



**RADIOACTIVE MATERIALS BRANCH
RADIATION PROTECTION SECTION**

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INFORMATION NOTICE 05-02

TO: All North Carolina Medical Licensees

FROM: W. Lee Cox, III, Manager
Radioactive Materials Branch

DATE: November 23, 2005

IN RE: **Notice of Intent to Exercise Temporary Enforcement Discretion Effective
November 23, 2005**

This agency has been made aware of the situation involving a voluntary recall of Molybdenum-99/Technetium-99m (^{99m}Tc) generators by Mallinckrodt, Inc. As such, we are exercising temporary enforcement discretion to allow medical use licensees to defer two (2) quality assurance/quality control tests until the supply is deemed adequate, effective immediately.

In a letter dated November 18 Mallinckrodt Inc., stated it anticipates the voluntary recall of ^{99m}Tc generators to last a minimum of six weeks. A copy of this letter is included in this information notice.

Pursuant to the North Carolina Regulations for Protection Against Radiation (15A NCAC 11 .0108(a)), the Radiation Protection Section, Radioactive Materials Branch is allowing medical use licensees to forego certain quality control tests on dose calibrators in light of the shortage of ^{99m}Tc .

15A NCAC 11 .0359(a)(4) requires that all medical use licensees perform linearity testing on dose calibrators from the highest dosage administered to patients, down to 30 microcuries. This test is normally done with an aliquot of ^{99m}Tc , using either the decaying-source method or by using a series of calibrated tubes to perform the test. Additionally, 15A NCAC 11 .0359(a)(5) requires testing for geometry dependence over the range of volumes and volume configurations. This test is normally done at installation, but would be repeated if the unit has been moved or repaired.

Because a limited supply of ^{99m}Tc is available for use, the Agency is waiving these two requirements for all medical use licensees effective November 23, 2005. This exception will remain in effect for at least six weeks, or until this Agency receives confirmation Mallinckrodt Inc. that it has re-started production and distribution of ^{99m}Tc generators, which ever is sooner.

Licensees do not have to notify the Agency if they defer either of these quality assurance tests. However, records of quality assurance/quality control for the dose calibrators should indicate that the test date was deferred as a result of this shortage. Licensees are required to conduct the tests as soon as adequate ^{99m}Tc is available.

The Mallinckrodt, Inc. letter of November 18 includes several recommendations for maximizing ^{99m}Tc for patient use. One of the recommendations is to use a lower dosage where medically applicable. Licensees are reminded to refer to their Diagnostic Clinical Procedures Manual (DCPM), which contains dosage ranges for diagnostic studies. If a lower dosage is medically advised, then the "new" dosage should be included with the written directive. Alternatively, an Authorized User could issue a "blanket exception" for certain studies which



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states the "new" dosage ranges. In either case, the licensee should retain documentation of the changes and make this available at the time of the next routine inspection.

If you have questions, please contact J. Marion Eaddy III, Health Physicist at (919) 571-4141. Additional information will be provided as soon as it becomes available.

Attachment: Letter dated 18 November 2005 from Mallinckrodt

November 18, 2005

Dear Valued Mallinckrodt Customer:

Mallinckrodt initiated a voluntary recall today of our Ultra-TechneKow[®] DTE Generator (Technetium Tc-99m Generator). This voluntary recall will affect generator availability for a minimum of six weeks from the date of the recall. Due to the significant impact of this action to the nuclear medicine industry, we feel it is our responsibility to provide some relevant information on the production interruption, the actions taking place to correct the situation and the impact to our customers.

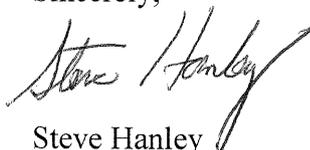
This voluntary recall is being conducted as a result of issues identified during routine sterility assurance process re-validation. Mallinckrodt has not received any reports of adverse events involving patient health or safety to prompt this recall. The required re-validation processes will take a minimum of six weeks to complete. Mallinckrodt is committed to taking whatever steps are necessary to ensure the safety of all our products, and will strive to resume production as soon as possible.

Mallinckrodt has been working diligently with alternate manufacturers and pharmacy chains to assist in procurement of generator supply. We are also working with industry leadership to communicate these issues and develop temporary solutions to most effectively and expeditiously manage through this shortage.

To maximize available technetium for patient use and manage this temporary shortage, please consider rescheduling non-critical procedures, injecting lower activities of technetium-based radiopharmaceuticals, where medically appropriate, and utilizing alternate isotopes or modalities for critical procedures. In order to provide alternative isotopes, we have bolstered our thallium production to allow for substitution in myocardial procedures.

Thank you for your support during this difficult market situation. Please contact your local sales representative or Mallinckrodt pharmacy for additional information.

Sincerely,



Steve Hanley
President
Imaging Division