

Updated Customer Frequently-Asked Question (FAQ) Document

Based on customer response, Mallinckrodt has updated this FAQ document in relation to the voluntary recall and halt in production of our Ultra-TechneKow® DTE Generator. The first series of questions and responses are new, with the original questions and responses following.

1. **What patient signs or symptoms should we watch for? If a patient had a scan recently, will they get sick?**

It's important to understand that the recall of our generator product was not in response to any reported adverse effect on patients, but rather due to an issue identified during routine post-production sterility testing. Because Mallinckrodt could not be certain the generators produced on February 23, 2007, met sterility testing requirements, they were recalled. As an additional precaution, Mallinckrodt decided to recall all generators made after that date. However, as of March 8, 2007 preliminary results of the repeat testing of the eluent from the February 23 generator have shown no growth. Similarly, all of the sterility testing for the lots produced after that date have shown no growth to date. However, since the final tests will not be completed for another week, this information does not change the fact these products are recalled and should not be used. **Based upon available information, our recommendation remains that patients exhibiting symptoms consistent with an infection should be screened for a possible fungal exposure.**

2. **What happened to your redundant generator line capacity?**

The original redundant line design was developed prior to the 2005 recall. It would have improved capacity, but would have generally copied our existing manufacturing technology. We have since revised our plan to include significant modifications to the redundant line design when compared with our current process. This approach, while taking longer to complete, should promote Mallinckrodt's ability to provide a more consistent supply.

3. **Is Mallinckrodt being too conservative with its QA / QC requirements?**

Absolutely not. When patient safety is involved, we know our customers agree that conservatism is the only approach. You should also note that our handling of this most recent production stoppage and recall was consistent with our obligations under applicable laws and regulations and in accordance with good manufacturing practices.

4. **What exactly happened?**

Upon receiving the test result that failed to meet established release requirements, Mallinckrodt immediately stopped generator production and launched an investigation to review the validity of the result. The preliminary results of our investigation suggested that the contamination may have been introduced to the sample vial during testing, leading us to believe that production could resume on Tuesday, March 6.

We aggressively worked over the weekend and during the course of the day on Monday, March 5 to identify the root cause of the contamination. These efforts were, however, unsuccessful, and by late on Monday we determined that irrefutable evidence of the source of the Penicillium had not been established. As a result, our standard operating procedures, as well as applicable laws and regulations, required us to take steps to revalidate our production process and recall all potentially affected product.

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MALLINCKRODT GENERATOR ISSUES – REV. CUSTOMER FAQ 3/9/07

5. What will you do (specifically) to ensure this event isn't repeated?

Mallinckrodt continues to invest heavily in new resources, including additional personnel and equipment, process and facility improvements, in an effort to create a robust and reliable manufacturing process. As with any complex manufacturing process, there is always the possibility that we will identify areas for improvement related to quality. These areas are then thoroughly investigated in order to implement appropriate changes designed to prevent or greatly minimize the possibility of any negative product impact.

Some of those recent and ongoing improvements include:

- Equipment and facility upgrades to improve the manufacturing process and environmental monitoring
- Improved process for sterility sampling
- Increased quality staff and enhanced training for all plant personnel
- Re-emphasis on quality culture throughout the plant
- Continuous review of all processes involved in manufacturing and product

6. Why don't other generator manufacturers have these types of problems?

Mallinckrodt cannot speak to the manufacturing processes employed by others. Generator manufacturing is very complex, dependent on not only sterility but also material supply, transportation issues, etc. The changes that we are working toward in our generator manufacturing process should help to reduce incidents like this in the future.

7. As an owner of a radiopharmacy, what are you going to do to help my business get back on its feet? Do you know you literally shut me down?

We realize the significant impact to our important radiopharmacy customers. We also know that as a pharmacist, you share our concern for patient safety. We began work immediately with alternative suppliers to promptly re-establish an adequate supply of technetium to the marketplace. A letter will be provided to you next week that you may forward on to your customers. This letter will specifically note the role Mallinckrodt played in your inability to service their needs.

8. Does Mallinckrodt understand how this has impacted my practice? I've lost patients, referrals and credibility.

We do recognize the inconvenience and we appreciate your patience and understanding during this difficult time. However, like you, our first commitment is to patient safety. A letter will be provided to you next week that you may forward on to both patients and referring physicians. This letter will specifically note the role Mallinckrodt played in your inability to meet their needs.

9. Is Mallinckrodt committed to the nuclear medicine industry?

Mallinckrodt is committed to patient safety, a consistent product supply, and the long-term viability of the nuclear medicine industry. When product shortages are unavoidable, we work quickly and diligently with other industry suppliers to minimize the impact to our customers and their patients.

10. Should we be concerned about the overall supply of radiopharmaceuticals in the market?

No. However it is important to recognize that the manufacturing of radiopharmaceuticals is a complex process which requires a significant amount of commitment and investment in the industry. As the only fully integrated manufacturer of radiopharmaceuticals, Mallinckrodt is well-versed in the fragility of this supply chain and does everything possible to alleviate product supply interruptions. Over the past year, we have invested heavily in new resources, including additional personnel and equipment, and process and facility improvements, in an effort to create a robust and reliable manufacturing process.

11. Why did you notify me so late?

We are always mindful of our customers' needs when making these decisions. Unfortunately, because of the complicated nature of generator manufacturing, investigations of possible product release or other production failures are time consuming and difficult to complete. To act in the best interest of patient safety, we must take action whenever the results of our investigations provide a basis for making a decision. In this instance, all efforts were made to avoid inconvenience to customers and patients. Once determinations were made, it was our obligation to immediately communicate with the market. We realize late evening notifications are challenging, but in this case they were unavoidable.

