INFORMATION COLLECTION: RELEASE OF INDIVIDUALS CONTAINING UNSEALED BYPRODUCT MATERIAL OR IMPLANTS CONTAINING BYPRODUCT MATERIAL

2800/039-01 OBJECTIVES

01.01 To determine if activities required by 10 CFR 35.75, "Release of individuals containing unsealed byproduct material or implants containing byproduct material," are conducted in a thorough manner and with sufficient regard for possible consequences of release of these individuals.

01.02 To gather information concerning licensees' implementation of NRC Information Notice 2003-22, "Heightened Awareness for Patients Containing Detectable Amounts of Radiation from Medical Administrations" (IN 2003-22).

01.03 To provide data for use by the Department of Health and Human Services' Agency for Healthcare Research and Quality (AHRQ) for analysis and publication in a peer-reviewed journal.

2800/039-02 APPLICABILITY

This Temporary Instruction applies to inspectors of medical use licensees.

2800/039-03 BACKGROUND

This Temporary Instruction provides additional direction to inspectors of medical use licensees.

NRC regulations, 10 CFR 35.75 and 35.2075, address release criteria and procedures for individuals containing unsealed byproduct material or implants of sealed byproduct material. When releasing individuals in accordance with 10 CFR 35.75, licensees are required to provide individuals with written instructions "on actions recommended to maintain doses to other individuals as low as is reasonable achievable if the total effective dose equivalent to any other individual is likely to exceed 1 mSv (0.1 rem)." Licensees must also "maintain a record of the basis for authorizing the release" of such individuals. As detailed in IN 2003-22, "when licensees are required to provide written directions to individuals released in accordance with 10 CFR 35.75 . . . authorized users are expected to evaluate the individual's capability to follow recommended written instructions before release, to determine if release at that time is advisable, and [to] stress the importance to the individual of following the written instructions." The IN also recommends voluntary

actions for all individuals who still contain detectable amounts of radiation after receiving diagnostic or therapeutic quantities of radiopharmaceuticals or brachytherapy implants.

The AHRQ intends to conduct an information collection project to examine the range of procedures and practices across medical facilities when releasing individuals who have received unsealed byproduct material or implants containing byproduct material. The goal of the AHRQ study is neither to evaluate the adequacy of the existing regulation nor its degree of compliance. Specifically, the AHRQ is concentrating its efforts on the following topics:

- how health care providers determine when individuals receiving containing unsealed byproduct material or implants containing byproduct material can be released from care
- what type of information is provided to these individuals to ensure the safety of their families and the public
- how this information is communicated to these individuals and by whom
- what information is (or can be) provided to released individuals who may activate radiation detectors at security checkpoints to ensure that the individuals understand why they emit radiation and carry the appropriate documentation to facilitate their processing should questions regarding their medical procedures arise.

By exploring the range of practices, the AHRQ expects that best practices may be identified and standardized procedures developed within the existing regulatory framework. The study findings will be disseminated to the health care community through a scholarly journal article.

NRC has decided to collaborate with the AHRQ staff in the performance of this project, as the findings will inform the NRC of the effectiveness of its regulations and common industry practices related to radiopharmaceuticals. As a part of their routine inspections, NRC inspectors will gather the information to be used in the study. AHRQ will be responsible for analyzing this data and summarizing the results in a publicly-available report. In addition, the study findings will be presented to the NRC Advisory Committee on the Medical Uses of Isotopes.

2800/039-04 INSPECTION REQUIREMENTS

04.01 Inspectors should perform a routine inspection in accordance with Manual Chapter 2800 and Inspection Procedures 87130, 87131, 87132 and 87134 to determine if activities required by 10 CFR 35.75, “Release of individuals containing unsealed byproduct material or implants containing byproduct material,” are conducted in a thorough manner and with sufficient regard for possible consequences of release of these individuals. This inspection should center around interviews with licensee staff with operational and procedural knowledge who are responsible for decision-making on release of individuals who have received unsealed byproduct material or implants containing byproduct material. This may include interviews with the radiation safety officer, nuclear medicine technologist, radiation therapy technologist, medical physicist or authorized user. The individual(s) most

appropriate for interviewing will be at the discretion of the inspector.

