Labeling Requirements for Imports

QUESTION: Since many packages are probably not opened at the customs entry, should there be any certification on the outside of the package?

ANSWER: A certification label need not be attached to the outside of a package containing a certified component(s). However, you must file a declaration upon entry of your product, as described in Title 19, Part 12, Section 12.91(b).

Certifying a Tube Housing Assembly

QUESTION: The requirement for leakage radiation and standby radiation applies to the diagnostic source assembly that includes the tube housing assembly and the beam limiting device. How does one certify a tube housing assembly separately from the beam limiting device?

ANSWER: You must ensure that the tube assembly which you are certifying is compatible with the beam limiting devices for which it is intended. This means that you must test your tube housing assembly on those beam limiting devices with which you want to specify compatibility. Compatibility may be specified in terms of manufacturer name and model number or in terms of generic physical characteristics.

Certification of Assembly of Components of Diagnostic X-Ray System (21 CFR 1020.30(d))

REF:BRH:DOC:MA 3703

Background

This opinion is issued in response to inquiries and misunderstandings concerning the definition of "date of installation" as called for in item 3e of "Report of Assembly of a Diagnostic X-ray System," FD 2579 (item 6 prior to 8/82). A number of manufacturers have incorrectly instructed their dealers and installers to withhold the submission of FD 2579 until the purchaser of an x-ray system formally accepts the installation and agrees to pay for it.

Opinion

The date of installation of an x-ray system or component is considered to be the date the x-ray system is released by the assembler for use by the facility on human patients. The assembler has fifteen (15) days from the date of installation to complete and distribute the FD-2579 before he will be considered to be in violation of the Code of Federal Regulations, Title 21, Section 1020.30(c).

Certify the Installation

QUESTION: The following is a question of terminology: When an assembler completes an installation, does he affirm that certified components were properly installed?

ANSWER: The term "certify the installation" does not appear in paragraph 1020.30(d) "Certification by Assembler." This paragraph states that the assembler is required to assemble, install, adjust, and test certified components in accordance with the instructions of the respective manufacturer, and assemblers who install certified components shall file a report of such assembly. Therefore, the assembler is certifying the assembly by affirming that certified components were installed according to the instructions of the manufacturer.

Installation of Certified Components

QUESTION: Can an assembler install a certified component into a system containing certified components that have been modified by the user (or repairman) such that a compliant installation cannot be made? If so, how does he report the noncompliant assembly on Form FD 2579?

ANSWER: No, unless Section 1020.30(d)(2) of the standard, which strictly defines the circumstances whereby an assembler may install a certified component with noncompatible component(s) of an x-ray system, is satisfied. All the following criteria must be met:

(a) Components of the existing x-ray system do not meet the manufacturer's specifications for compatibility, as given by the certified component manufacturer.

(b) There is no commercially available certified component of a similar type that is compatible with the existing x-ray system.

(c) The component(s) of the existing x-ray system not meeting the specification for compatibility (1020.30(d)) must be a certifiable component which does not bear a certification label due to date of manufacture.

In the situation you have described, the components of the existing system that preclude following manufacturers' instructions do not meet criteria (c) above. Therefore, an assembler is prohibited from installing a certified, noncompatible component on such a system.

Section 1020.30(d)(2) of the standard prohibits any modification of a certified component that will adversely affect the performance of the certified component with respect to the standard. If such a modification is found to be desirable, the user should seek advice from the appropriate State agency and/or the National Center for Devices and Radiological Health. An exemption or a variance may be necessary to allow the desired modification and subsequent installation of other certified components.

Late Report of Assembly

QUESTION: If an assembler does not recognize the labeling of a given component at the time of installation, he will not have reported it on FD 2579. His attention is directed, at a later date, to the fact that the component is certified. He realizes that he is in violation, although the violation is not willful.

He returns to the site, verifies the installation, and conducts all tests and adjustments to verify compliance.

We take the viewpoint that he shall file a supplementary FD 2579 giving actual installation date, and adding the "Comments" block notation:

"Late report of component installation because the labeling was not recognized."

ANSWER: No, he should file a second complete FD 2579 listing all components shown on the first form plus the overlooked component. A comment, as described, would be appropriate and should point out which component was overlooked.

