IDPH INFORMATION NOTICE 2010-03:  NEW REQUIREMENTS IN ADDITION TO THOSE CONTAINED IN 641-41.2(27) RELEASE OF PATIENTS OR HUMAN RESEARCH SUBJECTS CONTAINING RADIOPHARMACEUTICALS OR PERMANENT IMPLANTS.

Addressees:

All medical use licensees authorized for the therapeutic use of radioactive material including mobile vans and the University of Iowa.

Purpose:

The Iowa Department of Public Health (IDPH) is issuing this Information Notice (IN) to underscore the requirements in 641-41.2(27) allowing the release of patients or human research subjects containing radiopharmaceuticals or permanent implants. Licensees must consider the destination to which a patient will be released and consider the potential for exposure to others. Although 641-41.2(27) does not expressly prohibit the release of a radioactive patient to a location other than a private residence, IDPH strongly discourages this practice. IDPH is requiring that licensees provide discharge instructions to a second competent adult in addition to the patient to be released under 641-41.2(27). This second adult must sign the discharge instructions along with the patient to show that they have received and understand such instructions. The location to which the patient will be released must also be documented.

Background:

On August 17, 2010, IDPH received a call involving the oral administration of a therapeutic dose of Iodine-131. The patient lived alone and was released with instructions for the next week which included limiting close personal contact to others and avoidance of public areas. The patient was admitted to the hospital the day after the Iodine-131 therapy administration in a condition that rendered them unable to relay the information of the dose to hospital personnel. The administering licensee and authorized user were not made aware of the patient’s situation until ten days post admission. The licensee contacted IDPH upon learning of this situation and was informed to investigate and conduct dose reconstruction for all individuals who may have had contact with the patient. Although radiation from a patient released from licensee control under 641-41.2(27) is no longer regulated by IDPH, this incident caused several members of the general public to receive an unnecessary dose of radiation.

Discussion:

IDPH licensees must ensure that their staff fully understand and adhere to the requirements contained in the regulations and this IN. IDPH has developed this IN to convey the importance of patient adherence to the release criteria after the oral administration of Iodine-131, other radiopharmaceuticals or permanent implants. IDPH believes this additional requirement will improve compliance with the regulations and minimize the likelihood of potentially exposing the public to unnecessary doses of radiation.
Contact:

It is expected that licensees will revise their patient release policies and procedures to include this new IDPH requirement. Such revisions will be reviewed by IDPH during the next health and safety inspection of the licensee. If you have any questions regarding the information contained in this notice, please notify this office.

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