## **Bristol-Myers Squibb** Pharmaceutical Research Institute

Richard L. Gelb Center for Pharmaceutical Research and Development

5 Research Parkway P.O. Box 5100 Wallingford, CT 06492-7660

Br. 2

August 25, 2009

Elizabeth Ullrich Commercial and R&D Branch Division of Nuclear Materials Safety Region I

King of Prussia, Pennsylvania 19406

63029266

Re: Bristol-Myers Squibb (License No. 06-27843-02) Amendment

Dear Ms. Ullrich,

By this letter I am requesting an amendment to license 06-27843-02, Bristol-Myers Squibb, Wallingford, CT 06492 to comply with the requirements for NARM. I am requesting changes to the BMS site license as described below.

- Add fluorine-18 at 600 mCi in any form to the license
- Add Remesh Padmanabha, Fiona McPhee and Jonathan O'Connell to the license as principal investigators (training/experience attached)
- Increase the site limit for carbon-14 from 3 curies to 5 curies
- Delete chlorine-36, scandium-46, selenium-75, strontium-85, rubidium-86, niobium-95, tin-113, iodine-131, xenon-133, cerium-141, and gadolinium-153 from the license as we do not use these isotopes.
- Delete Margie Goldstein and Hsu-Tso Ho as principal investigators from the license. They are no longer employed with BMS.

If you have any questions or concerns please call me at 203 677-6342, e-mail at carl.noonan@bms.com or write to the above address. Thank you.

Sincerely

Carl Noonan

Associate Director

Environment, Health & Safety

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### Bristol-Myers Squibb Research & Development –Wallingford

Name:	Ramesh Padmanabha Date: 08/24/2009			
Job Ti	tle: Principal Scientist			
Depart	ment Name: Lead Discovery			
A. <u>Tł</u>	RAINING IN USE OF RADIOACTIVE MATERIALS:			
	provide the names and dates of the college(s) or university you attended where you received training in the use of radioactive materials. <u>University of Georgia, Athens, GA</u> Yale University, New Haven, CT			
Form	al Course Work:			
	be the formal course work you have had in the following areas:  Principles and practices of Radiation Protection  Video and Instruction at Bristol-Myers Squibb Co.			
2.	Radioactivity measurements, standardization, monitoring techniques and instruments.  General Biochemistry and Labs, University of Georgia. Included the theory and practice on the use of radioactive materials in research, plus hands on experience in the lab.			
3.	Mathematics and calculations basic to the use and measurement of radioactivity.  General Biochemistry and Labs, University of Georgia. Included the theory and practice on the use of radioactive materials in research, plus hands on experience in the lab.			
4.	Biological effects of radiation  General courses on genetics, University of Georgia. Included the causes of mutations and the use of radiation in cancer treatments.			
	N-THE-JOB TRAINING  provide a brief description of the on-the-job training you have received.			
filter b	Training in graduate school on safe laboratory practices using 32P and 35S in the setting up and ag of protein kinase assays and in DNA sequencing. The kinase assays were performed using binding methods with 32P- ATP. DNA sequencing was performed using 35S –ATP.  Other training included the use of 125I labeled antibodies for Western Blot analysis. Similar ch was carried out at Yale University.			

## <u>Isotope Use & Experience</u>

Isotopes Handled	Maximum Quantities Handled	Where Experience was gained	Duration of Activities	Type of Use
32P	1 mCi	University of Georgia, Yale University	10 years	Kinase assays
35S	1 mCi	University of Georgia, Yale University	10 years	DNA sequencing
1251	0.5 mCi	University of Georgia, Yale University	10 years	Western blots
33P	4.0 mCi	Bristol-Myers Squibb Co.	16 years	HTS kinase screens
3Н	4.0 mCi	Bristol-Myers Squibb Co.	16 years	HTS screens

# Bristol-Myers Squibb Research & Development –Wallingford

Name: Fiona McPhee Date: August 12, 2009

Job Title: Senior Principle Scientist

Department Name: Virology

#### A. TRAINING IN USE OF RADIOACTIVE MATERIALS:

Please provide the names and dates of the college(s) or university you attended where you received formal training in the use of radioactive materials.

