



CardinalHealth

Cardinal Health
Nuclear Pharmacy Services
7000 Cardinal Place
Dublin, OH 43017
614.757.5000 main
800.234.8701 toll free

Br 2

cardinalhealth.com

(34-31473-02)

L31473

03038569

02500

2012 AUG -3 1:26 PM
RECEIVED
REGION 1

July 30, 2012

Elizabeth Ullrich
Licensing Assistance Team
U.S. Nuclear Regulatory Commission, Region I DNMS
2100 Renaissance Blvd., Suite 100
King of Prussia, PA 19406-2713

FAX TO: 610.337.5269

Re: Additional Information for New Radioactive Materials License 34-31473-01, Mail Control Number 577398, Borschow Hospital & Medical Supplies, Inc., a Cardinal Health company, Guaynabo, Puerto Rico.

Licensing / Ms. Ullrich:

Cardinal Health 414, LLC on behalf of Borschow Hospital & Medical Supplies, Inc., a Cardinal Health company, (hereafter Cardinal Health) submits additional information in response to the letter dated July 16, 2012 which indicated that our application for the new license would be void without prejudice. Cardinal Health provides additional information as indicated in our letter of reply dated June 26, 2012 to items requested by NRC in the letter dated June 12, 2012. The NRC request is in italics followed by the Cardinal Health response.

1. *For each person to be named on the license provide either a) the name and license number on which they may already be listed as an ANP or provide the required supporting information for each person, as described in section 8.7.2 of NUREG 1556, Vol. 13, Rev. 1.*

Cardinal Health submits the training and experience of Richard Rosado Maldonado, R.Ph. as an Authorized Nuclear Pharmacist (ANP) and Radiation Safety Officer to be named on the license. Richard Rosado Maldonado is listed as ANP on Cardinal Health Florida radioactive material license number 3453-5. Documentation of training is enclosed in **Attachment A**.

2. *Please identify by name the people you want listed as an AU on the license and provide the required supporting information for each person, as described in section 8.7.2 of NUREG 1556, Vol. 13, Rev. 1.*

Cardinal Health defers the request or addition of any applicable qualified non-pharmacist authorized users for this license to future amendment request(s).

578071

(Reference MC No. 577398)

NMSS/RGN1 MATERIALS-002

3. *Please identify by name the person you want listed as the pharmacy RSO on the license and provide the required supporting information for each person, as described in section 8.7.1 of NUREG 1556, Vol. 13, Rev. 1.*

Cardinal Health identifies Richard Rosado Maldonado, R.Ph. as the pharmacy RSO on the license. The duties of the Pharmacy Radiation Safety Officer (PRSO) are enclosed in **Attachment B**. Documentation of ANP training is enclosed in Attachment A. NUREG-1556, Vol. 13, Rev. 1, Section 8.7.1 (10 CFR 30.33(a)(3)) indicates that, "Any individual who has sufficient training and experience to be named as an ANP is also considered qualified to serve as the facility RSO".

4. *Has the facility described in the application been constructed and is it ready for occupancy?*

Cardinal Health submits that the facility is constructed and it is estimated that the occupancy and pharmacy opening date will be in late August 2012.

5. *Provide a copy of the registration or license from the Puerto Rico Board of Pharmacy for the new Borschow pharmacy, as required by 10 CFR 32.72.a.*

Cardinal Health has submitted an application for the Borschow Puerto Rico Board of Pharmacy license which will be posted and available for inspection by the first day of business in August 2012.

We regret any delay in providing the information requested for this new license application. If you have any questions regarding this request, please contact Dan Hill at 614.757.5074.

Sincerely,



Willie Regits, Ph D.
Corporate Radiation Safety Officer
Director, Health Physics
Nuclear Pharmacy Services

/dh

Enclosure: Attachment A: ANP Training
Attachment B: PRSO Duties

cc: PR NRC License File (2)
Richard Rosado, PRSO, PR
Shirley Rodriguez Danner, PR
Steve D'Amico
Deborah Weitzman, SVP, Borschow

ATTACHMENT A

Documentation of Training

Authorized Nuclear Pharmacist

ESTADO LIBRE ASOCIADO DE PUERTO RICO
Commonwealth of Puerto Rico

106009

DEPARTAMENTO DE SALUD
Department of Health

OFICINA DE REGLAMENTACION Y CERTIFICACION
Office of Regulation and Certification
DE PROFESIONALES DE LA SALUD
of Health Professionals
CERTIFICADO DE REGISTRO
(REGISTRY CERTIFICATE)

