

May 23, 1988

LTR 88 - 153

Rediction Safety Office (N/C 932) 338 Citrical Sciences—North Wing Box 8666, Chicago, Illinois 60660

Donna Beth Howe Office of Nuclear Material Safety and Safey and U.S. Nuclear Regulatory Commission Washington, D.C. 20555

Dear Dr. Hove,

The University of Illinois at Chicago, UIC, which operates the University of Illinois Hospital, UIH, was issued a Type A Specific License of Broad Scope by NRC Region III on November 24, 1986. A copy is attached for reference. This license permits routine medical uses via group licensing and the conduct of medical research. Since June 1, 1987 when Illinois became an agreement state, this license has been administered by the Illinois Department of Nuclear Safety, IDNS, whose regulations have not yet been updated to incorporate the major changes to Part 35.

An important and urgent issue has arisen at UIC for which an official interpretation of NRC's regulations is sought. It is understood that the NRC no longer regulates UIC, however, NRC's interpretation is important because IDNS regulations should eventually be in general agreement.

The UIH Nuclear Medicine Section is contemplating the preparation of some of their own radiopharmaceutical kits based on the composition formulation found in FDA approved kits. These kits will be used only at UIC and will not be fold or given to any other institution, hospital, company, etc. Our Director of Nuclear Medicine explains that kits have been prepared not only in this hospital but in numerous other hospitals and University centers for many years, that this practice meets with FDA approval, and that the NRC has not raised an objection. Preparation of pyrophosphate kits used to label red blood cells with Tc-99m is cited as the most common example. Do NRC regulations permit or prohibit the preparation of kits for internal use by licensees?

It is important that this issue be resolved within the next several weeks. A prompt reply would be greatly appreciated. If you have any further questions, please call me at 312-995-7429.

Sincerely,

Raymond C. Barrall

Director, Radiation Protection

Enclosure

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