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Use of Electronic Signatures for NRC Documents Related to the Medical Use of Byproduct Material Maintained at Licensees' Facilities

Comment On: NRC-2010-0330-0001

Request for Comments on the Use of Electronic Signatures for NRC Documents Related to the Medical Use of Byproduct Material Maintained at Licensees' Facilities

Document: NRC-2010-0330-DRAFT-0001

Comment on FR Doc # 2010-26391

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RULES AND DIRECTIVES
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General Comment

See attached file(s)

Attachments

NRC-2010-0330-DRAFT-0001.1: Comment on FR Doc # 2010-26391

*SONSI Review Complete
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Add = A. Cooperhane
(ALT 2)*

Comments regarding use of electronic signatures on NRC documents

The increasing adoption of electronic medical records is prompting the use of electronic signatures. For NRC rules relating to Medical Use of byproduct material, a prime instance involves the use of an electronic signature on a written directive for a radiopharmaceutical.

The issue of electronic signatures is not limited to NRC documents. Rather, it applies to all written orders for medical care. Over the past few years there has been very strong support for medical facilities to adopt Computerized Physician Order Entry – that is, the physician would electronically place medical orders on a computer rather than hand-writing them. The primary advantage, of course, is legibility – many errors occurred in the past because the physician’s handwriting was not legible and his/her order was mis-read. Computerized entry also offers additional advantages, such as links to standard drug doses, contraindications and precautions, professional practice guidelines, etc.

In our institution we have recently adopted a system for electronic medical records. Related to drugs in general, this system is used for computerized physician order entry, pharmacy dispensing, nursing administration, and billing. Radiopharmaceuticals are drugs, so they are viewed similarly and require nuclear medicine physician order entry via computer, nuclear pharmacy dispensing, nuclear medicine technologist administration, and billing. Hence, NRC “written direction” equals radiopharmaceutical “drug prescribing”. The security, accuracy, integrity, and other factors relating to these electronic signatures must be in compliance with requirements and standards of The Joint Commission, the state board of medicine, the state board of pharmacy, and other regulators. These agencies have the same concerns as those expressed by NRC. For instance, the Drug Enforcement Administration (DEA) takes its role in regulating prescribing, dispensing, and administering narcotics and other controlled substances VERY seriously.

Therefore, I urge NRC to not waste their time and effort in re-inventing the wheel. Rather, I strongly urge NRC to work with other regulatory agencies and accreditation organizations in a collaborative manner so that all entities are singing from the same song book and that all regulatory requirements are consistent and compatible.

Thank you for your consideration of my comments.