

November 22, 2010

Colleen Casey
U.S. Nuclear Regulatory Commission
Region III Materials Licensing Branch
2443 Warrenville Road
Suite 210
Lisle, Illinois 60532-4352

Re: Additional Information to Control Number 572968 and Amendment to
Radioactive Material License 13-16558-01

Dear Ms. Casey,

This letter is in response to your communication of September 12, 2010 with our receipt of Amendment No. 60 to our NRC Material License No. 13-16558-01. We offer the following information in response to your requests:

1. Regarding the clarification of our request in the letter dated June 10, 2010 for the license amendment authorization for the use of Iodine-123 MIBG as a line item, this request was in error since the isotope is already authorized under 10 CFR 35.200. Therefore, we would like to withdraw this request of June 10, 2010 for our license amendment.
2. Regarding our request for the deletion of check sources used in Nuclear Medicine, we are in agreement with the NRC that a license amendment is not required since these sealed sources meet the criteria of disposal of short-lived isotopes under CFR 35.65. Therefore, we would like to withdraw this request of June 10, 2010 for our license amendment.
3. Regarding the finite possession limits for items listed in Subitem Nos. 8C for 35.300 and 8F for 31.11, we would state our maximum possession limit for No. 8C for 35.300 as not to exceed one curie. Our maximum possession limit for No. 8F for 31.11 would be not to exceed one millicurie.

In addition, we would like to request the following amendments to our Material License:

1. Removal of the following individuals as authorized users for medical use:
 - a. Gurbachan S. Kapoor, M.D.
 - b. Ivan Chermel, M.D.
 - c. Nobuo Nakagawa, M.D.



Northlake Campus
600 Grant Street
Gary, Indiana 46402

Midlake Campus
2269 West 25th Avenue
Gary, Indiana 46407

Southlake Campus
8701 Broadway
Merrillville, Indiana 46410

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2. The addition of Markus Yoon, M.S., as an HDR Authorized Medical Physicist for this license. Please find the attached supporting documents for this request, including Mr. Yoon's copies of degree, copy of Indiana license, reference letters, and proof of brachytherapy training, including form 313A.

We are hopeful this additional information will satisfactorily address the NRC issues that had been identified. We appreciate your time in reviewing our request for the license amendment.

Please feel free to contact me at 219-886-4540, or you may feel free to contact Gary Dillon, Radiation Safety Officer, at 219-738-5598.

Sincerely,

A handwritten signature in dark ink, appearing to read "Denise Dillard", with a stylized flourish at the end.

Denise Dillard, Vice-President
Government and External Affairs
T&R Officer

cc: Gary Dillon
Mary Jo Hagan

**AUTHORIZED MEDICAL PHYSICIST TRAINING AND EXPERIENCE
AND PRECEPTOR ATTESTATION**
[10 CFR 35.51]APPROVED BY OMB: NO. 3150-0120
EXPIRES: 3/31/2012

Name of Proposed Authorized Medical Physicist

Markus Yoon

**Requested
Authorization(s)**
(check all that apply)

- ☐ 35.400 Ophthalmic use of strontium-90 ☐ 35.600 Teletherapy unit(s)
☒ 35.600 Remote afterloader unit(s) ☐ 35.600 Gamma stereotactic radiosurgery unit(s)

PART I -- TRAINING AND EXPERIENCE
(Select one of the three methods below)

*Training and Experience, including Board Certification, must have been obtained within the 7 years preceding the date of application or the individual must have obtained related continuing education and experience since the required training and experience was completed. Provide dates, duration, and description of continuing education and experience related to the uses checked above.

☐ **1. Board Certification**

- a. Provide a copy of the board certification.
b. Go to the table in 3.c. and describe training provider and dates of training for each type of use for which authorization is sought.
c. Skip to and complete Part II Preceptor Attestation.

☐ **2. Current Authorized Medical Physicist Seeking Additional Authorization for use(s) checked above**

- a. Go to the table in section 3.c. to document training for new device.
b. Skip to and complete Part II Preceptor Attestation

☒ **3. Education, Training, and Experience for Proposed Authorized Medical Physicist**

- a. Education: Document master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university.

Degree

M.S.

Major Field

Medical Radiation Physics

College or University

Rosalind Franklin University

- b. Supervised Full-Time Medical Physics Training and Work Experience in clinical radiation facilities that provide high-energy external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services.

- ☒ Yes. Completed 1 year of full-time training in medical physics (for areas identified below) under the supervision of Gary Dillon M.S. who meets the requirements for an Authorized Medical Physicist.

AND

- ☒ Yes. Completed 1 year of full-time work experience in medical physics (for areas identified below) under the supervision of Gary Dillon M.S. who meets the requirements for an Authorized Medical Physicist.

