



Healthcare

Mallinckrodt

November 18, 2006

Mallinckrodt has initiated a voluntary recall of our DTE generator (UltraTechneKow®). We have anticipated questions our customers may have related to Tc 99m generator supply issues. Our answers are provided below.

How will this information be communicated to Mallinckrodt customers?

A formal recall notice was distributed on November 18. Additional customer letters with instructions on product returns and further information will follow.

Why are we having the recall?

This voluntary recall is being conducted as a result of sterility issues we identified during routine sterility assurance process re-validation at Mallinckrodt's radiopharmaceutical manufacturing facility.

How were the issues identified?

Mallinckrodt conducts periodic sterility assurance evaluations on process equipment as part of their standard operating procedure. Results from recent tests did not meet established criteria.

What is the extent of the recall?

The voluntary recall covers all Mallinckrodt generators with a request for immediate discontinuation of use of any Mallinckrodt generators in the market. Instructions on product return will follow.

Will it extend to the patient level?

Patient doses should not be formulated from any Mallinckrodt generators at this time. No adverse events related to the recall have been reported.

How long is Mallinckrodt expected to delay production?

Mallinckrodt is committed to taking whatever steps are necessary to ensure the safety of all of our products and will strive to resume production as soon as possible. Remedial actions including successful re-validation of the affected process will take a minimum of six weeks to complete. We will periodically update the market of our progress in resolving the issue.

What steps are being taken to supply nuclear pharmacies and customers with generators?

We are currently evaluating every possible solution for the supply issues that have arisen. In addition to pursuing the earliest resolution of our manufacturing issues, we have initiated plans with alternative suppliers for our pharmacies and customers.

Can the demand for technetium be mediated?

Since cardiology comprises a major portion of technetium usage, utilizing Thallium for cardiac scans, where medically appropriate, would enable cardiac nuclear scans to continue with less overall technetium. This would reserve the limited Tc supply for procedures where no acceptable substitution can occur.

What alternative imaging modalities can be used?

We are currently working with industry groups and societies such as SNM and ASNC to provide guidance on appropriate alternatives for existing procedures.

Will these problems keep occurring in the future?

Mallinckrodt Nuclear Medicine places the highest priority on patient safety and quality assurance. In early 2004, we began investing over \$100 million in our Maryland Heights facility to assure our commitment to providing safe, reliable and efficient manufacturing.

Were any adverse events reported to prompt this action?

No adverse events related to this recall have been reported.

What capacity exists to supply the market while Mallinckrodt is not producing generators?

Mallinckrodt is currently communicating with alternative manufacturers to assess and assist their ability to supply the marketplace.

When will Mallinckrodt pharmacies be able to obtain generators for use in unit dose preparations for customers?

We expect to have limited technetium supply from other vendors available to produce doses as early as Tuesday, November 22 throughout our network of Mallinckrodt nuclear pharmacies.

What steps is Mallinckrodt taking to provide customers with generators?

We are working collaboratively with the industry to maintain generator availability for the marketplace, including our own pharmacies. In the interim, customers needing generators should contact Bristol-Meyers Squibb as an alternate supplier.

Are any other products impacted?

No other products are affected by this recall.

Who can we contact regarding product quality issues or patient adverse events?

If any adverse events occur with our products, they should be instructed to call Mallinckrodt corporate product monitoring at 888-744-1414, option 2 then, option 1.