UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406

DEC. 26 1990

Dr. Paul J. Merges
Director, Bureau of Radiation
New York State Department of Environmental Conservation
50 Wolf Road
Albany, New York 12233

Dear Dr. Merges:

Subject: Technical Assistance Report for the Becton Dickinson Company, Orangeburg, New York

This letter refers to the technical assistance provided to the State of New York during its inspection on December 13-14, 1990 at the Becton Dickinson Company, Orangeburg, New York. The assistance was provided by Dr. Jason C. Jang and Ms. Laurie Peluso of this office.

A report, in the format of an NRC Inspection Report, is enclosed which describes the areas reviewed and the NRC staff comments. Although the enclosed report is in the format of an NRC Inspection Report, the technical assistance which the NRC staff provided should not be considered an inspection, since only the State of New York has regulatory jurisdiction over byproduct material activities at the Becton Dickinson Company.

If you have any questions regarding our findings, please do not hesitate to call me at (215)337-5213 or Dr. J. Jang of my staff at (215)337-5220.

Sincerely,

for Dr. Robert J. Bores, Chief,
Effluents Radiation Protection Section
Facilities Radiological Safety and
Safeguards Branch
Division of Radiation Safety and
Safeguards

Enclosure: Technical Assistance Report for the Becton Dickinson Company

Bureau of Radiation
New York State Department of Environmental Conservation (DEC)

cc w/encl:
S. Zobel, Bureau of Radiation, New York State DEC
W. Varcasio, Bureau of Radiation, New York State DEC
J. McGrath, NRC:I, Regional State Agreements Officer

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U.S. NUCLEAR REGULATORY COMMISSION
REGION I
TECHNICAL ASSISTANCE REPORT

Facility Name: Becton Dickinson Advanced Diagnostics
13 Mountain View Avenue
Orangeburg, New York 10962-1294

At: Orangeburg, New York

Conducted: December 13-14, 1990

Conducted by: for Iwen C. Jang 12-26-90
L. Peluso, Radiation Specialist, Effluents Radiation Protection Section (ERPS), Facilities Radiological Safety and Safeguards Branch (FRS&SB) — date

Jason C. Jang 12-26-90
J. C. Jang, Sr. Radiation Specialist, ERPS, FRS&SB, Division of Radiation Safety and Safeguards (DRSS) — date

Approved by: for J. Roth 12/26/90
R. J. Bores, Chief, ERPS, FRS&SB, DRSS — date

Summary;

Areas Reviewed: Radioactive liquid and gaseous effluent control programs including: sampling techniques, analytical procedures, quality assurance/quality control in the measurement laboratory, and implementation of the above programs.

Results: A number of weaknessess were identified, as described in this report.

DETAILS

1.0 Individuals Contacted

1.1 Becton Dickinson Company

*J. Bill, Regulatory Compliance
J. Conant, Manager, Nuclear Materials Licensing
*A. Decker, Jr., Radiation Safety Officer
L. Gaedke, Quality Assurance
R. Piovanetti, Plant Manager
C. Seifert, Quality Assurance
*G. Vrany, Plant Engineer
R. Wurzel, Vice President, Regulatory Affairs & Quality Assurance

1.2 Becton Dickinson's Consultant

*W. van Pelt, President, Wesley R. van Pelt Associates, Inc.

1.3 New York State Department of Environmental Conservation

*W. Varcasio, Environmental Radiation Specialist I
*S. Zobel, Environmental Radiation Specialist II

1.4 Nuclear Regulatory Commission (NRC)

*J. Jang, Senior Radiation Specialist
*L. Peluso, Radiation Specialist

*Denotes personnel who attended at the exit meeting on December 14, 1990.

2.0 Introduction

The Becton Dickinson Company (BD Company) is located in Orangeburg, New York. The BD Company produces radioimmunoassay kits which contain radionuclides. The major radionuclide handling laboratory of the BD Company is the Manufacturing Iodination Laboratory. This laboratory is used for the production of I-125 labeled analytes for radioimmunoassay use. Other laboratories are the Bulk Tracer Preparation Laboratory, the Serum Iron Laboratory, The R&D Hood, and the R&D Iodination Laboratory. Iodine-125 (I-125), Co-57, and Fe-59 are used in the above laboratories. The BD Company discharges the radioactive wastes through the stack and the sanitary sewer systems.