NOMBRE (NAME)	RICHARD ROSADO MALDONADO
PROFESIÓN (PROFESSION)	PHARMACIST
NÚM. DE LICENCIA (LICENSE NO.)	5068
NÚM. DE REGISTRO (REGISTRY NO.)	109357
VÁLIDO DESDE (VALID FROM)	APRIL 1, 2012
VENCE EN (DUE DATE)	JULY 31, 2013

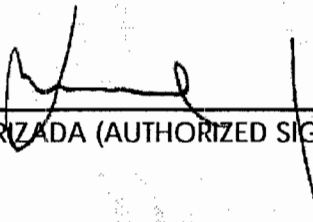
CERTIFICAMOS QUE ESTE PROFESIONAL CUMPLIÓ CON EL REQUISITO ESTABLECIDO POR LA
(WE CERTIFY THAT THIS PROFESSIONAL HAS COMPLIED WITH REQUISITES ESTABLISHED)

LEY NÚM. 11 DE 23 DE JUNIO DE 1976 SEGÚN ENMENDADA.
(BY ACT NO. 11 OF JUNE 23, 1976 AS AMENDED)

LA LICENCIA DEBERÁ RECERTIFICARSE A LA FECHA DE VENCIMIENTO O ANTES.
(THE LICENSE MUST BE RECERTIFY THE DATE DUE OR BEFORE)

DADA EN SAN JUAN, PUERTO RICO HOY. APRIL 10, 2012
(GIVEN IN SAN JUAN, PUERTO RICO ON)




FIRMA AUTORIZADA (AUTHORIZED SIGNATURE)

NO TRANSFERIBLE (NON TRANSFERABLE)

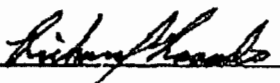
ADVERTENCIA: CUALQUIER ALTERACION O BORRADURA CANCELA ESTA CERTIFICACION.
ANY ALTERATION OR ERASURE VOIDS THIS CERTIFICATION.
ESTE DOCUMENTO NO ES TRANSFERIBLE / THIS DOCUMENT IS NOT TRANSFERABLE.

201204102013073160324

**DOCUMENTATION OF AUTHORIZED NUCLEAR PHARMACIST
TRAINING**

I hereby certify that the pharmacist listed below has been satisfactorily trained and that the individual has achieved a level of competency sufficient to independently operate a nuclear pharmacy.

Pharmacist Name (print) Richard Rosado

Pharmacist Signature 

Date 1/13/03

Preceptor Name (print) Noel Rodriguez, R.Ph., BCNP

Preceptor Signature 

Date 1/13/03

Location San Juan, P.R.
JAN 13 2003 14:03

RADIOISOTOPE HANDLING EXPERIENCE

Name: Richard Rosado

Date: 01/15/03

Document the actual use/handling of radioactive material under the supervision of an Authorized Nuclear Pharmacist.

ISOTOPE	MAXIMUM ACTIVITY HANDLED	USE See key below: 1,2,3,4,5,6,7	EXPERIENCE Actual clock hours (Include date range of experience)	WHERE EXPERIENCE GAINED
Mo-99	10 Ci	1,7	07/29/02 to 10/04/02 400 Hours	Syncor Carolina de Puerto Rico
Tc-99m	12 Ci	3,4,5,6,7		
I-131	150 mCi	1,3,4,5,6	10/28/02 to 11/29/02 200 Hours	
Xe-133	N/A			
I-123	N/A		12/23/02 to 01/15/03 144 Hours	
Ga-67	150 mCi	1,3,4,5,6		
Tl-201	50 mCi	1,3,4,5,6		
Co-57	10 mCi	1,2		
Cs-137	250 uCi	1,2		
In-111	1.3 mCi	1,3,4,5,6	744 Total Hours	

Key for "Use": the number, or numbers, entered under "Use" should correspond to the handling experience for each isotope.

