DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

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Dear Dr. Rodriguez:

FDA has become aware of possible confusion related to Electronic Product Radiation Control (EPRC) certifiable components[1] that are used to modify existing medical x-ray imaging equipment (radiography, mammography, fluoroscopy, and computed tomography systems), particularly when the component used for the modification (the "modification component") and the original system are from different manufacturers. An example of such a modification component is a digital detector that also functions as an x-ray control, as defined in 21 CFR 1020.30(b).

According to 21 CFR 1020.30(q)(1), "Diagnostic x-ray components and systems certified in accordance with § 1010.2 of this chapter shall not be modified such that the component or system fails to comply with any applicable provision of this chapter..." The issue is whether a modification to an existing system can be assumed to be compliant with the performance standards if both the original system and the modification component have been cleared (or approved) separately and both are certified electronic products.

An assumption of compliance cannot be supported through the use of cleared (or approved) and certified components alone. The original system may comply with the performance standards, and the modification component may, when tested independently, also comply with the performance standards, but the combination when operated together may fail to comply with the performance standards. *Any modification that results in the system or a certified component failing to comply with the performance standards is not permitted in the absence of a variance or exemption (21 CFR 1020.30(q)(1)).*

In general, manufacturers must certify that each component or system complies with the relevant performance standards. Certification means the manufacturer guarantees the component or system will perform as required by the performance standards when it is assembled, installed, adjusted, tested, and maintained in accordance with the manufacturer's instructions. Certification of a component does not mean that it may then be used in any diagnostic x-ray system without further evaluation. Specifically, "manufacturers of products subject to §§ 1020.30 through 1020.33 shall certify that each of their products meet all applicable requirements when installed into a diagnostic x-ray system according to instructions." (21 CFR 1020.30(c)) *A component manufacturer can only certify to a component's ability to function in compliance with the standard when the*

[1] "Component" means "an essential functional part of a subassembly or of an assembled electronic product, and which may affect the quantity, quality, direction, or radiation emission of the finished product." (21 CFR 1000.3)

system of which it is a component is properly assembled and installed according to the manufacturer's instructions.[2]

Compatibility requirements are intended to ensure compliance among components assembled into a finished system. Therefore, as part of the certification process for the modification component, FDA expects the manufacturer of the modification component to identify and evaluate compatible systems and/or components, and provide instructions, including specifications, to ensure compliance with the relevant performance standards once it is installed in those systems or with those components (21 CFR 1020.30(c)).

The manufacturer of a modification component must provide the assembler with instructions for assembly, installation, adjustment and testing of the component sufficient to assure that the modification component *and the entire system* will comply with the performance standards if the instructions are followed. "...manufacturers are responsible for providing assembly instructions adequate to assure compliance of their components with the applicable provisions of §§ 1020.30 through 1020.33." (21 CFR 1020.30(c)) "Such instructions shall include specifications of other components compatible with that to be installed when compliance of the system or subsystem depends on their compatibility. Such specifications may describe pertinent physical characteristics of the components and/or may list by manufacturer or model number the components which are compatible." (21 CFR 1020.30(g))

FDA requires the manufacturer of the original system to provide to anyone who requests it, at a cost not to exceed the cost of publication and distribution, the assembly, installation, adjustment and testing (AIAT) instructions required by 21 CFR 1020.30(g) and the information for users required by 21 CFR 1020.30(h). The AIAT instructions and the information for users may contain critical information regarding testing for compliance with applicable federal performance standards.

However, there are limits on the information that 21 CFR 1020.30(g) and 21 CFR 1020.30(h) require the manufacturer of the original system to provide. The manufacturer of the original system is not required to disclose trade secrets or confidential information. Also, the manufacturer of the original system may provide the user or its own service personnel with additional documentation or enhanced software programs, with privileged access codes. This additional documentation or enhanced software programs may operate in conjunction with other proprietary accessories or functions. Such additional documentation, enhanced software, proprietary accessories or functions may increase the value of the system to the user. The manufacturer of the original system is not required to disclose proprietary accessories or functions, additional documentation or enhanced software programs to third parties unless this information is part of the AIAT instructions

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[2] Information Disclosure by Manufacturers to Assemblers for Diagnostic X-ray Systems. Available at http://www.fda.gov/downloads/Radiation-EmittingProducts/ElectronicProductRadiationControlProgram/IndustryGuidance/UCM136731.pdf

specified in 21 CFR 1020.30(g) or part of the user information specified in 21 CFR 1020.30(h).[3]

We hope that this communication clarifies FDA's expectations. We would be happy to discuss this issue further with the appropriate MITA committee.

Sincerely,

Mary S. Pastel, Sc.D.
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[3] Information Disclosure by Manufacturers to Assemblers for Diagnostic X-ray Systems. Available at http://www.fda.gov/downloads/Radiation-EmittingProducts/ElectronicProductRadiationControlProgram/IndustryGuidance/UCM136731.pdf