The Department of Environmental Conservation (DEC) of New York State requested the NRC to provide technical assistance in evaluating the BD Company's radioactive gaseous and liquid effluent control programs

including, analytical procedures, sampling techniques, quality control program in the measurement laboratory, and air cleaning systems. Therefore, representatives of the NRC accompanied representatives of the DEC on an inspection, conducted during December 13-14, 1990, of the following areas.

- o Sampling techniques for radioactive gaseous and liquid effluents
- o Analytical procedures for the effluent samples
- o Quality Assurance (QA) and Quality Control (QC) program for the measurement laboratory
- o Determination of the iodine collection efficiency of charcoal beds for the air cleaning systems

Representatives of the DEC and the NRC toured the above laboratories, radioactive gaseous and liquid effluent sampling areas, and the measurement laboratory on December 13, 1990.

3.0 Radioactive Liquid Effluent Controls

Liquid radioactive waste and other industrial waste water are collected in the neutralization tank prior to discharge to the sanitary sewer system. An automatic composite sampler (ISCO 3700 Series) is installed to sample liquid effluent prior to discharge. The BD Company is collecting approximately 75 milliliters of liquid effluent samples once an hour using the automatic composite sampler. The BD Company, then analyzes the daily and/or composite liquid samples for I-125, Co-57, and Fe-59. The total volume entering the neutralization tank is measured using an ultrasonic device (Fisher Porter Model 50US3145ABB, Ultrasonic Open Channel Flowmeter/Totalizer). The daily average discharge from the neutralization tank has been determined to be about 5,100 gallons/day.

Based on the above reviews, the inspector determined that the current hourly sampling frequency might not collect a representative sample because the daily average discharge volume is about 5,100 gallons while the collecting sample volume is about 0.5 gallons (about 1.8 liters). (Significant changes in effluent concentrations could occur between composite samplings without detection.) The NRC representative stated that the sampling frequency of the automatic composite sampler should be increased, perhaps from an hourly frequency to every 15 minutes to collect more representative composite samples. The NRC representative also noted that the BD Company did not add preservatives to the composite samples, nor in fact, to any samples. The addition of preservatives to samples and/or composite samples is crucial to keeping many radionuclides in solution to assure representative analyses can be conducted.

The NRC representative, however, stated that the installation of the automatic composite sampler and the ultrasonic flowmeter device were major improvements to implement a better liquid radioactive effluent control program.

4.0 Radioactive Gaseous Effluent Controls

4.1 Sampling Points

Areas and/or hoods where I-125 is used exhaust through five (5) independent ventilation systems equipped with activated charcoal filter banks. The radioactive gaseous effluent samples are collected at the downstream side of the filtration systems. One ventilation system, called "Area 4 System", has two sampling points, upstream and downstream of the filtration system, with which to determine the iodine collection efficiency for the charcoal filter banks.

4.2 Sampling Technique

The BD Company is using commercially made particulate filter paper holders (Gelman Scientific, Inc. No. 1119) and filter paper and in-house assembled charcoal sampling devices to collect particulate and I-125, respectively. The particulate filter paper holder and two charcoal sampling devices (cylindrical dimensions: 3/4-inch diameter and 2-inch long) are connected in series using tygon tubes. The effluent sampling flowrates vary from 8 liters per minute (lpm) to 18 lpm. The sampling volume is determined using a flowmeter and the known sampling time. Tygon tubing is used between the isokinetic probe and the sampling point. The NRC representative examined the current sampling equipment and techniques and identified the following deficiencies.

- The two end caps of the charcoal sampling device examined did not seal completely and air in-leakage occurred. As a result, the apparent effluent sample volume might not be representative of the true effluent sample volume.

- The accuracy of the flowmeter being used to determine the volume of the air sample is questionable. The NRC representative observed the air flow indicator at the sampling point was very unstable and could lead to errors in obtaining accurate readings.

- There were no guidelines for adding charcoal (quantity) into the sampling device. Therefore, information relating to the iodine collection efficiency for the in-house charcoal devices was not available. As a result, the determination of iodine collection efficiency as used by the BD Company may not be reliable (See Section 5.2 of this report for details).

- The inspector discussed with BD Company representatives the use of tygon tubing as the sample line between the in-duct probe and the sampling point and the fact that the line was not heat traced. Condensation could have occurred in the sampling line which could have resulted in plateout of radionuclides from the sampling stream. The BD Company representatives indicated that this would be reviewed and the line may be replaced with a stainless steel, heat-traced line to eliminate such line losses.