1. Ordering, shipping, receiving radioactive materials and performing related radiation surveys
2. Calibrating, using and performing checks for proper operation of dose calibrators, scintillation detectors, survey meters, and, if appropriate, instruments used to measure alpha- or beta-emitting radionuclides
3. Calculating, assaying and safely preparing dosages for patients or human research subjects
4. Using appropriate internal controls to avoid mistakes in the labeling and/or administration of by product material
5. Using procedures to prevent or minimize contamination and using proper decontamination procedures
6. Learning emergency procedures to handle and contain spilled materials safely, including related decontamination procedures, surveys, and wipe tests
7. Eluting Tc-99m from generator systems, assaying the eluate for Tc-99m and for Mo-99 contaminations, and processing the eluate with reagent kits to prepare Tc-99m labeled radioactive drugs

TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

Richard Rosado

Location of Training	Date(s) of Accordance	Course Title	Total Clock Hours of Course	BREAKDOWN OF COURSE CONTENT IN CLOCK HOURS*					
				Radiation Physics & Instrumentation	Radiation Protection	Math Pertaining to Radioactivity	Radiation Biology	Radiopharmaceutical Chemistry	
SYNCOR INT'L CORPORATION, WOODLAND HILLS, CA	10/7/2002 to 10/25/2002 AND 12/3/2002 to 12/20/2002	SYNCOR AUTHORIZED NUCLEAR PHARMACIST /AUTHORIZED USER TRAINING PROGRAM	227	92	50	24	25	36	
*Note: Show a breakdown of hours by institution, dates, and subjects. List each hour only once (i.e., under the most applicable subject category)			TOTAL HOURS	227	92	50	24	25	36

**University of Arkansas for Medical Sciences
College of Pharmacy**

This is to certify that

Richard Rosado

*has successfully completed didactic training requirements for the
Nuclear Pharmacy Authorized User Program.*

December 20, 2002



L.D. Milne, Ph.D.
Dean

Nicki Hilliard, Pharm.D., BCNP
Program Director

SYNOR INTERNATIONAL CORPORATION

certifies that

Richard Rosado

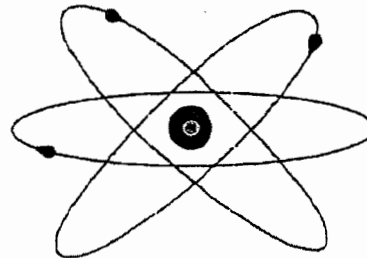
successfully completed the

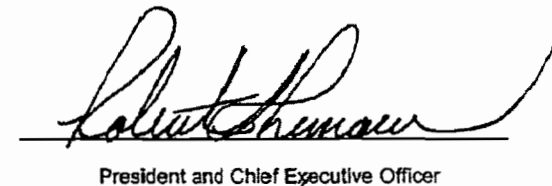
Authorized Users Training Program

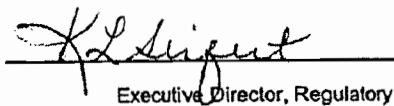
on

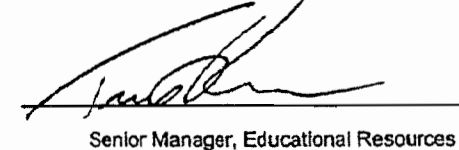
December 20, 2002


Senior Corporate Vice President, Q&R




President and Chief Executive Officer


Executive Director, Regulatory


Senior Manager, Educational Resources

STATE OF FLORIDA
DEPARTMENT OF HEALTH
BUREAU OF RADIATION CONTROL

RADIOACTIVE MATERIALS LICENSE
SUPPLEMENTAL SHEET

CARDINAL HEALTH 414, LLC
Nuclear Pharmacy Services, Quality & Regulatory
7000 Cardinal Place
Dublin, OH 43017

With reference to correspondence dated December 7, 2010, State of Florida Radioactive Materials License Number 3453-5 is hereby amended.

TO CHANGE CONDITION 12 TO READ:

CONDITIONS

12. A. Licensed material shall be used by, or under the supervision and in the physical presence of at least one of the below listed nuclear pharmacists. Licensed material may also be used by, or under the supervision and in the physical presence of a visiting nuclear pharmacist. A visiting nuclear pharmacist may work for up to 60 days each calendar year, provided the licensee's management approves, in writing, each visiting nuclear pharmacist; the licensee maintains a copy of that individual's licensure from the Florida Board of Pharmacy as a nuclear pharmacist; and the licensee maintains a record of each visitation. Copies of these records shall be maintained for 5 years after the visiting nuclear pharmacist's last visit.

Authorized Users	Authorized Users
Hossein Izadjoo, R.Ph. JoAnna Snyder, R.Ph. James Hardee, R.Ph. Hoa Thai Nguyen, R.Ph.	Arthur Bowman, R.Ph. Timothy D. Mumau, R.Ph. Phillip Phaneuf, R.Ph. Richard Rosado-Maldonado, R.Ph.

