

State of North Carolina  
Department of Environment,  
Health, and Natural Resources

Division of Radiation Protection

James B. Hunt Jr., Governor  
Wayne McDevitt, Secretary  
Richard M. Fry, Director



November 7, 1997

## DRP Information Notice 97-1

### Memorandum

**To:** Radioactive Material Licensees

**From:** J. Aaron Padgett, Chief  
Radioactive Materials Section

**Subject:** Information of Interest to All Licensees

A handwritten signature in black ink, appearing to read "J. Aaron Padgett". The signature is written in a cursive style and is positioned to the right of the "From:" field.

This Information Notice contains information that may be of interest to licensees. No response or any other action is required of licensees as a result of this Information Notice. The items are as follows:

#### 1. Release of Patients Administered Radiopharmaceuticals or Permanent Implants

The Nuclear Regulatory Commission recently amended its regulations to allow licensees to release patients following administration of radiopharmaceuticals or permanent implants as long as the dose to an individual member of the public is unlikely to exceed 500 mrem from exposure to the released patient. A similar revision to the North Carolina radiation protection regulations is underway. The N.C. Radiation Protection Commission has approved the proposed rule change. It must now proceed through the State review process before the proposed rule change can become part of the N.C. Radiation Protection Regulations. This review process will require longer than one year if all goes well.

To allow licensees to take advantage of these relaxed release requirements in the interim, the Division of Radiation Protection will allow exceptions to the 100 mrem dose limit for members of the public as provided for by 15A NCAC 11 .1611, item (c). This item allows the Agency to permit the exposure of a member of the public up to 500 mrem annually if a licensee applies to the agency for prior authorization. Prior authorization from the Agency will be in the form of a license amendment. Upon receipt of an application for such an amendment request, the Agency will proceed to amend the license as requested to allow the release of patients administered radiopharmaceuticals or permanent implants in accordance with DRP Regulatory Guide 97-001. Licensees making the request for such an amendment will be required to provide a written commitment to follow the provisions of DRP Regulatory Guide 97-001 in the release of these patients. The resulting license amendment will tie-down the letter from the licensee.

2. **Administrative Penalty**

The Division of Radiation Protection (DRP) recently assessed an administrative penalty in the amount of \$5000.00 against a mobile nuclear medical licensee, Southeastern Imaging. The administrative penalty was assessed as a result of problems identified during inspections associated with the administration of a radiopharmaceutical by the licensee without a prior written directive from an authorized user and to the wrong patient. The wrong radiopharmaceutical was administered because the patient's identity was not verified by the medical technician as required by procedure. In addition, the mobile service was not authorized to possess the radioactive material administered to the patient. Other violations of the North Carolina regulations for protection against radiation were identified during investigation of this event. Inspection of the nuclear pharmacy involved in the incident revealed that programs and procedures in place to prevent the pharmacy from transferring radioactive material not included in a customer's license were ineffective. Improvements have been implemented by the nuclear pharmacy and are being monitored by the Agency to determine their effectiveness.

3. **Deliberate Radiation Exposure of Students**

A Nuclear Medicine Technician employed in a hospital recently decided to play a "practical joke" on some students from a nearby technical school. The students rotate into the hospital for practical work experience. The Technician contaminated a rock with Tc-99 and told the students that the rock was a meteorite that had landed in his yard. The students handled the rock with their bare hands. A survey performed by the students indicated radiation levels between 50 and 100 millirem per hour. The Nuclear Medicine Supervisor overheard what was underway but did nothing to stop the "joke." An investigation of the event by Hospital Management and the Division of Radiation Protection was conducted. The Nuclear Medicine Technician was discharged from his position by the Hospital, and the Nuclear Medicine Supervisor was demoted to the position of Nuclear Medicine Technician.

4. **Misadministration Resulting From Loss of Power on Theratronics 1000 Teletherapy Unit**

The NRC has issued Information Notice 97-64 that describes a misadministration that occurred due to loss of electrical power. While a patient was being treated, a thunderstorm resulted in loss of electrical power twice. In each case the technologist reset the machine to allow treatment continuation. Upon completion of treatment, the patient commented that the wrong site might have been treated. The technologist then noticed that the light field was not aligned to the intended treatment site. A movement of about 8 inches in the longitudinal direction of the treatment table was noted during recreation of the event. The manufacturer of the unit, Theratronics, concluded that the licensee had not operated the unit

in accordance with the operating instructions. Section 4.7 of the Operator Manual contains a warning statement that states, “[i]f Table 23T is equipped with the ‘free float’ option, when the power is off, the lateral and longitudinal motions will be free. Take care to prevent injury when unloading the patient.” Users of the Theratronics 1000 teletherapy unit are reminded that they should clearly understand the manufacturer operator’s manual.

