and violations of EPRC standards or identify defects related to IEC standards, in order to support regulatory actions.

Collect samples according to procedures defined in the Investigations Operations Manual, Chapter 4, and coordinate any sample collection activity as instructed in CPGM 7382.845 Inspection of Medical Device Manufacturers with CDRH or WEAC to ensure proper procedures are followed and chain of custody is observed to maintain sample integrity.

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PART IV

ANALYTICAL

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

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PART V

REGULATORY/ADMINISTRATIVE FOLLOW-UP

A. REGULATORY PHILOSOPHY AND STRATEGY

Diagnostic X-ray equipment is subject to radiation safety performance standards and is regulated under Subchapter C - Electronic Product Radiation Control of the FFDCA (beginning at Sec. 531 of the FFDCA (21 U.S.C. 360hh)). Subchapter C provides authority to require product recalls for noncompliant or defective radiation-emitting electronic products. EPRC provisions specify that, for violations of sufficient severity, the Secretary of HHS may require the manufacturer to repair, replace or refund the cost of the violative products at no cost to the user/purchaser. In addition, because products covered under this compliance program are also medical devices, Subchapter A – Drugs and Devices of the FFDCA provides authority to require product recalls for medical devices that may cause a serious risk to health.

Failures to comply with the EPRC regulations include:

- Introduction into commerce of any electronic product which is defective or does not comply with an applicable performance standard
- Failure to establish and maintain an adequate quality control and testing program
- Failure to maintain or submit required reports
- Failure to maintain or make available distribution records
- Failure to certify products as compliant
- False certification of products

When violations under both Subchapters are observed, regulatory/administrative action under Subchapter C is preferred, but both EPRC and medical device portions of the FFDCA may be used in conjunction. EPRC is a Center program area. Therefore, CDRH concurrence is required for any advisory actions (Warning Letter, Untitled Letter, etc.) citing EPRC failures to comply. ORA is responsible for recommending classification, and CDRH is responsible for the final review. For regulatory action follow-up activities, contact CDRH for any inspectional guidance pertaining to EPRC violations. ORA has direct reference authority to issue certain regulatory correspondences as described in Chapter 4 of the RPM. For example, ORA has direct reference authority to issue Warning Letters and Untitled Letters to assemblers of diagnostic X-ray equipment based on field test results; and may approve corrective action plans for X-ray assemblers. Where ORA does not have direct reference authority to issue EPRC regulatory correspondences, ORA must consult and coordinate with CDRH/DRH. EIRs, exhibits, etc will be available in OSAR and may be uploaded in CMS, per Division policy. CDRH is to copy ORA on all EPRC-related correspondence.

For example, an inspection may cover a variety of regulatory program areas such as EPRC, QS, pre-approval, MDR, C&R, etc. When EPRC violations are being considered, it is helpful for ORA and DRH to communicate early and often.

ORA is to consult CDRH if additional guidance is required to classify inspection and test observations. If the inspection also covered 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.

B. REGULATORY ACTION

In determining the appropriate regulatory action based on inspection and test findings, ORA and CDRH are to consider factors including, but not limited to, the following:

- Likelihood of nonconforming/defective product having been distributed
- Violations that are critically relevant to safety and/or device effectiveness, which may present risk to health
- Adequacy of the design and quality control testing program, and the degree to which devices fail due to nonconformances that may have been discovered and corrected during production had proper testing been conducted
- Existence of product known to be nonconforming/defective in distribution which was not adequately addressed by the Corrective and Preventive Action (CAPA) subsystem
- Failures to report MDR-reportable events for radiation exposure-related defects or failures to comply
- Progress (or lack thereof) from noncompliance to compliance (e.g., no FDA 483 response vs. FDA 483 response(s) that indicate identification and early implementation of corrective action)
- Repeat observations (i.e., reverse progress, no progress) over multiple inspections
- Inspection/compliance history
- Days since inspection (e.g., 4-month target for Warning Letter issuance from FDA 483 issuance)
- Potential effectiveness of verbal communication vs. written communication (Regulatory Meeting vs. Untitled Letter)
- Potential benefit in public communication of violations
- Level of FDA awareness between inspections (e.g., extent to which the firm engages FDA via communication and MDR; failure to submit required MDRs indicates a need for more stringent inspectional/compliance follow-up)
- Risk to health of device (e.g., high-risk, low-risk high-exposure, etc.)
- Volume of distribution and percentage thereof to the US (e.g., 2 units of 1 device over a 1-year period vs. extensive importation of multiple devices)
- Ongoing Agency strategic compliance efforts
- Shortage of devices subject to a prospective Import Alert

For medical devices, possible advisory actions are Warning Letters (with or without Import Alert), Untitled Letters, and Regulatory Meetings. For medical devices, some possible

enforcement actions include Seizure, Injunction, and Civil Money Penalty. For radiation-emitting products, possible advisory actions include Program Disapproval, Major Notification of Noncompliance Letter, Minor Notification of Noncompliance Letter, and Cease and Desist Letter.

C. 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.

Division 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 Divisions suggest regulatory activity with appropriate state representatives, 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. This coordination with state representatives will be handled by CDRH.