License Number: 3453-5
 Amendment No.: 22
 Control Number: 20101217-3069

LICENSEE COPY
 Page 1 of 2 Page(s)

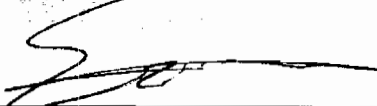
Category: [3B]
 Expiration Date: 4/30/2013

STATE OF FLORIDA
DEPARTMENT OF HEALTH
BUREAU OF RADIATION CONTROL

RADIOACTIVE MATERIALS LICENSE
SUPPLEMENTAL SHEET

12. B. The radiation safety officer is Amanda Sacca.
C. The corporate radiation safety officer is Willie Regits, Ph.D.

For the Bureau of Radiation Control:


Eric Lieberman
Environmental Specialist II
4052 Bald Cypress Way – Bin C21
Tallahassee, FL 32399-1741
(850) 245-4545

Issuance Date: JAN 10 2011

A party whose substantial interest is affected by this order may petition for an administrative hearing pursuant to sections 120.569 and 120.57, Florida Statutes. Such proceedings are governed by Rule 28-106, Florida Administrative Code. A petition for administrative hearing must be in writing and must be received by the Agency Clerk for the Department, within twenty-one (21) days from the receipt of this order. The address of the Agency Clerk is: Agency Clerk, 4052 Bald Cypress Way, BIN # A02, Tallahassee, Florida 32399-1703. The Agency Clerk's facsimile number is 850-410-1448. A copy of the petition should also be sent to: Bureau Chief, Bureau of Radiation Control, 4052 Bald Cypress Way, BIN # C21, Tallahassee, FL 32399-1741. The Bureau Chief's facsimile number is 850-487-0435. Mediation is not available as an alternative remedy. Your failure to submit a petition for hearing within 21 days from receipt of this order will constitute a waiver of your right to an administrative hearing, and this order shall become a "final order." Should this order become a final order, a party who is adversely affected by it is entitled to judicial review pursuant to Section 120.68, Florida Statutes. Review proceedings are governed by the Florida Rules of Appellate Procedure. Such proceedings may be commenced by filing one copy of a Notice of Appeal with the Agency Clerk of the Department of Health and a second copy, accompanied by the filing fees required by law, with the Court of Appeal in the appropriate District Court. The notice must be filed within 30 days of rendition of the final order.

License Number: 3453-5
Amendment No.: 22
Control Number: 20101217-3069

LICENSEE COPY
Page 2 of 2 Page(s)

Category: [3B]
Expiration Date: 4/30/2013

ATTACHMENT B

Pharmacy Radiation Safety Officer Duties

The day-to-day delegated duties of the PRSO are as follows:

1. General surveillance over all activities involving radioactive material, including routine monitoring and special surveys.
2. Ensuring compliance with NRC/Agreement State regulations as well as conditions of the Radioactive Material License.
3. Monitoring the performance of fume hoods that are associated with isotope work.
4. Serving as the primary source of radiation protection information for personnel at all levels of responsibility.
5. Supervising and coordinating the receipt, opening, and delivery of all shipments of radioactive material arriving at the nuclear pharmacy.
6. Supervising and coordinating the preparation of all shipments of radioactive material leaving the nuclear pharmacy.
7. Supervising the distribution and processing of personnel monitoring equipment.
8. Conducting training programs in proper procedures for the use of radioactive material.
9. Supervising and coordinating the radioactive waste disposal program.
10. Supervising the safe storage of all radioactive materials not in current use.
11. Ensuring that sealed sources are leak-tested at proper intervals.
12. Maintaining an inventory of all radioactive materials and limiting the quantity of radionuclides at the facility to the amounts authorized by the license.
13. Authorization from the Corporate RSC to cease any and all operations which the PRSO deems to be unsafe to employees, the public or environment, or activities that are in violation of Federal and/or Agreement State regulations and the radioactive materials license, as it pertains to radioactive materials or transport thereof. Please see the sample Delegation of Authority which authorizes this.
14. The PRSO will review radiation surveys in unrestricted and restricted areas to determine that dose rates and amounts of contamination were at ALARA levels during the previous quarter.

NOTE: In the absence of the PRSO (e.g., in the early morning when only one authorized user may be present, when the PRSO is sick or on vacation), another authorized user must assume the duties of the PRSO and ensure compliance with NRC regulations as well as conditions of the Radioactive Material License.

This is to acknowledge the receipt of your letter application dated

7-30-12, and to inform you that the initial processing which includes an administrative review has been performed.

New (Docket # 03038569)
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** 578071.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.