



Br. 1

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

cardinalhealth.com

March 23, 2015

Licensing Assistance Team
U.S. NRC, Region I DNMS
2100 Renaissance Blvd.
King of Prussia, PA 19406

34-31473-02 MD

RLJ

Re: Amendment Request for Radioactive Materials License ~~34-31473-02~~, Cardinal Health
PR 120, Inc., Guaynabo, Puerto Rico.

03038569

Licensing:

Cardinal Health 414, LLC and Cardinal Health P.R. 120, Inc., hereafter Cardinal Health, requests an amendment for the above referenced radioactive materials license to add Julian Ramon Morales Brignac, R.Ph. as an Authorized Nuclear Pharmacist. Documentation of training is enclosed.

If you have any questions regarding this request, please contact me at 614.757.9586.

Sincerely,

Glenn Sullivan
Manager, Health Physics
Quality and Regulatory
Nuclear Pharmacy Services

/dh

Encl: Training Documents
Original + 1 copy

cc: Alexis Gomez, PRSO, Loc. 7650
Shirley Danner, Loc. 7650
Wayne Boudreaux
License File 7650 (3)

RECORDED & INDEXED

586392
NMSS/RGN1 MATERIALS-002



Cardinal Health
Nuclear Pharmacy Services
Quality and Regulatory Department
7000 Cardinal Place
Dublin, OH 43017
tel 614.757.5000
fax 614.652.4596

www.cardinal.com

DOCUMENTATION OF AUTHORIZED NUCLEAR PHARMACIST TRAINING

The training outline in the Authorized Nuclear Pharmacist Guideline has been completed. The Pharmacist is qualified to assume the duties and responsibilities outlined in the guideline.

I hereby certify that the above training has been satisfactorily completed and that the individual has achieved a level of competency sufficient to independently operate a nuclear pharmacy.

Pharmacist Name (Print) Julian R. Morales

Pharmacist Signature: Julian Morales Date: 3/18/15

Preceptor Name (Print) Shirley J. Danner

Preceptor Signature: Shirley J. Danner Date: 03/18/2015

Send this document with a completed **Radioisotope Handling Experience Form** and a photocopy of the pharmacist's license to the Quality and Regulatory Department.

RADIOISOTOPE HANDLING EXPERIENCE

Name: *Julian R. Morales*

Date: *03/18/2015*

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

ISOTOPE	SINGLE HIGHEST mCi 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
Co-57	<i>5.3 mCi</i>	<i>1, 2</i>	<i>01/02/15 - 01/09/15 40 hrs</i>	Cardinal Health
Cs-137	<i>194.9 uCi</i>	<i>1, 2</i>		
F-18				
Ga-67	<i>25 mCi</i>	<i>1, 3, 4, 5</i>	<i>11/25/14 - 12/31/14 80 hrs</i>	San Juan Puerto Rico
I-123				
I-131	<i>200 mCi</i>	<i>1, 3, 4, 5</i>	<i>01/12/15 - 03/18/15 384 hrs</i>	Loc # 7650
In-111				
Mo-99	<i>19 Ci</i>	<i>1, 3, 4, 5, 7</i>		
Tc-99m	<i>15 Ci</i>	<i>1, 2, 3, 4, 5, 6, 7</i>	<i>TOTAL 504 hrs</i>	
Tl-201	<i>20 mCi</i>	<i>1, 3, 4, 5</i>		
Xe-133				
Y-90				

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

Estado Libre Asociado de Puerto Rico
Departamento de Salud



Licencia Núm. 4723

LA JUNTA DE FARMACIA

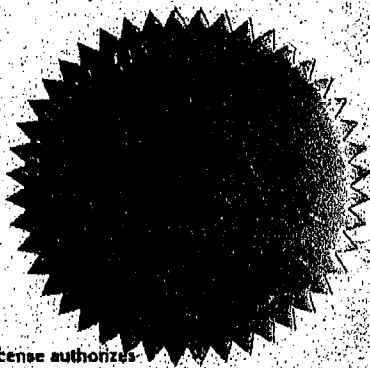
expide esta licencia a

Julían Ramón Morales Bagnac

por virtud de la cual se le autoriza a ejercer como **Farmacéutico(a)**
bajo las provisiones de las leyes que regulan esta práctica en Puerto Rico.

