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

January 2, 2008

Docket No. 03034187 License No. 52-25361-01MD

Joel A. Cordero, R.Ph.
Associate Director Operations
Bristol Myers Squibb Radiopharmaceuticals, Inc.
150 Federico Costa Street, Suite #1
San Juan, Puerto Rico 00918-1303

SUBJECT: INSPECTION 03034187/2007001, BRISTOL MYERS SQUIBB RADIOPHARMACEUTICALS, INC., SAN JUAN AND PONCE, PUERTO RICO SITES, AND NOTICE OF VIOLATION

Dear Mr. Cordero:

On November 11 through December 10, 2007, Todd Jackson and Lizette Roldán of this office conducted a safety inspection at the above address and at the Ponce site of activities authorized by the above listed 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 the electronic mails dated December 6 and 10, 2007, and the facsimile sent December 10, 2007 by Rolando Garcia of your organization, were also examined as part of the inspection. The findings of the inspection were discussed with Mr. Garcia 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.

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 Todd Jackson of my staff at 610-337-5308 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:
Rolando Garcia, R.Ph., Radiation Safety Officer
Commonwealth of Puerto Rico

Please contact Todd Jackson of my staff at 610-337-5308 if you have any questions regarding this matter.

Sincerely,

Original signed by James P. Dwyer

James P. Dwyer, Chief
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Enclosure:
Notice of Violation

cc:
Rolando Garcia, R.Ph., Radiation Safety Officer
Commonwealth of Puerto Rico

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NAME	TJackson/tjj		JDwyer/jpd					
DATE	1/02/2008		1/02/2008					

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NOTICE OF VIOLATION

Bristol Myers Squibb Radiopharmaceuticals, Inc.
San Juan, Puerto Rico

Docket No. 03034187
License No. 52-25361-01MD

During an NRC inspection conducted on November 11 through December 10, 2007, one violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

> 10 CFR 20.1101(d) requires the licensee to establish a constraint on air emissions of radioactive material to the environment, excluding Radon-222 and its daughters, such that the individual member of the public likely to receive the highest dose will not be expected to receive a total effective dose equivalent (TEDE) in excess of 10 millirem (0.1 mSv) per year from these emissions. If a licensee subject to this requirement exceeds this dose constraint, the licensee shall report the exceedance as provided in 10 CFR 20.2203 and promptly take appropriate corrective action to ensure against recurrence.
>
> Contrary to the above, as of November 11, 2007, the licensee had not established a constraint on air emissions of radioactive material to the environment at the San Juan facility such that the individual member of the public likely to receive the highest dose will not be expected to receive from these emissions a TEDE in excess of 10 millirem (0.1 mSv) per year from these emissions. Specifically, the licensee was not aware of the 10 millirem per year constraint on air emissions and, because of this, the licensee could not report an exceedance and promptly take corrective action to ensure against recurrence. Although the licensee was performing surveys and monitoring the concentration of gaseous radioactive material released from the facility to verify compliance with the TEDE of 100 millirem per year for a member of the public required by 10 CFR 20.1301 using the annual average concentration values specified in Table 2 of Appendix B to Part 20, this data had not been used to determine the total effective dose equivalent (TEDE) to the individual member of the public likely to receive the highest dose from these emissions.
>
> This is a Severity Level IV violation (Supplement IV).

Pursuant to the provisions of 10 CFR 2.201, Bristol Myers Squibb Radiopharmaceuticals, Inc. 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 _2_ day of _January_ 2008