D. 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 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.

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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/radiation-emittingproducts/electronicproductradiationcontrolprogram/lawsandregulations/ucm118156.htm

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

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

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

3. Regulatory Procedures Manual (RPM)
   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/inspections-compliance-enforcement-and-criminal-investigations/inspection-references/investigations-operations-manual

5. Compliance Program 7382.845 - Inspection of Medical Device Manufacturers
   https://www.fda.gov/media/80195/download

6. FDA Web Sites

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

   ORA home page

https://www.fda.gov/about-fda/fda-organization/office-regulatory-affairs

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

eNSpect
http://enspect.fda.gov/eFieldOpsPortal

Online Search and Retrieval System
https://osar.fda.gov/

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

Product Code Classification Database (searchable)
Product Classification

Electronic Products District Use Codes
http://qmis.fda.gov/mc/Main/MASTERControl/vault/view_pdf.cfm?ui=041620060748&infocardID=VJDSGSNUH5BRDIFWHS

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

Reporting Guides

- "A Guide for the Submission of Initial Reports on Diagnostic X-Ray Systems and Their Major Components"
- "A Guide for the Submission of Initial Reports on Computed Tomography X-Ray Systems.", and
- "A Guide for the Submission of an Abbreviated Initial Report on X-Ray Tables, Cradles, Film Changers or Cassette Holders Intended for Diagnostic Use"

The abbreviated guide (third document) recognizes that the requirements for the covered products focus on limited sections of the general guide and provides a less complex report for these products. It should be noted that it is acceptable for the manufacturers of these components to use the full format guide and many have done so.

B. ATTACHMENTS

Attachment A Applicability of IEC Standards

Attachment B Diagnostic X-Ray Product Codes

Attachment C Modality Specific Information for General Radiographic X-Ray Systems

(Including Dental Systems)

Attachment D Modality Specific Information for Fluoroscopic X-Ray Systems

Attachment E Modality Specific Information for Computed Tomography X-Ray Systems

C. PROGRAM CONTACTS

CDRH/Office of In-Vitro Diagnostics and Radiological Health (OIR)
Division of Radiological Health (DRH)

Contact for support in planning and executing inspections, classification of items of non-compliance, and for interpretation and current policy on EPRC requirements and applicable IEC standards.

Due to future personnel changes, please contact CDRH's RadHealth mailbox at RadHealth@fda.hhs.gov. Additionally, management contact information can be obtained at the following link: CDRH Management Directory.

Office of Regulatory Affairs

Winchester Engineering and Analytical Center contacts:

Name	Phone	Email	Position
Brian Baker	(781) 756-9701	brian.baker@fda.hhs.gov	WEAC Director
Edmond Baratta	(781) 756-9742	edmond.baratta@fda.hhs.gov	Radiation Safety Officer
Thomas Gilmore	(781) 756-9857	thomas.gilmore@fda.hhs.gov	Engineering Director, WEAC
Jim Cherniack	(781) 756-9711	james.cherniack@fda.hhs.gov	Laser Safety Officer

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PART VII

CENTER RESPONSIBILITIES

OMDRHO/Divisions recommend classification of the EIRs, and CDRH is responsible for the final review of inspections made under this program and for the issuance of letters with EPRC violations. Exceptions where the Division has direct reference authority are noted above in Part V, under section B, 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.

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ATTACHMENT A

APPLICABILITY OF IEC STANDARDS TO SPECIFIC MEDICAL DEVICE CLASSIFICATION

Classification Regulation	IEC 60601-1-3 General	IEC 60601-2-28 X-Ray Tube	IEC 60601-2-43 Interventional X-ray Equipment	IEC 60601-2-44 Computed Tomography	IEC 60601-2-45 Mammography	IEC 60601-2-54 Radiography and Radioscopy	IEC 60601-2-63 Extra-Oral Dental Equipment	IEC 60601-2-65 Intra-Oral Dental Equipment
21 CFR 872.1800							X	X
21 CFR 872.1810							X	
21 CFR 892.1600			X			X		
21 CFR 892.1610						X		
21 CFR 892.1630			X					
21 CFR 892.1650			X			X		
21 CFR 892.1660			X					
21 CFR 892.1670	X							
21 CFR 892.1680						X		
21 CFR 892.1700	X							
21 CFR 892.1710					X			
21 CFR 892.1715					X			
21 CFR 892.1720						X		
21 CFR 892.1730						X		
21 CFR 892.1740						X		
21 CFR 892.1750				X				
21 CFR 892.1760		X						
21 CFR 892.1830	X							
21 CFR 892.1860	X							

21 CFR 892.1880	X							
21 CFR 892.1980	X							

When a manufacturer claims conformance to an IEC standard, they accept the requirements of a radiation-related clause of that standard as design specification. Per 21 CFR 1003.2(b)(1), an electronic product shall be considered to have a defect when a product which utilizes electronic product radiation to accomplish its primary purpose and from which such emissions are intended, and as a result of its design, production or assembly it fails to conform to its design specifications relating to the emission of electronic product radiation. Therefore if a manufacturers fails to meet a radiation-related clause or requirement of an IEC standards, its considered a defect.

