



## GE Healthcare

3520 Progress Drive  
Bensalem, PA 19020  
USA

T 215 245 7805  
F 215 245 4922

*Nns82*

June 11, 2007

U. S. Nuclear Regulatory Commission  
Region I  
475 Allendale Road  
King of Prussia, PA 19406

*03031990*

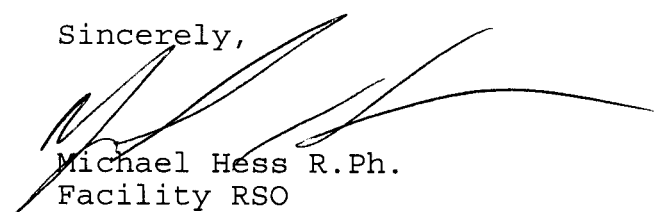
Re: License No. 37-27830-02MD

On behalf of Medi Physics Inc, d.b.a. GE Health, I would like to make the following change to the above mentioned license:

1. Please add Michael Lipcavage as an authorized nuclear pharmacist. Michael is a newly registered pharmacist in Pennsylvania. Enclosed please find a copy of Michael's training and experience as required in part 35.55.
2. Please remove Chris Hoffman, Brenda Salvadore and Daniel Shearer as they no longer work for our company.

Thank you for your assistance. I can be reached at (215)245-7805 to answer any questions you may have.

Sincerely,

  
Michael Hess R.Ph.  
Facility RSO

RECEIVED  
REGION 1  
2007 JUN 12 AM 10:35

*140652*

NMSS/RGN1 MATERIALS-002

## TRAINING AND EXPERIENCE AND PRECEPTOR STATEMENT

## PART I -- TRAINING AND EXPERIENCE

**Note:** Descriptions of training and experience must contain sufficient detail to match the training and experience criteria in the applicable regulations.

1. Name of Individual, Proposed Authorization (e.g., Radiation Safety Officer), and Applicable Training Requirements (e.g., 10 CFR 35.50)

Michael Lipcavage, Authorized Nuclear Pharmacist

2. For Physicians, Podiatrists, Dentists, Pharmacists -- State or Territory Where Licensed

Pennsylvania

## 3. CERTIFICATION

Specialty Board	Category	Month and Year Certified

Stop here when using Board Certification to meet 10 CFR Part 35 training and experience requirements.

## 4. DIDACTIC OR CLASSROOM AND LABORATORY TRAINING (optional for Medical Physicists)

Description of Training	Location	Clock Hours	Dates of Training
Radiation Physics and Instrumentation	University of New Mexico online	100	6-1-04 TO 8-11-04
Radiation Protection	University of New Mexico online	30	6-1-04 TO 8-11-04
Mathematics Pertaining to the Use and Measurement of Radioactivity	University of New Mexico online	20	6-1-04 TO 8-11-04
Radiation Biology	University of New Mexico Online	20	6-1-04 TO 8-11-04
Chemistry of Byproduct Material for Medical Use	University of New Mexico Online	30	6-1-04 TO 8-11-04
OTHER Clinical Pharmacy	University of New Mexico Online	50	6-1-04 TO 8-11-04

## TRAINING AND EXPERIENCE AND PRECEPTOR STATEMENT (continued)

U.S. NUCLEAR REGULATORY COMMISSION

## 5a. WORK EXPERIENCE WITH RADIATION

Description of Experience	Name of Supervising Individual(s)	Location and Corresponding Materials License Number	Dates and Clock Hours of Experience
Compounded various Runs eluting Generators and making Kits utilizing up to 80Ci of Tc99m	Michael Hess	3520 Progress Dr. Bensalem, PA 19020 37-27830-02MD	3/06 to Present 490 hrs
Compounded Prostatecint and Octreoscan Kits with In <sup>111</sup>	Michael Hess	3520 Progress Dr. Bensalem, PA 19020 37-27830-02MD	10 hrs
Performed White Blood cell tagging with both In <sup>111</sup> Oxip and Tc99m Ceretec	Michael Hess	3520 Progress Dr. Bensalem, PA 19020 37-27830-02MD	20 hrs
Calculated and drew Sm-153 dose	Michael Hess	3520 Progress Dr. Bensalem, PA 19020 37-27830-02MD	5 hrs
Performed Package Check-in.	Michael Hess	3520 Progress Dr. Bensalem, PA 19020 37-27830-02MD	10 hrs
Performed Wipes and Surveys	Michael Hess	3520 Progress Dr. Bensalem, PA 19020 37-27830-02MD	40 hrs
Performed Linearity and Constancy on dose Calibrators	Michael Hess	3520 Progress Dr. Bensalem, PA 19020 37-27830-02MD	10 hrs
Drew Tl201 and Ga-67 doses	Michael Hess	3520 Progress Dr. Bensalem, PA 19020 37-27830-02MD	60 hrs

