

## Docket File Information

SAFETY INSPECTION REPORT  
AND COMPLIANCE INSPECTION

## 1. LICENSEE

**Bayer Pharmaceuticals Corporation**  
**400 Morgan Lane**  
**West Haven, Connecticut**

REPORT NOS 2005-001

## 2. NRC/REGIONAL OFFICE

**U.S. Nuclear Regulatory Commission**  
**Region I, 475 Allendale Road**  
**King of Prussia, Pennsylvania 19406-1415**

## 3. DOCKET NUMBER(S)

030-30292

## 4. LICENSE NUMBER(S)

06-13053-04

## 5. DATE(S) OF INSPECTION

March 15, 2005

## 6. INSPECTION PROCEDURES USED

87126

## 7. INSPECTION FOCUS AREAS

03.01 through 03.07

## 8. INSPECTOR

John Nicholson

## SUPPLEMENTAL INSPECTION INFORMATION

## 1. PROGRAM CODE(S)

03610

## 2. PRIORITY

3

## 3. LICENSEE CONTACT

Bill Galdenzi

## 4. TELEPHONE NUMBER

203 812-3132



Main Office Inspection

Next Inspection Date: March 2008

Field Office \_\_\_\_\_



Temporary Job Site \_\_\_\_\_

## PROGRAM SCOPE

This is a broad scope type A R&D license conducting pharmaceutical research. There has been a consolidation of the research activities recently. At the time of the inspection, approximately 26 laboratories that were authorized to work with licensed material are being decommissioned. Sciencetech has been contracted to perform the work. This decommissioning project is expected to be completed by the end of April 2005. This will leave about 50 laboratories authorized for work with licensed material. There are about 120 personnel working with radioactive material. About 50 of these are principal investigators who are issued in-house permits that are protocol and radionuclide specific. The majority of the material used is P-33, followed by C-14, H-3, I-125 and S-35. There has been no P-32 ordered since 2000, and no iodinations since at least 1998. There are no active protocols where radioactive material is used in animals, and no work of this type was taking place currently. About 300 packages are received every quarter.

There was only one sealed source on hand, Ni-63 15 mCi, model no. G1533A. The licensee recently returned several Ni-63 sources back to the manufacturers.

The radioactive material is used in three buildings: B-24, B-31, and B-36. B-36 houses the large high through-put screening (HTPS) laboratory. This lab utilizes the majority of the licensed material on-site, mainly P-33. The receiving area will be moving in a couple of weeks to B-27. The waste storage areas are located in the basement of B-24. The licensee holds material for decay-in-storage, which eventually goes out as medical waste for incineration and ships out long lived material. Philotechnics is the waste broker. Mixed waste is shipped to NSSI. The HTPS lab generates large amounts of plastic well plates as waste. Waste is shipped out about once every quarter.

Research personnel perform informal, undocumented surveys of their immediate work area at the end of the day that radioactive material was used. They perform documented surveys monthly. The RSO conducts quarterly surveys of all radioactive material use/storage areas. The RSO places all orders for licensed material. Research personnel are able to document their use of material through an on-line database inventory system.

Annual program reviews are performed by an outside consultant, the most recent in February 2005. The results are reviewed by the Radiation Safety Committee (RSC) which meets quarterly. The RSC is composed of administrative and research personnel and is chaired by a Senior Research Fellow. The RSO conducts extensive health and safety audits of all laboratories including radiation safety related items twice a year.

In April 2004, the licensee changed their method of providing financial assurance to a parent company guarantee. They will be submitting a letter increasing the amount from \$750K to \$1,125K before the end of March 2005.