Otorgada bajo la firma y sello de esta Junta,

el día 19 de diciembre del año de Nuestro Señor mil novecientos noventa y siete



Presidente de la Junta
o Representante Autorizado

TRANSLATION: This license authorizes
the above named professional to
practice his/her profession.

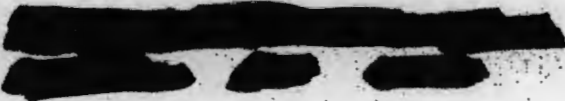


COLEGIO DE FARMACEUTICO

PO Box 360206, San Juan, P. R. 00936-0206 • Tel. 78

2 de mayo de 2014

JULIAN R MORALES BRIGNAC



COLEGIO FARMACEUTICOS DE PR
PO BOX 360206 SAN JUAN PR 00936-020
787-753-7157
CAJERO: MRE # OF ITEMS: 1
Terminal ID: Cajal

COLEGIACION 2014-2015	\$100.00F
SUB TOTAL:	\$100.00
TAX MUNICIPAL:	\$0.00
TAX ESTATAL:	\$0.00
TOTAL:	\$100.00
CHK:	\$100.00
CAMBIO:	\$0.00

Socio: MORALES BRIGNAC JULIAN
No. Socio: 004723

05/07/2014 03:38:15 PM 9403

RECUERDE SACARLE COPIA A ESTE RECIBO
GRACIAS

-----HIDE TU RECIBO-----

IVULOTO : CAEXL-A2R3C
ST DRAW037 MAYO/10/2014
CONTROL : 166-597922

-----CON EL IVULOTO TODOS GANAMOS-----

Certificación de Colegiación 2014 - 2015

Se certifica que el licenciado **JULIAN R MORALES BRIGNAC** con número de licencia **004723** es miembro activo del Colegio de Farmacéuticos de Puerto Rico.

Esta certificación vence el 30 de junio de 2015

Lcda. Milagros Morales

Lcda. Milagros Morales
Directora Ejecutiva



Sello Oficial

PERSONAL INFORMATION WAS REMOVED BY NRC. NO COPY OF THIS INFORMATION WAS RETAINED BY THE NRC.

Colegio de Farmacéuticos de Puerto Rico

Es miembro activo de esta institución para el periodo de:

JULIAN R MORALES BRIGNAC

Licencia: 004723

• www.colegiodefarmaceticospr.org

ESTADO LIBRE ASOCIADO DE PUERTO RICO
Commonwealth of Puerto Rico
DEPARTAMENTO DE SALUD
Department of Health

155416

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)	<u>JULIAN R MORALES BRIGNAC</u>
PROFESIÓN (PROFESSION)	<u>Farmacéutico (a)</u>
NÚM. DE LICENCIA (LICENSE NO.)	<u>4723</u>
NÚM. DE REGISTRO (REGISTRY NO.)	<u>91831</u>
VÁLIDO DESDE (VALID FROM)	<u>1/SEP/2013</u>
VENCE EN (DUE DATE)	<u>31/AGO/2016</u>

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. 20 de agosto del 2013
(GIVEN IN SAN JUAN, PUERTO RICO ON)



[Handwritten Signature]
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.

201308202016083192479

COMMONWEALTH OF PUERTO RICO
DEPARTMENT OF HEALTH

155416

OFFICE OF REGULATION AND CERTIFICATION
OF HEALTH PROFESSIONALS

REGISTRY CERTIFICATE


NAME	<u>JULIAN R MORALES BRIGNAC</u>
PROFESSION	<u>PHARMACIST</u>
LICENSE NO.	<u>4723</u>
REGISTRY NO.	<u>91831</u>
VALID FROM	<u>SEP/01/2013</u>
DUE DATE	<u>AUG/31/2016</u>

WE CERTIFY THAT THIS PROFESSIONAL HAS COMPLIED WITH REQUISITES ESTABLISHED

BY ACT NO. 11 OF JUNE 23, 1976 AS AMENDED.

