NUDOCS

MALLINCKRODT
Nuclear Medicine

November 29, 1994

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Director, Office of Enforcement
U.S. Nuclear Regulatory Commission
ATTN: Document Control Desk
Washington, D.C. 20555

RE: Docket No. 030-29675
License No. 24-04206-10MD
EA 94-202

Dear Sirs:

This refers to the NRC inspection conducted on September 8, 1994 at our Warren Michigan radiopharmacy and the subsequent Notice of Violation and Proposed Imposition of Civil Penalty. Please reference NRC inspection report No. 030-29675/94001 (DRSS).

REPLY TO A NOTICE OF VIOLATION

The following reply to the NRC Notice of Violations contains Mallinckrodt Medical, Inc. Nuclear Medicine Division's, acknowledgement of each alleged violation, the reason for the violation and the immediate and future corrective actions for each alleged violation noted in your letter of November 3, 1994 regarding our facility in Warren, Michigan.

Notice of Violation

1. Condition 29 of License No. 24-04206-10MD requires, in part, that licensed material be possessed and used in accordance with statements, representations and procedures contained in an application dated January 29, 1992, and a letter dated September 25, 1992.

   a. Item 1. of letter dated September 25, 1992, entitled "Precautionary Measures for Handling Quantities of Liquid Radioiodine," states when the measured concentration beyond both charcoal traps exceeds 10% of the maximum permissible concentration (MPC) for iodine-131, one or both of the traps will be replaced as necessary.

   Contrary to the above, on numerous occasions since January 7, 1994, the measured concentration beyond both charcoal traps significantly exceeded 10% of the MPC for iodine-131 and the charcoal traps were not replaced. (01013)

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Reply to Notice of Violation (1.a.)

We acknowledge and admit to this violation. We determined the reason for this violation was based upon the fact that the RSO, Mike Grawburg, focused on the maximum permissible air concentration measured after charcoal filtration and did not take the necessary actions stipulated within the license application when action limits were exceeded. In addition, this RSO became too dependent on a consultant who performed the radiation safety audits at this facility and thus did not actively involve himself in all the associated conditions listed within the license.

Following the NRC inspection on September 8, 1994, Mallinckrodt determined that the filtration system should be replaced with the next generation filtration system. As a result, our immediate and future corrective actions have been to install a new, state of the art filtration system. This system was installed, validated and certified operational on October 18, 1994. Subsequent air concentration measurements have shown that this facility is not exceeding 10% of the maximum permissible concentration for iodine-131 pursuant to license conditions. Further, the technical specifications and functional parameters were reviewed with the RSO of this facility. Likewise, a thorough review of this license condition was conducted with the RSO.

Notice of Violation

b. Item 10.7.7 of the section of the application dated January 29, 1992, entitled "General Rules For Safe Use of Radioactive Material" requires that every vial, syringe and capsule containing more than 10 microcuries of a gamma emitting radiopharmaceutical shall be assayed in a dose calibrator prior to distribution.

Contrary to the above, on March 2, 1994, a technician dispensed a 46 microcurie capsule of iodine-131, a gamma emitting radiopharmaceutical to a medical facility, but failed to assay the iodine-131 in a dose calibrator prior to distribution. (01023)

Reply To Notice of Violation (1.b.)

We acknowledge and admit to this violation. We determined that this misadministration occurred because the technician involved did not adhere to normal operating procedures. In order to implement a corrective action to assure no reoccurrence of said misadministration, the following procedure was enacted. An assay procedure for each and every radioactive item within a prescription was instituted, even though the radioactive level might be below assay accuracy. This procedure was put in place to assure that submicrocurie quantities were not inadvertently filled with items of a greater quantity of activity.

Further, all pharmacists and technicians were retrained as to the proper and appropriate procedures to fully verify the appropriate filling of each prescription. Each individual within the laboratory was retrained with an outline of the appropriate training schedule and each individual signed a document acknowledging the completion of this retraining. All prescriptions filled by a technician will be verified by a licensed nuclear pharmacist.