FOOD AND DRUG ADMINISTRATION
COMPLIANCE POLICY GUIDES

GUIDE 7133.03

CHAPTER 33 - RADIOLOGICAL HEALTH

SUBJECT: Certification and Identification of X-ray Components - Sections 1010.2 and 1020.30(e)

BACKGROUND:

The Code of Federal Regulations, Title 21, Section 1020.30(e) requires that manufacturers of components of diagnostic x-ray equipment subject to the Performance Standard shall: (1) permanently inscribe or affix thereon the model number and serial number of the component so as to be: (2) legible and accessible to view.

Manufacturers who do not indicate a model designation on the component, but instead have listed such terminology as part numbers, style numbers, type numbers, catalog numbers, and transformer numbers do not meet the intent of Section 1020.30(e). It has been found that a manufacturer may list the model designation on the component but this designation applies to the complete x-ray system and not to an individual component. Other manufacturers have placed the model designation on the component but do not identify it as such. Still other manufacturers have given model names which are not unique to the components involved and some identification labels contain both a catalog number and a model number that are easily confused.

Another problem closely related to the one discussed above concerns what is meant by "legible and accessible to view" as it appears in Section 1020.30(e) of the Standard. Many manufacturers and assemblers are installing certified components in a manner that precludes the easy identification of the component. Some are installed such that the inspector must crawl around on his hands and knees to read the label, others require the use of a mirror for reading, while still others require removal of some part of the x-ray system to identify the component. The Bureau has previously stated that the only label that must be conspicuous is the warning label but that all required labels must be accessible to view if the certified component is accessible to view.

POLICY:

To comply with the requirements of 21 CFR 1020.30(e) which requires that a model number and serial number be inscribed or affixed to a component, the word "model" or "type" must appear as part of the manufacturer's required identification of certified x-ray components. A model designation may

describe only one certified component and may not be used to describe an assemblage of components except as specified in Section 1020.30(e) or as specifically approved by the Bureau. Similarly, the words (or reasonable abbreviation of) "serial number" must appear as part of the serial identification of a certified component.

The label bearing this identification and other information required by 21 CFR 1010.2, 1010.3, and 1020.30(e) shall be in a location that is readily accessible to view to anyone inspecting the x-ray machine after it is installed in a user location without having to unbolt, unlock, or relocate the x-ray system to read such a label. The identification and certification labels shall be on the outside of the equipment and not on a side that is normally placed against a wall. It is realized that for some components such as a tube housing assembly mounted under a table, the identification and certification labels cannot be in view from outside the completed system. In such a case, the identification and certification labels shall be mounted on the component, although the component itself is not visible. However, if the identification or certification label is behind a door, panel, under a table, etc., which is readily accessible and can be opened or removed without the need to unbolt, unlock, or relocate the x-ray system, wording shall appear on the door, panel, etc., indicating the location of the identification and/or certification labels.

Changes in a manufacturer's model designations must be reported by the manufacturer to the Bureau by way of a supplement to their applicable initial reports.

Cassette Holder Which is Considered a Part of a Certified Positive Beam Limitation (PBL) System

Ref: NCDRH:DOC:MA 356

This is a clarification to the FDA position regarding the certification status of a cassette holder used in a radiographic (only) x-ray system utilizing a C-arm configuration and a certified PBL system.

A stationary C-arm radiographic (only) x-ray system classified as a stationary general purpose x-ray system is subject to the provisions of 21 CFR 1020.31(e) for field limitation and alignment. As such, it must provide positive beam limitation (PBL).

With the cassette holder (image receptor) permanently mounted at one end of a C-arm configuration, it is the FDA position that the cassette holder is an integral part of the PBL system. Thus, it is not subject to separate certification and identification. The certification and identification label located on the system's collimator is sufficient for the entire PBL system.

Location of ID Nameplate

QUESTION: We would like further interpretation of Sections 1010.3 and 1020.30(e) concerning the location of the identification nameplate. That is, does legible and accessible to view when the product is fully assembled for use mean that (1) the nameplate must not be inside a panel removable with a screwdriver, (2) it must be on the outside of equipment but not against the wall, or (3) it cannot be inside a panel when the panel can be opened without a tool but with a key? It is felt that the identification and nameplate usually do not add to the aesthetic appearance of the product and, therefore, it is usually placed in an inconspicuous location.

