*Applicability of Certain Requirements*

*of the Standard to Different Types*

*of Diagnostic X-Ray Systems*

## Applicability of Certification for Diagnostic X-Ray Systems Not Used on Humans

REF:NONE

There are many situations where diagnostic x-ray equipment is installed and is never used for exposure to living persons. Some examples are veterinary clinics, technologist schools that use only "phantoms," pathology laboratories, and certain industrial applications.

Components certified to comply with the Performance Standards for Diagnostic X-Ray Equipment are installed in these situations.

The National Center for Devices and Radiological Health does not require certification by an assembler who installs certified components in situations where they will not be used to expose humans for diagnostic or visualization purposes. Nor is it required that "the type called for by the standard" be installed.

Manufacturers of components specifically designed for nonhuman use are subject to initial and annual report requirements as specified in 21 CFR Subchapter J.

If the x-ray system contains certified components and is later installed for use of exposure to humans, all of the certified components must be in compliance and an assembler's report (Form FD 2579) must be filed.

## Instructions for Mobile Mode Installation of CT Scanners

REF:BRH:DOC:MA 340

Since CT scanners used in a transportable mode (truck or trailer installation) could be subjected to special or accentuated safety problems related to mechanical shock, torsion, vibration, variable electrical supply, temperature and humidity variations, etc., special instructions for installation or assembly of CT scanners in a transportable mode might be appropriate or necessary. If such special instructions are or will be provided with any of your models, a copy of such instructions should be submitted to the National Center for Devices and Radiological Health as a supplement to the initial report covering such CT scanner model.

The Office of Health Practices Assessment, through the Assistant Secretary for Health, makes recommendations to the Health Care Financing Administration regarding reimbursement policy under Federally-funded programs such as Medicare. It is reasonable to anticipate that any recommendation regarding reimbursement for mobile CT scanning will reflect the requirements that such CT scanner models be reported to the Center as being certified by the manufacturer to meet the FDA performance standard under mobile use conditions and that the assembler's report specify the assembly or installation of a CT scanner in a mobile mode or facility.

Supplements to initial reports in the manner indicated offer no guarantee that the Office of Health Practices Assessment will recommend reimbursement, or that the Health Care Financing Administration will adopt the recommendation. However, the report supplements should provide answers to some questions or concerns raised in regard to the equipment safety aspects of the mobile use of CT scanners.

August 21, 1985 Ref:MA:OC:DRP:XPB:384

TO: MANUFACTURERS OF COMPUTED TOMOGRAPHY (CT) X-RAY SYSTEMS

SUBJECT: "Date of Manufacture" and "Applicability of Requirements" for CT X-Ray Systems

This letter states the Food and Drug Administration's (FDA) position regarding certain questions which arose after performance standards for CT systems were published. This letter supersedes the March 25, 1985, letter on the same subject.

1. Some people have argued that 21 CFR 1020.30(a)(2), published in the August 31, 1984, FEDERAL REGISTER, made most of the requirements in 1020.30 which were in effect for CT systems manufactured before November 29, 1984, inapplicable to CT systems manufactured between November 29, 1984, and September 3, 1985. This was not the FDA's intent.

   The August 31 publication promulgated requirements which were incorporated into 1020.30 specifically for CT and exempted CT from one requirement (i.e., the aluminum equivalence of the tabletops). These became effective November 29, 1984. The FDA did not intend, however, to make the applicable 1020.30 requirements in effect before November 29 inapplicable to CT systems manufactured after that date. The FDA intends to publish in the FEDERAL REGISTER technical amendments which will clearly state that all of 1020.30 applies to all CT systems manufactured after November 29, 1984. The FDA expects CT manufacturers to fully comply with all 1020.30 requirements applicable to CT systems. In addition, the dose information required by 1020.33(c)(2) and the information required by 1020.33(c)(1) as it affects 1020.33(c)(2) must be provided to the purchaser. All of section 1020.33 applies only to CT systems manufactured after September 3, 1985.

2. The amendments published in the August 31, 1984, FEDERAL REGISTER specify requirements applicable to CT systems, not to individual components. However, FDA still expects the major components specified in 1020.30(a) and used in a CT system to be certified. In addition, the CT gantry shall be certified and must display both certification and identification labels. The specified components must be compatible with the gantry. By issuing this letter, the FDA has now defined the date of manufacture of the gantry as the date of manufacture of the CT system. The CT system must meet all applicable requirements as determined by the date of manufacture of the gantry. The FDA intends to publish in the FEDERAL REGISTER technical amendments which clearly require certification of the CT gantry and state that the date of manufacture of the gantry is the date of manufacture of the CT system.

