



**STATE OF NEW YORK
DEPARTMENT OF HEALTH**

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

Richard F. Daines, M.D.
Commissioner

James W. Clyne, Jr.
Executive Deputy Commissioner

June 28, 2010

**RE: Radiation Equipment Registrations
(BERP Notice No. 2010-2)**

Dear Registrant:

This notice provides information to all registrants authorized to use radiation-producing equipment by a New York State Department of Health registration.

Recent changes in regulations, business policy and staffing at the Bureau of Environmental Radiation Protection (BERP) have prompted this informational notice to all facilities with registered radiation-producing equipment. Many of our guides, regulations and informational notices can be found on our web site at <http://www.nyhealth.gov/radiation>.

No response to this notice is necessary. You may call this office at 518/402-7580 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 or write to:

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

Sincerely,

Alexander Damiani, MS, MPH
Chief, Radiation Equipment Section
Bureau of Environmental Radiation Protection

Notice to Registrants

BERP Notice No 2010-2

1. **Registrations.** Registrations are issued to radiation installations as defined in Part 16. This is defined as a place or facility where Radiation Producing equipment is used (including mobile units). Registrations are not transferable. If the facility or medical practice is sold, the seller must notify the Department and the new owner must apply for a registration before the equipment is first used. Please contact this office at 518/402-7570 to apply for a new registration.
2. **Equipment Update.** Changes in your registered equipment can be made by calling this office at 518/402-7570 for existing registrations. Adding a new modality (radiographic, dental, analytical equipment, fluoroscopic, etc.) may affect your registration annual fee. However, adding an additional machine of a modality already on your registration will not incur additional registration fees.
3. **Registration Closure.** Contact this office to close your registration. Please note that the registration remains active until this office receives written notification of your closure. Closure requires the submission of documentation verifying the disposition of the x-ray equipment. You will continue to be responsible for the radiation safety program and the registration fees until this office has received your equipment disposition form.
4. **Overdue Fee.** Unpaid annual fees will result in late charges of 18% APR. Late fees are usually assessed only up to a set point in time after which the registration may be suspended and the equipment sealed. Continued usage of the equipment after the registration has expired or been suspended will result in fines or other administrative actions. Unpaid accounts may be turned over to the Attorney General's Office for collection.
5. **Signature(s).** Registration applications, registration renewals, variance requests and other official correspondences must have original signatures by the appropriate individual(s). BERP can fax or email most forms directly to the registrant, however, the signed originals must be returned before the request can be processed.
6. **Radiation Safety Officer.** 10 NYCRR 16.5(c) requires that facilities provide a Radiation Safety Officer who meets the requirements listed in 16.2(a)(99). The RSO must be fully aware of his/her responsibilities to oversee the day-to-day radiation safety program and must be delegated the authority to implement this program.
7. **10 NYCRR Part 16.** Please note that the regulations on ionizing radiation, 10 NYCRR 16 (referred to as "Part 16"), can be downloaded from the Department's web site. The link is <http://www.nyhealth.gov/radiation>
8. **10 NYCRR Part 89.** Changes were made in the law governing the practice of radiologic technology in 2007 and the corresponding regulations (Part 89) were updated in 2009. The new regulations can be found on the Department's web site, but the most important changes include the licensure of nuclear medicine technologists, certification requirements for radiologic technologists to inject contrast media and a continuing education requirement in order to renew the registration.

9. **Inspections.** The Department of Health is authorized to conduct inspections of registered radiation equipment facilities at all reasonable times. These inspections may be scheduled or they may be unannounced. Interfering with an inspection can result in a Notice of Violations, fines, registration suspension or other enforcement actions. Mammography inspections conducted under MQSA will be scheduled per the FDA requirements.
10. **Common Violations.** The following list includes some of the most common violations of 10 NYCRR 16 that have been cited by BERP staff at inspections over the past few years. The majority of violations are Quality Assurance related (10 NYCRR 16.23). Please note that many facilities such as dental, veterinary, podiatry and most non-human use facilities are exempted from 16.23
1. No Quality Assurance manual or the Quality Assurance manual is not specific to this facility or appropriate for the equipment in use at this facility. [16.23 (a)(1)(i)].
 2. Failure to follow/implement QA manual [16.23 (a)(1)(i)].
 3. Incomplete or inadequate Digital Radiography (DR) or Computed Radiography (CR) QA [16.23 (a)(1)(i)].
 4. Charting of Processor QA done improperly including incorrect crossover film charting, testing not done every day exams are conducted and QA results out of limits but no corrective actions taken [16.23 (a)(1)(ii)].
 5. Repeat/Reject analysis not done [16.23 (a)(1)(ix)].
 6. Policy and Procedures not current, not available or incomplete. This includes radiation safety items not related to QA such as pregnant worker policy, patient holding policy, dosimetry usage policy etc.
 7. Initial and annual training as required by 16.13 (c).
 8. Use of unlicensed operator of radiation producing equipment. [16.19 (a)(1)].
 9. Entrance Skin Exposures (ESE) are above acceptable levels [16.23 (a)(1)(i)].
 10. Exposure switch operable outside the control booth. [16.56 (a)(6)].