

May 19, 2009

Mr. Mark Satorius
U.S. Nuclear Regulatory Commission, Region III
2443 Warrenville Road, Suite 210
Lisle, Illinois 60532-4352

**RE: NRC License 24-04206-01
Docket Number 030-00001
CAL 03-08-001**

Dear Mr. Satorius:

Mallinckrodt is providing this letter in response Items 1, 2 and 4 of the U.S. Nuclear Regulatory Commission (NRC) Confirmatory Action Letter (CAL) issued on February 1, 2008. Mallinckrodt previously provided information in response to the CAL via letters dated March 28, 2008, August 18, 2008 and November 26, 2008. This letter documents completion of all corrective actions associated with the CAL as well as provides information associated with the proposed discontinuation of the distribution of the "Updated Important Product Notification," dated June 27, 2008.

As reported in our letters dated August 18, 2008 and November 26, 2008, Mallinckrodt had completed the majority of corrective actions associated with the investigation into elevated reports of molybdenum-99 (Mo-99) breakthrough. Since Mallinckrodt has completed most of the corrective actions, updates are only provided for those items that remained open on November 26, 2008. Please note the item numbers in the paragraphs below correspond to the item numbers in our March 28, 2008, August 18, 2008 and November 26, 2008 letters.

3. Design, write, and perform a Design of Experiment (DOE) to establish and understand the role of Chemical 1 in Component 1 and its relationship to Mo breakthrough.

As noted in our November 26, 2008 letter Mallinckrodt completed the testing to establish and understand the role of Chemical 1 in Component 1 and its relationship to Mo-99 breakthrough. Based upon this testing, Mallinckrodt secured a different type of Component 1 with low Chemical 1 content. Mallinckrodt subsequently completed process validation runs utilizing this new component. The results of the validation runs were

submitted to the FDA in January 2009. Mallinckrodt began manufacturing generators with the new component on February 20, 2009.

13. Create label for top of generator reminding users to perform a Moly breakthrough test on each elution of the generator.

Mallinckrodt began using the labels on December 3, 2008.

Implementation of our corrective actions has significantly reduced the frequency of Mo-99 breakthrough reports. Since the final corrective action was completed on February 20, 2009, Mallinckrodt has received only two customer complaints associated with a Mo breakthrough ratio that exceeds 0.15 μCi of Mo-99 per mCi of Tc-99m at 12 hours post elution. This frequency is below historical levels. Mallinckrodt has instituted an effectiveness check to ensure corrective actions remain successful. Specifically, two complaints of elevated Mo breakthrough associated with any three consecutive lots of generators will initiate an investigation to determine root cause and identify corrective actions.

In addition to providing information associated with the completion of our corrective actions, this letter also provides information associated with Item 4 of the Confirmatory Action Letter. Item 4 states that prior to discontinuing distribution of the "Important Product Notification" Mallinckrodt must contact the NRC to discuss three specific pieces of information. These items have previously been discussed with Mr. Robert Gattone of your staff. Specific responses are outlined below.

1) Why distribution of the Notification is no longer necessary:

Mallinckrodt believes the notification is no longer necessary because corrective actions have successfully addressed the increased frequency of Mo breakthrough.

2) Mallinckrodt's understanding of the Food and Drug Administration's (FDA) perspective on whether or not distribution of the Notification is no longer necessary.

Through discussions with Mallinckrodt the FDA has determined that the Notification can be discontinued. The FDA indicated we should provide a general correspondence indicating the date that the Product Notification was discontinued.

3) Whether or not you have completed all of the necessary corrective actions to prevent recurrence.

As indicated above, Mallinckrodt has completed all of the necessary corrective actions to prevent recurrence.

Based upon the above information Mallinckrodt plans to discontinue the Product Notification letter beginning with generators distributed on June 19, 2009.

Mallinckrodt remains fully committed to complying with all NRC regulatory requirements and addressing all areas of concern. We believe the corrective actions we have implemented will ensure continued compliance with all NRC requirements. If you have any questions related to this matter, please feel free to contact me at 314-654-7998 or Jim Schuh at 314-654-7981.

Sincerely,



Mitzi Pennington
Manufacturing Site Director

cc: Patricia H. Duft – Mallinckrodt
Robert Gattone – US NRC Region III
Jim Schuh – Mallinckrodt
Kay Yoder – Mallinckrodt

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UNITED STATES US

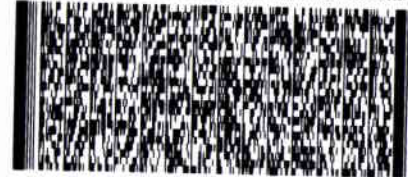
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US NRC REGION III
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