04.02 Inspectors should collect information described in Attachment 1 and interview facility staff to determine the following:

- guidelines and decision-making processes for the release of individuals who have received unsealed byproduct material or implants containing byproduct material; and
- guidelines and common practices for communicating risk and safety information to these individuals and recommended actions post-release.

If a licensee has multiple modalities (e.g., nuclear medicine and brachytherapy) involving release of individuals containing unsealed byproduct material or implants containing byproduct material, multiple forms should be used (i.e., one for each department).

04.03 Inspectors should collect copies of any educational materials distributed to individuals as a part of the nuclear medicine and/or brachytherapy programs. This information should be forwarded along with Attachment 1 as described in the next section.

2800/039-05 REPORTING REQUIREMENTS

Inspectors should provide the information collected in accordance with Attachment 1 and Item 04.03 within 30 days of completion of the inspection to Cindy M. Flannery, Medical Safety and Event Assessment Branch, Division of Materials Safety and State Agreements, Office of Federal and State Materials and Environmental Management Programs, Mail Stop T8F3, fax: (301)415-5369.

2800/039-06 COMPLETION SCHEDULE

The intended schedule for completion of this Temporary Instruction is three months from the date of issuance, with a possible extension to six months. A review by NRC HQ staff will be conducted at three months from the date of issuance to determine if enough data has been obtained for an adequate statistical sample for the study.

2800/039-07 EXPIRATION

This Temporary Instruction remains in effect six months from the date of issuance.

2800/039-08 CONTACT

Questions regarding this Temporary Instruction should be addressed to Cindy M. Flannery, Medical Safety and Event Assessment Branch , Division of Materials Safety and State Agreements, Office of Federal and State Materials and Environmental Management Programs, at 301-415-0223.

2800/039-09 STATISTICAL DATA REPORTING

Staff hour expenditures or administrative effort required for the implementation of this Temporary Instruction should be entered/charged under TAC #LA0328, "Temporary Instruction-Information Collection: Release of Patients with Radiopharmaceuticals-344232A-N."

2800/039-10 ORIGINATING ORGANIZATION INFORMATION

10.1 Organizational Responsibility. Medical Safety and Event Assessment Branch, Division of Materials Safety and State Agreements, Office of Federal and State Materials and Environmental Management Programs initiated this Temporary Instruction.

10.2 Resource Estimate. Inspections conducted under this Temporary Instruction are expected to require an additional 30 minutes of staff hour expenditure per inspection. If multiple modalities or multiple licensee sites must be inspected, or if multiple licensee personnel are involved with release of individuals described in this Temporary Instruction, inspectors may require additional time to collect the information.

2800/039-11 REFERENCES

11.1 NRC Information Notice 2003-22: Heightened Awareness for Patients Containing Detectable Amounts of Radiation From Medical Administrations

11.2 10 CFR 35 Medical Use of Byproduct Material

11.3 NUREG-1556, Volume 9, Rev. 1, "Model Procedure for Release of Patients or Human Research Subjects Administered Radioactive Materials"

END

Attachment:

1. Information Collection Interview Outline
2. Revision History Page

Attachment A

INFORMATION COLLECTION INTERVIEW OUTLINE

Inspector's name and Region:_____

Date of inspection: _____

A. General facility information

1. Facility name/location:

2. License number:

3. Docket number:

4. Number of beds:

5. Estimated number of procedures administered annually:

   ____ Inpatient diagnostic
   ____ Outpatient diagnostic
   ____ Inpatient therapeutic (radiopharmacuetical)
   ____ Outpatient therapeutic (radiopharmacuetical)
   ____ Inpatient manual brachytherapy (35.400 and 35.1000)
   ____ Outpatient manual brachytherapy (35.400 and 35.1000)

6. Top 5 common diagnostic and therapeutic procedures involving unsealed byproduct material or implants containing byproduct material at this facility:

Diagnostic Procedures	Estimated number of procedures performed annually	Range of radioactivity administered (mCi) per individual	Percentage treated as outpatient
1.			
2.			
3.			
4.			
5.			