AUTHORIZED MEDICAL PHYSICIST TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

3. **Education, Training, and Experience for Proposed Authorized Medical Physicist** (continued)

b. Supervised Full-Time Medical Physics Training and Work Experience (continued)

If more than one supervising individual is necessary to document supervised training, provide multiple copies of this page.

Description of Training/ Experience	Location of Training/License or Permit Number of Training Facility/Medical Devices Used+	Dates of Training*	Dates of Work Experience*
Medical Physics	Community Hospital Munster, IN Methodist Hospital Merrillville, IN	Aug. 2006 - Aug. 2009 Sept. 2009 - Current	Aug. 2006 - Aug. 2009 Sept. 2009 - Current
Performing sealed source leak tests and inventories	Community Hospital Munster, IN Methodist Hospital Merrillville, IN	Aug. 2006 - Aug. 2009 Sept. 2009 - Current	Aug. 2006 - Aug. 2009 Sept. 2009 - Current
Performing decay corrections	Community Hospital Munster, IN Methodist Hospital Merrillville, IN	Aug. 2006 - Aug. 2009 Sept. 2009 - Current	Aug. 2006 - Aug. 2009 Sept. 2009 - Current
Performing full calibration and periodic spot checks of external beam treatment unit(s)			
Performing full calibration and periodic spot checks of stereotactic radiosurgery unit(s)			
Performing full calibration and periodic spot checks of remote afterloading unit(s)	Community Hospital Munster, IN Methodist Hospital Merrillville, IN	Aug. 2006 - Aug. 2009 Sept. 2009 - Current	Aug. 2006 - Aug. 2009 Sept. 2009 - Current
Conducting radiation surveys around external beam treatment unit(s), stereotactic radiosurgery unit(s), remote after loading unit(s)	Community Hospital Munster, IN Methodist Hospital Merrillville, IN	Aug. 2006 - Aug. 2009 Sept. 2009 - Current	Aug. 2006 - Aug. 2009 Sept. 2009 - Current

Supervising Individual**

Tony Hill M.S.

License/Permit Number listing supervising individual as an authorized Medical Physicist

License # 13-16558-01

for the following types of use:

☒ Remote afterloader unit(s) ☐ Teletherapy unit(s) ☐ Gamma stereotactic radiosurgery unit(s)

+ Training and work experience must be conducted in clinical radiation facilities that provide high-energy external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services.

* 1 year of Full-time medical physics training and 1 year of full time work experience cannot be concurrent.

** If the supervising medical physicist is not an authorized medical physicist, the licensee must submit evidence that the supervising medical physicist meets the training and experience requirements in 10 CFR 35.51 and 35.59 for the types of use for which the individual is seeking authorization.

AUTHORIZED MEDICAL PHYSICIST TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

3. Education, Training, and Experience for Proposed Authorized Medical Physicist (continued)

c. Describe training provider and dates of training for each type of use for which authorization is sought.

Description of Training	Training Provider and Dates		
	Remote Afterloader	Teletherapy	Gamma Stereotactic Radiosurgery
Hands-on device operation	Nucletron Aug 2006 - Current		
Safety procedures for the device use	Nucletron Aug 2006 - Current		
Clinical use of the device	Nucletron Aug 2006 - Current		
Treatment planning system operation	Nucletron Aug. 2006 - Current		

Supervising Individual

If training is provided by Supervising Medical Physicist, (If more than one supervising individual is necessary to document supervised training, provide multiple copies of this page.)

License/Permit Number listing supervising individual as an authorized Medical Physicist

for the following types of use:

☒ Remote afterloader unit(s) ☐ Teletherapy unit(s) ☐ Gamma stereotactic radiosurgery unit(s)

If Applicable:

Authorization Sought	Device	Training Provided By	Dates of Training
35.400 Ophthalmic Use of strontium-90			

d. Skip to and complete Part II Preceptor Attestation.

AUTHORIZED MEDICAL PHYSICIST TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

PART II – PRECEPTOR ATTESTATION

Note: This part must be completed by the individual's preceptor. The preceptor does not have to be the supervising individual as long as the preceptor provides, directs, or verifies training and experience required. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each.

First Section

Check one of the following:

1. Board Certification

☐ I attest that _____ has satisfactorily completed the requirements in
Name of Proposed Authorized Medical Physicist
 10 CFR 35.51(a)(1) and (a)(2).

OR

2. Education, Training, and Experience

☒ I attest that Markus Yoon has satisfactorily completed the 1-year of full-time
Name of Proposed Authorized Medical Physicist
 training in medical physics and an additional year of full-time work experience as required by 10 CFR 35.51(b)(1).

