

1



Jeb Bush
Governor

John O. Agwunobi, M.D., M.B.A.
Secretary

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PROPOSED RULE **35**
(68FR19321)

May 21, 2003

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USNRC

May 21, 2003 (3:32PM)

Secretary, U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

OFFICE OF SECRETARY
RULEMAKINGS AND
ADJUDICATIONS STAFF

ATTN: Rulemakings And Adjudications Staff

RE: RIN 3150-AH08

Dear Mr. Secretary:

Below are comments on the above referenced direct rule making from the State of Florida, Department of Health, Bureau of Radiation Control.

1. Section 35.315(b) "Safety precautions" states, "A licensee shall notify the Radiation Safety Officer, or his or her designee, and an authorized user as soon as possible if the patient or human research subject has a medical emergency or dies.

We agree with NRC in that it may be difficult to notify "the" authorized user in the event of an emergency or the patient dies but strongly believe changing the requirement to any authorized user is not in the best interest to protect public health and safety or the environment. We propose that the language be changed to require that the authorized user notified be one qualified for the type of procedure the patient or human research subject received.

In addition, the language needs to be refined to require that the authorized user notified is one currently identified on the licensee's license. While this is probably what was intended, the current language would allow any authorized user on any medical use license to be notified to satisfy this requirement.

Due to the wide difference in response to health and safety issues between patients that receive diagnostic, radiopharmaceutical therapy, brachytherapy, high dose rate remote afterloader, teletherapy procedures, and procedures utilizing new technologies (i.e., intravascular brachytherapy, Gliasites, etc.), the authorized user notified needs be authorized for the same procedure that the patient or human research subject received.

The response needed for a patient that dies after receiving 1100 megaBq (30 millicuries) of Tc-99m will be vastly different if that patient received 7400 megaBq (200 millicuries) of I-131 or a patient that has just received I-125 permanent implant of 60-80 seeds or Cs-137 temporary brachytherapy implants. In addition the response needed for patients receiving therapy from new technologies is very dependent on the isotope, treatment methodology, chemical and physical form of the radioactive material administered.

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SECY-02

Secretary, U.S. Nuclear Regulatory Commission

May 21, 2003

Page 2

Therefore to adequately protect health and safety and the environment in the event that a patient dies or has a medical emergency, an authorized user named on the licensee's license, and authorized for these procedures should be notified.

We propose the following revision to Section 35.315(b)

"A licensee shall notify the Radiation Safety Officer, or his or her designee, and an authorized user *identified on the license authorized for the procedures the patient or human research subject received*, as soon as possible if the patient or human research subject has a medical emergency or dies.

Or

"A licensee shall notify the Radiation Safety Officer, or his or her designee, and an *equivalent* authorized user *identified on the license*, as soon as possible if the patient or human research subject has a medical emergency or dies.

2. Section 35.432(b) states, "Instead of a licensee making its own measurements as required in paragraph (a) of this section, the licensee may use measurements provided by the source manufacturer or a calibration laboratory accredited by the American Association of Physicist in Medicine that are made in accordance with (a) of this section."

NRC should be aware that a radiopharmacy may also provide brachytherapy source calibration services as part of their distribution license. For example, the distribution of permanent I-125 or Pd-103 brachytherapy sources. The radiopharmacy is not a source manufacturer or a calibration laboratory accredited by the AAPM. Although the radiopharmacy would be authorized to distribute the source under their license authorized by 10 CFR 32.74, their source calibration could not be used by medical use licensees.

We propose that the following revision to section 35.432(b).

"Instead of a licensee making its own measurements as required in paragraph (a) of this section, the licensee may use measurements provided by the source manufacturer, a calibration laboratory accredited by the American Association of Physicist in Medicine, or a *licensee distributing sources under section 32.74* that are made in accordance with (a) of this section."

Not allowing the current practice of allowing radiopharmacy source calibrations to be accepted by medical use licensees may delay treatment of patients while the licensee performs the source calibration.

I hope this provides the information you need. If you have any questions, please contact me.

Sincerely,



Michael N. Stephens
Environmental Administrator

Secretary, U.S. Nuclear Regulatory Commission

May 21, 2003

Page 3

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