3. As used in paragraph 2, CT gantry means tube housing assemblies, beam-limiting devices, detectors, and the supporting structures and frames

which hold these components. The proposed technical amendments will include this definition.

4. Assemblers of CT systems shall use the form FDA 2579. However, for item 4 e, beam-limiting device, the assembler shall provide the manufacturer and model number of the CT gantry instead of the beam-limiting device. The assembler shall also record the date of manufacture of the CT gantry in the comments section.

December 5, 1983 Ref:MA:DRP:XPB:377

TO: MANUFACTURERS AND ASSEMBLERS OF DIAGNOSTIC X-RAY EQUIPMENT

SUBJECT: Installation of Digital Image Processing Systems

We are writing this letter to the x-ray industry to state the agency's position concerning installation of add-on digital image processing systems and to identify the manufacturer's and assembler's responsibility for any modification(s) performed on existing x-ray equipment during installation of these systems.

Previous compliance policy guides state that digital image processors that do not function as x-ray controls currently are not included in the list of components to which the standard is applicable; therefore, no assembler certification is required.

The regulations (21 CFR 1020.30(q)) permit the owner to modify his equipment, provided the modification does not result in noncompliance with the performance standard. The following discussion outlines the agency's position regarding the requirements and responsibilities applicable to add-on digital image processors which do not require certification by their manufacturer.

The owner of a piece of x-ray equipment may modify or request any other person to modify his x-ray equipment (See 21 CFR 1020.30(q)(2)). The installation of a noncertifiable device, i.e., digital image processor, into a diagnostic x-ray system constitutes modification of diagnostic x-ray components and systems under 21 CFR 1020.30(q). The person performing these modifications must insure that the finished modifications are compliant with all applicable provisions of the diagnostic x-ray standard. Complete details of any modification performed and results of the testing must be documented by or provided to the owner who requested this modification. This documentation should be included in the user's instructions. The equipment would be subject to FDA inspection for compliance with the standard including the required accuracy specifications (original equipment manfacturers' and the owner-authorized changes, as appropriate).

When the owner or his employee performs these modifications, he must document and retain the date and details of each modification in the service record and/or the user's instructions. This documentation must include appropriate testing to insure that the modified diagnostic x-ray system is compliant with all applicable provisions of the diagnostic x-ray standard (21 CFR 1020.30 - 32).

When the owner hires another person to perform these modifications, that person must document the date and details of the modifications in the service statement and, when available, the user's instructions. This documentation must include appropriate testing to insure that the modified diagnostic x-ray system is compliant with all applicable provisions of the diagnostic x-ray standard (21 CFR 1020.30 - 32). This documentation must be provided to the owner of the x-ray system.

If the installation of a digital image processor involves a series of modifications by different persons, each person must document the modification he performs as described in the preceding paragraphs. The person who completes the last modification to a certified diagnostic x-ray system will be held liable for compliance with all applicable requirements of the diagnostic x-ray standard (21 CFR 1020.30 - 32).

Although most add-on digital image processors do not currently require certification, we believe that a responsible manufacturer should develop compatible interfacing packages along with the device. We do have regulatory alternatives to address those digital image processors or x-ray system modifications that represent an unreasonable risk to patient and/or operator.

This letter formally details the procedures for assuring that every phase of the installation is traceable to the responsible individual—the person who actually performs the modification.

Manufacturers and/or assemblers must advise purchasers of add-on digital image processors in writing either prior to or at the time of sale that they, as the owners, will be required to have any necessary modifications performed to their x-ray equipment. Purchasers must be warned that these modifications may void the manufacturer's warranty for the x-ray control. Purchasers must also be advised of their responsibilities, under the Radiation Control for Health and Safety Act of 1968, to record the date and details of the modification and evidence that the modification does not result in a failure to comply with the diagnostic x-ray standard (21 CFR 1020.30 - 32).

*Reporting and Recordkeeping Requirements*

*for*

*Assemblers and Manufacturers*

## Accidental Radiation Occurrences and Foreign Manufacturers

**QUESTION:** Referencing paragraph 1002.20, Accidental Radiation Occurrences. Does this requirement apply to foreign manufacturers?

