ARIZONA RADIATION REGULATORY AGENCY

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ARRA INFORMATION NOTICE **2013-IN-06**:

THE NEED TO REVIEW I-131 PROCEDURES IN REGARD TO RELEASING PATIENTS TREATED WITH RADIOIODINE; THE LEVEL AT WHICH A WRITTEN DIRECTIVE IS NECESSARY; WHETHER A GROUP 200 PHYSICIAN IS ABLE TO ORDER A DIAGNOSTIC IMAGING PROCEDURE USING RADIOIODINE; AND WHETHER AN OUTPATIENT CLINIC IS PERMITTED TO TREAT THERAPY PATIENTS WITH RADIOIODINE

ADDRESSES

All licensees who administer radioiodine (I-131).

PURPOSE

The Arizona Radiation Regulatory Agency is issuing this information notice (IN) to inform licensees, who administer radioiodine, of the Agency's concern for some licensees exposing members of the public to radiation levels in excess of the level which has been deemed to be safe (500 mRem). The Agency is asking licensees to review their procedures and make the necessary changes to ensure safe radiation practices are being conducted.

DESCRIPTION OF CIRCUMSTANCES

Item 1:

Licensees treating thyroid patients for cancer are to 1) perform a survey and 2) if applicable, a calculation, to determine what action to take in regards to the release of the treated patient. If the survey does not permit the patient be released without concern, a calculation must be performed to determine if the exposure to a member of the public will exceed 500 mRem. The Agency has seen examples of treated patients being released with exposure levels incorrectly calculated, because the internal component of the radiation exposure, discussed in Appendix U, from the patient is not included in the determination. However, in some cases, the internal component may be ignored if it is less than 10% of the external exposure calculation. Appendix U contains many example calculations that should be reviewed to better understand the requirement. It is important to remember that in any case, instruction must be given to the patient before discharge.

Item 2:

Beginning in 2007 with the adoption of the requirements in 10 CFR 35, any dosage of I-131 greater than 30 microcuries would require a written directive. It is stated in Item 7 of NUREG 1556, that authorized users who had the authority to prescribe diagnostic dosages prior to 2007 shall be permitted to continue this use. Physicians wishing to prescribe diagnostic dosages after the 2007 date will be required to complete the training requirements in 10 CFR Subpart E. The Agency will adopt a new licensing methodology to list physicians with this authorized use.

Item 3:

With the trend in medicine to care for patients away from the hospital setting, there appears to be an increase in the number of I-131 treatments initiated at outpatient clinics. It is important to note the above discussion concerning exposure to members of the public is very important in this instance as well. As stated above, members of the public shall not receive greater than 500 mRem. In this endeavor, the licensee will have to hold a treated patient at the clinic, treat the patient with multiple smaller dosages, or secure a room at a local hospital where a treated patient can be sequestered. A formal request must be submitted to the hospital and an amendment request submitted to the Agency with a memorandum of understanding (MOU) describing the radiation safety protocols that will be followed by the supporting clinic staff.

DISCUSSION

It has come to the Agency's attention that radioiodine (I-131) is being used without meeting the requirements contained in Article 7 of Title 12. Recently, licensees were granted authorization to release patients treated with I-131 in amounts greater than 33 Ci. The release is authorized in A.A.C. R12-1-717. This authorization is a federal standard that incorporates guidance in Appendix U of NUREG 1556, Vol. 9, Rev. 2. In meeting the requirements, licensees must consider all factors affecting radiation exposure to members of the public who may come in contact with the treated individual after their release.

In conjunction with these factors, unqualified/unauthorized users have been administering I-131 to patients in quantities greater than authorized in A.A.C R12-1-707. Lastly, there are authorized users who have chosen to treat patients in outpatient clinics and release these patients, and expose members of the public to radiation in excess of the regulatory limit of 500 mRem, as specified in A.A.C. R12-1-717. A licensee is not permitted to release a patient containing large therapy dosage just because there is no place to hold the patient.

NUREG 1556, Volume 9, Revision 2 is available on the internet at http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v9/r2/ . If this is not convenient, the Agency will provide a copy of Appendix U. All licensees should note that Regulation Guide 8.39 is no longer being used to establish release criteria. The affected licensees should contact the Agency immediately to obtain assistance in resolving any of these issues.

CONCLUSION

With the change in requirements in 2007, the release of therapy patients has created many issues for the Agency. There is interest in dosages from 200 – 300 mCi of radioiodine, and patients are willing to pay for a hotel stay rather than contaminate their homes or expose family members to radiation. Patients released exposing the public to radiation in excess of the regulatory limit may result in a civil penalty. A Phoenix hospital recently paid a $3000.00 civil penalty for violating the above mentioned rules.

Should a licensee find the Agency's position unacceptable, a written request for assistance should be sent to the Agency stating that patient care is affected unfavorably and how the licensee would continuing to provide medical care without harming the citizens of Arizona. Questions or concerns may be directed to Brian Goretzki, Manager of the Radioactive Materials Program, at 602-255-4845 ext 234.

Sincerely,

Aubrey V. Godwin, M.S., C.H.P.
Director

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