

APPENDIX A

NOTICE OF VIOLATION

Becton Dickinson Immunodiagnostics

Docket No. 30-8377  
License No. 43-14991-01

As a result of the inspection conducted March 25-26, 1981, and in accordance with the Interim Enforcement Policy, 45 FR 66754 (October 7, 1980), the following violations were identified:

1. License Condition 15 requires, in part, that licensed activities be conducted in accordance with statements, representations, and procedures contained in the letter with attachments dated April 14, 1977.

- a. Sections II.B.4 and 5 of the Radiological Control Manual attached to the letter state that air sampling for iodine-125 will be performed monthly in laboratory and non-laboratory areas.

Contrary to this requirement, such sampling was not performed during November and December 1979 and during February, May, June, and August 1980.

- b. Section II.C.1 of the Radiological Control Manual states that urine samples will be obtained monthly from all laboratory personnel handling hydrogen-3 compounds and the samples will be measured for hydrogen-3 content.

Contrary to this requirement, such sampling was not performed during September and December 1979 and during February, June, August, October, and November 1980.

This is a Severity Level IV violation (Supplement VII.D.2).

2. 10 CFR 20.201(b) requires that the licensee make or cause to be made such surveys as may be necessary for him to comply with the regulations in 10 CFR 20.

Contrary to this requirement, adequate surveys had not been made since January 1979 in regard to 10 CFR 20.103(a)(1) which requires that no licensee shall use licensed material in such a manner as to permit any individual in a restricted area to inhale a quantity of such material in excess of the intake limits specified in Appendix B, Table I, Column 1 of 10 CFR 20.

This is a Severity Level IV violation (Supplement VII.D.1).

3. 10 CFR 20.103(b)(2) requires, in part, that whenever the intake of radioactive material by an individual exceeds the 40-hour control measure, the licensee shall make such evaluations and take such actions as are necessary to assure against recurrence. The licensee shall maintain records of such occurrences, evaluations, and actions taken in a clear and readily identifiable form suitable for summary review and evaluation.

Contrary to this requirement, such records were not maintained for two individuals exposed on January 13, 1981, to 90 times the product of the maximum permissible concentration (MPC) of iodine-125 and the exposure time in hours, that is, 90 MPC-hours. Also records were not maintained for a 73 MPC-hour exposure to a single individual on November 7 and 10, 1980.

This is a Severity Level VI violation (Supplement VII.F).

4. 10 CFR 20.401(c)(2) requires, in part, that records of the results of surveys to determine compliance with 10 CFR 20.103(a) shall be maintained until the Commission authorizes their disposition.

Contrary to this requirement, records of the results of air sampling during iodination procedures were not maintained between January 1979 and September 1980.

This is a Severity Level VI violation (Supplement VII.F).

5. 10 CFR 30.41 requires, in part, that no licensee shall transfer byproduct material to any person who is not authorized to receive such material under terms of a specific license or a general license or their equivalents issued by the Commission or an Agreement State.

Contrary to this requirement, quantities of hydrogen-3 and iodine-125 were shipped to a New York state licensee in excess of the licensee's possession limits as indicated below:

	<u>I-125 (mCi)</u>	<u>H-3 (mCi)</u>
Recipient's possession limits	0.20	1.00
Shipment on January 20, 1981	0.95	2.28
Shipment on February 17, 1981	0.95	3.00
Shipment on March 17, 1981	0.66	0.42

This is a Severity Level IV violation (Supplement VII.D.1).

6. 10 CFR 71.5(a) requires, in part, that no licensee shall transport any licensed material outside of the confines of his plant or other place of use, or deliver any licensed material to a carrier for transport unless the licensee complies with the applicable requirements of the regulations appropriate to the mode of transport of the Department of Transportation in 49 CFR Parts 170-189.

- (a) 49 CFR 173.391(a) requires, in part, that limited quantities of radioactive materials in normal form not exceeding 1 millicurie of Transport Group IV radionuclides are excepted from the provisions of 49 CFR 173.393, if certain conditions are met.