ATTACHMENT B

DIAGNOSTIC X-RAY PRODUCT CODES

ID	Translation of Proposed Code	Product Name	RH Radiation Type	CDRH Panel Code	CDRH Medical Specialty Code	Product Code
216	Dental Diagnostic X-Ray Equipment	Unit, X-Ray, Extraoral With Timer (Panoramic, Intraoral Dental System)	94	76	DE	EHD
218	Dental Diagnostic X-Ray Equipment	Unit, X-Ray, Intraoral Source	94	76	DE	EAP
219	Dental Diagnostic X-Ray Equipment	Dental X-Ray Film Holder*	94	76	DE	EGZ
220	Dental Diagnostic X-Ray Equipment	X-Ray Beam Aligner, Dental*	94	76	DE	EHA
221	Dental Diagnostic X-Ray Equipment	Cephalometer	94	76	DE	EAG
165	Medical Diagnostic X-Ray Equipment	Collimator, X-Ray	94	90	RA	EHB
166	Medical Diagnostic X-Ray Equipment	Collimator, Automatic Radiographic	94	90	RA	IZW
167	Medical Diagnostic X-Ray Equipment	Collimator, Manual Radiographic	94	90	RA	IZX
168	Medical Diagnostic X-Ray Equipment	System, X-Ray, Tomography, Computed	94	90	RA	JAK
169	Medical Diagnostic X-Ray Equipment	System, X-Ray, Topographic	94	90	RA	IZF
170	Medical Diagnostic X-Ray Equipment	Cradle	94	90	RA	KXH
171	Medical Diagnostic X-Ray Equipment	Film Changer	94	90	RA	KPX
172	Medical Diagnostic X-Ray Equipment	System, X-Ray, Photofluorographic	94	90	RA	IZG
173	Medical Diagnostic X-Ray Equipment	Fluoroscopic System, Image Intensified	94	90	RA	JAA
174	Medical Diagnostic X-Ray Equipment	Fluoroscopic System, Non-Image Intensified	94	90	RA	JAB
175	Medical Diagnostic X-Ray Equipment	Camera, X-Ray, Fluorographic Cine or Spot	94	90	RA	IZJ
176	Medical Diagnostic X-Ray Equipment	General Radiographic Mobile/Portable System	94	90	RA	IZL
177	Medical Diagnostic X-Ray	System, X-Ray, Stationary	94	90	RA	KPR

* Product is not a certifiable diagnostic x-ray component. Manufacturers of only * components are not inspected under this program. Manufacturers of * components may be inspected if they manufacture certifiable components.

	Equipment					
178	Medical Diagnostic X-Ray Equipment	Mammographic System	94	90	RA	IZH
179	Medical Diagnostic X-Ray Equipment	Mammographic System, Full Field Digital	94	90	RA	MUE
180	Medical Diagnostic X-Ray Equipment	Radiation Therapy Simulation System	94	90	RA	KPQ
181	Medical Diagnostic X-Ray Equipment	Spot Film Device	94	90	RA	IXL
182	Medical Diagnostic X-Ray Equipment	Holder, Radiographic Cassette, Wall-Mounted	94	90	RA	IXY
183	Medical Diagnostic X-Ray Equipment	X-Ray Beam Limiting Device	94	90	RA	KPW
187	Medical Diagnostic X-Ray Equipment	Generator, High-Voltage, X-Ray, Diagnostic	94	90	RA	IZO
188	Medical Diagnostic X-Ray Equipment	Screen, Intensifying, Radiographic	94	90	RA	EAM
189	Medical Diagnostic X-Ray Equipment	X-Ray Table	94	90	RA	KXJ
190	Medical Diagnostic X-Ray Equipment	X-Ray Table, Stationary Top	94	90	RA	IXQ
191	Medical Diagnostic X-Ray Equipment	X-Ray Table, Tilting	94	90	RA	IXR
192	Medical Diagnostic X-Ray Equipment	X-Ray Table, Non-Tilting, Powered	94	90	RA	IZZ
193	Medical Diagnostic X-Ray Equipment	Diagnostic X-Ray Tube Housing Assembly	94	90	RA	ITY
194	Medical Diagnostic X-Ray Equipment	Tube, Mount, X-Ray, Diagnostic*	94	90	RA	IYB
195	Medical Diagnostic X-Ray Equipment	Radiographic Aperture	94	90	RA	IZS
196	Medical Diagnostic X-Ray Equipment	Radiographic Grid*	94	90	RA	IXJ
197	Medical Diagnostic X-Ray Equipment	Radiographic Film Cassette*	94	90	RA	IXA
198	Medical Diagnostic X-Ray Equipment	Radiographic Camera, Focal Spot	94	90	RA	IXH
199	Medical Diagnostic X-Ray Equipment	Holder, Head, Radiographic	94	90	RA	IWY
200.	Medical Diagnostic X-Ray Equipment	Chair, Pneumoencephalographic	94	90	RA	HBK
201	Medical Diagnostic X-Ray Equipment	Barrier, Control Panel, X-Ray, Moveable	94	90	RA	IWX
202	Medical Diagnostic X-Ray Equipment	System, Computer, Digitizer for Screening Mammograms*	94	90	RA	MWE

* Product is not a certifiable diagnostic x-ray component. Manufacturers of only * components are not inspected under this program. Manufacturers of * components may be inspected if they manufacture certifiable components.

