X-Ray Producing Machines: Policy Regarding Regulatory Compliance

PURPOSE: To address the regulatory oversight of X-ray producing machines at Duke University Medical Center and the Duke University academic campus.

SCOPE: The scope of this policy is limited to issues of compliance pertaining to 15A NCAC 11.0600 and 11.0800. The Radiation Safety Office will coordinate with Duke University Health System administration to address specific roles and responsibilities as this oversight program evolves. This policy applies to all clinical and academic departments which utilize X-ray radiation emitting devices including:

A. Nonmedical use (academic campus)
B. Medical use (Medical Center and affiliated facilities)

DEFINITION: “X-ray Producing Machine” means: (a) any device manufactured specifically for the purpose of producing X-rays, or (b) any device that incidentally emits X-rays and the dose rate at 5 cm from any accessible surface, with shielding removed, exceeds 0.5 millirem per hour (15A NCAC 11.0202). This includes, but is not limited to, all radiographic and fluoroscopic X-ray units, CT scanners, X-ray diffractometers, cabinet irradiators, mobile bone densitometers, and some electron microscopes.

POLICY:

1. X-ray Authorized User (XAU) is responsible for:
   A. Obtaining approval from the Radiation Safety Office prior to ordering or acquiring X-ray equipment;
   B. Notifying the Radiation Safety Office of the receipt of any new equipment and the removal, transfer, service, repair, disposal, etc. of any current equipment;
   C. Completing the Duke X-Ray permit registration (http://www.safety.duke.edu/RadSafety/xray.asp);
   D. Submitting a completed FDA 2579 form (provided by manufacturer within 15 days of installation) to Radiation Safety Office;
   E. Developing equipment-specific X-ray Standard Operating Procedures (SOPs) and submitting to the Radiation Safety Office for approval;
   F. Restricting the use of equipment until SOPs have been approved and training completed.

2. X-ray Departmental Supervisors are responsible for:
   A. Ensuring X-ray users complete training specified in the X-ray permit and by the Radiation Safety Officer;
   B. Ensuring that SOPs are reviewed and/or updated annually;
C. Maintaining documents for regulatory and permit compliance, including a current copy of the NC Protection Against Radiation Regulations (15A NCAC 11);
D. Ensuring personnel wear appropriate radiation monitoring badges;
E. Posting of warning signs and labels required by the NC Radiation Protection Section.
F. Communicating with the Clinical Imaging Physics Group* regarding image quality or utilization issues for diagnostic medical use X-ray systems in Radiology at DUH.

3. X-ray Departmental Business Managers are responsible for:
   A. Notifying the Duke Radiation Safety Office of any new X-ray equipment installation, removal, or any changes in equipment;
   B. Paying annual state registration fees;
   C. Maintaining copies of any information about the unit, such as FDA Form 2579, and a current copy of the NC Protection Against Radiation Regulations (15A NCACN 11);
   D. Upon installation of new equipment, notifying the Duke Radiation Safety Office to conduct a regulatory compliance audit including radiation surveys.

4. For medical use X-ray systems only, Duke University Health Systems Clinical Engineering department is responsible for:
   A. Conducting annual compliance testing;
   B. Troubleshooting and addressing technical problems;
   C. Communicating with Radiation Safety Office regarding issues of non-compliance;
   D. Working with the Clinical Imaging Physics Group* regarding issues of image quality, radiation safety, and utilization for diagnostic medical use X-ray systems in Radiology at DUH;
   E. Any technical concerns pertaining to safety or compliance.

5. Duke University Radiation Safety Officer is responsible for:
   A. Ensuring that X-ray equipment be properly registered with the NC Radiation Protection Section;
   B. Maintaining inventory of X-ray equipment by location and serial numbers;
   C. Performing a regulatory audit including radiation surveys within 30 days of the first operation of new equipment;
   D. Conducting a shielding plan review prior to the installation of new X-ray equipment.
   E. Informing Clinical Engineering department of any regulatory changes which affect the annual evaluation requirements and updating their methods to maintain compliance.
   F. Informing the Clinical Imaging Physics Group* of any regulatory changes which affect the annual evaluation requirements and updating their methods to maintain compliance for diagnostic medical use X-ray systems in Radiology at DUH.

6. For diagnostic medical use X-ray systems used by Radiology at DUH, The Clinical Imaging Physics Group* is responsible for:
A. Pursuing and maintaining professional accreditations for the imaging operations (eg, ACR accreditations);
B. Providing evidence based advice and justification for imaging equipment purchases;
C. Independent inspection and quality control of the imaging equipment to assure efficient utilization, maintenance of patient dose as low as reasonably achievable, and optimized image quality;
D. In cooperation with Radiation Safety, performing acceptance testing of imaging equipment prior to clinical use;
E. Informing Departmental Supervisors of any operational issues that would require corrective actions by the operators/users of the equipment;
F. Informing Radiation Safety Officer of any patient and personnel safety issues that would require corrective actions or education;
G. Informing Clinical Engineering department of any equipment malfunction issues that would require repair;
H. Oversight of annual compliance testing by Clinical Engineering to be consistent with current medical physics methods and procedures;
I. Educating relevant personnel about medical physics principles that would improve the quality and safety of the imaging operation.

*This program involving the Clinical Imaging Physics Group is an implementation of Phase 1 of the CIPG initiative, instituted to ensure high-quality, low-dose, efficient, and accredited operation of medical imaging equipment at Duke University. Envisioned as a phased implementation, Phase I of the initiative focuses on Radiology equipment at Duke University Hospital.
X-ray Device Registration and X-ray Equipment Disposition Form

X-Ray Authorized User Name: ________________________________________________

Department: ______________________________________________________________

E-Mail & Phone: ______________________________________________________________

X-Ray Supervisor Name & Contact Information: _________________________________

Please provide the following information for the X-ray producing device under your management,

<table>
<thead>
<tr>
<th>Location (Bldg &amp; Room)</th>
<th>Equipment Type: circle one (delete or add)</th>
<th>Manufacturer</th>
<th>Model</th>
<th>Serial Number</th>
<th>Installation Date</th>
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Please complete form and return to:
Netiti Moori, Radiation Safety Office
Fax 919-668-2783