Oxford University, England 1987 - 1990; Max Planck Institute in Martinsried, Germany 1991-1993; UCSF, USA 1993-1995

#### **Formal Course Work:**

Describe the formal course work you have had in the following areas: I was the Radiation Safety Representative for the Organic Chemistry Department at Oxford University. An informal course was taken that covered instruments to measure radioacitivity, protection, setting up of experiments (up to 100 mCi for synthetic reactions), use and disposal of radioactivity.

Other sites required watching videos, and being shown what to do by fellow colleagues

- 1. Principles and practices of Radiation Protection Hands on training with video instruction
- 2. Radioactivity measurements, standardization, monitoring techniques and instruments. <u>Training at Bristol-Myers Squibb</u>
- 3. Mathematics and calculations basic to the use and measurement of radioactivity. <u>Training at Bristol-Myers Squibb</u>
- 4. Biological effects of radiation Training at Bristol-Myers Squibb

#### **B. ON-THE-JOB TRAINING**

Please provide a brief description of the on-the-job training you have received.

Organic Chemistry: Working with 100 mCi of tritiated reagents for chemical synthesis, required working in a hood with columns and separating funnels, designated equiment for NMR analysis; similar experience obtained in radiosynthetic labs at SmithKline and French Working with P32, and later S35 as a student and post-doc for DNA and/or RNA sequencing Working with blood and cells radiolabeled with P32/P33 to monitor biochemical pathways/viral lifecycle

## <u>Isotope Use & Experience</u>

Isotopes Handled	Maximum Quantities Handled	Where Experience was gained	Duration of Activities	Type of Use
H-3	100 mCi	U. Oxford, SK&F	2 years	Organic synthesis
S-35	100 μCi	Max-Planck, UCSF, BMS	1991 - 2001	Labeling cells
P-32	100 μCi	Max-Planck	2 years	DNA/RNA synthesis
P-33	100 μCi	BMS	3 years	Labeling cells

### Bristol-Myers Squibb Research & Development –Wallingford

Name: Jonathan O'Connell	Date: 24 <sup>th</sup> August 2009
Job Title: Associate Director	
Department Name: <u>Lead Discovery</u>	
A. TRAINING IN USE OF RADIOACTIVE M	MATERIALS:
Please provide the names and dates of the colleged formal training in the use of radioactive materials. <u>University of Manchester, Manchester, England (University of Glasgow, Glasgow, Scotland (1998)</u>	1989-1993)
Formal Course Work:	
<ul><li>Squibb, CT. Annual refresher courses ther</li><li>2. Radioactivity measurements, standardizati General Biochemistry at the University of</li></ul>	ection versity of Manchester g at GlaxoSmithKine, UK and at Bristol Myers
3. Mathematics and calculations basic to the General Biochemistry at the University of around radiation theory. Formal courses at	use and measurement of radioactivity.  Manchester explained all the calculation based to BMS have also explained this extensively.
4. Biological effects of radiation University training in biochemistry clearly	y explained the biological effects of radiation.
B. ON-THE-JOB TRAINING	
Please provide a brief description of the on-the-jo Extensively used <sup>32</sup> P, <sup>33</sup> P, <sup>125</sup> I, <sup>3</sup> H and <sup>14</sup> C through at Glaxo (UK) and BMS (USA) over the last 17 training followed by yearly refresher training.	hout PHD. Course at Glasgow University and Career

# <u>Isotope Use & Experience</u>

Isotopes Handled	Maximum Quantities Handled	Where Experience was gained	Duration of Activities	Type of Use
32P	1 mCi	University of Glasgow, GSK	7 years	Phosphorylation exps
14C	0.1 mCi	University of Glasgow, GSK	7 years	Amino acid assays
1251	0.5 mCi	University of Glasgow, GSK	7 years	Western blots
33P	4.0 mCi	Bristol-Myers Squibb Co.	9 years	HTS screens
3H	4.0 mCi	Bristol-Myers Squibb Co.	9 years	HTS screens

includes an administrative re  There were no administratechnical reviewer. Pleas omissions or require additional reviews additional reviews and the second require additional reviews and the second requirements and the second representation of the second	tive omissions. Your application was assigned to a e note that the technical review may identify additional
Branch, who will contact you  Your action has been assign  When calling to inquire abou	een forwarded to our License Fee & Accounts Receivable is separately if there is a fee issue involved.  The Mail Control Number 1440
You may call us on (610) 33  NRC FORM 532 (RI) (6-96)	7-5398, or 337-5260. Sincerely, Licensing Assistance Team Leader