

NORTH CAROLINA DEPARTMENT OF
ENVIRONMENT AND NATURAL RESOURCES
DIVISION OF RADIATION PROTECTION



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May 17, 1998

DRP Information Notice 98-03

Memorandum

To: All North Carolina Medical Licensees
All NC Nuclear Pharmacy Licensees

From: J. Aaron Padgett, Chief
Radioactive Materials Section

Subject: Notice of Intent to Exercise Temporary Enforcement Discretion
Effective May 18, 1998

Pursuant to the North Carolina radiation protection regulations, the NC Division of Radiation Protection authorizes radiopharmaceutical manufacturing, commercial nuclear pharmacy, and medical use licensees to possess and use molybdenum-99 for the manufacture of molybdenum-99/technicium-99m generators and to possess and use molybdenum-99/technicium-99m generators by license condition.

Because there is no domestic supply of molybdenum-99 for radiopharmaceutical production, the major supplier for the United States is MDS Nordion in Canada. Labor conditions at the NRU reactor at the Chalk river Laboratories of the Atomic Energy of Canada Limited, which produces molybdenum-99 for MDS Nordion, have a potential for disruption of the supply of radiopharmaceuticals needed for medical diagnosis. In anticipation of a strike, it may be necessary for manufacturing licensees to stockpile molybdenum-99 or for other licensees to stockpile molybdenum-99/technicium-99m generators in order to mitigate disruption in the manufacture, supply, or use of the generators. Health and safety could be impacted if a strike occurred that disrupted the production of molybdenum-99. The Nuclear Regulatory Commission has already notified its licensees of its intent to exercise discretion to not enforce certain license requirements temporarily. The NC Division of Radiation Protection has also decided to exercise discretion not to enforce these same license requirements

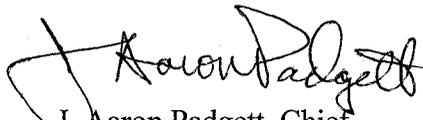
temporarily for North Carolina radioactive material licensees. This notice to not enforce certain license requirements will be effective for the period from May 18, 1998 through the end of the threat of a strike or the end of the strike and production disruption, whichever comes first.

Accordingly, the NC Division of Radiation Protection has concluded, until further notice, that it will not enforce license conditions or regulations restricting radiopharmaceutical manufacturing, commercial nuclear pharmacy, and medical use licensees' possession limits for molybdenum-99 for production of molybdenum-99/Technicium-99m generators, or possession limits for molybdenum-99/technicium-99m generators provided that:

- a. the molybdenum-99 concentration is determined for each technicium-99m eluate and contains no more than 0.15 microcurie of molybdenum-99 per millicurie of technicium-99m;
- b. the licensee does not administer to humans a radiopharmaceutical containing more than 0.15 microcurie of molybdenum per millicurie of technicium-99m;
- c. the licensee must maintain records of each elution or extraction for three years;
- d. the record of each elution or extraction contains the measured activity of the technetium in millicuries, the measured activity of the molybdenum in microcuries, the ratio of the measures expressed as microcuries of molybdenum per millicuries of technetium, the date and time of the measurement, and the initials of the individual who made the measurement; and,
- e. licensees comply with all other applicable requirements.

Please either write or call me if you have questions on the above policy.

Sincerely,



J. Aaron Padgett, Chief
Radioactive Materials Section