333 North Smith Avenue
St. Paul, MN 55102-2389
651-220-8000
www.allina.com

UNITED
HOSPITAL
Allina Hospitals & Clinics

5/16/2002

United States
Nuclear Regulatory Commission
Document Control Desk
Washington, DC 20555

SUBJECT: Response to Apparent Violations, EA-02-060.

This letter is in response to the April 22, 2002 letter, OI Report NO. 3-2001-043, and "NRC Information Notice 96-28" sent to United Hospital's administrator, Barbara Balik.

First, we would like to address the four items, paragraph 1 on page 2, of the 4/22/02 letter.

(1) the reason for the apparent violation (the direct cause) is that a casual employee at United Hospital willfully administered a non-measured activity of a NRC-licensed material without a verbal or written order from a licensed physician. This incident (indirect cause) occurred on a weekend, outside of normal operating hours when other department members were not at the hospital.

(2) the corrective steps that have been taken include the following:
   A. appropriate hospital staff (i.e. Administrators, RSO, RSC chairman, Risk Management) were immediately notified, and the appropriate paperwork (i.e. Incident Report) was filed with United's risk management.
   B. the involved person was dismissed from his position at United Hospital.
   C. the Nuclear Medicine Technology Certification Board (the above individual's certifying body) was contacted regarding their guidelines concerning this type of incident.
   D. the Nuclear Medicine Manager met with all of the Nuclear Medicine technologists individually, including those who were indirectly involved with the violation, and those who were responsible for training and procedure development/guidance. These interviews covered regulations 10 CFR 19.12(a)(4) and 10 CFR 30.10.

   The results achieved, from the above corrective steps, were elimination of the direct problem, and the identification of indirect issues.

(3) the corrective steps that will be taken to avoid further violations are putting into place the following:
   A. a *Self Study Packet*, with *Post Test* for competency evaluation, will be designed for all new NucMed staff. The packet will be given during their initial orientation.
   B. a method of *Competency Testing*, of existing staff, will be designed to ensure understanding of requirements and procedures, and assess preservation of this knowledge.

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C. implementation of 10 CFR 30.10 and 10 CFR 19.12(a)(4) into the yearly *Radiation Safety Training* so that NucMed staff are made aware and/or reminded of their responsibilities to their profession.

(4) the date when full compliance (i.e., completion of the *Self Study Packet* and *Competency Testing* methodology) will be July 1, 2002. Our *Immediate Corrective Actions* will include one-on-one training with new staff as part of new employee orientation (Initial Assessment of Competency).

Secondly, we would like to address paragraph 2 on page 2 of the 4/22/02 letter. The following is the outline that fully describes the depth and scope, of the *Radiation Safety Training*. This training is conducted annually for all Nuclear Medicine staff.

1. Potential Risks of Radiation Exposures
   - Allowable Dose to the Whole Body and Extremities
   - Risk of Leukemia/Cancer from being a Radiation Worker
   - Risk to the Fetus
2. ALARA
   - What is ALARA; 10 CFR 35.20.
   - United's ALARA levels.
   - Methods to keep doses to staff (time, distance, shielding) and patients ALARA
3. QMP
   - What is the QMP; 10 CFR 35.32
   - Review United's QMP and it's components (i.e. written directive)
4. General Radiation Safety Measures
   - Rules for safe Use of Radiopharmaceuticals
   - Review United's policies on the above topic
5. Emergencies Procedures
   - Xe-133 Gas Spill
   - Major/Minor Spills and the proper procedure/paper work the handle these spills
6. I-131 Precautions and Monitoring
   - Review United's policy on I-131 Therapy Administration
7. Use of Radioactive Gases
   - Review United's policy on the Use of Radioactive Gases
8. Breast Feeding Instructions
   - Radiation Safety instructions for breast feeding patients
   - Proper paper to be completed
9. Regulation and License Conditions
   - 10 CFR 35 Subpart C
   - 10 CFR 35 Subpart D
   - 10 CFR 35 Subpart E
   - 10 CFR 35 Subpart F

10. Personnel Dosimeters
    - Who needs to wear them and why.
    - Proper placement and storage when not in use.
11. Questions and Answers

The following is the new outline (changes highlighted) of the *Radiation Safety Training*. This training will continue to be conducted annually for all Nuclear Medicine staff.

1. Potential Risks of Radiation Exposures
    - Allowable Dose to the Whole Body and Extremities
    - Risk of Leukemia/Cancer from being a Radiation Worker
2. ALARA
    - What is ALARA; 10 CFR 35.20.
    - Methods to keep doses to staff (time, distance, shielding) and patients ALARA
3. QMP
    - What is the QMP; 10 CFR 35.32
    - Review United's QMP and it's components (i.e. written directive)
4. General Radiation Safety Measures
    - Rules for safe Use of Radiopharmaceuticals
    - Review United's policies on the above topic
5. Emergencies
    - Xe-133 Gas Spill
    - Major/Minor Spills and the proper procedure/paper work the handle these spills
6. I-131 Precautions and Monitoring
    - Review United's policy on I-131 Therapy Administration
7. Use of Radioactive Gases
    - Review United's policy on the Use of Radioactive Gases
8. Breast Feeding Instructions
    - Radiation Safety instructions for breast feeding patients
9. Regulation and License Conditions
    - 10 CFR 30.10
    - 10 CFR 19.12
    - 10 CFR 35 Subpart C
    - 10 CFR 35 Subpart D
    - 10 CFR 35 Subpart E
    - 10 CFR 35 Subpart F
10. Personnel Dosimeters
    - Who needs to wear them and why.
    - Proper placement and storage when not in use.
11. Questions and Answers

In conclusion, we would like to say that United Hospital has always had the appropriate documentation in place as to the proper procedure that must be followed when ordering and administering a radioactive pharmaceutical. The Nuclear Medicine staff is trained, not only through their initial orientation process, but continuously through annual training. This process has been confirmed through past NRC, State of Minnesota, and JCAHO reviews.

This incident, however, has caused United Hospital to conduct a complete and thorough review of the circumstances that led to the violation, resulting in changes to our education process. The failure of the two NucMed Technologists to promptly report to use any information about the June 17, 2001 incident did not change the end result (i.e. conducting a complete and thorough review of the circumstances that led to the violations, resulting in changes to our education process), yet delayed its' implementation.

If you request further information, please contact use immediately.

Sincerely,

Barbara Balik

Barbara Balik
President, United Hospital

Jane M. Johnson, M.S.
Medical Physicist, RSO

cc: Regional Administrator, NRC Region III
Enforcement Officer, NRC Region III