5.0 Review of Analytical Procedures

5.1 Radioactive Liquid Effluent Samples

Section XVIII-Sewer Sampling of the Radiation Safety Manual contains analytical procedures for I-125, Co-57, and Fe-59 in radioactive liquid effluent samples. The NRC representative reviewed these analytical procedures to determine the technical adequacy.

(1) Method for Iodine-125 Determination [Paragraph 18.3.(a) of the Radiation Safety Manual]

This procedure states, in part, that iodine carrier (0.1M of potassium iodide and 0.1% of sodium bisulfite) is added to 200 milliliters (ml) of the radioactive liquid effluent sample and stirred for several minutes. Then 10 ml of silver nitrate is added to precipitate silver iodide (AgI). After adding 40 ml of saturated sodium chloride, the mixture is stirred, and allowed to set for at least one hour in the dark. After one hour, the sample is filtered in order to collect AgI on the filter paper, then, the AgI is counted using a sodium iodide gamma counting system. A blank sample (200 ml of water) is also prepared and counted using the same analytical method.

The chemical yield for iodine for each sample is not determined. Instead, predetermined chemical yield is used for each sample for the defined period of time as described in Paragraph 18.3.(4) of the Radiation Safety Manual.

The analytical results and associated three standard deviations (uncertainties) are routinely reported as described in Paragraph 18.3.(5) of the Radiation Safety Manual.

(2) Method for Cobalt-57 and Iron-59 Determination [Paragraph 18.3.(b) of the Radiation Safety Manual]

This procedure states, in part, that one (1) ml of the radioactive liquid effluent sample is used as an aliquot and counted for 10 minutes using a sodium iodide gamma counting system. Reporting of the analytical results is the same as described above for I-125.

Based on the review of the above procedures, the NRC representative determined that the current analytical procedures deviated from good industrial practices and the principles of the analytical chemistry. As a result, the analytical results of I-125, Co-57, and Fe-59 may not be representative of the released effluents. The NRC representative indicated that these procedures should be rewritten to ensure more accurate measurement of radioactivity in the effluent samples. The NRC representative identified the following deficiencies in the two described procedures.

- The chemical yield of iodine for each iodine-125 sample must be determined and used for the activity calculation of each sample. Chemical yield varies from sample to sample because of the varying constituents of each sample and because of variations in the analytical technique.

- The iodine carrier solution must be calibrated in order to obtain the correct chemical yields. The NRC representative noted that the addition of sodium bisulfite is required by the procedure, however, there were no instructions for adding this chemical at predetermined intervals. Sodium bisulfite must be added to the carrier solution to keep iodide in the solution. The NRC representative identified that the iodine carrier solution in the measurement laboratory had degenerated (carrier solution was deep yellow color) due to lack of a reducing chemical, such as sodium bisulfite.

- Chemical purification steps for the iodine analysis should be incorporated in the procedure to ensure that other radionuclides do not interfere with the measurement of radioiodine (I-125).

- A one (1) ml aliquot for the analysis Co-57 and Fe-59 is very small and is not likely to be representative for the effluent samples. Chemical separation methods for Co-57 and Fe-59 using large volume samples should be incorporated to obtain representative analytical results. If those analytical methods are not readily available, then another gamma counting system (Ge[Li]) with a multi-channel analyzer system can be used to measure Co-57 and Fe-59 activities directly and accurately. A Ge(Li) gamma counting system using the Marinelli beaker allows the use of relatively large sample volumes.

- The procedures, in general, were not sufficiently detailed to implement the radioactive liquid and gaseous effluent control programs.

5.2 Radioactive Gaseous Effluent Samples

Section XVII-Monitoring of Roof Exhausts of the Radiation Safety Manual

contains procedures for sampling, counting, and calculating the radioactivity of gaseous effluents. The NRC representative reviewed the analytical results of I-125 and the determination of the iodine collection efficiency for the charcoal sampling devices. As described in the Section 4.2 of this inspection report, there are two charcoal sampling devices in series at each sampling point. The iodine collection efficiency was determined using ratio of I-125 activities in charcoals A and B as defined the following equation.

$$E = (1 - B/A)$$

where: E = iodine collection efficiency for Charcoal A (device nearest the air inlet)
A = I-125 activity in the Charcoal A
B = I-125 activity in the Charcoal B

The BD Company added the third charcoal sampling device (Charcoal C) after Charcoal B to comply with a DEC request. The NRC representative also reviewed these results. The measurement results of Charcoals A, B, and C were 203.1 pCi, 49.8 pCi, and 23.0 pCi, respectively, for a set of results for November 28, 1990. The iodine collection efficiency calculated by the BD Company was 75.5%. The BD Company used this efficiency to calculate the activity drawn through the sampling stream as 269 pCi (203.1 divided by 0.755). The NRC representative noted that actual amount of I-125 drawn through the system based on the above data was 275.9 pCi (sum of three analytical results) or more (iodine breakthrough could have occurred in the Charcoal C also).