ANSWER: Being legible and accessible to view does not imply that the label must be conspicuous. The intent of the standard is that an identification or certification label be in a location where one who is inspecting the x-ray machine when it is installed in a user location can read the label without having to unbolt or relocate the x-ray system. However, the warning label should be conspicuous. It should be so situated that a user of an x-ray machine could see the warning when he is looking at the main control panel.

Identification of Multiple Parts

QUESTION: Many items such at phototimers, brightness stabilizers (automatic exposure controls), and positive beam limiting systems (collimator, sensing tray, electrical chassis), are made up of many components located in or on other major components.

(a) How shall these items be identified with nameplates per Sections 1010.3 and 1020.30(e)? Must one model number be assigned to the two or more scattered parts?

(b) Where must nameplates be located?

ANSWER: Our response to (a) is that it is permissible for a manufacturer to assign more than one model number and nameplate to the scattered parts of major components; however, it is not always required.

In response to (b) it is not necessary that every physically separated piece of a major component be labeled. It is reasonable to label only the essential parts of a major component if desired. Please note that in the event two or more major components are sold as an integrated system (i.e., one catalog item which is not intended to be subdivided for use with other components), only one label is required. All tube housing assemblies must be labeled, since they are subject to replacement. Following is a list of major components and suggested label locations for each:

Major Component	Label location
Tube Housing Assemblies	On housing, including undertable tubes
X-ray Control	On each x-ray control panel
X-ray HV Generators	On generator housing
Spot Film Devices	On spot film device
Image Intensifier	On image intensifier
Tables	On table
Cradles	On cradle
Image Receptor Support	On the image receptor support
Film Changer	On changer (If separated control unit is provided, this must also be labeled)
Cassette Holders	On cassette holder
Beam Limiting Devices	On outside of collimator

Final Testing of Diagnostic X-ray Systems and Components Following Assembly

REF:BRH:DOC:MA 362

This is intended to establish NCDRH policy relative to final testing of a newly-assembled x-ray system or component before release to the user.

Manufacturer Responsibility - The FDA believes that plant-based manufacturers must include in their assembly instructions a specific requirement that the assembler perform a test(s) for the applicable requirements of the FDA performance standard at the time of installation. A thorough explanation of the equipment required and step-by-step instructions must be provided by the component or system manufacturer. The instructions should include a requirement to record key data to demonstrate at a later date that all tests were performed and that the equipment was left in full compliance with the standard. The FDA's National Center for Devices and Radiological Health will ensure that these assembler test instructions are provided through a close review of the information submitted by manufacturers in initial, model change, and annual reports. Plant-based manufacturers who do not include a final compliance test in their assembler instructions could be subject to disapproval of their quality control and testing programs.

Assembler Responsibility - Assemblers of diagnostic x-ray equipment must perform a test or tests for the applicable requirements of the FDA performance standard at the time of installation, if specified in the assembly instructions provided by the component or system manufacturer. Assemblers who do not perform and document such final compliance tests will be considered by the FDA to have issued a false and misleading certification and will, therefore, be subject to regulatory action by the Agency.

SECTION 1020.30(g) - INFORMATION TO BE PROVIDED TO ASSEMBLERS

Installation and Operating Instructions

QUESTION: The manufacturer must provide to assemblers the installation and operating instructions, etc., at no cost or not to exceed cost of publication and distribution. What is cost of publication and distribution?

ANSWER: The cost to the buyer cannot exceed printing, handling, and mailing costs.

Listing of Compatible Components

QUESTION: Regarding the listing of compatible components as required under 21 CFR 1020.30(g), we understand quite clearly that we must list one company's x-ray tubes and collimators and our buckys if they are to be used on our equipment. However, we are confused as to whether other companies must, in turn, list our components in their literature and specifications.

ANSWER: Component manufacturers are not required to list their products as being compatible with any other manufacturer's products. However, an assembler may mate only certified components that are compatible. Thus, unless one of the manufacturers states that certified components to be mated are compatible, an assembler who chooses to do so must submit his testing and quality control program to the National Center for Devices and Radiological Health. Most assemblers will not have the necessary testing equipment and expertise to perform the appropriate tests. Consequently, to ensure that his components can be used, it is advantageous to a manufacturer to list those components of other manufacturers that are compatible with his own.