**ANSWER:** Yes, if a foreign manufacturer or his designated American-based agent is subject to reporting requirements, then all the requirements are applicable. Our interest is in the manufacturing defect of any product that enters into the commerce of the United States, whether it is produced by a foreign or domestic manufacturer.

## Updating of Initial Reports

Revised Language Ref: BRH:DOC:MA 3736

Since August 1, 1974, some manufacturers have chosen to update initial reports through the annual report. The National Center for Devices and Radiological Health strongly recommends that each manufacturer update initial reports through (1) the submission of a new initial report, or (2) supplements to the affected initial report.

For proper administration and enforcement of the Performance Standards for Diagnostic X-ray Equipment, it is necessary that the FDA regional organization be informed as to the certification status of all affected components of diagnostic x-ray systems. The source of this information is the initial report(s) submitted to NCDRH by each manufacturer. When these initial reports are updated by methods other than (1) or (2), above, the probability is increased that the pertinent information concerning certified components may not be disseminated to regional personnel.

## Reporting Changes to Specifications

Ref: BRH:DOC:MA 4101

If manufacturers modify the design of certified x-ray equipment in a manner that affects or potentially affects performance regarding applicable Federal performance standards, they must supplement their initial reports of quality control and testing which describe the modifications and/or any testing program changes associated with such equipment. Since components are certified by the manufacturer to meet the requirements of the performance standard (with the manufacturing practices in effect at the time of manufacture), the Center considers any changes to the manufacturing practice of certified equipment to apply only to equipment manufactured after the effective date of the change.

The Performance Standards for Diagnostic X-Ray Equipment require that certain information concerning certified equipment be provided to the users. Since the user information must reflect the specifications at the time of manufacture, any changes in specifications subject to the standard may not be made arbitrarily.

In the past, manufacturers have made changes to technique factors accuracy, generator ratings, tube housing ratings, and BLD specifications. Sometimes these changes are made more than one time on the same model component. Therefore, the Center must keep several sets of specifications on each component. At present, the Center can only identify the date of notification for the changes.

This is to emphasize that when any changes are made to the manufacturing practice that will affect any of the performance standard requirements by changing component specifications, the manufacturer must indicate the following:

(a) The effective date the change will take place.

(b) The commencing serial number and date of manufacture of the certified component the new specifications will affect.

(c) The old values and new values of the parameters affected by the changes.

(d) The justification as to why these changes should apply to previously manufactured equipment, if such is desired.

The above information is requested for all manufacturing changes that have been employed to date on each certified component and which affect any specifications related to certification according to the standard.

## Foreign Manufacturers Required to Maintain Records

**QUESTION:** Paragraphs 1002.30(a)(1) and (2) call for maintaining records of (1) quality control procedures, and (2) test results. How does this apply to foreign manufacturers and what does NCDRH expect? That is, are records to be maintained at the foreign factory?

**ANSWER:** Since foreign manufacturers have quality control and testing programs, they will be responsible for generating records. As long as NCDRH knows where the records are kept it would not matter where they are stored. These records must be kept for five years. All records must be on call.

## Annual Report Submission

**QUESTION:** Is the importer or the manufacturer of x-ray units responsible for submitting annual reports?

**ANSWER:** As defined in Section 355(3) (42 U.S.C. 263c(3)) of the Radiation Control for Health and Safety Act and 21 CFR 1000.3(f), the importer is legally considered to be the manufacturer of all x-ray equipment imported from foreign manufacturers.

As a result, the importer is responsible for the submission of all information and reports pursuant to 21 CFR Part 1002, including the annual report required by Section 1002.11. The manufacturer may submit the required information on behalf of the importer. It cannot be overemphasized, however, that the importer is held responsible for defects in the products and all other manufacturer obligations as specified in the Act and regulations.

## Annual Reports and Field X-Ray Tube Reloading

**QUESTION:** When tube assembly reloading is done in the field, in manufacturer X's district office shop by an employee of manufacturer X, is the employee or the district manager now a manufacturer? Does he file an annual report? Assembly instructions and procedures would be equivalent to those used at headquarters factory site.

**ANSWER:** The replacement of an x-ray tube in a used "previously certified" tube housing constitutes manufacture of a new tube housing assembly. The manufacture and field reloading operations of previously certified tube housings should be included in the parent company's annual report. Neither the employee nor district manager has to file any records with the Center because it is the responsibility of the parent manufacturer to do so.