Therapeutic Procedures	Estimated number of procedures performed annually	Range of radioactivity administered (mCi) per individual	Percentage treated as outpatient
1.			
2.			
3.			
4.			
5.			

B. General information on individual interviewed

1. Name:

2. Title/Position:

3. Years of experience:

4. Years of experience in this facility:

5. In which of the following step(s) of byproduct material administration are you involved?

   ☐ Informing individuals that they will be receiving unsealed byproduct material or implants containing byproduct material

   ☐ Making a decision on when an individual can be released from the facility

   ☐ Communicating risk and safety information to individual

C. Procedure for individuals with detectable amounts of radioactivity who may activate monitors installed in public locations for increased security

1. Are you familiar with the NRC Information Notice issued on December 9, 2003 entitled “Heightened Awareness for Patients Containing Detectable Amounts of Radiation from Medical Administrations” and voluntary actions recommended in this notice?

   ☐ Yes
   ☐ No

2. Are the individuals administered therapeutic radiopharmaceuticals or manual brachytherapy implants informed that they may activate radiation detectors at airports, tunnels, and other public places?

☐ Not applicable
☐ Yes
☐ Why not?

3. Are the individuals administered diagnostic radiopharmaceuticals informed that they may activate radiation detectors at airports, tunnels, and other public places?

☐ Not applicable
☐ Yes
☐ No. Why not?

4. Does your facility provide documents to individuals to use if they are questioned by law enforcement or security personnel?

☐ Yes. What types of documents are provided? *Please provide us with a copy*
☐ No. Is your facility prepared to offer such documents on request?

☐ Yes
☐ No

5. How can law enforcement or security personnel verify that an individual has received a procedure involving byproduct material in your facility?

☐ By calling a telephone number we provided to the individual
☐ Will not be able to verify
☐ Other. Please explain.

6. If your facility provides a card or documentation for the individual to carry, who is the facility contact listed on the documentation? (provide no names please, just position or title)

7. Is this contact available at all times?

   ☐ Yes
   ☐ No

8. What procedures are in place in your facility to ensure that the contact person listed can get access to updated information related to the individual who carries the documentation?

9. In your experience, has your facility ever been contacted because somebody activated a radiation detector?

   ☐ No
   ☐ Yes. Please describe how your facility responded.

10. In your experience, are the current procedures regarding released individuals who can activate radiation detectors adequate?

    ☐ Yes
    ☐ No. What changes would you recommend?

D. Informed consent

1. How are individuals informed that they will receive unsealed byproduct material or an implant containing byproduct material?

2. When are individuals informed? (e.g., at registration, immediately before administration)

3. Who informs them?

E. Making a decision on release of individuals from your facility

For each of the questions, please specify if the answer for iodine administrations is the same or different than for other radionuclides.

1. How do you determine when an individual who received byproduct material or implants containing byproduct material can be released from your facility?

   ☐ By using default values (specify source)
   ☐ Based on administered activity
   ☐ Based on dose rate measured from patient
   ☐ Dose calculations using patient-specific parameters
   ☐ Other (specify)

   Please explain how each applicable category is used. Only address methods used at your facility.

2. Do you make this decision alone or in collaboration with others?

   ☐ Alone
   ☐ With others. Please explain respective roles

3. When is the determination on the timing of release made?

   ☐ Before administration of radiopharmaceutical or implant
   ☐ After administration of radiopharmaceutical or implant

4. If an individual indicates that they cannot meet release criteria (e.g. must take public transportation or cannot have sole use of bathroom) what additional information is collected to support release?

5. Based on your experience, please estimate what percent of patients indicate that they cannot meet at least one of the release criteria:

   _____ %

   Please indicate the most frequent release criteria for which concerns are raised:

   - ☐ Maintaining distance from other persons, including separate sleeping arrangements
   - ☐ Minimizing time in public places (e.g. using public transportation, shopping, visiting restaurants, etc)
   - ☐ Taking procedures to reduce the spread of contamination (e.g. sole use of bathroom)
   - ☐ Minimizing time with children and pregnant women

6. Have there been any changes/revisions to the procedures of releasing individuals in the past five years?

   - ☐ No
   - ☐ Yes. Please describe the changes.

