

U. S. NUCLEAR REGULATORY COMMISSION  
REGION I

Report No. 030-10043/90-001

Docket No. 030-10043

License No. 20-15930-01 Priority 6 Category E Program Code 3214

Licensee: Serono Diagnostics, Inc.  
100 Longwater Circle  
Norwell, Massachusetts 02061

Facility Name: Serono Diagnostics, Inc.

Inspection At: 100 Longwater Circle  
Norwell, Massachusetts

Inspection Conducted: May 24, 1990

Inspectors: Mark C. Roberts 8-7-90  
Mark C. Roberts, Health Physicist date

Elizabeth Ullrich 8/7/90  
Elizabeth Ullrich, Health Physicist date

Approved by: John D. Kinneman 8/7/90  
John D. Kinneman, Chief date  
Nuclear Materials Safety Section B

Inspection Summary: Closeout inspection on May 24, 1990 (Inspection  
No. 030-10043/90-001

Areas Inspected: Announced, closeout inspection limited to survey of facility for residual contamination prior to termination of license and release of facility for unrestricted use. Twenty-eight wipes were taken and assayed for removable I-125 and H-3 activity. The facility was surveyed to identify fixed radioactive contamination and licensed materials remaining.

Results: No violations were identified. No removable radioactive contamination was found. One test kit with a vial containing a small amount of I-125 was discovered in the refrigerator in the QC laboratory. A second kit containing a decayed I-125 source was also found in the same refrigerator. The Radiation Safety Officer removed both kits for proper disposal. No other remaining radioactive material was found. With this exception, the licensee's survey enclosed with their letter dated February 27, 1990, accurately reflects the condition of the facility.

## DETAILS

### 1. Persons Contacted

\*Paul Lovett, Jr., Quality Assurance Manager, RSO

### 2. Background

Serono Diagnostics Incorporated manufactured, packaged and distributed radioimmunoassay (RIA) Kits containing iodine-125 (I-125) and also performed research for new kits utilizing I-125 and tritium (H-3). The licensee no longer performs activities with radioactive material at this facility and submitted a final survey of the areas of the facility where licensed radioactive materials were used, and a request that the license be terminated.

Documents provided by the licensee indicate that the only unsealed sources of licensed material used at the facility were I-125 and a very small amount (1.5 microcuries (uCi)) of H-3. Licensed material was last used in February, 1989. Laboratory surveys performed by the licensee did not indicate any fixed or removable I-125 activity in any of the areas where licensed material had been used.

Documents included in the licensee's termination request indicate that all licensed material was shipped out on February 21, 1989. A radioactive waste shipment and disposal manifest for the licensed material was enclosed with the termination request.

### 3. Instruments Used in Surveys

Confirmatory measurements were made by the inspectors in the iodination laboratory, RIA Kit Assembly laboratory, QC laboratory and Warehouse. Radiation level surveys were performed with a Ludlum Model 16 Analyzer and thin Sodium Iodide Probe (NRC No. 19618). Background radiation level measured with this instrument was 30 counts per minute (cpm). Analysis of wipe samples performed using a Tennelec Gas-Flow Proportional Counter. The minimum detectable activity (MDA) for H-3 is 29 disintegration per minute (dpm) and the MDA for I-125 is 12 dpm.

### 4. Results of Confirmatory Surveys

Other than the one exception described in Section 5, no radiation levels in excess of 30 cpm were measured. Measurements were made in all areas where licensed material had been utilized.

Wipe samples were performed with filter paper disks in the iodination laboratory, the RIA Kit Assembly Laboratory, the QC laboratory and Warehouse. Each wipe was made over approximately 100 cm<sup>2</sup>. Specific locations of samples and the results obtained are listed in Appendix A.

No removable contamination exceeding the MDA for either H-3 or I-125 was measured.

No violations were identified.

5. Residual Materials

During the visual inspection of the walk-in refrigerator in the QC laboratory, two kits with radioactive markings were discovered on one of the shelves. Both kits were identified as containing I-125. Direct radiation measurements on one kit indicated approximately 500 net cpm. No indications above background were observed on the second kit. The Radiation Safety Officer removed both kits for proper disposal and/or defacement of radioactive markings. No other licensed material was found in any of the areas inspected. The Radiation Safety Officer instructed laboratory personnel to immediately notify him if any further licensed radioactive material was found.

No violations were identified.

6. Exit Interview

The results of the survey were discussed with the individual indicated in Section 1 of this report. The inspectors indicated, other than the one RIA Kit that was found, there were no other radiation levels in excess of background. The RSO stated that he would transport the RIA Kit to Serono's nearby Randolph, Massachusetts facility for proper disposal. The wipe samples taken by the inspectors were to be counted in the NRC regional office laboratory.



Appendix A

Results of Wipe Samples Taken at

Serono Diagnostics, Inc. on May 24, 1990

Location

1. Blank
2. Iodination Laboratory - Doorway
3. Iodination Laboratory - Floor in front of hood
4. Iodination Laboratory - Hood
5. Iodination Laboratory - Hood
6. Iodination Laboratory - Sink
7. Iodination Laboratory - Sink
8. Iodination Laboratory - Floor in front of hood
9. Iodination Laboratory - Drum Storage Bin
10. Iodination Laboratory - Drum Storage Bin
11. Iodination Laboratory - Left Benchtop
12. Iodination Laboratory - Right Benchtop
13. Iodination Laboratory - Floor, Center of Laboratory
14. Iodination Laboratory - Hood Exhaust Duct
15. RIA Kit Assembly Laboratory - sink 1
16. RIA Kit Assembly Laboratory - sink 2
17. RIA Kit Assembly Laboratory - floor, center
18. RIA Kit Assembly Area - Bench top
19. RIA Kit Assembly Area - Doorway
20. QC Laboratory - Floor in front of refrigerator
21. QC Laboratory - sink
22. QC Laboratory - Bench top
23. QC Laboratory - Floor, left
24. QC Laboratory - Floor, right
25. QC Laboratory - Refrigerator floor
26. Warehouse - Doorway
27. Warehouse - Floor, left
28. Warehouse - Floor, right

Results are reported in units of net DPM per 100 cm<sup>2</sup>. All results are less than the MDA for H-3 (29 dpm) and I-125 (12 dpm).