Interim Comment Summary Response
Chapter 6 X-Rays in the Healing Arts Update
(LAC 33:XV.602, 603, 604, 605, 606, 607, 610, 611, and 699) (RP068)

COMMENT 1: **Section 602.A. Definitions: *Qualified Expert (QE)***

-Under qualification b. the experience requirement is listed as "3 years of documented experience in CT environment." Because evaluations are required by QEs for general radiographic (603.A.3.) equipment and fluoroscopic equipment (605.D.), I suggest possible replacement language: "3 years of documented in the experience in CT environment (for purposes of CT evaluations), 3 years of documented in the experience in fluoroscopic environment (for purposes of fluoroscopic evaluations), or 3 years of documented in the experience in general radiographic environment (for purposes of general radiographic evaluations)." Or similar language.

-Likewise under qualification c. (the grandfathering clause) the language just refers to CT experience: "at least 3 CT units." I suggest: "at least 3 CT units (if pertaining to CT evaluations), or at least 3 fluoroscopic units (if pertaining to fluoroscopic evaluations), or at least 3 general radiographic units (if pertaining to general radiographic evaluations).

FOR/AGAINST: The department agrees with the comment; no arguments are necessary.

RESPONSE 1: The department agrees with the comment. Language has been added to update the definition. The definition has been changed to the following: *Qualified Expert*—an individual who ~~has demonstrated to the satisfaction of the department that such individual possesses the knowledge, training, and experience to measure ionizing radiation, to evaluate safety techniques, and to advise regarding radiation protection needs~~meets one of the following criteria:

a. a qualified medical physicist;

b. not board certified in the required subspecialty but with a graduate degree in medical physics, radiologic physics, physics, or other relevant physical science or engineering discipline from an accredited institution, and formal coursework in the biological sciences with at least one course in biology or radiation biology and one course in anatomy, physiology, or similar topics related to the practice of medical physics and three years of documented

experience in a clinical CT environment (for purposes of CT evaluations), three years of documented experience in fluoroscopic environment (for purposes of fluoroscopic evaluations), or three years of documented experience in general radiographic environment (for purposes of general radiographic evaluations);
c. grandfathered by having conducted surveys of at least three CT units between January 1, 2007, and January 1, 2010; or
d. an individual approved by the department.

COMMENT 2: **Section 602.A. Definitions: *Qualified Expert (QE)***
Qualification d. of a QE seems overly broad and should be removed entirely if your intention is to define what a qualified expert is. (If the Department feels it must have some power to grant exemptions, then I suggest limiting language to allow only an individual than can be approved by the department to one "who substantially meets the qualifications under criteria a., b. or c.")"?

FOR/AGAINST: The department disagrees with the comment.

RESPONSE 2: The department believes that part d of the definition for Qualified Expert (QE) needs to remain because it allows for other situations that may occur in the future.

COMMENT 3: Section 603.A.3. Does this mean that QE evaluations/involvement must be included for all general radiographic equipment registered in Louisiana, including, for example, general radiographic x-ray machines at doctor's private offices?

FOR/AGAINST: The department agrees with the comment.

RESPONSE 3: The department would like to clarify this regulation. The LAC 33:XV.603.A.3 states the following: 3. The qualified expert, if required in this Section, shall complete initial and routine compliance evaluations following nationally recognized procedures. These evaluations shall include a review of the required quality control tests. In the regulation it states "if required in this section". General radiography is not required to meet this regulation in this section.

COMMENT 4: Section 610.F.3. Accreditation. Does this mean if a unit (that uses the CT component only for attenuation correction) is accredited for PET or SPECT then automatically they need not comply with any of Subsections A. – D for CT? I am not following the intent of what must be tested for these combo systems. In my opinion we should still do

some annual evaluation and some weekly/daily QC for the CT component of these combo systems. I am confused by the language/intent of F.3. Could this be stated more clearly?

FOR/AGAINST: The department agrees with the comment; no arguments are necessary.

RESPONSE 4: The Department agrees with this comment. The Department has changed the regulation. LAC 33:XV.610.F has been updated to the following: F. PET CT and SPECT CT Systems. CT systems solely used to calculate attenuation coefficients in nuclear medicine studies shall meet the requirements in Subsections A – D of this Section, unless ~~otherwise exempted below~~the following criteria are met.