May 12, 1983 Ref:ORH:DOC:XPB:372

TO: ALL MANUFACTURERS AND ASSEMBLERS OF DIAGNOSTIC X-RAY EQUIPMENT

SUBJECT: Simplification of FD 2579, "Report of Assembly of a Diagnostic X-ray System"

This letter is intended to explain why the Office of Radiological Health (ORH) no longer requires assemblers to record on the FD 2579 the model and serial numbers of installed components other than beam limiting devices and tables.

Several inquiries have been received by ORH from x-ray equipment assemblers who questioned the absence of space on the FD 2579 to record model and serial numbers of controls, generators, vertical cassette holders, etc. These questions are best answered by consideration of the purpose of the FD 2579, which is to serve as the assembler's certification that he installed the components according to manufacturer's instructions. The FD 2579 is <u>not</u> intended to serve as a tracking system for x-ray components. A dealer or distributor who is also an assembler must fulfill the recordkeeping requirements of 21 CFR 1002.40 and 1002.41 by maintaining, separately or in combination with the FD 2579, a record of model and serial numbers of the components he installs. Space for recording date of manufacture is not provided because the FD 2579 is used to record the assembly of certified components only.

Some assemblers have expressed their concern that they may be held accountable for certified components which could be noncompliant or defective due to faulty manufacture or installation and which they did not install. Considering that the FD 2579 is required when a component is replaced, ORH does not recognize a valid need for including component serial numbers on the FD 2579. When a noncompliant component is found in an x-ray system, a review of the FD Forms 2579 maintained by the user will identify the assembler who performed the most recent installation of the component in question.

The assembler's record of model and serial numbers of specific components he has installed will then serve to determine the assembler's responsibility relative to the installation of the noncompliant component.

November 28, 1983 Ref:NCDRH:OC:XPB:374

TO: MANUFACTURERS, ASSEMBLERS, AND DISTRIBUTORS OF DIAGNOSTIC X-RAY SYSTEMS

SUBJECT: Instructions for Completing Form FDA 2579, "Report of Assembly of a Diagnostic X-Ray System"

Since the introduction of the new format of the Report of Assembly of a Diagnostic X-Ray System (FDA 2579), we have received several questions concerning the proper way to complete this report. Although we designed the new form to simplify the report, we need to clarify certain items.

The Report of Assembly (FDA 2579) is the assembler's certification for the installation of one or more certified components. The various sheets of the form must be distributed to the FDA (white sheet), the responsible State radiation control agency (yellow sheet), and the purchaser (pink sheet) within 15 days following the completion of the assembly. The assembly is considered completed when the unit is ready for use on patients. The assembler must retain his copy (buff sheet) for five years.

Information Required: (See Enclosure)

(A) Enter equipment location; hospital or office address where installed and telephone number.

(B) Enter assembler information; company name, address, and telephone number.

(C) 1) Enter a check in the first box of 3a, if a complete fully certified x-ray system is installed. A complete x-ray system must contain at least an x-ray control, a tube housing assembly, a beam-limiting device, and an x-ray generator and may contain other components.

2) Enter a check in the second box of 3a, if one or more certified components are installed to replace existing components in a system.

3) Enter a check in the third box of 3a if one or more certified components are added to an existing system, as opposed to replacing existing components.

NOTE: You may enter a check in both the second and third boxes if that best describes the installation.

(D) Enter a check in the appropriate box(es) for the system's intended use(s), and whether the system is stationary or mobile. (You may indicate more than one intended use if this is appropriate.) Also, provide the room location of the master x-ray control, and the completion date of the assembly (i.e., when the unit is ready for use on patients).

(E) Check the appropriate box regarding the master x-ray control:

A new installation when a new (unused) control is being installed.

Existing (Certified) when the master control is certified and not being installed or upon reinstallation of a used certified master control (such as relocation of the system).

Existing (Non-certified) when the master control is not certified and not being installed or reinstallation of a used uncertified master control is occurring (such as relocation of the system).

(F) Enter in 4e the manufacturer and model number for each certified beam-limiting device and x-ray table you install.

(G) Enter in 4f the quantity (number) of other certified components being installed. Place a number in each appropriate box, not a check mark or X. For the box labeled "other", the component must be certified and one not listed in 4e or 4f. Describe this component in the comments section at the bottom of the form.