203	Medical Diagnostic X-Ray Equipment	System, X-Ray, Angiographic	94	90	RA	IZI
204	Medical Diagnostic X-Ray Equipment	Solid State X-Ray Imager (Flat Panel/Digital Imager)	94	90	RA	MQB
213	Cabinet X-Ray Systems, Medical	Cabinet, X-Ray System, Medical*	94	90	RA	MWP
214	Medical Diagnostic X-Ray Equipment	Radiographic Cone	94	90	RA	IZT
215	Dental Diagnostic X-Ray Equipment	Radiographic Cone, Lead-Lined	94	90	RA	EAH
217	Dental Diagnostic X-Ray Equipment	System, X-Ray, Extraoral Source, Digital (Panoramic, Intraoral Dental System)	94	90	RA	MUH
224	X-Ray Film and Film Processing Materials	Radiographic Film*	94	90	RA	IWZ
225	X-Ray Film and Film Processing Materials	Reusable Image Media*	94	90	RA	LQA
226	X-Ray Film and Film Processing Materials	Digital Image Storage Device*	94	90	RA	LMB
227	X-Ray Film and Film Processing Materials	Programmer, Changer, Film/Cassette, Radiographic*	94	90	RA	IZP
228	X-Ray Film and Film Processing Materials	Processor, Radiographic-Film, Automatic, Dental*	94	90	RA	EGY
229	X-Ray Film and Film Processing Materials	Processor, Radiographic-Film, Automatic*	94	90	RA	IXW
230	X-Ray Film and Film Processing Materials	Processor, Cine Film*	94	90	RA	IXX
231	X-Ray Film and Film Processing Materials	Dryer, Film, Radiographic*	94	90	RA	EGW
323	X-Ray Film and Film Processing Materials	Controlled Temperature, Radiographic*	94	90	RA	EGT
233	X-Ray Film and Film Processing Materials	System, X-Ray, Film Marking, Radiographic*	94	90	RA	JAC
274	X-Ray Bone Densitometers	Densitometer, Bone	94	90	RA	KGI
184	Medical Diagnostic X-Ray Equipment	X-Ray Controls – Combination, Medical Diagnostic X-Ray Equipment	94	94	RH	RBZ
185	Medical Diagnostic X-Ray Equipment	X-Ray Controls – Fluoroscopic, Medical Diagnostic X-Ray Equipment	94	94	RH	RCA
186	Medical Diagnostic X-Ray Equipment	X-Ray Controls – Radiographic, Medical Diagnostic X-Ray Equipment	94	94	RH	RCB

* Product is not a certifiable diagnostic x-ray component. Manufacturers of only * components are not inspected under this program. Manufacturers of * components may be inspected if they manufacture certifiable components.

205	Medical Diagnostic X-Ray Equipment	C-Arm Fluoroscopic X-Ray System	94	94	RH	RCC
206	Medical Diagnostic X-Ray Equipment	X-Ray Image Receptor	94	94	RH	RCD
207	Medical Diagnostic X-Ray Equipment	Other	94	94	RH	RZZ
222	Dental Diagnostic X-Ray Equipment	Cephalometric Devices	94	94	RH	RCI
223	Dental Diagnostic X-Ray Equipment	Other	94	94	RH	RZZ
234	X-Ray Film and Film Processing Materials	Other*	94	94	RH	RZZ

District Use Code: XD (Medical X-ray)

* Product is not a certifiable diagnostic x-ray component. Manufacturers of only * components are not inspected under this program. Manufacturers of * components may be inspected if they manufacture certifiable components.

ATTACHMENT C

General Radiographic X-Ray Systems (Including Dental Systems)

Description:

Radiographic systems are comprised of x-ray equipment designed to capture projection radiographs of human anatomy. Most are designed for particular imaging needs, including: general radiography, portable (e.g., bedside) radiography, dental radiography (including intraoral and panoramic), and handheld dental x-ray equipment. Some systems such as R-F (radiographic-fluoroscopic) units may have the capability of imaging modes (e.g., fluoroscopy) in addition to radiography. The below diagram illustrates the most basic components of a radiographic x-ray system. The component marked "Detector" also may house the AEC detectors and a radiographic grid.

Common terms:

System components [ref: 1020.30(a)(i)(A)]**:** X-ray tube housing, x-ray control console, high-voltage generator, vertical cassette holder, control console, beam-limiting devices (e.g., collimator), tube stand, patient support/table, image receptor (film cassette or digital-based receptor (detector)).

Dental x-ray systems: Intraoral

Radiographic systems intended for dental imaging are also subject to most regulations under 1020.30 and 1020.31. These systems come in two general constructs: conventional stationary systems (either wall-mounted or mobile format), and newer, handheld devices. Both device types can be used either with conventional film or with newer digital intraoral x-ray sensors. Digital sensors may be either wired or wireless, and generally can provide acceptable image quality at lower doses compared with conventional film.