1. In lieu of LAC 33:XV.610.C.2, a qualified expert shall complete a performance evaluation of the CT system following manufacturer's protocol. The evaluation shall be completed at intervals of no less than 12 months, and no more than 14 months.

2. In lieu of LAC 33:XV.610.C.3, routine QC checks shall be completed at intervals not to exceed one week. These checks shall be established and documented by a qualified expert following manufacturer's protocol.

~~3. Accreditation. Unless otherwise authorized by the department, all diagnostic CT x-ray systems for human use shall be accredited by a department-recognized accredited organization.~~

LAC 33:XV.610.F.3 has been removed and other language changes have been made.

COMMENT 5: **Pages 24-26, number 7, letters a, b, and c and number 9, letter d:**

7……

a. all individuals shall be ~~positioned such that no part of the body will be struck by the useful beam unless~~ protected by not less than 0.5 millimeter lead equivalent;

b. the X-ray operator, other professional staff, and ancillary personnel shall be protected from the direct scatter radiation by protective aprons or whole body protective barriers of not less than 0.25 millimeter lead equivalent material; and

c. human patients who cannot be removed from the room shall be protected from the direct scatter radiation by whole body protective barriers of not less than 0.25 millimeter lead equivalent material or shall be so positioned that the nearest portion of the body is at least 2 meters from

both the tube head and the nearest edge of the image receptor.

9……

d. in those cases where the patient must hold the ~~film~~image receptor, except during intraoral examinations, any portion of the body other than the area of clinical interest struck by the useful beam shall be protected by not less than 0.5 millimeter lead equivalent material;

Comment: **One spot states "all individuals shall be protected by not less than 0.5 millimeter lead equivalent" then right below in b and c it states people that need 0.25, and d states 0.5 again. If we are saying in the direct beam is 0.5 and scatter radiation is 0.25 then this needs to be clarified.**

FOR/AGAINST: The department agrees with the comment; no arguments are necessary.

RESPONSE 5: The Department agrees with the comment. Part of LAC 33:XV.603.A.7.a has been added back to the regulation. LAC 33:XV.603.A.7.a has been changed to the following:

7. Except for human patients who cannot be moved out of the room, only the staff and ancillary personnel, including parents or guardians, required for the medical procedure or training shall be in the room during the radiographic exposure. The following conditions shall be met for those other than the patient being examined:
   a. all individuals shall be **positioned such that no part of the body will be struck by the useful beam unless** protected by not less than 0.5 millimeter lead equivalent;

The .5 millimeter lead equivalent is for usefull beam and .25 millimeter lead equivalent is for scatter radiation. Adding back "positioned such that no part of the body will be struck by the useful beam unless" clarifies the difference of the .5 and .25 millimeter lead equivalent.

COMMENT 6: **Page 26, number 11:**

11. All protective apparel and auxiliary shields shall be evaluated at intervals of no less than 12 months, and no more than 14 months, for integrity and clearly labeled with their lead equivalence.

Comment: **Clearly labeled with lead equivalents…..manufacture**

tags get removed and worn out, is this stating that we must write on the lead with a Sharpe? Other than the manufacturer label and writing on the lead, how else should the lead be labeled? Also, if our policy is to only purchase 0.5, will lead have to be labeled?

FOR/AGAINST: The department agrees with the comment; no arguments are necessary.

RESPONSE 6: The Department agrees with the comment. If the facility's policy is to only purchase 0.5 millimeter lead equivalent protective apparel and auxiliary shields and the policy is documented and available for review, then that would met the requirements of LAC 33:XV.603.A.11.

COMMENT 7: **Page 52, number 10:**
10. Displays of Values of AKR and Cumulative Air Kerma. Fluoroscopic equipment manufactured on or after June 10, 2006, shall display at the fluoroscopist's working position the AKR and cumulative air kerma. The following requirements apply for each X-ray tube used during an examination or procedure.

Comment: What about systems that do not display AKR or Cumulative Air Kerma? Are any other units acceptable? Later in the document on page 58, letter a, number iv, when discussing fluoroscopy you reference "peak skin dose, cumulative air kerma, or dose area product used if the information is available on the fluoroscopic system" are these not acceptable in this section also? If they are, this section needs to be updated to reflect all these units.

FOR/AGAINST: No arguments are necessary.