(H) Section 5 must be completed by the individual who installs and calibrates the equipment. He must enter his printed name, his signature, and the date of his signature.

The new form relaxes some of the reporting requirements for models and serial numbers of components. It does not, however, change any of the recordkeeping requirements of the regulations (21 CFR 1002.30 and 1002.40) which require manufacturers, dealers, and distributors to maintain records in a form which will enable traceability of model number and serial or other identification number of their products.

Although the form was designed as a self-mailer, the paper stock is thinner than expected and a number of forms have been damaged by mail handling equipment. We recommend that you place the forms in an envelope for mailing since this will help assure proper receipt and handling of the form.

Forms may be obtained by writing to:

Forms and Publications Distribution Center (HFA-268)
U.S. Public Health Service
5600 Fishers Lane
Rockville, Maryland 20857

Please specify the form number (FDA 2579) and how many you need.

| FOR FDA USE ONLY | DEPARTMENT OF HEALTH AND HUMAN SERV<br>PUBLIC HEALTH SERVICE<br>FOOD AND DRUG ADMINISTRATION<br><br>**REPORT OF ASSEMBLY OF A DIAGNOSTIC X-RAY SYSTEM** | *Form Approved; OMB No. 0910-0025*<br>*Use of this form is prohibited after December 31, 1984.*<br><br>C 311966 |
|---|---|---|

**1. EQUIPMENT LOCATION**

a. Name of Hospital, Doctor or office where installed (A)

b. Street Address (A)

c. City (A) | d. State (A)

e. Zip Code (A) | f. Telephone Number (A)

**2. ASSEMBLER INFORMATION**

a. Company Name (B)

b. Street Address (B)

c. City (B) | d. State (B)

e. Zip Code (B) | f. Telephone Number (B)

**3. GENERAL INFORMATION**

a. This report is for assembly of certified components which are *(Check appropriate box (es))*
- ☐ A complete x-ray system *(Includes x-ray control, tube housing assembly, beam limiting device, and x-ray generator)*
- ☐ A replacement of component(s) in the existing system
- ☐ An addition to the existing system (C)

b. Intended use(s) *(Check applicable box(es))* (D)
- ☐ General Purpose Radiography
- ☐ General Purpose Fluoroscopy
- ☐ Tomography *(Other than CT)*
- ☐ Angiography
- ☐ Podiatry
- ☐ Urology
- ☐ Mammography
- ☐ Chest
- ☐ Chiropractic
- ☐ CT Head Scanner
- ☐ CT Whole Body Scanner
- ☐ Head-Neck *(Medical)*
- ☐ Dental-Intraoral
- ☐ Dental-Cephalometric
- ☐ Dental-Panoramic
- ☐ Radiation Therapy Simulator
- ☐ Any Other *(Specify in comments)*

c. The X-ray System is *(check one)* (D)
- ☐ Stationary
- ☐ Mobile

d. The Master Control Is In Room (D)

e. Date of Assembly (D) _____ *(mo.)* _____ *(day)* _____ *(yr.)*

**4. COMPONENT INFORMATION** *(If additional space is needed for this section use another form, replacing the preprinted number with this Form Number and complete Items 1, 4 and 5 only)*

a. The master control is ☐ A new installation (E) ☐ Existing *(Certified)* ☐ Existing *(Non-certified)*

b. Control Manufacturer (E) | c. Control Model Number (E) | d. Control Serial Number (E)

Complete the following information for the certified components listed below which you installed. For beam limiting devices and tables enter the manufacturer and model number in the indicated spaces. For other certified components, enter in the appropriate blocks how many of each you installed in this system.

e. Selected Components

| | Manufacturer | Model Number |
|---|---|---|
| Beam Limiting Device | (F) | (F) |
| | (F) | (F) |
| | (F) | (F) |
| Tables | (F) | (F) |
| | (F) | (F) |

f. Other Certified Components *(Enter number of each installed in appropriate blocks)*
- ☐ X-ray Control (G)
- ☐ High Voltage Generator
- ☐ Vertical Cassette Holder
- ☐ Tube Housing Assembly *(Medical)*
- ☐ Dental Tube Head
- ☐ Cradle
- ☐ Film Changer
- ☐ Image Intensifier
- ☐ Spot Film Device
- ☐ Other *(Specify)*