Acceptable Statements for Compatible Components

QUESTION: Is it acceptable to use a statement that the component is compatible with all products bearing this company's nameplate? I recognize that this places the responsibility on my company to assure that the component is compatible; however, it would greatly simplify the documentation changes when adding or deleting products.

ANSWER: The procedure you have described is acceptable. However, it would mean that all components bearing your nameplate must be compatible regardless of when they were manufactured. Thus, 20 years from now a component that you certified must still be compatible with all components bearing your nameplate. This may present some difficult problems in the future.

SECTION 1020.30(h) - INFORMATION TO BE PROVIDED FOR USERS

Maximum Line Current Specifications

QUESTION: Paragraph 1020.30(h)(3)(ii) of the Performance Standard for Diagnostic X-Ray Equipment requires that when a generator may be used with various tube units, the manufacturer must specify maximum line current as a function of tube unit ratings.

Our past practice has been to satisfy maximum line current based on maximum generator ratings. In addition to providing best line characteristic, this practice has permitted upgrading of tube units without the need to replace the room power system. Therefore, the standard requirements do not appear reasonable, and the possibility exists that we have not interpreted it correctly. Please clarify this point.

ANSWER: It is not our intent to prevent you from supplying information relating to the generator rating by itself, but rather to give a system rating which will allow field measurement of parameters that are dependent upon maximum line current. It will still be essential that you give generator ratings so that they can be compared with the tube ratings. We would also encourage the installation of a line adequate for the maximum rated component such that the system could be upgraded in the future.

Measurement Basis

QUESTION: It is not clear what is meant by "measurement basis" in Section 1020.30(h)(3)(vii).

ANSWER: The regulations define technique factors such as peak tube potential, tube current, etc. However, the definitions are general in nature and more precise information is needed to interpret the manufacturers' indicated technique factors. Specifically, the criteria used to obtain the indicated technique factors should be given. For example, when measuring exposure time for three phase equipment, the beginning and end of the exposure cycle may be the 70-80 percent points on the high voltage waveform.

A statement of "measurement basis" is important since this is a basis for compliance measurements.

SECTION 1020.30(j) - WARNING LABEL

Label Placement

Revised Ref: BRH:DOC:MA 4150

Warning Label

There have been several cases where manufacturers have chosen to affix the warning label either on the top or side panels of the main x-ray control. While the labels themselves are legible, their placement would not be considered accessible to the user, thus defeating their purpose.

A warning label, by its nature, should be conspicuous to the user. It should be so situated that a user of an x-ray machine can see the warning when he is looking at the main control panel. This usually is the front panel of the x-ray control where the main power switch and technique factor indications are located.

Any other placement of the warning label would be considered in noncompliance with 21 CFR 1020.30(j).

Wording of Warning Label

QUESTION: Must the warning label be exactly as specified in Section 1020.30(j)?

ANSWER: The general rule is that warnings that differ slightly from the standard and are more forceful and restrictive in content meet the intent of the regulations.

Multiple Tube Head Systems

QUESTION: A hospital has an existing radiographic table, tube stand, tube, collimator, and a control with capability of energizing only the one tube. They purchase new equipment consisting of a head stand, tube housing assembly, and collimator (all certified) to add to the room. The new tube housing assembly (THA) is to be energized by the old generator.

We interpret the regulations to require that a light shall be mounted on the existing THA as well as the new THA. The old control must also be modified to give clear indication of which tube, old as well as new, is selected for energization. In summary, we interpret 21 CFR 1020.31(j) as being invoked to the system, even if part of the system has existed prior to the effective date of the standards.

ANSWER: The requirements apply only to the certified components and only the new THA would require the indicating light. When the old THA and control are replaced, the new certified components would have to have the required indicators.

SECTION 1020.30(k) - LEAKAGE RADIATION FROM THE DIAGNOSTIC SOURCE ASSEMBLY

Source Assembly as Encompassing the Entire Table Body

QUESTION: We have a tube mount/beam limiting mechanism that is designed for use in a spot-film table only. The beam limiting mechanism is an integral part of the fluoroscopic assembly as mounted in the table.

For purposes of radiation leakage testing, can we define the source assembly as encompassing the entire table body? We would then test for leakage radiation below the plane of the table top one meter from the source but, in any event, measured at a point outside the table enclosure.

ANSWER: When the beam limiting device is an integral part of an undertable tube mounting system and is not designed for use outside a table, it is reasonable to perform the test for leakage radiation with the tube and mounting assembly in place under the table. Therefore, the concept of the test you propose is acceptable.