AND

Second Section

Complete the following:

☐ I attest that _____ has training for the types of use for which authorization
Name of Proposed Authorized Medical Physicist
 is sought that include hands-on device operation, safety procedures, clinical use, and the operation of a treatment planning system.

AND

Third Section

Complete the following:

☒ I attest that Markus Yoon has achieved a level of competency sufficient to
Name of Proposed Authorized Medical Physicist
 function independently as an Authorized Medical Physicist for the following:

- ☐ 35.400 Ophthalmic use of strontium-90 ☐ 35.600 Teletherapy unit(s)
☒ 35.600 Remote afterloader unit(s) ☐ 35.600 Gamma stereotactic radiosurgery unit(s)

AND

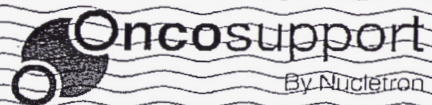
Fourth Section

Complete the following for preceptor attestation and signature:

☒ I meet the requirements in 10 CFR 35.51, or equivalent Agreement State requirements for Authorized Medical Physicist for the following:

- ☐ 35.400 Ophthalmic use of strontium-90 ☐ 35.600 Teletherapy unit(s)
☒ 35.600 Remote afterloader unit(s) ☐ 35.600 Gamma stereotactic radiosurgery unit(s)

Name of Preceptor <u>Gary Dillon M.S.</u>	Signature <u>Gary Dillon</u>	Telephone Number <u>219 138-5598</u>	Date
License/Permit Number/Facility Name			



CERTIFICATE OF TRAINING

awarded to:

Mark Yoon, MS

Community Hospital
Munster, IN

for completing the following course:

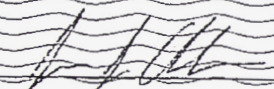
Brachytherapy Treatment Planning Version 14.3

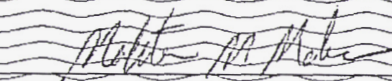
date

December 3-6, 2007

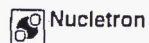
Presented by:

Nucletron Corporation, 8671 Robert Fulton Drive, Columbia, Maryland


James Clarke
Instructor


Mahta Mirzaei-McKee
Instructor

Certificate expires two years after last course day
19 MDCB Credits, MDCB Ref # MDCB041561
15.5 Category A CE, ASRT Ref # MDZ0142008



NUCLETRON TRAINING COURSE SIGN-IN FORM
PLATO BRACHYTHERAPY COURSE

DECEMBER 3-6, 2007

ATTENDEE NAME & SITE	SIGNATURE	EMAIL	PHONE
Heidi Aduddell Harrington Cancer Center Amarillo, TX CMD	Heidi Aduddell	haduddell@harringtoncc.org	806-354-5875x129
Jose Bencomo Texas Oncology Brownsville, TX PhD	Jose Bencomo	Jose.bencomo@usoncology.com	956-547-1680
Jennifer Cole Elliot Hospital Bedford, NH MS	Jennifer Cole	jcole@elliott-hs.org	603-663-2357
Chris Nelson MD Anderson Cancer Center Houston, TX PhD	Chris Nelson	chnelson@mdanderson.org	713-563-2471
Denise Nelson Lewistown Hospital Lewistown, PA CMD	Denise Nelson	Nelson2d@eeeaston.net dlnelson@lewisstownhospital.org	410-253-2866
David Nelson Lewistown Hospital Lewistown, PA PhD	David Nelson	Nelson2d@eeeaston.net dnelson@lewisstownhospital.org	410-253-2862
Kent Gifford MD Anderson Cancer Center Houston, TX PhD	Kent Gifford	kagifford@mdanderson.org	713-384-0330
Mark Yoon Community Hospital Munster, IN MS	Mark Yoon	markusvoon@gmail.com	229-436-3434
TRAINERS			
James Clarke	James Clarke	james.clarke@us.nucletron.com	410-312-4100
Mahta Mirzaei-McKee	Mahta Mirzaei-McKee		

ROSALIND FRANKLIN UNIVERSITY
OF MEDICINE AND SCIENCE

*on the recommendation of the College of Health Professions
the Board of Trustees has conferred the degree of*

MASTER OF SCIENCE
— IN —
MEDICAL RADIATION PHYSICS

upon

Mark Zoon

who has honorably fulfilled all the requirements for that degree



*Given in the city of North Chicago, Illinois,
this 2nd day of June, 2006.*

Ruth M. Palastin
Chairman, Board of Trustees

[Signature]
President

Wendy Rheault
Dean

Hubbard, Zickgraf, & Broadbent, Ltd.