Based on the review of these results and other test data, the NRC representative determined that the above equation for the collection efficiency was not appropriate because Charcoal B also showed iodine breakthrough. Therefore, the numerator of the equation should reflect the total iodine through the sampling system and not just the relative collection efficiency of Charcoals A to B. The following equation should be used to obtain the true collection efficiency for Charcoal A.

$$E = [1- (A + B + C + ...)/A]$$

Therefore, the quantification of the released I-125 by BD Company using the first formula was non-conservative, that is, more iodine was released than reported in the results.

6.0 Quality Assurance (QA) and Quality Control (QC) Programs in the Analytical Measurement Laboratory

The NRC representative noted that the analytical measurement laboratory did not have established QA/QC programs. Although the NRC representative identified aforementioned deficiencies, it was difficult to assess the analytical capability of the laboratory. However, the BD Company conducted interlaboratory comparisons with Teledyne Isotopes,

Inc. and the NRC representative reviewed selected comparison data (16 sets of results). Ratios (analytical results of the BD Company divided by the results of Teledyne) were computed by the NRC representative. The mean ratio, standard deviation, and the relative standard deviation were calculated and are listed in the following table. It appeared that the analytical results of BD Company for charcoals and particulates were higher than the Teledyne results (about 51% higher for charcoal samples; 103% higher for sewer samples; and 88% higher for particulate samples). The relative standard deviations indicated fairly large variations. The table also indicates that the mean measurements of the BD Company were nearly a factor of two higher than Teledynes' and showed wide variation from the Teledyne measurements.

Nuclide & Sample	Mean Ratio +/- s.d.* (BD Company/Teledyne)	Relative s.d.(%) (s.d./Mean)x100
I-125 Charcoal	1.51 +/- 0.33	21.9%
I-125 Sewer	2.03 +/- 0.76	37.4%
Particulates	1.88 +/- 0.87	46.2%

* s.d. = Standard Deviation

Based on the above reviews, the NRC representative identified the following needs in analytical measurement laboratory QA/QC programs.

- The BD Company should establish and implement QA/QC programs for the analytical measurement laboratory.
- Appropriate QC parameters (such as, quality control charts for standards measurements and backgrounds for the gamma counting system; shelf-lives for the iodine carrier solution and any other chemicals used in the analytical process; a program for analysis of spike, duplicate, and split samples; acceptance criteria for these comparisons; and investigation actions for the anomalous results) should be established.
- Training for the laboratory personnel in the areas of sampling and analytical techniques, counting statistics, QC parameters and programs, is needed.

The NRC representative, however, noted that the BD Company has used NIST (National Institute for Standards and Technology) traceable radioactive standards for the calibration of the gamma counting system. The NRC representative reviewed calibration results and they appeared acceptable. The NRC representative stated that using NIST traceable standards for the calibration was very good and in accord with good

industry practices.

7.0 Air Cleaning Systems

During the tour, the NRC representative identified that the pressure gauges on the air cleaning systems (delta pressure across the charcoal banks) were not readable due to deterioration of the plastic gauge lenses, with exception of the Area 4 System. The representative of the BD Company stated that a new ventilation and air cleaning system, combining of all the current ventilation and air cleaning systems, will be installed in the near future. The NRC representative also identified that the filtration housing access door gasket of one filter system was worn out and the air was leaking into the air cleaning system. The NRC representative stated that this deficiency should be corrected immediately.

The NRC representative also discussed with the representatives of the BD Company the areas of inspection and tests (ANSI N510-1980, Testing of Nuclear Air-Cleaning Systems) for the new air cleaning system. The BD Company indicated that this area would be reviewed.

9.0 Exit Meeting

The representatives of the DEC and the NRC met with the representatives of BD Company denoted in Sections 1.1 and 1.2 of this report at the conclusion of the inspection on December 14, 1990. The NRC representative summarized the purpose, scope, and findings of the review.