



Mallinckrodt
Pharmaceuticals

February 7, 2014

U.S. Nuclear Regulatory Commission
ATTN: Document Control Desk
Washington, DC 20555-0001

RE: Reply to a Notice of Violation
NRC License 24-04206-01, Docket Number: 030-00001

Dear Sir or Madam:

Mallinckrodt LLC is providing this letter to the Nuclear Regulatory Commission (NRC) in response to the Notice of Violation issued to Mallinckrodt on January 9, 2014. The alleged violation concerned Mallinckrodt's failure to ensure that a cyclotron target bunker had radiation cooling for one week before maintenance activities were performed in the bunker as required by Standard Operating Procedure.

On September 17, 2013, an employee mistakenly entered IBA cyclotron target bunker 1.2 to perform maintenance on the target header. Mallinckrodt's bunker entry procedure requires one week of decay before performing maintenance in a target bunker. The bunker entered had approximately five days of decay.

As a result of this event, an investigation was conducted. The investigation team was comprised of site Health Physics and Cyclotron Operations personnel. The team was tasked with identifying facts concerning the bunker entry, developing conclusions including roots causes, and identifying corrective actions to prevent recurrence.

The root cause of the operator entering the wrong target station bunker was determined to be insufficient system controls for entry into cyclotron bunkers. The existing system relied upon individual operators to review the maintenance schedule and to open the appropriate bunker based upon the schedule. In this case the operator erroneously opened bunker 1.2 instead of bunker 2.1 and proceeded to perform the maintenance in that bunker.

In order to address this issue, Mallinckrodt implemented a work practice requiring a second operator to verify that the correct target bunker has been selected for entry. All cyclotron operators were trained on this work practice as of December 20, 2013.

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In addition, Mallinckrodt is evaluating the feasibility of installing interlocks to prevent an operator from opening a bunker door prior to the required minimum cooling times.

Mallinckrodt remains fully committed to complying with all NRC regulatory requirements and addressing any areas of concern. We believe the corrective actions we have identified and implemented will ensure continued compliance with NRC requirements. If you have any questions related to this matter, please feel free to contact me at 314-654-3923 or Scott Surovi at 314-654-7444.

Sincerely,

A handwritten signature in black ink that reads "Dale Eyman".

Dale Eyman
Site Director

cc: Cynthia Pederson – U.S. NRC Region III
Eric Berry – Mallinckrodt
Dale Eyman – Mallinckrodt
Ken Lambert – US NRC Region III
James Schuh – Mallinckrodt
Scott Surovi – Mallinckrodt
Kay Yoder – Mallinckrodt