



NRC NEWS

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NRC ISSUES CONFIRMATORY ACTION LETTER AND SENDS SPECIAL INSPECTION TO MISSOURI COMPANY MANUFACTURING PRODUCTS FOR NUCLEAR MEDICINE

The Nuclear Regulatory Commission staff has issued a Confirmatory Action Letter to Mallinckrodt, Inc., a manufacturer of products used in nuclear medicine. The letter confirmed the company's commitment to investigate a problem identified with its molybdenum-99/technetium-99m generators used for diagnostic imaging. The company is located in Maryland Heights, Miss.

Technetium-99m is one of the most widely used isotopes for performing nuclear medicine diagnostic studies. Technetium-99m is delivered to nuclear pharmacies and hospitals in generators from which Technetium-99m can be extracted. Technetium-99m is produced from the radioactive decay of another nuclear isotope, molybdenum-99. The generators are designed to contain the molybdenum-99 while allowing the nuclear pharmacies and hospitals to withdraw the technetium-99m. NRC regulations require users to test the liquid the first time it is withdrawn from the generators to ensure that the liquid has acceptably low levels of molybdenum-99.

On Jan. 11, Mallinckrodt Inc. began receiving information from its customers that the liquid withdrawn from the generators showed higher levels of molybdenum-99. By Jan. 31, Mallinckrodt, Inc. had received information that more than 100 generators had higher levels of molybdenum-99 in the solution withdrawn from the generators.

The NRC learned on Jan. 24 of the increased levels of molybdenum-99 in the solution withdrawn from the generators produced by Mallinckrodt, Inc. The NRC initiated discussions with the company in order to understand the reasons for the increased levels of molybdenum-99 and the actions the company was taking to address the issue and to prevent its recurrence.

On Feb. 1, the NRC issued a Confirmatory Action Letter to Mallinckrodt documenting the NRC's understanding of the company's commitments to address the event.

In addition, the NRC dispatched a Special Inspection Team to evaluate the event, the company's response to the event, the company's past actions related to higher levels of molybdenum-99 in solution withdrawn from the generators, and the company's follow-up on commitments described in the Confirmatory Action Letter.

"We need to make sure we understand what caused the higher levels of molybdenum-99 in the solution withdrawn from the generators and to evaluate the company's response to the event," said Mark Satorius, Deputy Regional Administrator for the NRC Region III Office. "We also need to gain confidence that this problem will not recur."

Mallinckrodt has begun investigating the causes of the event. Based on preliminary investigation results, the company has taken actions to prevent a similar event. On Jan. 27, Mallinckrodt also began including a notification in all shipments to its generator customers regarding the presence of elevated levels of molybdenum-99 in solution withdrawn from some generators.

The special inspection will continue until the inspection goals are achieved.

The special inspection team will issue its report about 30-45 days after the completion of the inspection. The report will be available from the Region III Office of Public Affairs and in the agency's online document library at: <http://www.nrc.gov/reading-rm/adams/web-based.html>.

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