Replies to Notices of Violation

November 23rd, 2007

U.S. Nuclear Regulatory Commission Materials License No. 44-30124-01MD

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

Subject: Response to Docket No. 03033449 and Inspection 03033449/2007001, Pharmalogic, Ltd., Williston, Vermont Site and Notice of Violation

To Whom It May Concern:

On October 3rd, 2007 Pharmalogic, Ltd. of Williston, Vermont received a safety visit inspection by Thomas Thompson (hereafter referred to as Mr. Thompson) from the Region I Division of the Nuclear Regulatory Commission. In performing the safety inspection, Mr. Thompson found two instances where Pharmalogic, Ltd. warranted Notices of Violation (dated October 24th, 2007). Each violation will be addressed, with (1) the reasons that led to the notices of violation recounted (copied directly from the Notice of Violation), (2) the corrective steps that have been taken listed and the results achieved, (3) the corrective steps explained that will be taken to avoid further violations, and (4) the date given when full compliance will be achieved (e.g., Notice of Violation A, subpart 1 will be A1).

Notice of Violation A (taken from page 1 of the Notice of Violation letter from the NRC to Pharmalogic, Ltd.):

A1. 10 CFR 20.1501 requires that each licensee make or cause to be made surveys that may be necessary for the licensee to comply with the regulations in Part 20 and that are reasonable under the circumstances to evaluate the extent of radiation levels, concentrations or quantities of radioactive materials, and the potential radiological hazards that could be present.

Pursuant to 10 CFR 20.1003, survey means an evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal, or presence of radioactive material or other sources of radiation.

Contrary to the above, on October 3, 2007, the licensee did not make surveys to assure compliance with 10 CFR 20.1201(a) (2) (ii), which limits shallow-dose to the skin of the whole body or to the skin of the extremities to 50 rems. Specifically, the licensee's Radiation Safety Officer (RSO) failed to monitor his hands before exiting the area controlled for contamination where multiple curies of technetium-99m and multiple millicuries of iodine-131 (I-131) are regularly handled. Further, when the RSO's hands were surveyed by the inspector, an area of radioactive material contamination was identified.

This is a Severity Level IV violation (Supplement IV).

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A2. Further explanation of the event is as follows:

Mr. Thompson, the NRC inspector, had asked the RSO to show that the fan that provides negative air flow for the I-131 glove box where I-131 doses are prepared was functioning properly. Using the test suggested by the previous NRC inspector, Mr. Steve Hammann (hereafter referred to as Mr. Hammann), the RSO took a strip of paper and placed it in front of one of the openings to the glovebox, where both the RSO and Mr. Thompson determined that it was not indicative enough that proper air flow was being achieved. Mr. Thompson then asked the RSO to look at the fan for the glovebox, which required the RSO to lift up the top box unit that contained the fan for the glovebox.

This turn of events was so unexpected to the RSO that without gloves, he lifted the box using the box's handle, where it became apparent that the fan was not functioning (see Notice of Violation B, to follow). Mr. Thompson immediately asked for paperwork regarding the quarterly monitoring of air flow in the iodine room, which includes the I-131 glovebox. Surprised by this turn of events, and anxious to show the inspector that quarterly monitoring had been done within a month's time, the RSO rushed to get the information for Mr. Thompson, and in his haste forgot to monitor himself before heading into the non-restricted area of Pharmalogic, Ltd.'s lab. Upon reaching and touching the file cabinet which contained the Radiation Safety Records, the RSO realized his error on his own, and hastened back to the entry of the restricted area to check himself, where he and Mr. Thompson determined that his thumb was radioactive, most likely from the contact with the handle of the top box unit for the I-131 glovebox. Further inspection showed that the radioactivity had not been spread any further by the RSO.

Corrective action taken:

After Mr. Thompson left Pharmalogic, Ltd., the RSO was able to remove the majority of radioactivity from his thumb using a commercial cleanser, to the point where after using a Geiger-Muller counter, a reading of no more than 0.05 mRem/hr registered when monitoring the RSO's hands. Also, using a Ludlum 2200 scaler ratemeter, an alcohol wipe of both the RSO's hands registered under the action level of double the background count.