THE LICENSE MUST BE RECERTIFIED THE DATE DUE OR BEFORE.

GIVEN IN SAN JUAN, PUERTO RICO ON AUGUST 20, 2013



FIRMA AUTORIZADA (AUTHORIZED SIGNATURE)



NON TRANSFERABLE
ANY ALTERATION OR ERASURE VOIDS THIS CERTIFICATION.
THIS DOCUMENT IS NOT TRANSFERABLE.

201308202016083192479

PURDUE UNIVERSITY

WEST LAFAYETTE, INDIANA

COLLEGE OF PHARMACY
DEPARTMENT OF PHARMACY PRACTICE
NUCLEAR PHARMACY PROGRAMS

THIS CERTIFICATE IS AWARDED TO

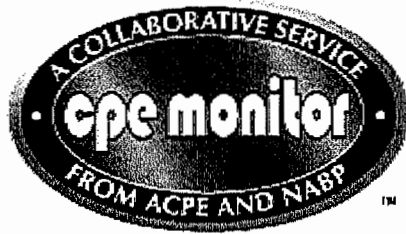
Julian Morales

AS EVIDENCE OF COMPLETION OF THE

NUCLEAR PHARMACY CERTIFICATE PROGRAM

January 5, 2015

Kara D Weatherman
Director of Nuclear Pharmacy Training Programs



CPE Monitor Statement

Participant Name

Julian Morales
NABP e-Profile ID: 699740

Provider Information

Purdue University College of
Pharmacy

Activity Information

Activity Title:	Nuclear Pharmacy Certificate Program-Live
Activity Date:	12/13/2014
ACPE UAN:	0018-0000-14-031-L04-P
Topic Designators:	General Pharmacy Topics
Contact Hours (CEU):	65.0 (6.5)
Live Hours:	65.0
Home Hours:	0.0
Activity Type:	Application-based

Disclaimer:

This statement contains information provided to NABP from the Accreditation Council for Pharmacy Education (ACPE), and can be used as proof of CPE credit in the event that the ACPE-accredited provider no longer issues such statements directly to participants. The CPE provider is responsible for the accuracy of the CPE course data on the statement; however, NABP affirms that the participation information has been matched to the corresponding e-Profile data within its systems, from which this statement was generated. Requests for changes to CPE course data must be directed to the ACPE-accredited provider that offered the course.

Print Date: 03/09/2015

Form Updated 08/11

TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES*

Trainee: Julian Morales
Date issued: January 5, 2015

Location of Training	Date(s) of Attendance	Nuclear Pharmacy Certificate Program	Total Clock Hours of Course	Breakdown of Course Content in Clock Hours				
				Radiation Physics & Instrumentation	Radiation Protection	Math Pertaining to Radioactivity	Radiation Biology	Radio-pharmaceutical Chemistry
Purdue University	December 2014 - January 2015	DVD-Workbook	150	51	33	13	21	32
	December 2014	On-Site	65	34	13	10	0	8
Total Hours Received			215					
Hourly breakdown by topic				85	46	23	21	40

* This form is representative of that which is used to apply for an NRC license amendment for an authorized user.

Director of Nuclear Pharmacy Training Programs: *Kara D Weatherman*
 Kara Duncan Weatherman, PharmD, BCNP, FAPhA
 Clinical Associate Professor of Pharmacy Practice
 Purdue University
 Nuclear Pharmacy Programs

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

3/23/15, and to inform you that the initial processing which includes an administrative review has been performed.

Amendment (34-31473-02MD)
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** 586392.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.

NRC FORM 532 (RI)
(6-96)

Sincerely,
Licensing Assistance Team Leader