Contrary to this requirement, 1.92 millicuries of tritium, a Group IV radionuclide, was transported as a limited quantity on February 17, 1981.

- (b) 49 CFR 173.395(a)(1) requires, in part, that each shipper of Specification 7A (49 CFR 178.350) Type A general packaging must maintain on file for at least one year after the latest shipment a complete certification and supporting safety analysis demonstrating that the construction methods, packaging design, and materials of construction are in compliance with the specification.

Contrary to this requirement, such records were not maintained for packaging used for Type A quantity shipments made during the period one year prior to March 26, 1981.

This is a Severity Level IV violation (Supplement V.D.1).

7. 10 CFR 20.203(d)(2) requires that each airborne radioactivity area shall be conspicuously posted with a sign or signs bearing the radiation caution symbol and the words:

CAUTION (or DANGER)  
AIRBORNE RADIOACTIVITY AREA

Contrary to this requirement, iodination rooms known to be airborne radioactivity areas were not so posted on March 25-26, 1981.

This is a Severity Level VI violation (Supplement VII.F).

8. 10 CFR 20.203(e)(1) requires that each area or room in which licensed material is used or stored and which contains any radioactive material in an amount exceeding 10 times the quantity of such material specified in Appendix C of Part 20 shall be conspicuously posted with a sign or signs bearing the radiation caution symbol and the words:

CAUTION (or DANGER)  
RADIOACTIVE MATERIAL(s)

Contrary to this requirement, a room in which such quantities of licensed materials were stored was not posted at the time of the inspection.

This is a Severity Level VI violation (Supplement VII.F).

Pursuant to the provisions of 10 CFR 2.201, Becton Dickinson Immunodiagnostics is hereby required to submit to this office within 25 days of the date of this Notice, a written statement or explanation in reply, including: (1) the corrective steps which have been taken and the results achieved; (2) the corrective steps which will be taken to avoid further violations; and (3) the date when full compliance will be achieved. Under the authority of Section 182 of the Atomic Energy Act of 1954, as amended, this response shall be submitted under oath or affirmation.

Dated 5/13/81

H. G. Switt for  
Glen D. Brown, Chief  
Technical Inspection Branch

APPENDIX B

SUMMARY OF ENFORCEMENT CONFERENCE  
BETWEEN REGION IV AND BECTON DICKINSON IMMUNODIAGNOSTICS  
ON APRIL 28, 1981

On April 28, 1981, representatives of Becton Dickinson Immunodiagnostics and Region IV met at the Region IV office, Arlington, Texas, to discuss the results of the March 25-26, 1981, inspection.

The violations observed during the March 25-26, 1981, inspection were presented and discussed. The NRC representatives expressed their concern regarding the number of violations identified during the inspection that indicate weaknesses in the licensee's management control system.

The licensee's representatives described steps taken since the inspection to correct the subject violations.

Enforcement options available to the Commission were reviewed.

APPENDIX C

ATTENDANCE LIST FOR APRIL 28, 1981, ENFORCEMENT CONFERENCE  
BETWEEN NRC AND BECTON DICKINSON IMMUNODIAGNOSTICS

For Becton Dickinson Immunodiagnosics

Dr. LaVell R. Johnson, Chairman, Radiation Safety Committee  
Mr. Alan D. Croft, Radiation Safety Officer  
Ms. Jane E. Ehrigott, Corporate Industrial Hygienist  
Mr. Bruce J. Hector, Corporate Legal Department  
Mr. Russell J. Arnsberger, Corporate Regulatory Affairs

For NRC, Region IV

Mr. John T. Collins, Deputy Director  
Mr. James E. Gagliardo, Director, Investigation and Enforcement  
Staff  
Mr. Glen D. Brown, Chief, Technical Inspection Branch  
Mr. R. Jerry Everett, Chief, Materials Radiation Protection  
Section  
Mr. Charles L. Cain, Radiation Specialist