MALLINCKRODT GENERATOR ISSUES – REV. CUSTOMER FAQ 3/9/07

12. Can I trust you to be a consistent supplier?

Mallinckrodt remains fully committed to the nuclear medicine industry and will work tirelessly to regain your trust and confidence. This commitment is evidenced, in part, by our heavy investment in new resources, including additional personnel and equipment, process and facility improvements. We will make every effort to maintain a robust and reliable manufacturing process.

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The following questions and responses were first supplied on Tuesday, March 6.

1. What steps are being taken to supply pharmacies and customers with generators? Will other companies be able to supply technetium to these customers while Mallinckrodt's production is halted?

We are currently evaluating every practical solution for the supply disruption the recall has caused. This includes working with other radiopharmaceutical suppliers in an effort to increase their production capabilities during the shortage. We also recommend considering the use of alternative products where medically appropriate in order to lessen the strain on technetium demand. See question 2 below.

2. Are there any substitute products on the market?

Since cardiology comprises a major portion of technetium usage, substituting Thallium for cardiac scans, where medically appropriate, would enable nuclear scans to continue, while reserving technetium for procedures where no reasonably acceptable substitution can occur. Refer to industry groups and societies such as the Society of Nuclear Medicine (www.snm.org) and the American Society of Nuclear Cardiology (www.asnc.org) for information related to appropriate modality substitutions.

3. When does Mallinckrodt anticipate resuming technetium production?

We are working aggressively to address the cause of the recall and are committed to taking whatever steps are necessary to ensure the safety of this product. We currently estimate that our product will be off the market until at least early April. We will periodically update the market of our progress.

4. Are any patients that have been injected with doses from Mallinckrodt's generators at risk? For instance, if a patient had a scan recently, will they get sick?

The possibility exists that patients receiving Tc 99m from a recalled generator may have been exposed to Penicillium, a common airborne contaminant. Patients who have received Tc 99m from a recalled generator presenting with symptoms consistent with an infection should be screened for a possible fungal exposure.

5. What populations are at risk?

Injection of a patient with eluate from a non-sterile generator could lead to a systemic microbial infection in the patient. Immune compromised and patients with severe co-morbidities would be at a higher risk if they were injected with eluate from a non-sterile generator.

6. Can the generators in the field be re-sterilized, or can the technetium be filter-sterilized, so we can continue to scan?

No.

7. What is the risk to patients if I keep using the generator?

Mallinckrodt has instituted a voluntary recall of the generators. Generators currently in the field should not be used under any circumstances.

8. How will information be communicated to Mallinckrodt customers?

Customer communications have been and will continue to be sent through Mallinckrodt field sales, pharmacies and posted to our web site.

MALLINCKRODT GENERATOR ISSUES – REV. CUSTOMER FAQ 3/9/07

9. Why are we having the recall?

We are conducting this voluntary recall as a result of issues we identified during routine sterility testing at Mallinckrodt's radiopharmaceutical manufacturing facility.

10. How were the issues identified?

Mallinckrodt conducts routine sterility tests as part of its standard operating procedures. Results from recent tests did not meet established criteria.

11. Why was the recall decision and subsequent production halt announced so late Monday night?

Upon receiving the test result that failed to meet established release requirements, Mallinckrodt immediately stopped generator production and launched an investigation to determine the validity of the result. The preliminary results of our investigation reaffirmed the integrity of our manufacturing process, and suggested that the contamination may have been introduced to the sample vial during testing. These preliminary results caused us to believe that production could resume on Tuesday. However, further investigation was unable to provide irrefutable evidence of the source of the Penicillium. As a result, while we continue to believe in the integrity of our manufacturing process, we believe the most responsible path is to re-validate the system and recall all potentially affected product.

12. What is the extent of the recall?

The voluntary recall covers generators manufactured on or after February 23 with directions to immediately discontinue use of any Mallinckrodt generators in the market. Instructions on product return are being sent to customers who have been identified as likely to have one or more generators from the listed lots in their current inventory.

13. Will it extend to the patient level?

Patient doses should not be formulated from any Mallinckrodt generators at this time.

14. How long is Mallinckrodt expected to delay production?

Mallinckrodt is committed to taking the necessary steps 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 sterility will take until early April to complete. We will periodically update the market of our progress in resolving the issue.

15. 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 are in the process of working with alternative suppliers for our pharmacies and customers.

16. 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.

17. What alternative imaging modalities can be used?

You may contact industry groups and societies such as SNM and ASNC to obtain guidance on appropriate alternatives for existing procedures.

18. Were any adverse events reported to prompt this action?

It's important to understand that the recall of our generator product was not in response to any reported adverse effect on patients, but rather due to an issue identified during routine sterility testing.

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

We are currently communicating with alternative manufacturers to determine their ability to supply the marketplace.

MALLINCKRODT GENERATOR ISSUES – REV. CUSTOMER FAQ 3/9/07

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

Availability will vary during this period. Please contact your local pharmacy directly for up to date information.

21. 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-Myers Squibb Medical Imaging (BMS) as an alternate supplier. BMS may be contacted directly at 800-299-3431.

22. Are any other products impacted?

No other products are involved in this recall.

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

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

26. Who should I contact with any other questions? Your local Mallinckrodt sales representative or Mallinckrodt pharmacy should be able to help you. You may also contact our customer service Department at 888-744-1414.