**5. ASSEMBLER CERTIFICATION**

I affirm that all certified components assembled or installed by me for which this report is being made, were adjusted and tested by me according to the instructions provided by the manufacturer(s), were of the type required by the diagnostic x-ray performance standard (21 CFR Part 1020), were not modified to adversely affect performance, and were installed in accordance with provisions of 21 CFR Part 1020. I also affirm that all instruction manuals and other information required by 21 CFR Part 1020 for this assembly have been furnished to the purchaser and within 15 days from the date of assembly, each copy of this report will be distributed as indicated at the bottom of each copy.

a. Printed Name (H) | b. Signature (H) | c. Date (H)

**6. COMMENTS**

FORM FDA 2579 (8/82)

White Copy - FDA HFX-490, 5600 Fishers Lane, Rockville, MD 20857

April 3, 1984 Ref:OC:DRP:XPB:MA:381

TO: ALL ASSEMBLERS OF DIAGNOSTIC X-RAY SYSTEMS

SUBJECT: Reporting Assembly of Digital Radiography and C-Arm Fluoroscopy Systems

The current version of the "Report of Assembly of a Diagnostic X-ray System", form FDA 2579, does not enable the Center to identify and locate installations of digital radiographic or C-Arm fluoroscopic equipment. To assist the Center in identifying such installations which do not conform with the more conventional equipment designs, assemblers of diagnostic x-ray equipment are requested to adhere to the following reporting procedures:

(1) When reporting the assembly of a system which utilizes a digital imaging system, assemblers should check as an intended use of the system (block 3b) "Any Other" and specify in the "Comments" section (block 6) the wording "Digital Imaging System."

(2) When reporting the assembly of a C-Arm fluoroscopy system, assemblers should check as a intended use of the system (block 3b) "Any Other" and specify in the "Comments" section (block 6) the wording "C-Arm System."

*Assembly, Reassembly, and Maintenance*

## Assembler or Installer

**QUESTION:** Form FD 2579 will be used to report assembly of diagnostic x-ray systems. In a case where the purchaser also installs a device in his system, does he then become the "assembler" or the "installer," as defined in the regulations?

**ANSWER:** He is the installer who, by law, now becomes the assembler.

## Donating Used Equipment

**QUESTION:** What will be the status of used equipment that has been donated?

**ANSWER:** Donated equipment is covered by the regulations in the same way as purchased equipment.

## Multiple Tubes and One Generator

**QUESTION:** A hospital has three connecting rooms. Room 1 has an x-ray unit, room 3 has an x-ray unit, and room 2 has a generator common to rooms 1 and 3. There is a certified component in the system in room 1. If a new component is installed in the system in room 3, must that component also be certified? The generator is the common link between systems.

**ANSWER:** The three rooms of equipment would be considered a single x-ray system, since they are interconnected. All replacements must be made with certified components, no matter which room is involved.

Only an identical exchange would allow the replacement of a used uncertified component (21 CFR 1020.30(p)(5)(ii)).

## Commercially Available

**QUESTION:** What is "commercially available" and how does an assembler determine this?

**ANSWER:** A component is "commercially available" if it can be supplied by any manufacturer within a reasonable time period. An assembler, in attempting to determine commercial availability of a component, should, as a minimum, take the following steps to find a compatible component:

(1) Consult the information supplied by the manufacturer of the certified component being installed to see if the manufacturer has made a determination of compatibility regarding the component or an alternate model for the system in question; if unsuccessful,

(2) consult the manufacturer(s) of the component(s) of the system not meeting the specification for compatibility to determine if alternate components exist which would be compatible and perform the intended functions; if unsuccessful,

(3) consult the FDA Regional/District Offices for assistance in obtaining a compatible component.

## Practitioner's Responsibility

**QUESTION:** What is the practitioner's responsibility for keeping certified equipment in compliance with the standard?

**ANSWER:** It is up to the practitioner to have his x-ray equipment maintained according to the schedule furnished by the manufacturer to ensure compliance with the standard for the life of the equipment. Failure to follow the manufacturer's maintenance instructions could relieve the manufacturer of responsibility for continued compliance. In addition, the practitioner may be required to comply with State x-ray equipment regulations, which in turn would have to be compatible with the Federal performance standard.

## Illegal Installations

**QUESTION:** User has been provided, in compliance with 21 CFR 1020.30(h)(3), statement of maximum line current and range of line voltage regulation, prior to purchase. In addition, he has been provided with suggested conductor sizes for the estimated conductor lengths.