A.B.R. CERTIFIED RADIOLOGICAL PHYSICISTS

5322 DAVIS STREET

SKOKIE, IL 60077

(224) 766-0750

August 18, 2010

HEMA

Dear Sirs:

Gary Dillon, MS, DABR was an Authorized Medical Physicist for the Nucletron V2 remote afterloader on USNRC license 13-15882-01 (Community Hospital, Munster, IN), and the Radiation Safety Officer for that license.

Mr. Dillon had several years work experience with the uSelectron Classic (V1) system at Community Hospital before the installation of the V2 uSelectron in December of 2006. He had two and a half years experience using the V2. He participated in the calibrations and source exchanges for both units. CH probably averaged around 100 treatments per year with each device during GD's tenure at CH.

Markus Yoon, MS, had at least two years work experience with the V2 uSelectron and participated in the calibrations and source exchanges. I supervised him in at least a dozen cases of brachytherapy with the uSelectron while I was the Regional Director of Medical Physics and Regional Radiation Safety Officer of the Community Healthcare System.

Sincerely,



Eric Zickgraf, PhD, FACR
ABR Certified Radiological Physicist



Mitchell E. Daniels, Jr.
Governor

Judith A. Monroe, M.D.
State Health Commissioner

Indiana State Department of Health

An Equal Opportunity Employer

October 16, 2009

Mark Yoon
1069 W 14th Place, #120
Chicago, IL 60608-2073

Re: Qualified Radiation Physicist Application

Dear Mr. Yoon:

You applied to the Indiana State Department of Health (ISDH) Division of Medical Radiology Services to have your name added to the list of Qualified Radiation Physicists. The information provided concerning your training, education, experience and professional references was evaluated by the Physicist Review Committee pursuant to 410 IAC 5-6.1-118.

You are hereby approved by the Indiana State Department of Health in the following categories for the purposes of 410 IAC 5-6.1-118:

Radiation Oncology Physicist

Your name will be added to the appropriate list that is distributed to all persons requesting this information. Your personal physicist number is **439**.

Enclosed please find copies of Indiana State Department of Health inspection forms. The Radiologic Health Rule 410 IAC 5 can be found on our Medical Radiology Services Program page at <http://www.in.gov/isdh/23279.htm> under "Laws and Regulations". If you need additional forms, you may e-mail Scovia Nabyesero-Kirya of my staff at SNabyesero-Kirya@isdh.IN.gov or call 317/233-7147. Please be sure to let us know when you have an address change so we may make the appropriate changes on the physicist list.

Sincerely,

David E. Nauth, Manager
Medical Radiology Services
Indiana State Department of Health
317/233-7563
ENCLOSURES



Governor Mitch Daniels'
IN SHAPE INDIANA

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2 Your Internal Billing Reference 10-24-7508
3 To
Recipient's Name Colleen Casey Phone 630 829-9856
Company U.S. Nuclear Reg. Commission
Address Region 3 Mtrls. Licensing Bd.
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REQUIRED. Available ONLY for
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FedEx 2Day to select locations.

4a Express Package Service
01 FedEx Priority Overnight
Next business morning. *FedEx
Shipments will be delivered on Monday
unless SATURDAY Delivery is selected.
05X FedEx Standard Overnight
Next business afternoon.
Saturday Delivery NOT available.
06 FedEx First Overnight
Earliest next business morning
delivery to select locations.
03 FedEx 2Day
Second business day. *Thursday
Shipments will be delivered on Monday
unless SATURDAY Delivery is selected.
20 FedEx Express Saver
Third business day.
Saturday Delivery NOT available.
4b Express Freight Service
70 FedEx 1Day Freight
Second business day. *Friday shipments will
be delivered on Monday unless SATURDAY
Delivery is selected.
80 FedEx 2Day
Second business day. *Monday units
only.
5 Packaging
06X FedEx Envelope
6 Special Handling
03 SATURDAY DELIVERY
No Signature Required
Package may be left without
obtaining a signature for delivery.
10 Direct Signature
Someone at recipient's address
may sign for delivery. Fee applies.
34 Indirect Signature
If no one is available at recipient's
address, someone at a neighboring
address may sign for delivery. For
residential deliveries only. Fee applies.
Does this shipment contain dangerous goods?
One box must be checked.
X No 04 Yes
As per attached
Shipper's Declaration
Yes
Shipper's Declaration
not required
06 Dry Ice
Dry Ice, 9 UN 1845
kg
Dangerous goods (including dry ice) cannot be shipped in FedEx packaging
or placed in a FedEx Express Deep Box.
Cargo Aircraft Only
7 Payment Bill to:
1X Sender
Acct. No. in Section
1 will be billed.
2 Recipient
3 Third Party
4 Credit Card
5 Cash/Check
Obtain recip
Acct. No.
Total Packages 1 Total Weight 1 lbs
Credit Card Auth.
606

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