Cephalometric and Panoramic equipment: May be stand-along equipment, however some new cone-beam CT devices intended for dental or ENT imaging may also provide cephalometric and/or panoramic x-ray imaging modes.

Main diagnostic x-ray system features:

Digital flat-panel x-ray detector: Also called x-ray detector, x-ray image receptor, or digital detector.

***Important Note: The requirement for certification of flat panel image receptors used in diagnostic x-ray systems depends on the specific application of the detector ~~will be used for~~ in that system. Under 21 CFR 1020.30(a)(1)(i)(F), it states "Image receptors that are electrically powered or connected with the x-ray system manufactured on or after June 10, 2006" are certifiable diagnostic x-ray components.

Currently, FDA is limiting the applicability of 1020.30(a)(1)(i)(F) to only those electrically-powered image receptors that are for use for fluoroscopy, including those systems where the same detector is

used for both fluoroscopy and radiography. The certification requirements apply to all electrically-powered image receptors (both hard-wired and wirelessly connected) used in those systems.

FDA is not requiring such certification of electrically-powered image receptors used in radiographic-only systems at this time, but reserves the right to require certification of image receptors used in radiographic-only systems in the future. FDA recommends that the manufacturers of such "radiographic-only" image receptors specify compatibility with specific systems or provide general system specifications sufficient to enable compatibility determination. Manufacturers should also provide schedules of any maintenance and/or testing that may be necessary for these devices.

In the future, FDA should be contacted to determine whether this policy is still in effect.***

Digital flat-panel x-ray detectors replace traditional film-based methods for image capture. Two most common digital technologies are computed radiography (CR), and digital radiography (DR). CR is an older technology that captures a latent image on a receptor that closely resembles a conventional film-screen cassette. An exposed CR cassette must be processed (CR reader) before an image can be displayed. DR systems typically directly convert a captured image to a display in near real-time. No intermediate processing is needed.

Some digital detectors can interface with an existing x-ray generator. Other detector systems are stand-alone devices that capture an x-ray without any physical connection to the x-ray generator. Most newer digital x-ray detectors are accompanied with software for device operation and at least basic image processing. Many are now available in large formats, eg. 43cm x 43cm. Traditional film cassettes came in a maximum typical size of 36cm x 43cm [14 inch x 17 inch].

Automatic Exposure Control (AEC): A technology that automatically terminates the production of x-rays when a sufficient exposure has reached a radiation-sensitive detector behind the image receptor to produce an acceptable/optimal final image. This feature is also referred to as a photo-timer. Most x-ray systems display (e.g., on an upright bucky) an outline of the locations of these AEC detector cells to assist clinical staff with proper positioning of the patient.

Source-image distance (SID): An x-ray exam-specific setting where the distance between the x-ray tube housing (source) and the image receptor is set, usually by adjusting the position of the tube housing. The “source” is the location of the x-ray tube focal spot, and is typically indicated as a spot (literally a dot) on the actual x-ray tube. The Image location is typically the entrance surface of the image receptor (e.g., either film cassette or digital x-ray detector).

Radiographic Grid: A thin array of parallel metallic grid lines positioned near the entrance surface of the image receptor to reduce the image-degrading effects of scatter radiation. (Similar to window blinds). Grids remove scatter, but also tend to increase patient exposure somewhat. They are specified by a grid ratio, e.g, 8:1. Grids are usually focused, meaning they are intended for a specific source-image distance (SID). A grid that is not properly focused will leave an apparent exposure gradient on the final image. Grids are usually encased inside the x-ray system bucky or into a thin metallic panel. A virtual grid is/can be a software-based feature that simulates the relative contribution from scatter

sources to an x-ray image, and attempts to remove that relative contribution by adjusting the output image accordingly.

Focal spot: The physical location within the x-ray tube housing where x-rays are produced. For distance reference, this location is usually indicated on the tube housing via a label or simple mark.

Technique factors: The x-ray equipment settings for a specific patient exam, and typically include settings for kVp, tube current (mA), exposure time (typically in milliseconds), SID (source-image distance), AEC detector configuration (if used), and grid selection. The product of tube current with exposure time (mA x seconds) is referred to as the 'mAs' for the exam, and may be displayed in lieu of separate values for exposure time and tube current.

Dose-area product (DAP) *also referred to as KAP (kerma-area product*)**:** Many x-ray systems provide for display of DAP or KAP. Typical units are Gy-cm^2 but can vary. A physical DAP meter is usually mounted to the beam exit port. A notable feature of this dose display metric is that the numerical value for DAP does NOT change along the beam path as long as the entire x-ray beam is captured by the DAP meter.

Reporting Requirements and Performance standards applicable to radiographic systems:

21 CFR 1000-1010

21 CFR 1020.30

21 CFR 1020.31

Relevant Consensus standards (and sub-clauses of interest):
All standards below refer to the latest versions that are recognized by FDA, see FDA Recognized Consensus Standards Database for the latest versions.

