March 1, 1971

Mr. Frank A. Schottelkorb
General Manager
Diagnostic Products Division
Mallinckrodt Nuclear
Box 10172, Lambert Field
St. Louis, Missouri 63145

Dear Mr. Schottelkorb:

This refers to your letters of January 21 and February 15, 1971, concerning pharmaceutical quality, control of iodine release in air effluents, and storage of waste radioactive material.

We are still not certain how your program for Quality Control will be administered from the way it is described in your most recent letter on pharmaceutical quality as well as your letter of November 13, 1970, on the same subject. If a product is not within specifications for pharmaceutical quality at the Maryland Heights, Missouri, Carlstadt, New Jersey, and Glendate, California facilities, the Manager of Quality Control, who is Mr. Raymond L. Coslet, or a designated representative on his staff will be notified. The Manager of Quality Control will then immediately report to the Director of Radiopharmaceutical Operations, who we assume is responsible for the programs at all three production facilities, or his designated representative. The Director of Radiopharmaceutical Operations is responsible for decisions about disposition of such materials, subject to appeal by the Manager of Quality Control to the General Manager, Diagnostic Products Division. "Designated representatives" and their method of operation are the subjects about which we would like further explanation. If both the Manager of Quality Control and the Director of Radiopharmaceutical Operations delegate their authority for decision making to their representatives in the three individual production facilities, it would not appear that administrative control is significantly improved over the situation which led to the incident last September when technetium generators were shipped after Quality Control detected serious molybdenum breakthrough. As a minimum, we believe it is essential that delegations of authority, for the purposes under discussion, can be made only to a staff level having overall responsibility for all three production operations and reporting directly to the General Manager without intermediate supervisors. We would like further clarification on this matter.

Your statement about not shipping generators which exceed regulatory limits for aluminum and molybdenum breakthrough seems unequivocal; however, your letter does not provide similar assurances for all other appropriate standards of radiopharmaceutical quality applicable to your radiopharmaceutical products

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whether they are specific regulatory requirements or those identified in recognized publications such as the U. S. Pharmacopoeia. We need similar assurances.

Your plans to improve air effluent control to the extent that you anticipate a reduction factor of 15 over the total quantity of iodine released in air effluents in 1970 are appreciated. The objective, of course, is to maintain radioactive materials released in air effluents as low as practicable. On this point, you listed four "criteria" in your letter of February 15, 1971, which will be used to determine the extent of treatment in any specific air effluent system. It is our view that the four points listed are not criteria but rather are factors which are taken into account in deciding what controls might be appropriate. We would like to have the criteria which will be applied in consideration of each of these points as well as your final criteria or design objective concerning release of iodine in any specific system.

The cows which you located 2500 feet from your facility are not used for dairy purposes. It might be necessary to search further to locate the nearest cattle used for dairy purposes. This will be considered further in light of our Independent Measurements Program when the grazing season resumes.

At least portions of your plans for improving your air effluent system and reducing levels of radiation in unrestricted areas are subject to approval of your Board of Directors, engineering, and installation. Please let us know when these steps have been completed.

Sincerely,

Original signed by
Richard E. Cunningham

Richard E. Cunningham
Assistant Director for
Plans and Technical Programs
Division of Materials Licensing

bcc: St. Br. Dist.
DML
CO, Hqs

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