IOWA DEPARTMENT OF PUBLIC HEALTH
Bureau of Radiological Health (BRH)
Lucas State Office Building, 5th Floor
321 East 12th Street, Des Moines, IA 50319
May, 2014

IDPH INFORMATION NOTICE: 2014 X-2: Certified vs uncertified x-ray equipment

ADDRESSEES: All service providers

PURPOSE

This IDPH Information Notice is to review the definitions of certified and uncertified x-ray equipment. This information should be reviewed by all service providers in order to verify that installation and service of x-ray equipment is completed according to FDA's Guidance for Industry and Food and Drug Administration Staff/Assembler's Guide to Diagnostic X-ray Equipment. The entire guide can be found at www.fda.gov/radiation-emittingproducts/electronicproductradiationcontrolprogram/
Click on "industry Guidance", then the Assembler's Guide.

Please read this information notice carefully and consult the IDPH website for rules cited in this notice.

REFERENCES

Excerpts from the Iowa Radiation Machines and Radioactive Materials Rules:
641-41.1(3)"e". Federal performance standards. All x-ray equipment shall comply with the applicable performance standards of 21 CFR 1020.30 to 1020.40 which were in effect at the time the unit was manufactured. All equipment manufactured before the effective date of 21 CFR 1020.30 to 1020.40 shall meet the requirements of the Iowa Rules. Persons registered to possess the affected radiation-emitting equipment in Iowa shall be responsible for maintaining the equipment in compliance with the appropriate federal performance standards.

FDA Classifications of components and systems by certification status states:

"Certified components" are components manufactured after August 1, 1974. Some certified components were manufactured before August 1, 1974, but met the FDA certification requirements.

"Certified x-ray system" is one that is assembled of all certified compatible components.

"Uncertified component" is a component manufactured before August 1, 1974, and not certified before that date by the manufacturer.

"Uncertified x-ray system" is one that is assembled of all uncertified components.

"Mixed system" is one that is composed of both certified and uncertified components.

Rules covering the assembly and reassembly of x-ray systems excerpted from 21 CFR 1020.30(d):

1. A new system, consisting of all unused components, may only be assembled with all certified or all uncertified (manufactured before August 1, 1974) components.
2. A complete x-ray system may be assembled from all uncertified (manufactured before August 1, 1974) components, without restriction, if all components were never previously assembled into an x-ray system.
3. A complete x-ray system may be assembled from all certified components, without restriction, if all components have documented necessary compatibility.
4. An existing x-ray system that contains all uncertified components may be reassembled. Additional or replacement components must all be uncertified or all certified. (This excludes repair or exact replacement of uncertified components.)
5. An x-ray system that contains one or more certified components may be reassembled. Additional or replacement components must all be certified. (This excludes repair or exact replacement of uncertified components.)
6. Exchange of an uncertified component for an identical uncertified component, or reinstallation of any component following repair of the component to its original condition, is not considered assembly or reassembly.
7. Uncertified components from a previously existing system may be reassembled with certified components to form a complete system. This is an upgrade. After the introduction of the first certified component into a system, all subsequent components must be certified unless an exact replacement for an existing uncertified component (repair) is installed. All but one component in an existing uncertified x-ray system may be replaced with certified components, however the certified components must be compatible.

DISCUSSION

As a registered service provider, IDPH requires you to replace parts in the x-ray equipment according to the above FDA requirements. Since all parts manufactured since 1974 must be certified therefore making most of the equipment "certified", we are using this notice to determine approximately how many uncertified systems are still in use. This information will be used in revision of the Chapter 41 Rules governing x-ray equipment.

CONCLUSION

1. Review the FDA "Assembler's Guide to Diagnostic X-ray Equipment."
2. Complete the survey at www.surveymonkey.com/s/GP7ZSML by July 31, 2014. Thank you for your input.

If you have any questions regarding this Notice, please contact Charlene Craig at 515-281-0415 or email charlene.craig@idph.iowa.gov.

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Angela Leek, Chief, Bureau of Radiological Health Date