- IEC60601-1 General requirements for basic safety and essential performance
- IEC60601-1-3 General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment
- IEC60601-2-28 Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis
- IEC60601-2-63 Particular requirements for the basic safety and essential performance of dental extra-oral X-ray equipment
- IEC 60601-2-65 Particular requirements for the basic safety and essential performance of dental intra-oral X-ray equipment
- IEC60601-2-54:2015: Particular requirements for the basic safety and essential performance of x-ray equipment for radiography and radioscopy (fluoroscopy)
- NEMA XR-30: X-ray equipment for radiography: Quality Control Tools for Digital Projection Radiography

Known issues/inspectional tips:

- 21 CFR 1020.30(h)(1)(ii): Ask for a schedule of the maintenance necessary to keep the equipment in compliance with this section and 1020.31.
- 21 CFR 1020.30(i): Ask for documentation on description of the modes of operation.
    - Identify the technique factors
    - Identify how the technique factors are controlled
- 21 CFR 1020.30(g): Ask to view the information provided to assemblers (and to others) including assembly instructions ensuring compliance with 21 CFR 1020.30 & 21 CFR 1020.31, and specifications with other compatible components. This is sometimes referred to as "AIAT instructions" (Assembly, Installation, Adjustment and Testing).
    - In regards to component integration, review their design controls to verify compatibility. Verify if specific models and/or detailed specifications of compatible components are provided to the end user.
- 21 CFR 1010.2: Verify certification requirements are met
- 21 CFR 1010.3: Verify identification requirements are met
- 21 CFR 1020.30(j): Verify warning label requirements are met including the addition of "maintenance schedules" to the warning
- 21 CFR 1020.30(m)(1): Verify HVL requirements are met

  NOTE: the last column of Table 1 was added in 2006 and pertains to systems manufactured after June 10, 2006
- 21 CFR 1020.31(a)(4): Verify accuracy technique factor requirements are met
- Ask manufacturer if they claim conformance with any of the identified IEC standards above in the previous section. If not, inform them that particular standards exists to address safety needs of radiographic systems. If so, choose a feature required in one of the particular IEC standards and ask them to walk through design controls, verification and validation for that feature.

Additional items NOT related to an inspectional activity: The following items may be helpful/informational to ask during an inspectional visit but are NOT necessary in order to conduct and complete inspection activities.

1. Inquire if the x-ray equipment provides display of patient dose indicators such as DAP.
2. Inquire whether the device labeling addresses the use of their device to image pediatric patients (is it labeled for pediatric patients?)
3. Inquire whether the radiographic system is compatible with detectors from different manufacturers (as applicable).

4. Some dental cone-beam CT systems can be confused with panoramic dental x-ray systems. Look for terms such as 3-D, volumetric, reconstruction, which may imply that the device is a CT system subject to different performance standards.

ATTACHMENT D

Fluoroscopic X-Ray Systems

Background of the modality

Radiographic and fluoroscopic x-ray systems produce two-dimensional images of the body's internal structures. X-rays are produced by an x-ray tube, are narrowed by the beam limiting device (collimator), pass through the desired portion of the body, are partially absorbed by the body, and reach an image receptor. The varying intensities of x-rays which exit the body are reflective of the composition and densities of the body structures.

Fluoroscopic x-ray systems employ the same basic concepts of image production as other radiographic x-ray systems. However, fluoroscopic systems produce these images repeatedly and in real time. This produces real-time images of the structures and contents of the in motion. Fluoroscopic x-ray systems can also be used to image materials and devices that are placed in the body during clinical procedures. These include, but are not limited to, imaging an ingested liquid as it passes through the digestive tract and monitoring the location of devices such as biopsy needles and instruments such as catheters, stents, blood clot filters, and other devices as they are moved through the vascular system. Fluoroscopic procedures can vary greatly in duration from a few seconds to minutes or even hours of x-ray exposure depending on the complexity of the procedure. Fluoroscopic systems are comprised of the following fundamental components which require Certification (21 CFR 1010.2(c)): X-ray control, HV generator, X-ray tube housing assembly, Beam limiting device (collimator), Patient support/table, Image intensifier/digital image receptor (detector), Air Kerma display.

Reporting Requirements and Performance standards applicable to fluoroscopic systems:

21 CFR 1000-1010

21 CFR 1020.30

21 CFR 1020.32

Relevant Consensus standards (and sub-clauses of interest):

All standards below refer to the latest versions that are recognized by FDA, see FDA Recognized Consensus Standards Database for the latest versions.

- IEC60601-1 General requirements for basic safety and essential performance
- IEC60601-1-3:2013 General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment
    - 7.1: Beam Quality (Half Value Layer)
- IEC60601-2-54:2015: Particular requirements for the basic safety and essential performance of x-ray equipment for radiography and radioscopy (fluoroscopy)
    - 201.9.2.3.1: Unintended movement interlocks

- 203.5.2.4.5: Accuracy of Air Kerma rates compared to specifications in Instructions for Use
- 203.6.4.3.104.4, 5, and 6: Accuracy of tube current and exposure time

- IEC60601-2-43:2010: Particular requirements for the basic safety and essential performance of x-ray equipment for interventional procedures.
  - 201.4.101 Recovery Management (Emergency mode) available
  - 201.4.102 Provides Radiation Dose Structured Report (RDSR)
  - 203.6.6 Removable grid on devices intended for pediatric use

  NOTE: Not all fluoroscopic systems are intended for use in interventional procedures. Therefore, IEC60601-2-43 may not be applicable.