Upon installation check-out, it is not possible to meet linearity and reproducibility specifications because line regulation is excessive. How shall this installation be reported on FD 2579?

**ANSWER:** The installation as described is illegal. An assembler may not install a unit on a line that does not meet the manufacturer's specifications.

However, it is acceptable to derate a unit so that the line is adequate for it. This involves the cooperation of the assembler and the manufacturer to determine how much to derate the unit. It also requires notification to the National Center for Devices and Radiological Health and insertion in the user's manual. Copies of pertinent test data should also be sent to the National Center for Devices and Radiological Health. When the unit is derated, the inactivated technique factors must be made physically inoperative and so indicated on the control panel.

*SPECIFIC CLARIFICATION*

*OF*

*SECTIONS 21 CFR 1020.30 - 21 CFR 1020.32*

*OF*

*THE RADIATION CONTROL REGULATIONS*

*FOR DIAGNOSTIC X-RAY EQUIPMENT*

*Sections 1020.30(a) - 1020.30(n)*

## SECTION 1020.30(a) - APPLICABILITY

### Replacement of Electronic Timers

**QUESTION:** We would like information regarding the applicability of the Performance Standard for Diagnostic X-Ray Equipment regarding replacement of electronic timers.

**ANSWER:** If a manufacturer wishes to enter a product into commerce that is not expressly listed in paragraph 1020.30(a)(1), but which functionally performs in a manner consistent with the definitions of one or more of the listed products (1020.30(b)), then he must certify that product. A timer designed to control x-ray exposure, although not expressly listed, performs in a manner consistent with the definition of an x-ray control and, as such, must be certified in accordance with paragraph 1020.30(c). This assumes, of course, that the timer is separately manufactured and marketed in its own housing.

### Manufacture of Cones

**QUESTION:** A customer has purchased and installed a new system of certified components, including a skull unit and a manual collimator. He determines that he prefers a "double diaphragm" cone such as his technicians had become accustomed to on previous skull units. The manufacturer, however, has discontinued the cone because he could not certify its compliance with the standard. Can anyone, such as the owner, the installer, or a local machine shop, legally fabricate such a cone?

**ANSWER:** Anyone may manufacture (fabricate) a BLD such as you describe, but it must be certified and the National Center for Devices and Radiological Health must have an initial report covering the quality control and testing procedures used in manufacture.

## Second SID for Chest and Spinal X-Ray Systems

Ref:ORH:DOC:XPB:368

FDA Compliance Policy Guide 7133.11, with an effective date of October 1, 1980, permits chiropractic radiography to be performed on non-PBL x-ray systems at a fixed SID. This policy does not restrict the size(s) of cassette(s) that can be used at the fixed SID.

The Office of Radiological Health has been informed that a radiographic study in common use in chiropractic practice requires the provision of two different SIDs. It is not the intent of the diagnostic x-ray equipment performance standard to unduly restrict the practice of chiropractic radiography, or to force practitioners to purchase expensive PBL collimation equipment. It is reasonable to permit the provision of a second SID, especially if the use of the second SID is limited by design to a situation in which PBL collimation is not required to function, if provided.

To this end, paragraph B.4 of the enclosed CPG is being revised by insertion of a new second sentence, as follows: "Such a system may be provided with a second SID if operation at the second SID is restricted by design to image receptors greater than 20 inches in length in the non-tilting vertically-mounted wall bucky stand or cassette holders." This change has no effect on the use of hang-on, non-bucky cassette holders, which is a permitted practice in non-PBL mode whether PBL is provided or not.

Since PBL is not required to function in the case where the image receptor is more than 20 inches in length, and since PBL is not required in a fixed-SID system having no x-ray table, two SID positions may be provided. The SID switches must be interlocked with the wall bucky stand or cassette holder so that exposure to the inserted film cassette at the longer SID is permitted only if the cassette length is greater than 20 inches. At the shorter SID, there is no restriction as to cassette size.

March 26, 1984 Ref:MA:OC:DRP:XPB:380

TO: MANUFACTURERS AND ASSEMBLERS OF DIAGNOSTIC X-RAY EQUIPMENT

SUBJECT: Definitions of "General Purpose X-ray System" and "Other Than General Purpose X-ray System"

Questions continue to arise concerning the definitions of "general purpose" and "other than general purpose" as they appear in 21 CFR 1020.31(d), (e), and (f) of the performance standard and the applicability of these sections to an installed x-ray system.

