UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

October 25, 1990

MEMORANDUM FOR: Those on Attached List

FROM: Richard E. Cunningham, Director
Division of Industrial and
Medical Nuclear Safety, NMSS

SUBJECT: POLICY AND GUIDANCE DIRECTIVE 90-7; INTERPETATIONS OF THE MEDICAL MISADMINISTRATION RULE (10 CFR SECTIONS 35.2 AND 35.33)

This directive documents existing policy that questionable cases involving medical misadministrations should be referred to Headquarters for review.

The misadministration rule is frequently subject to difficult interpretations to determine if it applies to a particular set of circumstances. There are situations where the rule is not applicable, but there is clearly a misadventure or "misadministration" in the common sense of the term. The Tripler incident, involving an infant who ingested breast milk containing radioactive iodine, is an example. Conversely, there are situations which might be reportable under the rule, although this is not readily apparent. For example, "backfitting" of prescriptions to fit certain unintended conditions could be a misadministration under certain circumstances.

When a medical licensee asks if an incident is a reportable misadministration, or if an inspector discovers a set of circumstances that might be a reportable misadministration, but it is not clearly so based on past experience and interpretations, the Region should:

1. Collect the facts attendant to the potential misadministration as comprehensively and accurately as feasible, including time sequences of actions and decisions of the physician.

2. Forward the information to the Director, Division of Industrial and Medical Nuclear Safety (IMNS).

IMNS will coordinate obtaining a determination by consulting with OGC, the Region, and other NRC organizations as appropriate.

Other reporting requirements in the rules have also been difficult to interpret in certain circumstances. The same referral procedure should be followed for such uses. Questions concerning this directive may directed to the Chief, Operations Branch, IMNS, FTS 492-3332.

Richard E. Cunningham, Director
Division of Industrial and
Medical Nuclear Safety, NMSS

DISTRIBUTION
NMSS r/f
IMNS r/f
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JHickey
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CVillarreal (Orig.+ copy of official
record & 5520 call-sheet

OFC	:IMOB	:IMAB	:IMNS				
NAME	:JHickey/ll	:LCamper	:RECunningham:				
DATE	:10/25/90	:10/25/90	:10/25/90	:			

Attached List for Memorandum dated: October 25, 1990

Subject: POLICY AND GUIDANCE DIRECTIVE 90-7; INTERPRETATIONS OF THE MEDICAL MISADMINISTRATION RULE (10CFR SECTIONS 35.2 AND 35.33)

Malcolm R. Knapp, Director
Division of Radiation Safety and Safeguards, RI

J. Philip Stohr, Director
Division of Radiation Safety and Safeguards, RII

Charles E. Norelius, Director
Division of Radiation Safety and Safeguards, RIII

A. Bill Beach, Director
Division of Radiation Safety and Safeguards, RIV

Ross A. Scarano, Director
Division of Radiation Safety and Safeguards, RV

John E. Glenn, Chief
Medical, Academic, and Commercial
Use Safety Branch, IMNS

Charles J. Haughney, Chief
Fuel Cycle Safety Branch, IMNS

John W. N. Hickey, Chief
Operations Branch, IMNS

Enclosure 3

DRAFT

GUIDELINES FOR IDENTIFYING POSSIBLE MEDICAL MISADMINISTRATIONS

The following guidelines are applicable when licensees ask if an incident is a reportable misadministration, or if an inspector discovers a set of circumstances that might be a reportable misadministration, and there are significant questions on the interpretation or reportability among the staff.

THERAPY EVENTS

(includes events with greater than 30 microcuries I-131 and I-125)

1. In all cases, keep a detailed log to document all telephone inquiries and/or discussions of the incident.

2. Obtain preliminary details describing the incident and potential misadministration, notify the Medical, Academic, and Commercial Use Safety Branch (IMAB), and schedule a reactive inspection with the licensee. The inspection should occur within two weeks of the incident.

3. During the inspection, schedule interviews with the principals involved to develop an accurate time sequence and description of the event. Do not rely entirely on summary information provided by other licensee personnel such as radiation safety officer, administrative department head, or hospital director.

4. Interviews should include questions on personnel involved with the incident, their training and experience, circumstances surrounding the incident, contributing factors, events leading to discovery, time sequence of actions and consequent decisions, immediate and proposed followup and corrective actions.

5. Review and obtain copies of pertinent documents such as physician prescription or directive, description of the treatment plan, and changes made to the plan or prescription. Depending on the case, other documents may also provide valuable information, such as equipment calibration and service records and training records.

6. Forward a written description of the incident to the Director, Division of Industrial and Medical Nuclear Safety (IMNS), for coordination with other appropriate NRC personnel and interpretation by the Office of the General Counsel (OGC).

7. If the event is discovered during the course of an inspection, Points 3 through 6 above are applicable.

DIAGNOSTIC EVENTS

1. In all cases keep a detailed log to document all telephone inquiries and/or discussions of the incident.

2. Most potential diagnostic misadministrations will not require an inspection to obtain an accurate description of the event. A phone discussion with the principals involved with the incident will normally be sufficient.

3. Develop an accurate time sequence and description of the event. Do not rely entirely on summary information provided by licensee personnel such as radiation safety officer or administrative department head, if not directly involved with the incident.

4. Questions to personnel should include training and experience, circumstances surrounding incident, contributing factors, events leading to discovery, time sequence of actions and consequent decisions, immediate and proposed followup and corrective actions.

5. Forward a written description of the incident to the Director, IMNS for coordination with other appropriate NRC personnel and interpretation by OGC.