



# STATE OF NEW YORK DEPARTMENT OF HEALTH

Flanigan Square, 547 River Street, Troy, New York 12180-2216

Antonia C. Novello, M.D., M.P.H., Dr.P.H.  
*Commissioner*

Dennis P. Whalen  
*Executive Deputy Commissioner*

December 14, 2005

**RE: Radioactive Materials Licensing Actions  
(Notice No. BERP 2005-3)**

Dear Licensee:

This notice provides information to all licensees authorized to use radioactive materials for human use (medical licenses) in regard to submission of amendment requests, radioactive waste monitor trips, training and experience requirements for authorized physician users, and other licensing issues.

Many amendment requests have been submitted with omissions or incomplete information, missing or inappropriate signature(s), and insufficient lead time to meet a licensee's target date. Other requests have been submitted in a non-timely manner (e.g., Radiation Safety Officer (RSO) discontinues his/her service). Such items delay the issuance of amendments or they reflect an issue of noncompliance (RSO issue).

The information provided in the attached documents should be helpful to expedite processing of your request(s). No response is necessary; however, you may call this office at 518/402-7590 if you have any comments or if my staff or I may be of assistance. You can also e-mail us at [berp@health.state.ny.us](mailto:berp@health.state.ny.us) or write to:

New York State Department of Health  
Bureau of Environmental Radiation Protection  
Radioactive Materials Section  
547 River Street, Flanigan Square – Room 530  
Troy, New York 12180-2216

Sincerely,

Robert E. Dansereau, Chief  
Radioactive Materials Section  
Bureau of Environmental Radiation Protection

RD:ks

Attachments: Licensing Guidance  
Authorized User Worksheet

1. **Closeout Surveys** (10 NYCRR 16.10(b)). Approval from this office must be received **prior** to releasing any area that was designated as a radioactive materials use area (i.e., a restricted area). A closeout survey must contain sufficient evidence to support the release of such areas. A radiological survey must include ambient exposure rate measurements as well as removable contamination wipes, and a description of the disposition of any radioactive material that was stored in the area(s). Licensee staff or other qualified individuals may conduct the radiological survey. A description of the instrumentation used, along with the calibration date(s) and a diagram showing all measurement locations, must also be provided. Incomplete submissions will result in a delay in issuing an amendment to release an area(s). Please note that broad scope licensees are required to observe the conditions of their license with respect to performing closeout surveys and decommissioning.
2. **License Termination.** Please note that the license remains active until terminated by the Department of Health. The expiration date is effectively a renewal term – the license does not automatically terminate if the annual fee is not paid, when you cease using licensed materials, or when a renewal application is not received prior to the expiration date. If you wish to terminate your license, you must submit a complete closeout survey as indicated in item #1 above. Note that additional information may be required.
3. **Overdue Fee.** License amendment requests will not be processed if the annual fee is overdue.
4. **Multiple requests.** An amendment request can contain as many changes to the license as needed – separate requests are not required for multiple changes. An exception is when a single item is of an urgent nature, in which case it is appropriate to submit a separate request. Also, please submit an original and one copy for all amendment requests, and retain a copy for your records. Please avoid the use of folders, page separators, binding, etc., as these items will be discarded to facilitate filing.
5. **Signature(s).** Amendment requests **must be signed by the appropriate individual(s)**. Requests from private practices need to be signed by the Radiation Safety Officer (RSO). An exception is the situation where the request is to change the RSO, in which case a partner or administrator may sign the request. Hospital licensees must have the requests signed by a senior administrator and either the RSO or Chair of the Radiation Safety Committee. A number of licensees have been reminded of this issue via cover letters to amendments; however, we continue to receive requests without the appropriate signatures from these same licensees. Please be advised that clerical staff has been directed to return amendment requests that do not have the appropriate signature(s). This policy will be enforced effective January 2, 2006.
6. **Change in RSO.** Please note that a request to change the Radiation Safety Officer must be submitted in a timely manner to ensure compliance with the regulations and your license. The replacement RSO must be fully aware of his/her responsibilities and be willing to accept the tasks associated with overseeing the day-to-day radiation safety program.
7. **PET Shielding.** We have received several amendment requests for fixed site PET imaging suites which did not have adequate shielding to accommodate the licensee's planned workload. Consequently, the facilities needed to reduce the number of patient scans or install additional shielding material to meet the exposure limits for members of the public (10 NYCRR 16.7). Please carefully review your, or your consultant's calculations, as well as the assumptions used, prior to installation of shielding. You may wish to submit your request to this office early in the planning stage so that a Radiological Health Specialist (RHS) can review the calculations prior to installation of the shielding and finished walls/ceilings.
8. **Radioactive Waste - Monitor Trips.** Many facilities have had waste returned to their facility due to the presence of radioactive materials in both regulated medical waste (RMW) and non-medical waste (black

