



December 3, 2007

NMBZ

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

03037092

RE: License # 29-31105-01

Dear Sir/Madam,

Novo Nordisk requests an amendment of our NRC license to add four Authorized Users to item 11. Those individuals would be: John Zhang, Maryann Gruda, Ruihua Chen, and Xaioman Yang. Summaries of the radioactive material experience for each of the proposed AU's are attached. In addition, please remove Eva Norling Olsen, Ph.D. as an Authorized User.

Thank you in advance for your time and effort.

Sincerely,

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

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REGION 1
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141535

Radioactive Material Experience Record

Name: John Zhang

Title: Staff Scientist

Room # 226

Telephone Ext. 732-214-2420

Experience

Formal Radiation Training:

College/University Courses:

Shanghai Medical University: Radiology

Short Courses: (indicate duration)

University of Kentucky; Radiation Safety training (2hr / every year)

University of South Alabama; Radiation safety training (2hr/every year)

Cornell Medical College; Radiation Safety training (2hr/every year)

Novo Nordisk; Radiation Safety training (2hr)

Specific isotope usage:

Nuclide	Chemical form	Physical form	Maximum quantity handled
	³⁵ S Methionine	liquid	5 mCi
³² P dCTP	DNA, RNA	liquid	200 uCi
³³ P UTP	RNA	liquid	1 mCi
	¹⁴ C Ornithine	liquid	100 uCi
	¹²⁵ I- protein	liquid	10 mCi (in planning)

Radiation detection equipment operated: (circle all that apply)

Beta survey meter ✓

low energy gamma detector ✓

well crystal detector

Dose rate meter
counter

high energy gamma detector

liquid scintillation ✓

RSO Review _____

Date _____

Radioactive Material Experience Record

Name: Maryann Gruda, Ph.D.
Room #214

Title: Staff Scientist
Telephone: 732-214-2419

Experience

Formal Radiation Training:

Institution, City	Date and duration	Name of course and short description
Applied Health Physics, Bethal Park	May 16, 2001 8 hours	Radiation Safety Officer Refresher Course
Applied Health Physics, Bethal Park	May 10-14, 1999 40 hours	Radiation Safety Officer Training Course
Kimeragen, Newtown, PA	1997-3 hour	Radiation Safety Training and Annual Reviews
Bristol-Myers Squibb, Princeton	11/92 1/2 day	Radiation Safety Training-Individual
Bristol-Myers Squibb, Princeton	10/93, 10/94 1 hour	Annual Review Radiation Safety
University of Pennsylvania, Philadelphia, PA	8/97-8/92 1 hour	Radiation Safety Training and Annual Reviews

Specific isotope usage:

Institution, City	Date and duration	Radio-isotope(s)	Max. Amount handled (mCi)	Type(s) of experiment or use
University of Pittsburgh, Pgh, PA	8/96-8/97	C ¹⁴	0.5 mCi	Enzymatic Assays
University of Pennsylvania, Philadelphia, PA	8/97-8/92	C ¹⁴ S ³⁵ , P ³²	1 mCi	DNA/RNA Labeling, Enzymatic Assays
Bristol-Myers Squibb, Princeton, NJ	11/92-1/96	C ¹⁴ S ³⁵ , P ³²	10 mCi	DNA/RNA/Protein Labeling, Enzymatic Assays
ValiGen (Kimeragen) Newtown, PA	9/97-2001	P ³³ , P ³²	1 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 counter

high energy gamma detector

liquid scintillation

RSO Review _____

Date _____

Radioactive Material Experience Record

Name: Xiaoman Yang

Title: Research Associate Scientist

Room # 267

Telephone Ext. 2439

Experience

Formal Radiation Training: Certificate

College/University Courses: Elbert Einstein Collage of medicine

Short Courses: (indicate duration) :

Elbert Einstein College of Medicine - Radiation Safety training 8 hours

Novo Nordisk - Radiation Safety Training 2hr

Specific isotope usage:

Nuclide	Chemical form	Physical form	Maximum quantity handled
3 H	glucose	liquid	500uci
C14	liquid		500uci
I-125	labeled protein (in planning)		10 mCi

Radiation detection equipment operated: (circle all that apply)

Beta survey meter

low energy gamma detector

well crystal detector

Dose rate meter
counter

high energy gamma detector

liquid scintillation

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Radioactive Material Experience Record

Name: Ruihua Chen

Title: Staff Scientist

Room # 222

Telephone Ext. 2410

Experience

Formal Radiation Training:

College/University Courses:

University of Kentucky Radiation safety training
Albany Medical College Radiation safety training
MUSC Radiation safety training

Short Courses: (indicate duration)

Specific isotope usage:

Nuclide	Chemical form	Physical form	Maximum quantity handled
32P	32p-dCTP	DNA	50 uCi
14C	14C-ornithine		100 uCi
14C	14C-putriscine		100 uCi
3H	3H-spermidine		100 uCi
125I	125I-albumin		100 uCi

Radiation detection equipment operated: (circle all that apply)

