

DCP/DCB

United States Nuclear Regulatory Commission  
Region III  
799 Roosevelt Road  
Glen Ellyn, Illinois 60137

*License File*  
*34-18309-01MD*

September 12, 1990

Gentlemen:

In response to the Notice of Violation that resulted from the inspection conducted at this facility by your office on July 18, 1990:

1. "... surveys were not made to assure compliance with the part of 10 CFR 20.101 that limits the radiation exposure to the extremity. Specifically, on July 18, 1990, a student pharmacist did not wear an extremity radiation monitor during elution of generators and during compounding of radiopharmaceuticals."

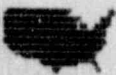
The student pharmacist in question was made to demonstrate thorough knowledge of regulatory requirements regarding limiting radiation exposure to extremities.

As a part of their training program, all student pharmacists will be required to demonstrate thorough knowledge of regulatory requirements regarding limiting radiation exposure to extremities. This will be effective as of October 1, 1990.

2. "Specifically, during the week of May 8, 1990, an individual who compounded I-131 capsules failed to perform a bioassay and during the week of May 28, 1990, at least one individual who compounded I-131 capsules failed to perform a bioassay. In addition, of the bioassays performed, one count is usually taken over the thyroid rather than the required three counts."

The individual in question has been reminded of the requirement to do a weekly bioassay for anyone who compounds I-131 capsules. All personnel have been reminded of the requirement to take three counts along the vertical midline of the neck when doing a bioassay.

All individuals who compound I-131 capsules shall be required to perform a weekly bioassay. If an individual does not compound I-131 capsules within a given week and does not perform a bioassay during that week, it shall be noted on that individuals bioassay record for that week that no I-131 capsules were compounded by that individual.

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All individuals who perform bioassays will take 3 readings along the vertical midline of the neck. The highest count of the three shall be recorded as the count for that bioassay. These will be effective as of October 1, 1990.

3. "... shipping papers have not been properly stored in vehicles while transporting radiopharmaceuticals (hazardous material). Specifically, a driver informed the NRC inspector that shipping papers are routinely stored in the shirt pocket or in the sun visor of the vehicle."

All drivers have been inserviced on the D.O.T. and NRC regulations governing the storage of shipping papers while transporting radiopharmaceuticals (hazardous material). All drivers are aware of the exact location for storage of shipping papers while transporting radiopharmaceuticals.

All individuals who transport radiopharmaceuticals shall be required to demonstrate knowledge of proper storage of shipping papers during such transport. This shall be effective as of October 1, 1990.

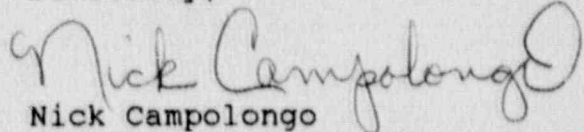
With regard to the items of concern:

1. efficiency of counting system for bioassay - The efficiency of the counting system is within regulatory limits. Upon investigation, it was learned that the value in question (45477cpm), was the result of a data entry error.
2. control at point of release of I-131 fumes - All required controls for handling and storage of liquid I-131 solution are in place and functioning well. While there were 3 dates this year in which MPC's were exceeded, this in itself does not mean that proper controls are absent. The concern regarding the 3 dates in question is well founded and noted. All personnel who handle I-131 solution shall be reminded of the necessity for careful handling of this product.
3. radiation monitor set on x100 scale - It was explained to the inspectors that this setting was used because this particular room monitor is located in the package receipt area. A lower setting results in the alarm being set off each time a generator is received. All personnel are aware of this and are instructed to note the change in the number of "clicks" when monitoring themselves prior to exiting the building. At the time of inspection, the inspectors indicated that they were satisfied with this explanation.
4. key to the waste room was found in the door - The key to the waste room is typically left in the door during the day. No outside personnel have access to our restricted area during working hours. The door to the waste room is locked each night before leaving and the key is stored in a secure place. This assures that after-hours delivery personnel do not have access

to any part of the restricted area, including the waste room.

During the inspection, one of the inspectors requested a copy of the procedure used to calibrate the flowmeters used on the I-131 glove box. These instructions and procedures will be sent under separate cover.

Sincerely,



Nick Campolongo  
Radiation Safety Officer  
Syncor International Corporation  
5225 Creek Road  
Cincinnati, Ohio 45242

cc: Richard Keesee  
Frank Comer