bag). Additionally, some residents (private as well as nursing homes) have encountered similar situations following their release after treatment with iodine-131, and in some situations from a diagnostic radiopharmaceutical. The events can be costly as well as time consuming to resolve. Please ensure that all waste, including “cold” waste, is monitored with your most sensitive radiation survey instrumentation prior to allowing housekeeping or other staff to remove waste containers from your nuclear medicine departments or affected patient rooms. Incontinent patients and their care providers, especially iodine therapy patients, should be advised of the need to store absorbent pads (diapers) for a specified period of time before placing such items into the waste stream.

9. **Medical Physicist Licensure.** We have received numerous calls regarding NYS licensure of medical physicists. Inquiries should be addressed to Mr. Thomas Monahan, Office of the Professions, NYS Education Department at 518/474-3817, ext. 560, fax number 518/486-4846, or e-mail to: [medphysbd@mail.nysed.gov](mailto:medphysbd@mail.nysed.gov). Applicable regulations can be found on the NYSED website: [www.op.nysed.gov/medphys.htm](http://www.op.nysed.gov/medphys.htm)
10. **Website/Part 16.** Please note that 10 NYCRR 16 (Part 16) is available on the Department’s website. <http://www.health.state.ny.us/nysdoh/phforum/nycrr10.htm>
11. **BERP E-mail and Facsimile.** You may contact this office via e-mail at [BERP@health.state.ny.us](mailto:BERP@health.state.ny.us). However, please do not use e-mail for an amendment request, as signatures are required (see item #5). If you have an urgent need and choose to submit a fax for an amendment request, please promptly mail the original documents. Our fax number is 518/402-7585.
12. **DOH Amendment Process.** Your RSO will receive an acknowledgement letter after we have received and logged your amendment request into our database. The acknowledgement letter will contain an assigned tracking number (e.g., DH No. 05-999) which will appear on all correspondence from this office in regard to that specific amendment request. The tracking number is unique to a specific amendment request. (If you later submit a new request, it will be assigned a different tracking number.) Please include both the license number and the tracking number for any inquiry or correspondence in regard to the amendment request. The request is then assigned to a Radiological Health Specialist (RHS) for technical review. If additional information is needed, a “more information” letter is prepared and mailed to the RSO. We will request a response within 30 days of receipt (36 calendar days). If a response is not received within that time frame, a follow-up letter will be issued which requests a response within 15 days. If we do not receive a response within the additional time period, your request will be “abandoned”. If you need additional time to respond to a “more information” letter, please contact this office.
13. **Amendment Status Inquiries.** You can reach the Radioactive Materials Section by phone at 518/402-7590, or e-mail (see item #11 for address). In order to efficiently address inquiries, please be guided by the following:
  - Wait at least 14 days before calling to check on the status of your request.
  - If you call on behalf of the RSO, you need to be knowledgeable in regard to the license, regulations, and issues relevant to the amendment request. Please have a copy of the amendment request, relevant information, and provide the license name and number, tracking number, and nature of your request.
  - The administrative professional will be able to assist you with simple requests only, such as: if the request has been received, to whom it was assigned for review, if the amendment has been issued, if the payment for the annual and/or late fee has been received, etc.
  - For all other inquiries, including the status of the technical review and estimate of when the amendment can be issued, please ask to speak to the RHS assigned to the request.
14. **Physician Training and Experience.** Please be guided by the following worksheet/summary of T & E requirements.

## **Worksheet for Adding a Medical Use Authorized User to a New York State Department of Health Radioactive Materials License**

Choose one of the following options and submit the documentation requested. Please note that all physicians must be licensed to practice medicine in New York State, and each physician's authorization will be limited with respect to existing authorization(s) and board certification(s).

