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School of Medicine

Division of Radiation Safety

September 27, 1996

Cynthia D. Pederson
Director
Division of Nuclear Material Safety
US Nuclear Regulatory Commission
Region III
Lisle, Illinois

Dear Ms. Pederson:

This letter is in response to your letter dated August 29, 1996 in which you provided the final report of an inspection of licensed activities at our institution conducted by Mr. Thomas Young and colleagues earlier this year. As you indicated in the letter we have already made corrective actions and I believe we are in compliance with the rules and regulations of the Commission and the US Department of Transportation that were cited in your letter.

In addition, you expressed a concern about the potential airborne activity releases associated with the preparation and use of a substantial amount of 131-I sodium iodide in the radiopharmacy of our nuclear medicine service. The reply to your concern is as follows:

First, I am confident that the routine use of the ^{131}I-NaI generates low levels of airborne activity. The current usage results in approximately 3.0 curies of 131I-NaI per year being prepared in the radiopharmacy fumehood whose exhaust is handled by a dedicated ventilation system that also maintains two imaging rooms designed for xenon-133 use at negative pressure. The final release site is an elevated stack located on the rooftop of the seventeen story West Pavilion of Barnes-Jewish Hospital. Although 3.0 curies is a large quantity of 131-I, the sodium iodide is typically received in vials of 50 mCi each in solution with a pH of 8 to 9. Since suppliers of 131-I NaI oral solution reformulated their preparations in 1979 by changing the pH and adding buffers, antioxidants and stabilizers, the volatile components (I_2 and HI) have been significantly reduced. We have performed a variety of measurements over the past 16 years to determine the fraction of the activity that is released from radioactive sodium iodide solutions used for variety of operations, e.g., dilution for oral therapy administration, radioiodination using a variety of labeling techniques, etc. In the case of the preparation for oral administration, the manipulation of the stock solution is the simplest -- withdrawal of the needed activity (typically 5 to 15 mCi) for the administration and dilution of the activity with sterile deionized water in the radiopharmacy fumehood. The

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airborne activity that escapes is small. In a related use, we have conducted airborne activity measurements for years in several different locations during administrations of oral 131I-131 for radiopharmaceutical therapy that require hospital confinement of the patient. The average activity trapped by an air sampler with a charcoal cartridge and located immediately adjacent ($\sim$1 foot) to the prepared dosage is approximately $2X10^{-5}$ µCi per mCi-min for sampling times of 4 to 15 minutes while the dosage is being administered. This represents a very small fraction of volatile activity from an open vial of a 131-I that is presented to the patient and administered with several rinsing steps.

An airborne activity sampler with a charcoal trap has been installed in the radiopharmacy fumehood immediately above ($\sim$3') the location used to prepare the unit dosages of 131-I sodium iodide. The results verify the expectation. The results for the past week yields a calculated 131-I decay-corrected airborne activity concentration of less than $1X10^{-12}$ µCi/ml during which a representative 58 mCi of unit 131-I dosages were prepared (58 mCi/wk X 52 wks/y $\approx$ 3.0 curies per year). The computed 131-I concentration inside the fumehood represents less than 0.5% of the Commission's limit for an effluent of 131-I. The reason for this lengthy discussion is to assure you that our routine preparation of 131-I dosages of sodium iodide solution yield acceptably low effluent concentrations. However, to satisfy your concern we have taken two actions. A radioiodine fumehood has been acquired and will be installed in the radiopharmacy fumehood for the preparation of the 131-I dosages and their storage. The fumehood is equipped with two charcoal filters in series and a fan that maintains negative pressure within the "mini" hood. It will be placed behind an L-shield for worker protection and the exhaust is handled by the dedicated ventilation system that serves the radiopharmacy fumehood and the 133Xe rooms. It will guard against any substantial 131-I release in case of an accident while preparing the unit dosages and will reduce the effluent concentration. The "mini" fumehood will be in service within 60 days. In addition, the dedicated airborne activity sampler will remain in the radiopharmacy fumehood. We only ask for one relief. If the average 131-I airborne activity in the fumehood at the site of the sampler is less than 1% of the 10CFR Part 20 limit for 131I ($2X10^{-10}$ µCi/ml) after 10 weeks of weekly determinations we will change from continuous air monitoring to a one week sampling period per calendar quarter as long as the average concentration is below the 1% value. In the event that the 131-I concentration exceeds 1% of the effluent limit we will revert to continuous sampling until the problem is identified and corrected and the subsequent weekly average is below 1%. Records of the airborne sampling will be maintained for review by Commission inspectors.

I trust that these modifications will satisfy your concerns about 131-I gaseous releases from the nuclear medicine radiopharmacy.

In closing, I would like to acknowledge the professionalism of Mr. Young. He is both very capable and thorough in his reviews, and we find him to be courteous and helpful. We have benefited from the inspections that he has conducted at our institution.

Sincerely,

John Eichling

John Eichling, Ph.D.

JE:fi

cc: Walter Davis, Jr.
Carlos Perez, M.D.
Barry Siegel, M.D.