UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

May 21, 2008

Docket No. 03029266 License No. 06-27843-02

Carl Noonan
Associate Director, Environmental Health & Safety
Bristol-Myers Squibb PRI
5 Research Parkway
Wallingford, CT 06492

SUBJECT: INSPECTION 03029266/2008001, BRISTOL-MYERS SQUIBB PRI, WALLINGFORD, CONNECTICUT SITE AND NOTICE OF VIOLATION

Dear Mr. Noonan:

On April 16 and 17, 2008, Dennis Lawyer of this office conducted a safety inspection at the above address of activities authorized by your NRC license. The inspection was an examination of your licensed activities as they relate to radiation safety and to compliance with the Commission's regulations and the license conditions. The inspection consisted of observations by the inspector, interviews with personnel, and a selected examination of representative records. Additional information provided in your correspondence dated April 24, 2008, and the telephone conversation on April 30, 2008 between you and this office, were also examined as part of the inspection. The findings of the inspection were discussed with you at the conclusion of the inspection.

Based on the results of this inspection, it appears that your activities were not conducted in full compliance with NRC requirements. A Notice of Violation is enclosed that categorizes the violation by severity level. You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

One potential area of concern identified during the inspection involved the level of supervision provided by the authorized users (AUs) named in Condition 11 of your license. The inspector determined that approximately 180 researchers, working in about 130 laboratories, were supervised by only 10 AUs; and, when questioned by the inspector, most of the researchers interviewed could not name the AU who supervised the use of licensed radioactive materials in their laboratory. While this finding does not prove there is a problem with AU oversight, and no safety concerns were identified in the research laboratories toured by the inspector, we want to make you aware of this finding so that you can consider the adequacy of AU oversight during your routine evaluations of your licensed program.

Current NRC regulations are included on the NRC's website at www.nrc.gov ; select **Nuclear Materials; Medical, Academic, and Industrial Uses of Nuclear Material;** then **Regulations, Guidance, and Communications Page.** The current Enforcement Policy is included on the NRC's website at www.nrc.gov ; select **About NRC; Organization and Functions; Office of Enforcement; About Enforcement;** then **Enforcement Policy.** You may also obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-866-512-1800. The GPO is open from 7:00 a.m. to 8:00 p.m. EST, Monday through Friday (except Federal holidays).

Please contact Dennis Lawyer at 610-337-5366 if you have any questions regarding this matter.

Sincerely,

Original signed by James P. Dwyer

James P. Dwyer, Chief
Commercial and R&D Branch
Division of Nuclear Materials Safety

Enclosure:
Notice of Violation

cc:
State of Connecticut

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Enclosure:
Notice of Violation

cc:
State of Connecticut

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DATE	5/21/2008		5/21/2008					

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NOTICE OF VIOLATION

Bristol-Myers Squibb PRI
Wallingford, CT

Docket No. 03029266
License No. 06-27843-02

During an NRC inspection conducted on April 16 and 17, 2008, one violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

10 CFR 20.1501(a) requires that each licensee make, or cause to be made, surveys that may be necessary for the licensee to comply with the regulations in Part 20 and that are reasonable under the circumstances to evaluate the extent of radiation levels, concentrations or quantities of radioactive materials, and the potential radiological hazards that could be present. A survey means an evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal, or presence of radioactive material or other sources of radiation. 10 CFR 20.1501(b) requires that the licensee ensure that instruments and equipment used for quantitative radioactive measurements are calibrated periodically for the radiation measured.

10 CFR 20.1906(b) requires, in part, that each licensee to monitor the external surfaces packages labeled with a Radioactive White I, Yellow II, or Yellow III label for: (1) radioactive contamination, unless the package contains only radioactive material in the form of a gas or in special form as defined in 10 CFR 71.4.

Contrary to the above, as of April 18, 2008, the licensee did not make, or cause to be made, surveys that may be necessary for the licensee to comply with the regulations in Part 20 and that are reasonable under the circumstances to evaluate the extent of radiation levels, concentrations or quantities of radioactive materials, and the potential radiological hazard that could be present. Specifically, the licensee did not make surveys to comply with 10 CFR 20.1906(b) in that 5 packages containing radioactive material, not in gaseous or special form, received by the licensee between March 12 and April 18, 2008, and labeled with a Radioactive White I label, were surveyed with a Radiation Alert Monitor 4ED that was calibrated for exposure rate not for radioactive contamination.

This is a Severity Level IV violation (Supplement IV).

Pursuant to the provisions of 10 CFR 2.201, Bristol-Myers Squibb PRI is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555, with a copy to the Regional Administrator, Region I, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a “Reply to a Notice of Violation” and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for

Information may be issued as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

If you contest this enforcement action, you should also provide a copy of your response to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, any response which contests an enforcement action shall be submitted under oath or affirmation.

Your response will be placed in the NRC Public Document Room (PDR) and on the NRC Web site. To the extent possible, it should, therefore, not include any personal privacy, proprietary, or safeguards information so that it can be made publically available without redaction. However, if you find it necessary to include such information, you should clearly indicate the specific information that you desire not to be placed in the PDR, and provide the legal basis to support your request for withholding the information from the public.

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days.

Dated This 21 day of May 2008