## 5b. SUPERVISED CLINICAL CASE EXPERIENCE

Radionuclide	Type of Use	No. of Cases Involving Personal Participation	Name of Supervising Individual	Location and Corresponding Materials License Number	Dates and Clock Hours of Experience

TRAINING AND EXPERIENCE AND PRECEPTOR STATEMENT (continued)

6. FORMAL TRAINING (applies to Medical Physicists and Therapy Physicians)

Degree, Area of Study or Residency Program	Name of Program and Location with Corresponding Materials License Number	Dates	Name of Organization that Approved the Program (e.g., Accreditation Council for Graduate Medical Education) and the Applicable Regulation (e.g., 10 CFR 35.490)

7. RADIATION SAFETY OFFICER -- ONE-YEAR FULL-TIME WORK EXPERIENCE

- ☐ YES Completed 1-year of full-time radiation safety experience (in areas identified in item 5a) under supervision  
☐ N/A of \_\_\_\_\_ the RSO for License No. \_\_\_\_\_

8. MEDICAL PHYSICIST -- ONE-YEAR FULL-TIME TRAINING/WORK EXPERIENCE

- ☐ YES Completed 1-year of full-time training in therapeutic radiological physics under the supervision of  
☐ N/A \_\_\_\_\_ who meets requirements for Authorized Medical Physicists; and
- ☐ YES Completed 1-year of full-time work experience (for areas identified in item 5a) for \_\_\_\_\_  
☐ N/A modality(ies) under the supervision of \_\_\_\_\_ who meets  
requirements of Authorized Medical Physicists for \_\_\_\_\_ modality(ies).

9. SUPERVISING INDIVIDUAL -- IDENTIFICATION AND QUALIFICATIONS

The training and experience indicated above was obtained under the supervision of (if more than one supervising individual is needed to meet requirements in 10 CFR 35, provide the following information for each) :

A. Name of Supervisor

Michael Hess

B. Supervisor is:

☒ Authorized User

☐ Authorized Medical Physicist

☒ Radiation Safety Officer

☒ Authorized Nuclear Pharmacist

C. Supervisor meets requirements of Part 35, Section(s) 35.55 and 35.57

for medical uses in Part 35, Section(s) \_\_\_\_\_

D. Address

E. Materials License Number

37-27830-02MD

TRAINING AND EXPERIENCE AND PRECEPTOR STATEMENT (continued)

PART II -- PRECEPTOR STATEMENT

**Note:** This part must be completed by the individual's preceptor. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each. This part is not required to meet the training requirements in 10 CFR 35.590.

Item 10 must be completed for Nuclear Pharmacists meeting the requirements of 10 CFR Part 35, Subpart J. Preceptors do not have to complete items 11a, 11b, or the certifying statements for other individuals meeting the requirements of 10 CFR Part 35, Subpart J.

☒ YES 10. The individual named in item 1 has satisfactorily completed the training requirements in 10 CFR ~~35.980~~ 35.55 and is competent to independently operate a nuclear pharmacy.

☐ YES 11a. The individual named in Item 1 has satisfactorily completed the requirements in Part 35, Section(s) and Paragraph(s) \_\_\_\_\_.

☐ N/A

☐ YES 11b. The individual named in Item 1. is competent to independently function as an authorized \_\_\_\_\_ for \_\_\_\_\_ uses (or units).

☐ N/A

12. PRECEPTOR APPROVAL AND CERTIFICATION

☒ I certify the approval of item 10 and certify I am an Authorized Nuclear Pharmacist;

or

☐ I certify the approval of items 11a and 11b, and certify I am an Authorized Nuclear Pharmacist;

or

☐ I certify the approval of items 11a and 11b, and I certify that I meet the requirements of \_\_\_\_\_ or equivalent Agreement State requirements to be a preceptor authorized \_\_\_\_\_ for the following uses (or units) of byproduct material: \_\_\_\_\_

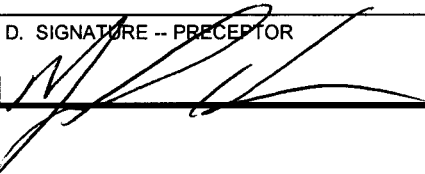
A. Address GE Healthcare  
3520 Progress Drive  
Bensalem, PA 19020

