



April 9, 2008

NMSBZ

RECEIVED
REGION 1
2008 APR - 10 PM 10:16

License Amendment Request
Division of Nuclear Materials Safety
U.S. Nuclear Regulatory Commission, Region I
475 Allendale Road
King of Prussia, PA 19406-1415

RE: License # 29-31105-01

03037092

Dear Sir/Madam:

Novo Nordisk requests an amendment of our NRC license as follows:

- 1) Item 7C: we will only use the bound form of Iodine 125 in which the I-125 has already been labeled onto proteins or peptides. We will use an outside specialized company to do the iodination procedure. In our case, the I-125 labeled products we receive will be in liquid solution.
- 2) Item 11 regarding using the licensed material in Subitem 6C (I-125): In addition to Scott Dennerlein, we request this licensed material could be used by, or under the supervision of Dr. Ruihua Chen and Xiaoman Yang. The experience forms of Dr. Chen and Ms Yang are attached.

Thank you in advance for your time and effort in reviewing this amendment.

Sincerely,

 M.D., Ph.D.

Marcus E. Carr, Jr., M.D., Ph.D.
Vice President, Research US

142303

NMSS/RGN1 MATERIALS-002

Radioactive Material Experience Record

Name: Ruihua Chen, Ph.D.
Room #222

Title: Staff Scientist
Telephone: 732-214-2410

Experience

Formal Radiation Training:

Institution, City	Date and duration	Name of course and short description
Novo Nordisk Research US	Jan 30, 2008 8 hours	Radiation Safety Training
Medical University of South Carolina, Charleston, SC	1998 8 hours	Radiation Safety Training
Albany Medical College, Albany, NY	1996-4 hours	Radiation Safety Training
University of Kentucky, Lexington, KY	1991- 8 hours	Radiation Safety Training

Specific isotope usage:

Institution, City	Date and duration	Radio-isotope(s)	Max. Amount handled (mCi)	Type(s) of experiment or use
University of Kentucky, Lexington, KY	3/91-11/95	C ¹⁴ H ³ , P ³²	0.5 mCi	Enzymatic Assays DNA/RNA Labeling
Albany Medical College, Albany, NY	2/96-9/97	I ¹²⁵ , C ¹⁴ , P ³²	5 mCi	Protein labeling*, Enzymatic Assays, DNA/RNA Labeling,
Medical University of South Carolina, Charleston, SC	5/98-6/00	C ¹⁴ , P ³²	10 mCi	DNA/RNA labeling Enzymatic Assays

Radiation detection equipment operated: (circle all that apply)

Beta survey meter

low energy gamma detector

well crystal detector

Dose rate meter

high energy gamma detector

liquid scintillation counter

Ruihua Chen

RSO Review _____

Date April 8, 2008

Radioactive Material Experience Record

* **Reference:** Chen R, B Gao, C Huang, RF Rotundo, F Blumenstock and TM Saba (2000). Increased transglutaminase-mediated multimerization of matrix fibronectin in lung endothelial cell layers exposed to tumor necrosis factor. *Am. J. Physiol.* 279: L161-L174

Radioactive Material Experience Record

Name: Xiaoman Yang

Title: Research Associate Scientist

Room # 267

Telephone Ext. 732-214-2439

Experience

Formal Radiation Training:

Institution, City	Date and duration	Name of course and short description
Albert Einstein College of Medicine	May, 2005; 4 hours	Radiation Safety Refresher Course
Albert Einstein	June, 2004; 4 hours	Radiation Safety Refresher Course
Albert Einstein	June, 2003; 4hours	Radiation Safety Refresher Course
Albert Einstein	July, 2002, 4 hours	Radiation Safety Refresher Course
Albert Einstein	July, 2001, 8 hours	Radiation Safety Training
Novo Nordisk Inc	Oct, 2007; 2 hours	Hands-on training: lab work with I-125 labeled proteins (supervised by RSO)
Novo Nordisk Inc	Dec, 2007; 8 hours	Radiation Safety Training

Specific isotope usage:

Institution, City	Date and duration	Radio-isotope(s)	Max. Amount handled (mCi)	Usage
Albert Einstein College of Medicine	2001-05	H ³	10 mCi	Protein/enzyme assay
Albert Einstein College of Medicine	2001-05	C ¹⁴	5 mCi	Protein/enzyme assay
Albert Einstein College of Medicine	2002-03	P ³²	500 uCi	DNA labeling
Novo Nordisk	Dec 2007- present	I ¹²⁵ -labeled protein	100 uCi (experiments supervised by RSO)	Protein/enzyme assay

Radiation detection equipment operated: (circle all that apply)

☒ Beta survey meter X
 ☒ low energy gamma detector X
 well crystal detector
☒ Dose rate meter X
 high energy gamma detector
 ☒ liquid scintillation counter X

RSO Review _____

Date _____

This is to acknowledge the receipt of your letter/application dated

4/9/2008, and to inform you that the initial processing which includes an administrative review has been performed.

☒ AMEND. 29-31105-01
There were no administrative omissions. Your application was assigned to a technical reviewer. Please note that the technical review may identify additional omissions or require additional information.

☐ Please provide to this office within 30 days of your receipt of this card

A copy of your action has been forwarded to our License Fee & Accounts Receivable Branch, who will contact you separately if there is a fee issue involved.

Your action has been assigned **Mail Control Number** 142303.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.