U. S. NUCLEAR REGULATORY COMMISSION
OFFICE OF INSPECTION AND ENFORCEMENT
REGION IV

REPORT OF INSPECTION

IE Inspection Report 81-01 License No. 43-14991-01

Priority: IV Category: E

Licensee: Becton Dickinson Immunodiagnostics
Automated Immunochemistry Systems
180 West 2950 South
Salt Lake City, UT 84115

Period of Inspection: March 25-26, 1981

Inspector: C. L. Everett Jr. 5/12/81
C. L. Cain, Radiation Specialist Date

Reviewed by: C. L. Everett 5/12/81
R. J. Everett, Chief, Materials Radiation Protection Section Date

Glen D. Brown, Chief, Technical Inspection Branch Date

Inspection Summary

Inspection on March 25-26, 1981 (Report No. 81-01)

Areas Inspected: Radiation protection program including organization, training, and reports; materials, facilities, and instruments; external exposure and contamination control; surveillance for airborne contamination; bioassay; effluent control and waste disposal; and material receipt and transport.

Results: Eight apparent violations were identified:

1. Failure to conduct licensed activities in accordance with application referenced in License Condition 15. (Section 5).

2. Failure to perform exposure determinations in regard to airborne radioiodine in accordance with 10 CFR 20.103(a)(1). (Section 5).

3. Failure to evaluate 40-hour control measure in accordance with 10 CFR 20.103(b)(2). (Section 5).

4. Failure to maintain records of surveys of airborne concentrations of radioiodine in accordance with 10 CFR 20.401(c)(2). (Section 5).

5. Transfer of material to recipient in excess of recipient's possession limits contrary to 10 CFR 30.41. (Section 8).

6. Failure to transport material in compliance with 49 CFR Parts 170-189. (Section 8).

7. Failure to post airborne radioactivity areas in accordance with 10 CFR 20.203(d)(2). (Section 5).

8. Failure to post a radioactive materials area in accordance with 10 CFR 20.203(e)(1). (Section 3).

DETAILS

1. Persons Contacted

Becton Dickinson

*Dr. LaVell R. Johnson, Vice President and Director of Research
*Dr. Richard H. Hales, Radiation Protection Officer
*Alan D. Croft, Radiation Safety Physicist
Robert Sutherland, Traffic Coordinator

Utah Bureau of Radiation and Occupational Health

T. Richard Downard

*Present at exit briefing.

2. Organization, Training, and Reports

The licensee's organization structure was found to be as described in the application. The inspector reviewed documented minutes of the Radiation Safety Committee Meetings. The inspector noted that Alan Croft had been recently hired to support the Radiation Safety Program. The inspector also reviewed radiation control monthly reports which summarized survey data. The licensee described the training program, and the inspector reviewed statements signed by workers stating that they had received training. Discussions with and observations of workers substantiated their knowledge of radiation safety work practices. The licensee presented various documented procedures relating to the Radiation Safety Program.

The inspector reviewed licensee reports to workers and personnel monitoring reports. The licensee stated that there had been no material thefts or losses and no overexposures to workers that would require reporting.

3. Materials, Facilities, and Instruments

The inspector reviewed monthly radioactive material inventory reports and ascertained that the material possessed by the licensee had apparently always been less than the license limits. The inspector observed postings as required by 10 CFR 19.11 but noted that laboratory areas containing licensed material were not posted as Radioactive Material Areas. The inspector explained to the licensee that failure to so post was in violation of 10 CFR 20.203(e)(1). The inspector reviewed instrument calibration records and inspected available instrumentation for proper operability. The inspector performed spot surveys of laboratory areas including floors, clean trash, waste storage areas, and shipping/receiving areas using an Eberline "Rascal" with a Model HP-210 detector. No contamination was detected.

4. External Exposure and Contamination Control

Licensee survey records indicated that radiation levels were low in both restricted and unrestricted areas. Personal dosimeters supplied by Eberline were exchanged monthly. Dosimeter data indicated external exposure to be very low.

The inspector reviewed weekly contamination survey records and daily lab coat survey records. Contamination levels were often indicated to be in excess of the action limit of 0.01 microcurie per 100 square centimeters as indicated in the Radiological Control Manual, page 7a.

5. Surveillance for Airborne Contamination

The inspector reviewed data relating to air sampling for iodine-125 in the production iodination room, the research and development (R&D) iodination room, and other laboratory and non-laboratory areas. Reports for the latter areas often stated that sampling was not performed due to lack of time or equipment. Sampling was not performed in laboratory and non-laboratory areas during November and December 1979 and during February, May, June, and August 1980. The inspector reminded the licensee that a commitment to perform such monthly sampling was included in the Radiological Control Manual, Sections II.B.4 and 5, which was incorporated in the license application. The inspector further stated that failure to perform such sampling was in violation of License Condition 15 which incorporates the license application by means of reference.

The inspector noted that data for the iodination rooms prior to September 1980 were reported in terms of instrument response, such as counts per minute, rather than in units which could be correlated to limits in Appendix B of 10 CFR 20. The inspector stated to the licensee that failure to maintain records of meaningful survey data was a violation of 10 CFR 20.401(c)(2).

