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Serono

SERONO LABORATORIES, INC.
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KØ

June 22, 1987

U.S. Nuclear Regulatory Commission
Region I
Nuclear Material Section B
631 Park Avenue
King of Prussia, PA 19406
Attn: Dr. Piccone

Dear Dr. Piccone:

In response to our conversation on June 11, 1987, please be advised of the following comments pertaining to points made in reference to Serono Laboratories New Application for License Approval (Mail Control #107287).

I. To clarify the statements made in the section titled - Supplement to Item 5, Radioactive Material, please refer to page 4 of Serono Laboratories Application for License Approval and note the following:

A. Element and Mass No.	B. Chem and/or Physical Form	C. Maximum Amt Which will be possessed at any one time
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1. 125-Iodine	any	500 millicuries
2. 129-Iodine	sealed source	0.1 millicuries

II. To clarify the statement made in the section titled - Supplement to Item 6 - Purpose(s) for Which Licensed Material Will Be Used, please refer to page 4 of Serono Laboratories Application for License Approval and note the following:

1. For research, development, laboratory analysis and storage of licensed material pursuant to the items and conditions of the license issued by the NRC. Serono Laboratories, Inc. will not perform radioiodinations nor will radioactive materials be used for purposes of animal research of any kind.

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U.S Nuclear Regulatory Commission

Attn: Dr. Piccone

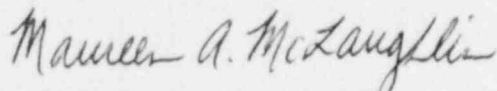
2. Iodine-129 will be used as a Gamma counter check source. It will be possessed in the form of a 'sealed source' and the stated possession limit of 0.1 millicuries represents the total activity of all sealed sources possessed by Serono Laboratories, Inc., at any one time.
- III. Any future procedural changes related to Serono Laboratories Application for License Approval will be provided to the NRC as amendments to the license.
- IV. As per your request the steps in SOP #03-006 pertaining to external monitoring of packages containing radioactive materials (surface monitoring and monitoring at a distance of one meter), have been revised. Please be advised of the corrected procedure, "Incoming Inspection of Radioactive Materials", that is attached.
- V. Serono Laboratories, Inc., understands that any or all of the following will require the submittal of an amendment to our byproduct material license:
- ° The use of an alternate organization to furnish and calibrate radiation detection instruments.
 - ° The use of an alternate radioactive waste disposal firm.
 - ° Major procedural revisions to the Radiation Safety Program.

Serono fully intends to comply with the wishes of the NRC in all matters pertaining to the above and will submit these documents to the NRC in a timely fashion as a means of keeping our file current.

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VI. We also understand that Serono Diagnostics, an affiliate company, is not a licensed radioactive waste broker and will therefore not be utilized by Serono Laboratories, Inc., for the purpose of waste storage and/or disposal. Serono Laboratories, Inc., will instead transfer all radioactive waste directly to a fully licensed waste disposal firm in accordance with applicable regulations.

Sincerely,

A handwritten signature in cursive script that reads "Maureen A. McLaughlin".

Maureen A. McLaughlin
Q.A. Supervisor/RSO

/flb