



UNITED STATES
NUCLEAR REGULATORY COMMISSION
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ALL AGREEMENT STATES, PENNSYLVANIA, VIRGINIA, NEW JERSEY

NRC INSPECTION VALUE ADDED FINDING: RADIOPHARMACY AIR SAMPLING AND COMPUTER PROGRAM PROBLEMS (STP-06- 050)

Purpose: To share with the Agreement States the Nuclear Regulatory Commission's (NRC) inspection findings that could be useful in their respective inspection program.

Background: The NRC Regional Offices routinely share with other NRC offices good practices they have incorporated into their inspection programs. Recently, the Office of State and Tribal Programs (STP) received a copy of such a document from the NRC Region III Office. STP determined that the good practices discussed in the document could be useful to the Agreement States. STP plans to continue to share such information.

Inspector Identifies Radiopharmacy Air Sampling and Computer Program Problems: During a routine inspection of a radiopharmacy licensee, a Region III materials inspector identified inaccurate calculations used by the licensee to determine unrestricted area air concentrations and problems with the licensee's computer program, used to verify client authorization for possession limits prior to delivery.

While reviewing licensee air monitoring records, the inspector noted that some results indicated unusually high weekly iodine-131 unrestricted area air concentrations such that, if those concentrations were sustained during the year, NRC regulatory limits would have been exceeded. Further review of the licensee's air sampling program revealed that the licensee's unrestricted area air sampling system was drawing air at 10-liters per minute. However, the licensee used 1-liter per minute for its air concentration calculations. This resulted in the licensee overestimating its unrestricted area air concentrations by a factor of 10. As a result, the licensee reviewed its past unrestricted air concentration results, documented the incorrect unrestricted air concentration results, corrected the sampling system flow rate value, and re-trained its staff on the issue. No violations of NRC regulatory limits for unrestricted area air concentrations were identified.

The licensee used a computer program to ensure that delivered radiopharmaceuticals were in accordance with licensee authorized limits. The inspector reviewed the licensee's computer program and identified that client-limit authorizations were not always correctly determined, and would allow amounts, in excess of the client's authorized limit, to be shipped. As a result of the inspector's findings, the licensee is reevaluating its software program to ensure that the program fulfills its intended function. No violations of NRC requirements were identified regarding shipments or transfers of radioactive materials.

Because the radiopharmacy relied on its consultant, who had reviewed the safety program for a number of years, it failed to identify both the air concentration and the computer program errors.

These findings illustrate the importance of: (1) verifying licensee assumptions used in calculations to show compliance with NRC regulatory requirements, and (2) verifying that licensee computer programs used to ensure compliance with NRC regulatory requirements operate as intended.

For additional information, please contact Michael LaFranzo at 630-829-9865.

If you have any questions on this correspondence, please contact me or the individual named below.

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