- I. If the physician is or has been an authorized user on a New York State or New York City radioactive materials license within the past seven years, simply reference the name of the facility and the license number in your amendment request. No further information is needed.
  
- II. If the physician has been board certified within the past seven years by the:  
  
American Board of Nuclear Medicine;  
American Board of Radiology;  
American Osteopathic Board of Radiology;  
American Osteopathic Board of Nuclear Medicine; or  
Royal College of Physicians and Surgeons of Canada,  
  
submit a copy of the physician's board certification with your request.
  
- III. If the physician has successfully completed an accredited residency program in radiology, nuclear medicine or radiation oncology within the past seven years, submit documentation of this training with your request.
  
- IV. If the physician was board certified and/or completed a residency program (as described in II. and III. above) more than seven years ago and has been an authorized user on an Agreement State or US NRC radioactive materials license within the past seven years, submit a copy of the radioactive materials license and documentation of training as specified in II. or III. above.
  
- V. For nuclear cardiologists who have not been an authorized user on a New York State or New York City radioactive materials license within the past seven years, submit documentation that the following training as specified in 10 NYCRR 16.2 (a) (134) has been completed:
  - a) 500 hours (not cases) of clinical radionuclide training at an institution (a hospital) under the tutelage of an authorized user. This documentation will need to be signed by the authorized user that provided training and the hospital's Radiation Safety Officer or chairperson of the Radiation Safety Committee. (Documentation that a physician is board certified in nuclear cardiology is NOT acceptable documentation of clinical training.)
  
  - b) 200 hours of radiation safety training provided by an accredited institution or organization which makes it eligible for Category I credit towards the Physicians Recognition Award of the American Medical Association. Documentation that a physician is board certified in nuclear cardiology is NOT acceptable documentation of radiation safety training.
  
- VI. For all physicians who have completed the initial training and experience requirements as described above but have not been an authorized user on a radioactive materials license within the past seven years, refresher training will need to be completed and documented. The training should include refresher radiation safety training and clinical radionuclide training under the supervision of an authorized user. Documentation of the refresher training must be signed by the authorized user that provided the training and will need to be submitted with documentation of their initial training and experience as described in II, III, or V.

## 200 Hour Didactic Training

To become an authorized user in New York State through tutelage, a physician must obtain clinical and didactic training as defined in 10 NYCRR 16.2 (134). A physician is required to obtain 200 hours of didactic radiation safety training through a program accredited for category I credits by the ACGME or other accrediting body. Residency programs in Radiology and Nuclear Medicine may offer such training (<http://www.acgme.org/adspublic/>). The Department of Health has reviewed courses from the following companies and considers them acceptable 200 hour courses in radiation safety:

<b>Associates in Medical Physics, LLC</b> 5288 Transportation Boulevard Cleveland, OH 44125	<i>Contact:</i> Frank Bloe <i>phone:</i> (216) 663-7000 <i>fax:</i> (216) 581-4361
<b>Consultants in Nuclear Medicine</b> 2910 West Estes Avenue Chicago, IL 60645-2934	<i>Contact:</i> Steven Karesh, Ph.D. <i>phone:</i> (708) 216-6353 <i>web page:</i> <a href="http://nucmedconsultants.com">http://nucmedconsultants.com</a> <i>email:</i> <a href="mailto:nucmedconsultants@comcast.net">nucmedconsultants@comcast.net</a>
<b>Health and Radiological Seminars, Inc.</b> 5310 Spectrum Drive Frederick, MD 21703	<i>Contact:</i> Janice J. Gabriel <i>phone:</i> (800) 969-4774 <i>web page:</i> <a href="http://hrsi-seminars.com">http://hrsi-seminars.com</a> <i>email:</i> <a href="mailto:info@hrsi-seminars.com">info@hrsi-seminars.com</a>
<b>Institute for Nuclear Medicine Education</b> 5660 Airport Boulevard, Suite 101 Boulder, CO 80301	<i>Contact:</i> Charles Rose <i>phone:</i> (800) 548-4024
<b>St. Elizabeth Medical Center</b> 736 Cambridge Street Boston, MA 02135	<i>Contact:</i> Alan B. Ashare, M.D. <i>phone:</i> (617) 789-2828 <i>fax:</i> (617) 562-7247