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

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X-RAY SERVICE PROVIDER INFORMATION MEMORANDUM

To: N.C. 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 Provider Issues

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 a number of issues from our x-ray service providers. According to the requirements of Rule .0205:

> (c) Each person applying for registration under Paragraph (a) of this Rule shall certify that he has read and understands the requirements of the rules in this Chapter.

In summary, the service provider must be aware of the following requirements and **must also inform the facility** of the following:

- A shielding plan must be submitted by a NC registered service provider prior to construction and installation, www.ncradiation.net/Xray/documents/plan_surveycklist.pdf. If the facility is making a modification to the room, they must consult with a registered NC service provider to determine if a new shielding plan is required.
- The equipment must not be installed prior to the RPS acknowledgment of the shielding plan.
- The equipment must be installed according to the shielding plan or a new shielding plan will be required.
- The facility and each radiation machine must be registered within 30 days of initial operation.
- A survey is required on all medical applications and may also be required on other applications when needed.

All service providers must also report the disposal of radiation machines to RPS using the Disposal or Removal of X-ray Machines form. **RPS will begin issuing citations to the service providers who fail to comply with the reporting requirements.**

Many of our service providers are having the following issues with the equipment labeling requirements:

- Selling or installing equipment without the FDA certification label. The certification label states that the product conforms to all applicable standards of Chapter 21 Code of Federal Regulations (21 CFR).
- Placing the certification label where is cannot be visualized. The label must be conspicuously posted for inspections.

- Selling or installing equipment without the warning label posted on the control. For all medical and dental equipment manufactured after June 10, 2006, must have "Warning: This X-ray unit may be dangerous to patient and operator unless safe exposure factors, operating instructions and maintenance schedules are observed."

Many of our service providers are not accurately completing the federal form FDA 2579. Here is a list of some of the issues:

- Failure to submit federal form FDA 2579.
- Assembler information omitted.
- Failure to sign and date the form.
- Someone other than the assembler signs the form.
- Equipment location address is not correct or omitted.
- Wrong or incomplete telephone number. Fail to add extensions when needed.
- Adding the zip code where the telephone number should be.
- Incorrect facility name for the location of where the equipment is installed.
- Incorrect serial numbers. The control serial number must be used.
- Omitting the date of assembly. Date of assembly should be entered even on mobile and portable equipment. You can use the delivery or shipment date.
- Omitting the date of manufacture.
- Failure to add the equipment to the form, instead using a letter to identify the equipment.
- Making changes on the form to the control serial number when the control serial number has not changed. For example, a tube is replaced and the technician will put the new tube serial number where the control serial number goes. If the equipment is not being replaced, but only the components, this needs to be explained in detail using the comments section.

It is the service provider's responsibility to make sure the names, addresses, model numbers, serial numbers, installation dates, etc… are all accurate on the form. If RPS continues to observe incomplete or inaccurate federal form FDA 2579's being submitted, we will forward the issues directly to the FDA.

Many of our dental service providers are having the following issues:

- Not advising the facility to make the necessary changes to their technique charts when they are converting from film to digital. Many service providers are advising the facility to only use one technique for all patients. Rule .0603(a)(1)(C) states: In the vicinity of each diagnostic X-ray system's control panel, a chart shall be provided, which specifies for all usual examinations and associated projections which are performed by that system, a listing of information including ***patient's anatomical size versus technique factors*** to be utilized at a given source to image receptor distance. The chart shall also provide: (i) type and size of the film or film-screen combination to be used, (ii) type and ratio of grid to be used, if any, and focal spot to film distance, (iii) type and placement of gonad shielding to be used.
- Not using the most current form for hand-held waiver requests found at, www.ncradiation.net/Xray/documents/handheldappl.pdf. Failure to use the most current form may result in the delay or denial of your waiver request.

Be advised that if your company is acting as a third party to a personnel monitoring 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.

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Please use the following email accounts:
XrayService@dhhs.nc.gov – for service registration submittals, service registration changes and service violation responses.
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 – for shielding plans.
Attachments:
Shielding Plan Requirements for Service Providers - www.ncradiation.net/Xray/documents/svcplanrevguide.pdf
Steps to Install X-ray Equipment - www.ncradiation.net/Xray/documents/Registration%20Steps.pdf
All email boxes - www.ncradiation.net/Xray/documents/MailBoxesList.pdf