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

March 12, 1979

ARMY, DEPARTMENT OF THE
US ARMY ELECTRONICS RESEARCH AND DE
DELSD-SF
FT. MONMOUTH NJ 07703
29-01022-10

TO ALL MEDICAL LICENSEES

The attached order amends certain medical licenses to:

(a) Require the performance of molybdenum-99 breakthrough tests prior to administration of technetium-99m to patients.

(b) Prohibit the use of technetium-99m containing greater than specified levels of molybdenum-99.

(c) Require the establishment of written procedures and training for performing the tests.

(d) Require that certain records be kept.

Since this order becomes effective immediately, and its provisions must be implemented within 10 days after the date of this order, it is important that you transmit this information to personnel in your nuclear medicine facility as quickly as possible and retain this order with your license records.

William J. Dircks, Director
Office of Nuclear Material Safety
and Safeguards

DD/12

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR MATERIALS, SAFETY, AND SAFEGUARDS
WASHINGTON, D.C. 20555

ORDER MODIFYING LICENSES (EFFECTIVE IMMEDIATELY)

I

A recent investigation revealed the possibility of greater than normal quantities of molybdenum-99 contamination in the technetium-99m from processes involving the elution or extraction of technetium-99m from molybdenum-99. The presence of the molybdenum-99 serves no diagnostic purpose. It could result in a radiation dose to a critical organ of one or more rems and should such doses occur in large populations of patients, they would be unacceptable from a public health and safety standpoint.

Approximately five to six thousand generators are shipped weekly presenting a potential for exposure of large numbers of persons from contaminated technetium-99m. There has been no estimate made of the numbers of licensees using technetium-99m from other sources.

Tests for the presence of molybdenum-99 in technetium-99m for human use should be performed on each elution or extraction. Information obtained during NRC inspections indicates that not all licensees routinely perform such tests. There are no uniform requirements in licenses, regulations, or package labeling for the performance of tests to determine the amount of molybdenum-99 present in the technetium-99m prior to administration to patients. The Nuclear Regulatory Commission (NRC) considers it necessary that, whenever feasible, steps be taken to minimize radiation exposure of patients and personnel. Radiation exposures from abnormal levels of molybdenum-99 in technetium-99m for human use are unnecessary and preventable.

II

From the foregoing, breakthrough tests* as described below are necessary to prevent unnecessary radiation exposures to patients and personnel as a result of the presence of molybdenum-99 in technetium-99m administered to patients. Accordingly, the Director, Office of Nuclear

*In this context, the phrase "breakthrough test" refers to the detection and quantitation of molybdenum-99 in any separated technetium-99m, whether from a generator elution or other extraction process.

Materials, Safety and Safeguards has found pursuant to 10 CFR 2.204 of the Commission's regulations that the public health, safety or interest requires that this Order be made effective immediately.

III

In view of the foregoing and pursuant to the Atomic Energy Act of 1954, as amended, and the regulations in 10 CFR Parts 2, 30, and 35, IT IS HEREBY ORDERED THAT:

Effective immediately, any license which authorizes possession and use of molybdenum-99/technetium-99m generators and any license which authorizes extraction or separation of technetium-99m from molybdenum-99 not contained in generators is amended to add the following conditions:

(1) Beginning as soon as feasible but within ten (10) days of the date of this order, molybdenum-99 breakthrough tests shall be performed prior to the administration of technetium-99m to patients.

(2) Beginning as soon as feasible but within ten (10) days of the date of this order, technetium-99m containing more than one (1) microcurie of molybdenum-99 per millicurie of technetium-99m or more than five (5) microcuries of molybdenum-99 per dose of technetium-99m shall not be administered to patients. The limits for molybdenum-99 contamination represent maximum values and molybdenum-99 contamination should be kept as low as reasonably achievable below these limits.

(3) Beginning as soon as feasible but within ten (10) days of the date of this order, the licensee shall establish written procedures for personnel performing molybdenum-99 breakthrough tests including all necessary calculations and steps to be taken if quantities of molybdenum-99 in excess of the above specified limits are detected.

(4) Personnel performing molybdenum-99 breakthrough tests shall be given specific training in performing these tests prior to conducting such tests.

(5) The licensee shall maintain for inspection by the Nuclear Regulatory Commission records of the results of each molybdenum-99 breakthrough test performed and records of training given to personnel performing the molybdenum-99 breakthrough tests.

(6) Records described in item (5) shall be maintained for two (2) years following performance of the tests.

IV

Any licensee to whom this Order applies may, within 20 days from the receipt of this Order, request a hearing. Any request for such hearing shall be filed with Mr. R. Cunningham, Director, Division of Fuel Cycle and Material Safety, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. Such a request for a hearing SHALL NOT STAY THIS ORDER.

V

In the event a hearing is requested within the time specified, the issues to be considered at such a hearing shall be:

(1) Whether the circumstances described in section I above existed, and

(2) Whether on the basis of such circumstances, this ORDER should be sustained as regards the licensee.

FOR THE NUCLEAR REGULATORY COMMISSION

William J. Dircks, Director
Office of Nuclear Material Safety
and Safeguards

Dated at Bethesda, Maryland
this 12th day of March, 1979.