These corrective actions were taken immediately after the incident regarding the misadministration on March 2, 1994. The retraining, verification for technician work by a licensed nuclear pharmacist, and the new assay procedure are anticipated to reduce the possibility of a reoccurance regarding the above misadministration.

Notice of Violation

c. Item 10.10 of the section of the application dated January 29, 1992, entitled, "Precautionary Measures for Handling Millicurie Quantities of Liquid Radioiodine", describes the procedures for calibration of instrumentation and measurement of individuals who dispense iodine-131 in excess of quantities which exceed the licensee's guidelines. The procedure requires a two minute count to be made of both the calibration source and the individual's thyroid. It also requires a background count of ten minutes.

Contrary to the above, between December 22, 1993, and September 9, 1994, the licensee routinely counted the individuals thyroid, background, and calibration source for only one minute. (01033)

Reply To Notice of Violation (1.c.)

We acknowledge and admit to this violation. However, weekly thyroid burden measurements for all personnel handling iodine-131 were performed and recorded on a weekly basis as required. The procedure used to measure the individual's thyroid burden, while technically acceptable, was different than the counting interval listed in the license application. Because the facility's procedure manual lists a different counting interval than described by license condition, we have determined that this contributed to the error in counting times.

Immediately after the inspection on September 8, 1994, the thyroid monitoring procedures pursuant to license condition were reestablished, and have been and will be followed henceforth.

Notice of Violation

d. Item 10.8 of the section of the application dated January 29, 1992, entitled "Emergency Procedures" requires that a decontamination kit be located within the facility.

Contrary to the above, a decontamination kit was not located within the facility. (01043)

Reply to Notice of Violation

We acknowledge and admit to this violation. We determined the reason for this violation was a lack of understanding regarding the NRC's interpretation of a kit. Although all necessary materials were readily available within the radiopharmacy laboratory, we recognize that this does not constitute a kit as described pursuant to this license condition.

As such, immediate corrective actions were taken after the inspection on September 8, 1994 to establish a kit with all necessary materials listed pursuant to the information indicated within the license application. These items were placed within a container and said container was labeled as a decontamination kit and placed within the radiopharmacy laboratory.

In addition to the kit, materials utilized for decontamination are still being maintained at various sites throughout the laboratory to facilitate an appropriate response when a spill occurs or contamination is detected. All radiopharmacists and technicians were retrained regarding the necessity of having a spill kit and the necessary materials required, pursuant to license conditions.

Notice of Violation

2. 10 CFR 30.41(c) requires that, prior to transferring byproduct material, the licensee verify that the transferee's license authorizes the receipt of the type, form and quantity of byproduct material to be transferred. 10 CFR 30.41(d) specifies acceptable methods for this verification.

   Contrary to the above, on August 31, 1994, the licensee transferred byproduct material to an individual and failed to verify by acceptable methods that he was authorized to receive the type, form and quantity of byproduct material. This is a repeat violation. (01053)

Reply to Notice of Violation (2.)

We acknowledge and admit to this violation. We have determined the reason for this violation was based upon the fact that the individual, an employee of the company, was a member of the company's medical physics consulting group (NMA), and therefore, the physical verification of authorization was not performed.

In order to implement corrective actions to assure no reoccurrence of said violation, a current copy of the NMA materials license was given to the RSO of the Warren Michigan radiopharmacy. This copy of NMA's license, with the approved users list attached, will be maintained on file by the RSO and will be used to verify all subsequent transfers of material from the Warren nuclear pharmacy to any NMA consultant in the future. The RSO at this facility was retrained on the requirements of this license condition. This information and the retraining process was completed immediately after the inspection on September 8, 1994.