We are writing this letter to the x-ray industry to revise and restate FDA's definitions of "general purpose" and "other than general purpose" for the purposes of 21 CFR 1020.31. Copies of this letter will be sent to all FDA District Offices and FDA field x-ray inspectors. This letter incorporates the original definitions, issued in 1979, and appearing on page 10 of the Assembler's Guide; the contents of our November 24, 1982, letter in which we permitted the limited use of a second SID; and our recent change permitting the limited use of tilting cassette holders.

Definitions: "General Purpose"
"Other Than General Purpose"

A. An x-ray system, designed for and limited by its design for diagnostic purposes to only one of the following body regions, is classified as "other than general purpose" for the purposes of 21 CFR 1020.31.

1 - extremities
2 - head or head and neck
3 - thoracic
4 - abdominal

B. An x-ray system, designed for and limited by its design for diagnostic purposes to only one of the following specialized applications, is classified as "other than general purpose" for the purposes of 21 CFR 1020.31.

1 - System designed for cystographic, urologic, or other specialized exams of the kidney, bladder, and/or urinary tract.

2 - Dental x-ray system designed for use with intraoral and/or extraoral image receptors.

3 - Cephalometric x-ray system or dental x-ray system designed for use with extraoral image receptors whenever special cephalometric devices are attached.

4 - An x-ray system designed specifically for chest or spinal radiography when installed:

a. With a single fixed source-to-image-receptor distance (SID) along the horizontal axis

or

b. with two SIDs along the horizontal axis when exposure at one of the two SIDs is restricted to image receptors with a dimension greater than 50 centimeters (20 inches).

Either a or b may be installed with a permanently-mounted vertical cassette holder or Bucky (tilting or non-tilting) but not with a permanent x-ray table. If installed with a tilting vertical cassette holder or Bucky, exposure shall not be possible when the x-ray beam axis is within ±3 degrees of the vertical and the image receptor plane is within ±3 degrees of perpendicular to the x-ray beam axis. Mobile or hang-on cassette holders or mobile tables may be used without restriction in such systems.

5 - Mammographic x-ray system.

6 - Therapy simulation x-ray system.

7 - System designed for and installed in operating rooms.

8 - Pantomographic x-ray system.

9 - Tomographic x-ray system (when used in the tomographic mode of operation).

C. Any x-ray system, which by its design is not limited to radiographic examination of a specific anatomical region and does not meet the requirements of paragraphs A or B preceding is considered to be "general purpose" for the purposes of 21 CFR 1020.31.

## Radiography/Fluoroscopy Image Processing Systems Including Digital Systems

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There are two general types of radiography (and/or fluoroscopy) image processing systems available. The first type incorporates a component that is used only to electronically process and store the electronic signal from a detector that transforms x-ray photons into electronic signals. The second type incorporates similar processing and signal storage, and has the additional capability of affecting or controlling one or more of the x-ray exposure technique factors; i.e., tube potential, tube current, and/or exposure time. It may be capable of exposure initiation and/or termination, independent of the usual exposure control function.

The first type of image processing system is related to an x-ray system in much the same way as a film processor is related to a conventional diagnostic x-ray system. It is used with a diagnostic x-ray system, but does not affect the compliance of the x-ray system with the Performance Standards for Diagnostic X-ray Equipment. Therefore, this image processing system is not subject to the provisions of the standard.

The second type of image processing system meets the regulatory definition of an x-ray control because it directly affects or controls at least one of the technique factors. X-ray controls require certification and must be reported to the National Center for Devices and Radiological Health (NCDRH) as required by 21 CFR 1002.10. The manufacturer of this type of image processing system must submit an initial report to NCDRH that describes the quality control and testing program under which the product is manufactured. This initial report must be submitted before the system can be introduced into commerce and must follow the reporting guide specified by NCDRH.

Initial reports should be directed to the Director, Office of Compliance (HFK-100), National Center for Devices and Radiological Health, Food and Drug Administration, 5600 Fishers Lane, Rockville, Maryland 20857.

Both types of radiography (and/or fluoroscopy) image processing systems are subject to the premarket notification requirements of the Food, Drug and Cosmetic Act. Ninety (90) days prior to introduction of a new medical device into commerce, the manufacturer must file a 510(k) notification with the Food and Drug Administration. Information submitted in either the initial report or the premarket notification may be incorporated in one, in detail, and in the other by reference, without the need of duplication.