## **5. Contaminated Lead Products**

Some lead products including medical shielding products have been distributed that contain contamination in the form of Pb-210 and its daughter nuclides Bi-210 and Po-210. The contaminated lead was provided from a single supplier between November 1996 and May 1997. It was used to make a variety of products. The products included x-ray machine drapes, aprons, gonad shields, and sheet shielding. The contaminated lead may also have been incorporated into a number of commercially distributed products including brushes for electric motors, bullets, lead shot, lead roof flashing, and galvanizing compounds. A number of firms have manufactured or distributed contaminated lead products. For a list of affected products either contact the Conference of Radiation Control Program Directors at 502-227-543 or the FDA’s Internet site at <http://www.fda.gov/cdrh/safety.html>. The FDA recommends the survey of medical devices containing lead and purchased after October 1, 1996. The survey should be conducted using a thin window GM instrument in contact with the product. If present, the contamination will be easily detected using this type of instrument. Bi-210 emits a 1.16 MeV beta radiation. Dose rate is reported to be approximately 0.6 to 3 millirad per hour at contact. FDA requests that users who discover shielding products with contaminated lead to report this information directly to MEDWATCH, the FDA voluntary reporting program by phone at 800 FDA-1088 or FAX at 800-FDA-0178.

## **6. Radiography Equipment Problem**

During routine performance of industrial radiography a radiographer noticed stiffness requiring additional pressure on the drive cable of the SPEC 150 exposure device being used. The camera was secured and the drive wheel and cable inspected. The radiographer’s inspection revealed the outer spiral of the cable was broken. In the process of removing the cable from the conduit the inner cable broke. Radiography was terminated and the RSO notified. The SPEC Engineering Department performed an analysis on the cable. Their report indicates that corrosion was the cause of the cable breakage.

## **7. Failures of HDR Remote Afterloading Device Source Guide Tubes, Catheters and Applicators**

Licensees who use HDR devices should be aware of their potential for failure. Some known failures reported by the FDA are briefly summarized as follows:

- Inspection findings at Nucletron Corporation included reported failures of Ring I/U tube

applicators, Flexiguide cone catheters breaking inside patients, problems with numbers wearing off transfer tubes, catheter length variations, and one reported problem with an esophageal catheter.

- A similar inspection of Omnitron Corporation found numerous reported failures with their Flexineedle applicators, and GYN and standard catheters. Reports indicate that components of the Flexineedle applicators have separated inside patients and, in some cases, have not been retrieved.
- A user reported that a Gamma Med II source guide tube broke away from a vaginal cylinder. This resulted in the HDR source being driven onto the table, rather than into the vaginal cylinder. A subsequent check for defects by the user of all guide tubes and applicators revealed that six bronchial, one tandem, and two intracavity tubes were defective.

Users of these devices should consider the necessity of preplanned emergency surgical procedures as an integral part of their emergency procedures for HDR patient treatments.

## **8. Distribution and Use of Fludeoxyglucose (FDG) Flourine-18**

The use of FDG as an imaging agent has been restricted to broad medical licensees fortunate enough to have a cyclotron located at their medical facility. This restricted distribution is being changed. DRP has worked with a licensee who wishes to distribute FDG, the N.C. Board of Pharmacy and the N.C. Department of Agriculture to arrive at a consensus position that allows distribution of FDG. FDG has been included in the Group II of Publication 97-01, "List of Radioactive Materials Approved for the Four 'Groups of Diagnostic Uses' as Defined in 15A NCAC 11 .0321"

## **9. Unauthorized Use of Radioactive Material**

A Nuclear Medicine Technician employed by a hospital in North Carolina recently removed a diagnostic dose of radioactive material from the hospital without the knowledge of other hospital staff, and administered the dose to a close relative. The relative was transported to the hospital and "scanned" by the Nuclear Medicine Technician. The Technician reported a "spill" to the RSO to cover use of the dose. The hospital and the Division of Radiation Protection investigated the incident. The hospital terminated the Nuclear Medicine Technician from her position at the hospital.