Recent data for the iodination rooms were documented in units of microcuries per milliliter of sampled air and thus were readily comparable with Appendix B limits. The inspector determined that these air samples frequently indicated levels in excess of Appendix B, Table I, limits; however, none of the areas had ever been posted as airborne radioactivity areas. The inspector informed the licensee that failure to post the areas was a violation of 10 CFR 20.203(d)(2).

The licensee was questioned in regard to exposure calculations for workers exposed to high airborne concentrations of iodine-125. The licensee stated that such determinations had not been made. The inspector responded that failure to perform such evaluations was a violation of 10 CFR 20.201(b). The inspector performed several exposure calculations and found two instances in which the 40-hour control measure was exceeded. These are summarized as follows:

Case 1

Two individuals worked in the production iodination room for an unknown period while an air sample was being taken on January 13, 1981. The sample which was taken over a 6-hour period indicated an activity equivalent to 15 times the maximum permissible concentration (MPC) referenced in Appendix B, Table I. The indicated exposure was 90 MPC-hours.

Case 2

One individual worked in the production iodination room on both November 7 and November 10, 1980.

Date	MPC Multiple	Sample Time (hours)	MPC-hours
11/7/80	17.6	2.0	35.2
11/10/80	31.2	1.2	37.4
		Total Exposure	72.6

The licensee was unable to substantiate the periods during which the room was occupied. The inspector stated to the licensee that failure to maintain records of such occurrences was a violation of 10 CFR 20.103(b)(2). The inspector determined that the licensee had made attempts at engineering and process controls satisfying the intent of 10 CFR 20.103(b)(1).

6. Bioassay

The inspector reviewed data relating to thyroid scans for individuals engaged in work with radioiodine. The scans often indicated intakes in excess of 20% of the weekly limit (40 MPC-hours). The licensee stated that serum thyroxine tests had been performed on those who exceeded the limit; however, the tests had never confirmed any case of radioiodine-induced hypothyrodism.

The inspector also reviewed urine bioassay data for tritium and noted that samples were not always obtained monthly as committed to by the licensee in Section II.C.1 of the Radiological Control Manual. Sampling had not been performed during September and December 1979 and during February, June, August, October, and November 1980. The inspector stated to the licensee that failure to perform the sampling monthly was a violation of License Condition 15.

7. Effluent Control and Waste Disposal

The inspector reviewed iodine-125 stack sampling data. Although several occasions were noted where concentrations were in excess

of the MPC (Appendix B, Table II, of 10 CFR 20), data indicated annual releases well below regulatory limits. Also releases of radioiodine and tritium to the sanitary sewer system were found to be within regulatory limits. The inspector reviewed records of waste shipments to burial sites.

8. Material Receipt and Transport

The licensee presented records of material receipt and survey which the inspector determined met regulatory requirements. The inspector also reviewed records of product shipments to customers holding specific licenses. (The licensee was not inspected with regard to his other licenses which authorize material shipments to customers holding general licenses and to customers exempt from licensing.) The licensee was found to have secured copies of recipients' licenses; however, one case was found where the licensee shipped material in excess of the recipient's licensed possession limits. Shipments to Dianetics Medical Laboratory, Syosset, New York, are summarized below:

	Iodine-125 (mCi)	Hydrogen-3 (mCi)
Recipient's possession limits	0.20	1.00
Shipment to recipient on 1/20/81	0.95	2.28
Shipment to recipient on 2/17/81	0.95	3.00
Shipment to recipient on 3/17/81	0.66	0.42

The inspector stated to the licensee that such transfers were in violation of 10 CFR 30.41.

The inspector reviewed licensee activities relating to transportation of licensed material in compliance with 49 CFR 170-189. Licensee records indicated that such activities included transport of products to recipients holding a specific license and transport of wastes to burial sites in Nevada and Washington. The following violations were disclosed during the review:

1. The licensee shipped 1.92 millicuries of tritium in organic chemical form as a limited quantity shipment. This shipment on February 17, 1981, was in excess of the one millicurie limit for Transport Group IV material shipped as a limited quantity. The inspector cited this shipment as in violation of 49 CFR 173.391(a).

2. The licensee was found to be shipping Type A quantities in cartons which were properly marked and labeled but for which there were no certifications and supporting safety analyses demonstrating that the construction methods, packaging design, and materials of construction were in compliance with Specification 7A criteria.

The inspector explained to the licensee that such records must be maintained for one year after each shipment and that failure to do so, as in this case, was a violation of 49 CFR 173.395(a)(1).

Cartons used by the licensee were found to be marked both "Type A" and "Limited Quality" so as to assure proper marking regardless of the activity of the product shipped. The inspector discussed with the licensee that although such dual marking was not prohibited by the regulations, the inappropriate legend on each carton should be marked out in order to eliminate apparent contradiction.

The inspector reviewed all other aspects of product and waste transportation and found no further violations.

9. Exit Interview

The inspector met with the individuals indicated in Paragraph 1 at the conclusion of the inspection on March 26, 1981, and summarized the findings.