



North Carolina Department of Health and Human Services  
Division of Health Service Regulation

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August 28, 2015

X-RAY SERVICE PROVIDER INFORMATION MEMORANDUM

To: NC X-ray Sales and Service Providers  
From: Jenny Rollins, Radiology Compliance Branch Manager  
NC DHHS, Division of Health Service Regulation, Radiation Protection Section  
Subject: Sales and Service Vendors, Providing Services without the Required Registration

The Department of Health and Human Services, Division of Health Service Regulation, Radiation Protection Section (RPS) is committed to protecting the public and occupational radiation workers from unnecessary exposure to ionizing radiation generated from radiation machines. RPS inspects facilities to ensure compliance with the North Carolina Rules Against Radiation Protection, 10A NCAC 15.

RPS inspection staff have seen an increase in the number of unregistered service providers. According to the requirements of Rule .0205:

- (a) Each person who is engaged in the business of installing or offering to install radiation machines and machine components or is engaged in the business of furnishing or offering to furnish any equipment services listed in Paragraph (d) of this Rule in this state to any agency licensee or registrant, shall apply for registration of such services with the agency prior to furnishing or offering to furnish any of these services.
- (d) For the purpose of this Section, equipment services include:
  - (1) direct sale and transfer of radiation machines and machine components to end users;
  - (2) installation or servicing of radiation machines and associated radiation machine components;
  - (3) diagnostic radiographic facility and shielding design;
  - (4) diagnostic fluoroscopic facility and shielding design;
  - (5) diagnostic area radiation survey, e.g., shielding evaluation;
  - (6) radiation instrument calibration;
  - (7) therapeutic facility and shielding design, area radiation survey or calibration;
  - (8) personnel dosimetry service; and
  - (9) general health physics consulting, e.g., independent diagnostic radiation output measurements, dose analysis, design of safety programs and radiation safety training programs, non-healing arts facility and shielding design and area radiation surveys.

**\*This includes equipment bought through the internet. The seller must be a registered service provider with the state of North Carolina.**

The application for Class I, Sales and Service, can be found at, [www.ncradiation.net/Xray/documents/1and2appl.pdf](http://www.ncradiation.net/Xray/documents/1and2appl.pdf).

Radiation Protection Section

[www.ncdhhs.gov](http://www.ncdhhs.gov) • [www.ncradiation.net](http://www.ncradiation.net)

Tel 919-814-2250

Location: 5505 Creedmoor Road, Suite 100 • Raleigh, N.C. 27612

Mailing Address: 1645 Mail Service Center • Raleigh, N.C. 27699-1600

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In addition, Rule .0206 states:

- (a) Persons, registered pursuant to Rule .0205 of this Section, who sell, lease, transfer, lend, dispose of, assemble or install radiation machines in this state shall, within 30 days after each calendar quarter, notify the agency at the address in the Rule .0111 of this Chapter, of:
  - (1) Whether any radiation machines were installed, transferred, or disposed of during the calendar quarter;
  - (2) The name and address of persons who received radiation machines during the calendar quarter;
  - (3) The manufacturer, model and serial number of each radiation machine transferred or disposed of;
  - (4) The date of transfer of each radiation machine.
- (b) The information specified in Subparagraphs (a)(2), (3) and (4) of this Rule may be omitted from the quarterly reports required in (a) of this Rule for any diagnostic x-ray system which contains certified components when a copy of the assembler's report prepared in compliance with 21 CFR 1020.30(d) is submitted to the agency.

The agency has allowed our service providers to submit the federal form FDA 2579 (Report of Assembly), in lieu of the quarterly report. For the disposal of radiation machines or machines that don't require a federal form FDA 2579, the **N.C. Report of Sales or Installation of X-ray Machines form** located at the following link, [www.ncradiation.net/Xray/documents/rptofassembly.pdf](http://www.ncradiation.net/Xray/documents/rptofassembly.pdf) or the **Disposal or Removal of X-ray Machines form** can be used for reporting.

Be advised that if your company is acting as a third party to a dosimetry provider as part of your service, you must also be registered for Class VIII, personnel dosimetry services. The company that processes the film badges or thermoluminescent dosimetry (TLD badges) for your clients must also be registered and hold a current personnel dosimetry accreditation from the National Voluntary Laboratory Accreditation Program (NVLAP). You must provide a copy of the NVLAP certificate with your application. The application for Class VIII, personnel dosimetry services can be found at, [www.ncradiation.net/Xray/documents/class6thru9appl.pdf](http://www.ncradiation.net/Xray/documents/class6thru9appl.pdf).

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Please use the following email accounts:

[XrayService@dhhs.nc.gov](mailto:XrayService@dhhs.nc.gov) – for service registration submittals, service registration changes and service violation responses.  
[FDA2579@dhhs.nc.gov](mailto:FDA2579@dhhs.nc.gov) – for federal form FDA 2579 (Report of Assembly) and Report of Sales/Installations or Disposal of X-ray Systems form.  
[shieldingdesign@dhhs.nc.gov](mailto:shieldingdesign@dhhs.nc.gov) – for shielding plans.

Attachments:

Shielding Plan Requirements for Service Providers - [www.ncradiation.net/Xray/documents/svcplanrevguide.pdf](http://www.ncradiation.net/Xray/documents/svcplanrevguide.pdf)

Steps to Install X-ray Equipment - [www.ncradiation.net/Xray/documents/Registration%20Steps.pdf](http://www.ncradiation.net/Xray/documents/Registration%20Steps.pdf)

All email boxes - [www.ncradiation.net/Xray/documents/MailBoxesList.pdf](http://www.ncradiation.net/Xray/documents/MailBoxesList.pdf)

Please contact Jon Granger at (919) 814-2323 or email, [XrayService@dhhs.nc.gov](mailto:XrayService@dhhs.nc.gov) for questions or additional assistance.