- NEMA XR-24: Primary User Controls for Interventional Angiography X-Ray Equipment.

  NOTE: As of late 2017, NEMA plans to withdraw this standard.

- NEMA XR-27: X-ray equipment for interventional procedures: User Quality Control Mode

Inspectional Tips:

- 21 CFR 1020.30(m)(1) Verify that revised beam quality (HVL) requirements are met. The last column of Table 1 was added in 2006 and pertains to systems manufactured after June 10, 2006
- 21 CFR 1020.32(g)(2) C-arm systems with small (<45 cm) source-to-image receptor distances should be labeled for extremity use only and may require additional instructions for the use of "optional means of spacing"
- 21 CFR 1020.32(k) Air kerma rate & cumulative air kerma display. Verify that the manufacturer ensures the display is accurate within the required +/- 35%. Manufacturers may state tighter accuracy specifications, which they then must meet.
- Ask manufacturer if they claim conformance with IEC 60601-2-54 amd IEC 60601-2-43 (if applicable). If not, inform them that this particular standard exists to address safety needs of fluoroscopic systems. If so, choose a feature required in IEC 60601-2-54 and IEC 60601-2-43 (if applicable) ask them to walk through design controls, verification and validation for that feature.

Common terms:

Air kerma/Air kerma rate / cumulative air kerma: The basic quantity for characterizing x-ray exposure. Many/most newer fluoroscopy systems have some means for displaying one or more quantities although air kerma and cumulative air kerma must both be available. Typical units are mGy but can vary. These measurements can be used to infer estimates for patient dose.

C-arm: A fluoroscopy system where the image receptor (either image intensifier or digital image receptor) and x-ray tube are mounted on a large "C" that can articulate about patient.

Cine: A mode of operation that captures a "video" sequence of images. This mode typically uses higher exposure rates than routine fluoroscopy

Diagnostic source assembly: The combination of the x-ray tube housing assembly (tube housing, tube, HV and/or filament transformers) with a beam limiting device (collimator) attached.

Digital acquisition / digital photospot: Still images taken from the image receptor, usually at a higher radiographic technique compared to the standard fluoroscopy mode. Ex: several digital spot images are typically captured as part of a routine upper gastrointestinal fluoroscopy exam.

Dose-area product (DAP) *also referred to as KAP (kerma-area product)***:** Many fluoroscopy systems provide for display of DAP or KAP. Typical units are Gy-cm^2 but can vary. A physical DAP meter is mounted to the beam exit port. A notable feature is that the numerical value for DAP does NOT change along the beam path.

Frame rate: The rate at which individual fluoroscopic images are obtained to simulate a constant video stream. Lower frame rates reduce patient dose at the cost of decreasing the visibility of moving objects (temporal resolution).

Image intensifier: Analog-based image receptor which converts (and amplifies) the x-rays which have passed through the patient into visible light to be recorded by a device such as a CCD camera for display on a monitor. Final output signal is NOT digital. Image intensifiers represent older technology that is being overtaken by digital flat panel detectors. While a digital flat panel detector used in a radiographic-only system may not require EPRC (Rad Health) certification, digital flat panel detectors for use in fluoroscopy and image intensifiers always require EPRC (Rad Health) certification.

Interventional/Angiography procedures: Complex fluoroscopic procedures that typically involve diagnosing or treating a pre-existing patient condition. These procedures are typically done in a sterile environment, and involve the participation of a number of clinical staff. Depending on the intervention, patient x-ray doses can be significant and facilities should have (but are not required to by FDA) a patient dose management program in place. Not all fluoroscopic systems are intended for interventional procedures.

ATTACHMENT E

Computed Tomography X-Ray Systems

Background

Computed Tomography (CT) is a non-invasive medical examination or procedure that uses specialized X-ray equipment to produce cross-sectional images (slices) of the body. These images are used for a variety of diagnostic and therapeutic purposes. Over the past 30 years, CT technology has rapidly advanced and now includes such performance and safety features as rapid helical scanning, automatic tube-current modulation, various methods of incorporating multiple energy spectra acquisitions for added physical information in reconstructed images, the development of cone-beam x-ray sources with flat-panel detectors (cone-beam CT), non-linear iterative reconstruction algorithms for improved image quality or reduced radiation dose, and others. These new technological features have greatly expanded the frequency with which such exams are performed, with an estimated 10% annual growth in number of CT exams until recently.

Cone-beam CT (also called CBCT or 3-D CT) is a means of capturing and displaying volumetric x-ray data using a methodology that is similar to that for conventional CT. In CBCT a very broad beam in the shape of a cone or pyramid is employed, sufficiently broad to allow a single-rotation acquisition that entirely encompasses the anatomy of interest. CBCT is now available either as an add-on feature for certain fluoroscopic systems or as a stand-alone, dedicated device. As dedicated systems, CBCT devices are finding widespread use in dentistry as well as with ENT and extremity imaging. Dedicated CBCT devices are classified by FDA as CT devices under 21 CFR 892.1750 and are also regulated as electronic products under 21 CFR 1020.33. Fluoroscopic x-ray systems that can also acquire CBCT images in addition to their primary fluoroscopic mode of operation are usually classified according to their primary fluoroscopic mode of operation under 21 CFR 892.1650.