B. Materials License Number  
37-27830-02MD

C. NAME OF PRECEPTOR (print clearly)

Michael Hess

D. SIGNATURE -- PRECEPTOR



E. DATE

6-11-07



**UAMS**  
**COLLEGE OF PHARMACY**  
UNIVERSITY OF ARKANSAS FOR MEDICAL SCIENCES

**OFFICE OF THE DEAN**

Education Building II/6-104  
4301 West Markham, #522  
Little Rock, AR 72205-7199

501-686-5557  
501-686-8315 (fax)

[www.uams.edu/cop](http://www.uams.edu/cop)

**Pharmaceutical Sciences Department  
Biomedical Research Center**

501-686-5937  
501-686-6057 (fax)  
**Education Building II**  
501-686-6280  
501-526-6510 (fax)

**Pharmacy Practice Department**

501-686-6390  
501-296-1168 (fax)

**Doctor of Pharmacy Degree  
Non Traditional Program**

501-686-7124  
800-245-3256 (toll free)  
501-526-6872 (fax)

**Arkansas Poison Control**

501-686-5540  
800-3POISON (toll free)  
501-296-1451 (fax)

**Drug Information**

501-686-5072  
888-228-1233 (toll free)

**Continuing Education  
Program**

501-686-5396

August 19, 2004

Michael Lipcavage  
GE Healthcare  
1067 Hanover Street  
Wilkes Barre, PA 18706

Dear Michael,

Congratulations on your completion of Nuclear Education Online program for nuclear pharmacy training. We hope that you have gained the fundamental knowledge of the profession on which to build experience and expertise in this specialty area of pharmacy.

The faculty would also like to congratulate you for your outstanding performance. You earned the distinction of the NEO "Honor Roll" with a course performance score greater than 90%.

We appreciate your participation in the program and wish you the best in your career.

Best regards,

*Nicki Hilliard*

Nicki Hilliard, Pharm.D, MHSA, BCNP, FAPhA  
Associate Professor of Nuclear Pharmacy  
University of Arkansas for Medical Sciences

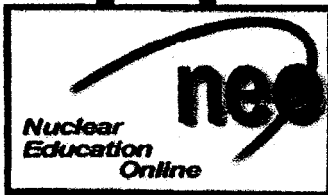


# Certificate of Completion

The University of Arkansas for Medical Sciences  
and the  
University of New Mexico Health Science Center  
certify that

*Michael Lipcavage*

has completed the didactic education requirements for  
Authorized Nuclear Pharmacist education  
as specified by the Nuclear Regulatory Commission.



## Nuclear Pharmacist Education and Training

*John A. Preper*  
Dean, UNM College of Pharmacy

*Stephen Johnson*  
Dean, UAMS College of Pharmacy

*Ronald H. Winters*  
Dean, UAMS College of Health Related Professions

*Nicki Hilliard*  
Executive Committee, Associate Professor

*[Signature]*  
Executive Committee, Assistant Professor

*Marta Becker*  
Executive Committee, Assistant Professor

August 11, 2004

**University of Arkansas for Medical Sciences  
and  
University of New Mexico Health Science Center**

**Nuclear Pharmacist Education**

**Michael Lipcavage**

Nuclear Pharmacy Courses & Training	Nuclear Physics	Instrumentation	Radiation Safety	Radiation Biology	Radiochemistry	Total
	004-039-01-201-H-01	004-039-01-200-H-01	004-039-01-203-H-01	004-039-01-202-H-01	004-039-01-204-H-01	
Radiation Physics & Instrumentation	75	25				100
Radiation Protection			30			30
Math & Measure of Radioactivity	5	5			10	20
Radiation Biology				20		20
Radiochemical Chemistry					30	30
Clinical Radiochemistry					50	50
TOTALS	80	30	30	20	40	250

Course dates: June 1 – August 11, 2004

*Nicki Hillard*

Nicki L. Hillard, Pharm.D., BCNP  
Associate Professor of Nuclear Pharmacy

Jeffrey Norzberg, Pharm. D., M.S., BCNP  
Associate Professor of Nuclear Pharmacy



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

6/11/2007, and to inform you that the initial processing which includes an administrative review has been performed.

☒ ATTEND. 37-27830-02 MA  
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

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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 140652.  
When calling to inquire about this action, please refer to this control number.  
You may call us on (610) 337-5398, or 337-5260.