7. In your view, are the current facility procedures adequate?

   - ☐ Yes
   - ☐ No. What changes would you recommend?

F. Providing instructions to individuals upon release from your facility on actions recommended for maintaining doses to other individuals as low as is reasonably achievable

Please provide us with copies of all materials

1. Do you use specific guidelines in making a decision on what types of instructions are provided to individuals?

   ☐ No
   ☐ Yes. Please explain

2. If the total effective dose equivalent to any other individual is likely to exceed 1 mSv (0.1 rem), the individual released from your facility receives:

   ☐ Both oral and written instructions
   ☐ Written instructions only
   ☐ Oral instructions only
   ☐ No specific instructions

3. If the total effective dose equivalent to any other individual is NOT likely to exceed 1 mSv (0.1 rem), the individual released from your facility receives:

   ☐ Both oral and written instructions
   ☐ Written instructions only
   ☐ Oral instructions only
   ☐ No specific instructions

4. Do the instructions differ depending on the radionuclide?

   ☐ No
   ☐ Yes. Please elaborate.

5. When are the instructions provided?

   ☐ Before the procedure
   ☐ After the procedure
   ☐ Either before or after

6. Which of the following may influence the type of instructions given to the released individual? Please explain.

   ☐ Individual breast-feeds an infant
   ☐ Individual cares for an infant/young child but does NOT breast-feed

7. If the released individual needs constant care from a caregiver at home, are instructions provided for the caregiver?

   ☐ Yes
   ☐ No

8. If an individual asks questions or expresses concerns about unsealed byproduct materials or implants, is additional information or counseling offered?

   ☐ No
   ☐ Yes. Who provides the information/counseling?

9. Based on your experience, please estimate what percent of individuals express concerns related to radiation or radioactivity and/or request additional information?

   ☐ Individuals never express concerns or request information
   ☐ 10%
   ☐ 10-30%
   ☐ 30-50%
   ☐ 50-70%
   ☐ 70%

10. Have you received any training in patient education/counseling?

    ☐ Yes. Please elaborate

    ☐ No. Would you consider such training beneficial?
        ☐ Yes
        ☐ No

11. Have there been any changes/revisions to patient communication procedures or instructional materials in your facility in the past five years?

    ☐ No
    ☐ Yes. Please elaborate

12. In your experience, are the current patient communication procedures adequate?

    ☐ Yes
    ☐ No. What changes would you recommend?

13. Is it possible for an individual administered therapeutic radiopharmaceuticals or manual brachytherapy implants to leave your facility without the knowledge that they emit detectable levels of radiation remaining from their procedure?

    ☐ No
    ☐ Yes. Please give examples how this might happen.

14. Is it possible for an individual administered diagnostic radiopharmaceuticals to leave your facility without the knowledge that they emit detectable levels of radiation remaining from their procedure?

    ☐ No
    ☐ Yes. Please give examples how this might happen.

PLEASE REMEMBER TO PROVIDE COPIES OF ALL EDUCATIONAL/SAFETY INSTRUCTIONS AS WELL AS MATERIALS FOR PRESENTATION AT SECURITY CHECKPOINTS.
THANK YOU!

Attachment 2
Revision History for TI 2800/039

Commitment Tracking Number	Issue Date	Description of Change	Training Needed	Training Completion Date	Comment Resolution Accession Number
N/A	CN 06-026 10/13/06 2.	TI 28000/039 has been issued to determine the manner in which licensed activities are conducted in accordance with the requirements in 10 CFR 35.75. Information concerning medical use licensees' implementation of NRC Information Notice 2003-22, "Heightened Awareness for Patients Containing Detectable Amounts of Radiation from Medical Administrations" (IN 2003-22) will be collected and data will be provided to the Department of Health and Human Services' Agency for Healthcare Research and Quality (AHRQ) for analysis. None	NO N/A	N/A N/A	ML062630314