We recognize this violation is a repeat reoccurance. However, we have noted that these were two very unique and specific scenarios, each being unrelated in nature. Regardless, the requirement of verification of an authorize recipient prior to the transfer of byproduct material in all situations is the important distinction. This matter has been reviewed with the RSO at this facility.

In addition, similar retraining actions were taken within Mallinckrodt's radiopharmacy system in order to reassure continued compliance in this area.

Notice of Violation

3. 10 CFR 20.1902(e) requires that the licensee post each area or room in which there is used or stored specified amounts of licensed material with a conspicuous sign or signs bearing the radiation symbol and the words "Caution, Radioactive Material(s)" or "Danger Radioactive Material(s)".

   Contrary to the above, as of September 8, 1994, the entrance to the nuclear pharmacy laboratory, an area in which specified amounts of licensed material was used and stored, was not posted as required. (01063)

Reply to Notice of Violation (3.)

We acknowledge and admit to this violation. However, no adequate conclusion could be reached regarding the reasons as to why the posting, "Caution, Radioactive Materials," was not properly displayed on the entrance to the laboratory of the radiopharmacy. Further, we have noted that previous consulting audits for this facility indicated that postings such as this were properly displayed within the radiopharmacy.

Immediate corrective actions were taken and a "Caution Radioactive Material" sign was re-posted at the entrance to the laboratory at the conclusion of the NRC inspection, on September 8, 1994.

Notice of Violation

4. 10 CFR 71.5(a) requires that licensees, who transport licensed material outside the confines of their plants or deliver licensed material to a carrier for transport, comply with the applicable requirements of the regulations appropriate to the mode of transport of the Department of Transportation (DOT) in 49 CFR Part 170-189.

   49 CFR Part 177.842(d) requires that packages containing radioactive material be so blocked and braced that they cannot change position during conditions normally incident to transportation.

   Contrary to the above, on September 9, 1994, the licensee transported a package containing licensed material and the package was not blocked and braced such that it could not change position during conditions normally incident to transportation. Specifically, packages containing licensed material were placed in the hatchback of a vehicle with no blocking or bracing to prevent the containers from moving during transportation. (01073)

Reply to Notice of Violation (4.)

We acknowledge and admit to this violation. We determined the reason for this violation was due to the RSO's interpretation of the applicable DOT regulations for the transportation of license material as it pertains to the vehicle in question. Specifically, the RSO concluded that the requirements of blocking or bracing to prevent the container(s) from moving in transport were, in effect, achieved due to the small, physical dimensions of the trunk area for the Dodge Shadow vehicle.

Our evaluation of this situation revealed two important findings. First, the other eight vehicles currently in use at this facility maintained adequate materials sufficient to block and brace packages containing licensed materials for transportation. And second, this concern regarding blocking and bracing was discussed during previous NRC inspections and resulted in no comments regarding the disapproval of this procedure.

As a result, we recognize the contributing cause to this violation was a difference or change in the interpretation as it applies to the acceptability of blocking and bracing of packages within the Dodge Shadow vehicle. Our corrective actions were to install a rack within the trunk of this vehicle, which is similar to the blocking and bracing materials used in the other eight vehicles. This installation process was achieved the same day of the inspection.

In order to assure continued regulatory compliance, a similar rack system, or other such material appropriate to adequately block and brace packages, will be utilized in each delivery vehicle maintained at the Warren, MI facility. The RSO was retrained regarding the condition of this regulatory requirement. Likewise, similar actions were taken within Mallinckrodt Medical's radiopharmacy system in order to reassure continued compliance in this area.

Area of Concern

Within the cover letter to the Notice of Violation and Proposed Imposition of Civil Penalty, dated November 3, 1994, the NRC stated that Mallinckrodt Medical, Inc. should address the radiopharmacy's actions to evaluate and improve the radiopharmacy's self assessment program to assure that it is causing the identification and lasting correction of program deficiencies.