RESPONSE 7: The Department would like to clarify LAC 33:XV.605.A.10. LAC 33:XV.605.A.10 is only required for fluoroscopic equipment manufactured on or after June 10, 2006. This date comes from the Food and Drug Administration (FDA) regulation in Code of Federal Regulations (CFR) Title 21 Part 1020.32(k). LAC 33:XV.605.E.3.a.iv is for fluoroscopically-guided interventional (FGI) procedures using any fluoroscopic equipment, not just those manufactured on or after June 10, 2006.

COMMENT 8: **Page 56, number 2 and letter h:**
2. All persons operating, or supervising the operation of, fluoroscopy systems shall have completed a minimum of two hours of training that includes but is not limited to the following:
h. principles and operation of the specific fluoroscopic X-ray

system(s) to be used;

Comment: Who is training the physicians? Are the physicians getting this training in medical school? Licensed technologists obtain well more than 2 hours in all of these categories, other than "specific fluoroscopic X-ray system(s) to be used."
So, is this stating that each individual must have a minimum of 2 hours of training on each individual system throughout the facility?

FOR/AGAINST: No arguments are necessary.

RESPONSE 8: The Department would like to clarify LAC 33:XV.605.B.2. The two hours of training in LAC 33:XV.605.B.2 does not mean two hours for each unit, it means a total of two hours where the information in LAC 33:XV.605.B.2.a-j are met. The regulations do not state where personnel receive the two hours of training, only what it shall include and that it be documented.

COMMENT 9: **Page 58, letter E, number 2, letter a:**
E. Additional requirements for facilities performing fluoroscopically-guided interventional (FGI) procedures are as follows:
2. establish and implement FGI procedure protocols as follows
a. the registrant shall establish and implement written protocols, or protocols documented in an electronic report system, that include but are not limited to the following:.....

Comment: With the vast multitude of doctors performing FGI procedures, each have their own way of completing each exam. To have a standard protocol is extremely difficult to ensure these would be utilized by every doctor.
What all is considered interventional? .....what about OR cases and biopsies, are these considered interventional as well?

FOR/AGAINST: No arguments are necessary.

RESPONSE 9: The Department would like to clarify LAC 33:XV.605.E.2.a. The FGI procedure protocols in LAC 33:XV.605.E.2.a is a basic procedure that includes items in LAC 33:XV.605.E.2.a.i-iv. LAC 33:XV.605.E refers to FGI procedures and the following is the definition for FGI Procedures: *Fluoroscopically-Guided Interventional (FGI) Procedures*—an interventional diagnostic or therapeutic procedure performed via percutaneous or other access routes, usually with local anesthesia or intravenous sedation, which uses external ionizing radiation in the form of fluoroscopy to localize or characterize a lesion,

diagnostic site, or treatment site, to monitor the procedure, and to control and document therapy.

COMMENT 10: Page 98, letter B:
B. Operator Requirements. Operators shall complete training specific to patient positioning and the operation of the DXA system.

Comment: **What are the training requirements? Is there a manual?**

FOR/AGAINST: No arguments are necessary.

RESPONSE 10: The department would like to clarify LAC 33:XV.611.B. The training in LAC 33:XV.611.B refers to training per the manufacturer's recommendations.

COMMENT 11: Page 98, letter C, number 1:

1. in the absence of a survey performed by or under the supervision of a qualified expert determining the minimum distance the operator may be from the patient and radiation source, the operator, ancillary personnel, and members of the general public shall be positioned at least two meters from the patient and DXA system during the examination.

Comment: **Physicists have said they** don't survey DXA systems, **due to such a low energy source**.....do we need them to start **performing surveys on this equipment**? Also, does the physicist **have to state every time they service** the equipment what the safe **distance is?**

FOR/AGAINST: No arguments are necessary.

RESPONSE 11: The Department would like to clarify LAC 33:XV.611.C.1. A survey is not required annually. An initial survey by a qualified expert when the equipment is installed can establish the minimum distance required by LAC 33:XV.611.C.1. If a survey is not performed then LAC 33:XV.611.C.1 shall be met.

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COMMENT #	SUGGESTED BY
01 – 04	James Terry, PhD, DABR, DABMP
05 – 11	Carmen George, MSRS, R.T.(R)(ARRT) Baton Rouge General Medical Center.

Comments reflected in this document are repeated verbatim from the written submittal.

Total Commenters: 02
Total Comments: 11