CBCT devices currently pose a challenge with respect to dosimetry because the methods of computing CTDI using the standard cylindrical phantom typically are not applicable. Most of these systems typically display cumulative dose-area product (DAP) or air kerma-area product (KAP). Because these newer CBCT devices employ a digital x-ray detector they are required to provide routine technique factors and associated dose indicators in their labeling (eg. user manual).

Reporting Requirements and Performance standards applicable to CT systems:

21 CFR 1000-1010

21 CFR 1020.30

21 CFR 1020.33

Relevant Consensus standards (e.g. IEC Standards):

All standards below refer to the latest versions that are recognized by FDA, see FDA Recognized Consensus Standards Database for the latest versions.

- IEC60601-1 General requirements for basic safety and essential performance
- IEC60601-1-3 General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment
- IEC 60601-2-44 Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography (not applicable to CBCT)
    - 203.106 Control of RADIATION output – Automatic Exposure Control
    - 203.107 Safety measures against excessive x-radiation, parts g and h – CT Dose Check Feature
- IEC 60601-2-63 Particular requirements for the basic safety and essential performance of dental extra-oral X-ray equipment (only applicable to dental CBCT devices, not other CT devices)
- IEC 61223-3-5 Acceptance tests - Imaging performance of computed tomography X-ray equipment
- IEC 61223-2-6 (to be combined with 61223-3-5 for future editions) Constancy tests - Imaging performance of computed tomography X-ray equipment
- NEMA XR-25 Computed Tomography Dose Check (not applicable to CBCT)
- NEMA XR-26 Access Controls for Computed Tomography (not applicable to CBCT)
- NEMA XR-28 Supplemental Requirements for User Information and System Function Related to Dose in CT (not applicable to CBCT)

Inspectional Tips:

- While 21 CFR 1020.33 applies to dental/extremity/ENT CBCT devices, many sections of the performance standard that refer to section/slice thickness can't be met by these devices. Ask whether the firm has requested a variance from these portions of the standard.
- 21 CFR 1020.33(c): Requires user manual pages containing user information (operating conditions, dose, imaging performance)
- 21 CFR 1020.33(d): Requires inclusion of imaging-performance phantom for quality assurance and a section of the user manual dedicated to instructions for performing QA with this phantom. CBCT devices regulated under 21 CFR 1020.33 must also include this phantom and user manual section. The phantom must be provided to the purchaser with the CT or CBCT system.

- Ask about one of the required device capabilities under 21 CFR 1020.33 [scanner indications of operation, auto-stop, manual-stop, indication/alignment of tomographic planes, status indicators for beam-on, shutter-open, CT number of user-selected pixel array]. Ask manufacturer to walk through design controls, verification, and validation for at least one of these device features.

- Ask manufacturer if they claim conformance with IEC 60601-2-44. If not, inform them that this particular standard exists to address safety needs of CT devices (note that this standard applies to conventional CT only, not CBCT). If so, choose a feature required in IEC 60601-2-44 and ask them to walk through design controls, verification and validation for that feature.

Important terms:

Multi-slice: Refers to the ability of the CT scanner to collect data on many slices during each x-ray tube rotation about the patient. Common multi-slice formats are 4, 16, 32, 64, and 128-slice formats.

Helical scanning: a mode in which the patient support table continuously moves the patient through the CT gantry bore while x-ray data are collected. The effective path of the x-ray beam traces out a virtual helix, hence the name for this common scanning mode.

Tube current modulation: A technology that provides a form of automatic exposure control for CT equipment. When this feature is engaged, the CT scanner adjusts one or more scanning parameters to account for differing sizes of the scanned anatomy, similar to the AEC feature of conventional radiographic equipment. Each CT equipment manufacturer will have its own expression for this feature.

Computed Tomography Dose Index (CTDI): The basic dosimetric quantity for CT is derived from scanning a standard, cylinder-shaped plastic phantom (16-cm diameter for head and pediatric protocols, 32-cm for adult body protocols). The CTDI is NOT a dose value associated with a single patient; the above mentioned phantoms are NOT equivalent to a standard size patient. The CTDI comes in various expressions, such as $CTDI_{100}$, $CTDI_{w}$, $CTDI_{FDA}$ and $CTDI_{vol}$. While each is determined and interpreted in a unique way, all forms of CTDI express a reference dose acquired by means of a standard reference phantom, and are associated with a unique set of CT scanning parameters.

Iterative Reconstruction: A specific type of CT reconstruction algorithm compared with the older standard method known as filtered back projection (FBP); both are methods of converting x-ray transmission data into a 3D image volume. In iterative reconstruction (IR), the image is passed through several rounds of processing, which increases computation time but reduces image noise. Once considered a high end feature, iterative reconstruction is now commonly available on both conventional (multi-slice) and cone-beam CT systems (such as for dental applications). This reconstruction methodology can be used to potentially lower patient dose (dose reduction and image quality claims are frequently made for IR).