



## Important Product Notification

January 26, 2008

Dear Covidien Imaging Solutions Pharmacy Customer:

Covidien is writing to inform you of a reported post-marketing quality control issue that involves our Ultra-TechneKow® DTE Generator (Technetium Tc-99m Generator).

Per our package labeling, the expiration time of the Sodium Pertechnetate Tc 99m solution is no later than 12 hours after time of elution. Additionally, each eluate of the generator should not contain more than the USP limit of 0.15 microcuries molybdenum Mo 99 per millicurie technetium Tc 99m per administered dose at the time of administration (0.15uCi Mo99/mCi Tc99m).

Recently, we have received reports from our customers in which the concentration of molybdenum Mo 99 to technetium Tc 99m does not meet the 12 hour expiration time as stated in our package labeling. The lot numbers affected are: 8005, 8006, 8007, 8008, 8009, 8010, 8011, 8012 and 8013. Covidien has been in communication with both the Food and Drug Administration and the Nuclear Regulatory Commission regarding this matter.

In order to ensure that there are no safety or health issues, we urge you to follow the Covidien package labeling and USP guidelines for the Ultra-TechneKow DTE Generator.

**Each eluate of the generator should be tested and should not contain more than the USP limit of 0.15 microcuries molybdenum Mo 99 per millicurie technetium Tc 99m per administered dose at the time of administration (0.15uCi Mo99/mCi Tc99m).**

We apologize for any inconvenience this may have caused and thank you for your continued support. We are requesting that you report all instances of Mo 99 in excess of 0.15 microcuries per millicurie technetium at 12 hours post elution to our Product Monitoring Department at 800-778-7898. Please, also contact us with any questions or concerns.

Sincerely,

Maria Chianta, PharmD  
Director, Product Monitoring