Leakage Testing

QUESTION: Is it agreed that when measuring leakage from the diagnostic tube housing, the main beam will be blocked at the end of the cone in such a manner to ensure the measurement of leakage radiation? May I dump the entire main beam into a black body absorber?

ANSWER: Please note that radiation which "...passes through the tube housing port and the aperture of the beam limiting device ...," 21 CFR 1020.30(b)(40), is considered part of the useful beam even though it is not part of the "x-ray field" and is, therefore, not subject to the leakage requirement. Therefore, your proposal of blocking the end of the beam limiting device is appropriate. This will be a somewhat more restrictive test than dumping the entire useful beam into a "black body" asborber. It would also be appropriate to block the port of the tube housing assembly for this test.

Positive Means to Ensure That at Least The Minimum Filtration is Present

QUESTION: What is considered positive means to ensure that at least the minimum filtration needed to achieve the beam quality requirements is in the useful beam during each exposure as specified in Section 1020.30(m)? Specifically, would a special tool with appropriate warnings and instructions that would disengage the filtration elements where special (mammography) radiographic techniques require temporary disengagement of the filter and/or mirror optic system meet the requirements of "positive means"?

ANSWER: We would not accept a special tool as being a "positve means." By "positive means" it is intended that the manufacturer design the equipment so that the filter(s) cannot be easily removed, and the probability of use of the equipment without the proper filters is reduced. "Positive means" should ensure that the proper filtration is in the beam without the operator having to remember to take some action to ensure this. Although special tools may be used to remove the filter during servicing, the equipment should be such that it is not necessary for the operator to routinely add and/or remove it.

Measuring Compliance for Capacitor Energy Storage Equipment

QUESTION: Section 1020.30(m), "Beam Quality," states that measuring compliance for capacitor energy storage equipment shall be determined with the maximum quantity of charge per exposure. Regarding the actual method, we have a question as follows:

Should this maximum quantity of charge be interpreted as:

(i) The maximum quanity stored in capacitors for each charging (namely, the product of its capacitance and charged voltage), or

(ii) the maximum selectable or pre-determined quantity for each exposure that is designed to be generated by the unit being measured?

ANSWER: The intent of the standard is consistent with option (ii). The maximum selectable discharge available on the unit, as designed, should be used and not the maximum stored in the capacitors.

Filtration and Beam Quality

QUESTION: Is the compensation filter used to obtain a uniform exposure at the surface of the film covered by the standard? The filter is only in the edges of the x-ray beam.

ANSWER: The Performance Standards for Diagnostic X-Ray Equipment do not place requirements directly on the filtration but rather address beam quality and set requirements as in Table 1, 21 CFR 1020.30(m). We would test your unit for compliance by opening the compensation filter to the widest setting and making the half-value layer determination.

Tolerance Levels of Technique Factors and Inherent Filtration

QUESTION: The standard requires each manufacturer to establish and state his own tolerance levels of technique factors. If, for example, a manufacturer produces an x-ray system rated nominally at 70 kVp and has established a kVp tolerance of plus or minus 5 percent, must the inherent filtration be at least 2.2 mm of Al equivalent filtration rather than 1.5 mm, as specified in the standard?

ANSWER: The question misinterprets the requirement of the standard. If a machine is designed to operate at 70 kVp, then the appropriate range for measurement of half-value is the 50 to 70 kVp range, regardless of whether or not the measured kVp exceeds 70.

SECTION 1020.30(n) - ALUMINUM EQUIVALENT OF MATERIAL BETWEEN PATIENT AND IMAGE RECEPTOR

Requirements for Film Changer with Image Intensifier

QUESTION: We have a film changer whose front panel meets the 1 mm requirement. However, we occasionally mount an image intensifier under the film changer. The total filtration between patient and image intensifier now includes the changer front panel, the screens, film, grid--if used--and film compressor plate. The total of all this is approximately 10 mm Al equivalent. Is this kind of application covered in the regulations?

ANSWER: No. However, the intent of the regulations is violated by the introduction of 10 mm Al equivalent between the patient and the image receptor. If this practice is continued, it may be necessary for the Center to amend this paragraph to limit the total Al equivalent that may be so located. The manufacturer is urged to devise an acceptable alternative.