In addition, we recognize the concerns the NRC raised regarding the alleged programmatic weaknesses at this facility which include the concern for the knowledge of license conditions and NRC requirements, accountability regarding compliance, and the overall effectiveness of the corporate self-assessment program.

Reply to Area of Concern

While we acknowledge and recognize the concerns raised by the NRC regarding the implementation of our radiation safety program at the Warren, MI facility, it is our strong belief that these weaknesses identified by the NRC were an isolated incident. However, because of the nature and the seriousness of the concerns raised, we are developing a complete in-house review of our radiopharmacy radiation safety program.

The corrective actions regarding Mallinckrodt's radiopharmacies' self-assessment program were initiated in October and will be on going until mid-year 1995. Initially direct contact has been made with all auditors of the self-assessment program calling attention to the concerns for the effectiveness of the self-assessment program and to its ability to adequately identify program deficiencies. The initial evaluation of the self-assessment audit concerned the overall base knowledge of the radiation safety officer and each nuclear pharmacy self-assessment auditor. The radiation safety officer and the self-assessment auditor are being evaluated on their technical knowledge and understanding, their level of competency, and their level of objectivity in determining and reporting potential weaknesses in the Radiation Safety Program to Mallinckrodt's management.

To further address potential concerns for objectivity and reporting to management, the auditing program has been modified. The auditor operating within the same radiopharmacy location will no longer audit their site's radiation safety program. This corrective action taken is anticipated to eliminate the concern for objectivity and reporting of findings to management.

In addition, a four member task force was assembled and trained to specifically identify problematic weaknesses within our radiopharmacy operating systems. This program was put in place on October 19, 1994. All facilities were ranked based upon the size and complexity of the radiopharmacy operations and were subsequently scheduled for a three to five day on-site evaluation. Each evaluation has been structured to identify and address potential weaknesses within the radiation safety program, to include a review of the base knowledge and technical understanding of the radiation safety officer, facility manager, and the NMA auditor at that specific radiopharmacy location.

Any potential weaknesses noted within our radiation safety program will be summarized and shared among our nuclear pharmacy operations and reported to management of Mallinckrodt Medical. All program weaknesses will be immediately corrected as soon as practical. For those existing weaknesses which may be complex in nature and difficult to remedy immediately, precautionary measures will be taken in order to protect against radiation hazards arising from activities conducted at that specific radiopharmacy and to ensure that all regulatory and licensing conditions are not compromised. A definitive interval of time will be established in order to ensure suitable corrective actions have been taken in a timely fashion.

In order to insure that long-lasting corrective actions will be maintained, the written auditing process itself will be modified to address any and all specific problems or potential problems which are identified by the aforementioned task force. The self-assessment auditor of a radiopharmacy will be required to evaluate each Mallinckrodt Medical radiopharmacy utilizing the auditing procedure identified by the task force. Such an evaluation will be included as part of the routine quarterly radiation safety evaluation report for the radiopharmacy. Quarterly evaluations will be summarized and reported to management listing areas of concern where corrective action may be needed. Quarterly evaluations will follow the previously established procedures associated with the audit reporting to management except for areas of immediate concern which will be reported promptly, and separately, to corporate management at Mallinckrodt Medical, Inc. in order to assure the timeliness of corrective actions.

We appreciate the NRC acceptance of our immediate corrective actions and the reduction of proposed penalties. In payment of those penalties, enclosed is a check in the amount of $6,250.00.

Mallinckrodt Medical takes its obligations for safety and regulatory compliance seriously. We trust the above mentioned corrective actions are satisfactory to the Nuclear Regulatory Commission. Should their be any additional questions, please feel free to contact me at (314) 895-2200.

Sincerely,

Warren K. Fadling

Warren K. Fadling
Director Nuclear Pharmacies
Nuclear Medicine Division
Mallinckrodt Medical, Inc.

Enclosure
WKF/mjc

cc: Peter Vermeeren, Senior Vice President
Jim Carlile, Senior Vice President