

CPG Sec. 398.600 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, * * 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 *Center for Devices and Radiological Health (CDRH)* 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 *CDRH*. 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 *CDRH* by way of a supplement to their applicable initial reports.

Material between asterisks is new or revised

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