A3. Corrective steps taken to avoid further violations:

The RSO refreshed his memory regarding 10 CFR 20.1501, 10 CFR 20.1003, and 10 CFR 20.1201(a)(2)(ii) by rereading these portions of the CFR (Code of Federal Regulations) to emphasize in his mind the importance of following these rules, even under odd circumstances. Following this, the RSO discussed the event with his partner and manager, Mr. Thomas DeFranco (hereafter referred to as Mr. DeFranco), and both agreed that despite odd circumstances, it is important to always remember to perform a survey of oneself when leaving the restricted area of the lab to prevent potential contamination of unrestricted areas (especially any areas outside the lab).

A4. Full compliance was considered achieved by the RSO when he had completed his reading of the above-mentioned passages from the CFR and had discussed the incident with his partner

and manager, Mr. Thomas DeFranco (as stated in A3 above) on October 11th, 2007. The RSO feels confident that he will not repeat this unfortunate event.

Notice of Violation B (taken from page 1 through 2 of the Notice of Violation letter from the NRC to Pharmalogic, Ltd.):

B1. Condition 22 of License No. 44-30124-01MD requires that licensed material be used in accordance with statements, representations and procedures contained in letter dated July 8, 1994.

Page 2, paragraph 2, of the July 8, 1994 letter, states that, at a minimum, the linear air flow in the glove box used for I-131 capsule compounding will be maintained at 50-70 feet per minute with a minimum exhaust flow of 25 cubic foot per minute and that measurements with an anemometer will be taken daily to assure that the minimum air flow is being maintained.

Contrary to the above, on October 3, 2007, the licensee did not maintain air flow in the glove box and did not check for the minimum air flow with an anemometer. Specifically, when asked to demonstrate that adequate air flow existed in the glove box on the day of the inspection, the licensee's RSO used a strip of paper to test the air flow and, following this test, stated that adequate flow existed in the glove box. When the inspector questioned the adequacy of the test method, the fan motor was checked and was found to be not functioning.

This is a Severity Level IV violation (Supplement VI).

B2. Further explanation of the event is as follows:

When asked by the NRC inspector, Mr. Thompson, to provide evidence of air flow into the glovebox, the RSO used the method that was suggested at the last inspection by Mr. Hammann, which was to use a strip of paper to show negative air flow for the glovebox. After using this method, the RSO showed that there was movement of the paper indicating a negative air flow for the glovebox. Mr. Thompson pointed out, however, that the movement of the paper could be caused by the air movements of the iodine room in general, and was therefore not sufficient to the task. Mr. Thompson then asked to see the fan unit used to control air flow for the glovebox. The RSO complied by lifting the top unit containing the fan for the glovebox for inspection, which is when they both discovered that the fan was not functioning. The glovebox was then deemed unusable both by Mr. Thompson and the RSO until the fan was functioning properly again or replaced, and proper air flow was achieved. Customers likely to need I-131 products were notified that until the situation was remedied, no I-131 products would be made at Pharmalogic, Ltd..

Corrective steps were taken to fix or replace the fan while Mr. Thompson continued his inspection, and shortly after he left the fan was replaced completely so that work could continue in the I-131 glovebox. In addition, following a suggestion of Mr. Thompson's, gauges on both the I-131 glovebox top unit and the I-131 fume hood were enabled to show at a glance that constant negative pressure was being exerted by the fans for both units to create constant negative air flow for both units.

B3. Prior to this Notice of Violation, the actions detailed in B2 were thought to be sufficient, as this was the recommendation of the NRC inspector, Mr. Thompson for resolution of the problem on October 3rd, 2007. In light of the information included in this Notice of Violation B, Pharmalogic, Ltd. shall perform a daily measurement with an anemometer to assure that a minimum airflow of 50-70 feet per minute is attained for the glovebox.

B4. Full compliance with the actions described in B3 shall be achieved by November 30th, 2007.

If my manager, Thomas DeFranco, or I can be of more assistance, please contact us at Pharmalogic, Ltd. by phone at 802-862-9944 or by e-mail at pharmalogicltd@yahoo.com.

Sincerely,

Stephen Sopchak, R.Ph., RSO
Pharmalogic, Ltd.
Williston, VT 05495