

October 16, 2006

AGENCY INFORMATION NOTICE MA-06-0 1: GUIDELINES FOR THE RESPONSIBILITY FOR THE ADMINISTRATION OF RADIOACTIVE MATERIALS TO HUMAN SUBJECTS

Addressees

All medical use licensees.

Purpose

The Radiation Control Program (the Agency) is issuing this information notice to draw the attention of medical use licensees to the requirements for the administration of radioactive materials to human subjects. The regulations in 105 CMR 120.500 require that the licensee shall apply for and receive a license amendment before permitting anyone, except a visiting authorized user, to work as an authorized user under the license. The exception to this requirement would be a case involving an individual under the supervision of an authorized user as allowed by regulations.

It is expected that recipients will review the information for applicability to their facilities and consider appropriate actions.

Description of Circumstances

It has recently come to the attention of the Agency that nuclear medicine is being practiced in some institutions in a manner which makes it difficult to identify the person authorizing the use of radioactive materials on human subjects. All administrations of radioactive materials to human subjects must be done by an authorized user, a person acting under the supervision of an authorized user or ordered by an authorized user or a person under the supervision of an authorized user. The authorized user is named on the license or, on a permit issued by the radiation safety committee of the licensee.

Discussion

The responsibility of the authorized user to the supervised individual is stated in the regulations. The authorized user is responsible for instructing the supervised individual and periodically reviewing the individuals -use of radioactive material, and is responsible for the acts and omissions of the supervised individual.

If radioactive material is administered by order of an authorized user or a person under the supervision of an authorized user, the link between the order and the person making the order should be clear and deliberate.

Our inspection staff will address this issue during future inspections. This information notice does not constitute any new requirements, therefore, no specific action nor written response is required. If you have questions about the information in this notice, please contact the Technical Contact listed below or the Officer of the Day at (6.17) 242-3035.

Sincerely,

ORIGINAL SIGNED BY ROBERT WALKER

Robert Walker, Director

Massachusetts Radiation Control Program

Technical Contact:

Kenath O. Traegde

(617) 242-3035, X2027

Email: kenath.traegde@state.ma.us

This information is provided by the Radiation Control Program within the Department of Public Health.