Beta survey meter

low energy gamma detector

well crystal detector

Dose rate meter
counter

high energy gamma detector

liquid scintillation

Ruihua Chen

RSO Review _____

Date Nov 2, 2007

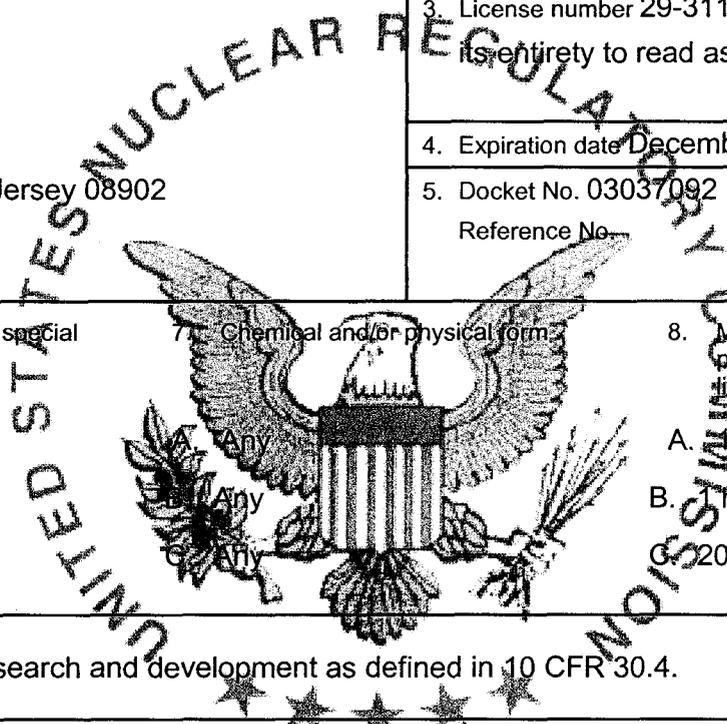
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MATERIALS LICENSE

Amendment No. 01

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

<p>Licensee</p> <p>1. Novo Nordisk Inc.</p> <p>2. 685 Highway Route 1 North Brunswick, New Jersey 08902</p>	<p>In accordance with the letter dated January 10, 2007</p> <p>3. License number 29-31105-01 is amended in its entirety to read as follows:</p> <p>4. Expiration date December 31, 2015</p> <p>5. Docket No. 03037092 Reference No.</p>	
<p>6. Byproduct, source, and/or special nuclear material</p> <p>A. Phosphorus 32</p> <p>B. Sulfur 35</p> <p>C. Iodine 125</p>	<p>7. Chemical and/or physical form</p> <p>A. Any</p> <p>B. Any</p> <p>C. Any</p>	<p>8. Maximum amount that licensee may possess at any one time under this license</p> <p>A. 1 millicuries</p> <p>B. 1 millicuries</p> <p>C. 20 millicuries</p>
<p>9. Authorized use:</p> <p>A. through C. Research and development as defined in 10 CFR 30.4.</p>		



CONDITIONS

- 10. Licensed material may be used or stored only at the licensee's facilities located at 685 U.S. Highway 1. New Brunswick, New Jersey.
- 11. Licensed material in Subitems 6.A. and 6.B. shall be used by, or under the supervision of, Eva Norling Olsen, Ph.D.. Licensed material in Subitem 6.C. shall be used by, or under the supervision of, Scott Dennerlein.
- 12. The Radiation Safety Officer for this license is Scott Dennerlein.
- 13. The licensee shall not use licensed material in or on human beings.

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number

29-31105-01

Docket or Reference Number

03037092

Amendment No. 01

14. The licensee shall not use licensed material in field applications where it is released except as provided otherwise by specific condition of this license.
15. The licensee is authorized to hold byproduct material with a physical half-life of less than or equal to 120 days for decay-in-storage before disposal without regard to its radioactivity if the licensee:
- Monitors byproduct material at the surface before disposal and determines that its radioactivity cannot be distinguished from the background radiation level with an appropriate radiation detection survey meter set on its most sensitive scale and with no interposed shielding; and
 - Removes or obliterates all radiation labels, except for radiation labels on materials that are within containers and that will be managed as biomedical waste after they have been released from the licensee; and
 - Maintains records of the disposal of licensed materials for 3 years. The record must include the date of disposal, the survey instrument used, the background radiation level, the radiation level measured at the surface of each waste container, and the name of the individual who performed the disposal.
16. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."
17. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. The U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.
- Application dated October 21, 2005 (ML053060089)
 - Letter dated November 22, 2005 (ML053330477)

For the U.S. Nuclear Regulatory Commission

Date February 8, 2007

By

Original signed by Thomas K. Thompson

Thomas K. Thompson
Commercial and R&D Branch
Division of Nuclear Materials Safety
Region I
King of Prussia, Pennsylvania 19406

Thursday, February 08, 2007 4:01:48 PM

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

12/3/2007, and to inform you that the initial processing which includes an administrative review has been performed.

Amended 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** 141535.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.