

X-ray Unit Listening Session

Presentation Comments

Slide one - X-ray Program Listening Session

- Introductions

Slide two – Minnesota Rules, Chapter 4732

- Chapter 4732 rules regulates diverse areas of ionizing radiation.
- Partnership dedicated to radiation protection, and that is to maintain doses to the public and healthcare workers ALARA.
- X-ray program rulemaking preparations.
 - Gap analysis – Identified 3 top areas needing review according to each rule header.
 - Implementation of the rulemaking process – How we will roll the process out to stakeholders.
 - Definitions – Focusing on outdated definitions, updating them accordingly, and inserting place holders for new definitions that are missing.

Slide three – Minnesota Rules, Chapter 4732

- Process for rules.
- Administrative Procedure Act, Minnesota Statutes, Chapter 14.
- Government's three distinctive parts.
 - Legislative
 - Executive
 - Judicial
- Agency details – oversight Office of Administrative Hearings (OAH).
- Process provides:
 - Certainty
 - Predictability
 - Consistency
- Agency details – expertise, enforcement body working together with public input.

- Formal process steps:
 - Request for Comments published in the State Register July 18, 2016
 - Purpose is to notify public of plan to amend rules.
 - Request for comments.
 - The public has at least sixty days to weigh in informally before the agency can act.
 - Executive branch communicates with the Governor's Office.
 - Rule Development and SONAR Writing
 - Rules drafted into a regulatory framework
 - SONAR - Statement of Need and Reasonableness.
 - Justify how all rules we adopt are reasonable and necessary.
 - Draft of Rules to the Governor's office for approval.
 - Rules Proposed
 - The public has at least thirty days for comment.
 - Notice of intent to adopt rules is in one of three forms.
 - Proposed Rules→ Notice to adopt→ No Hearing.
 - Proposed Rules→ Notice to adopt→ Hearing.
 - Proposed Rules→ Notice to adopt→ Dual Notice. Hearing date but no hearing unless 25 people request one.
 - Hearings are legislative style.
 - Public opportunity to tell Administrative Law Judge (ALJ) what it likes, doesn't like, and suggest changes.
 - Additional comment period.
 - Rebuttal regarding what has come up in the process.
 - Final steps and filing with Secretary of State.
 - Governor
 - Fourteen days to veto rules.
 - No veto.
 - Rules effective in five days after Notice of Adoption published in State Register.

Slide four – Advisory Committee

- Advisory Committee

- Voluntary 12-15 members serve in representative capacity.
- Consensus building.
- Important voices for agency to hear.
- Public holds power of persuasion.
- Commissioner makes decision

Slide five – Focus Groups

- Focus groups and the use of an Advisory Committee – Ideally one member of the Advisory Committee is on the Focus Group.
 - Topic area.
 - 1- 2 meetings.
- MDH intends to convene 4 to 5 focus groups to focus on a particular modality or issue area.

Slide six – Focus Groups

- MDH brings consensus language to the Advisory Board Committee.
 - Communication shared between the focus groups and the advisory group.
 - Communication goes both ways between groups.

Slide seven – Example Focus Group

- Example as to what a Focus Group for Computed Tomography may look like.
 - Medical physicists.
 - Radiologist.
 - Physician.
 - Service provider.
 - QC technologist for CT.
 - Professional Association.

Slide eight – Survey Results

- Survey Results.
 - Top areas stakeholders stated where they would like to see a change.
 - 70 responses to this survey, which is approximately 50% of the individuals who received the survey took the time to respond.
 - Appreciative of thoughtfulness and time taken to express concerns.

- Provided possible solutions.

Slide nine – Survey Results

- Survey Results.
 - Areas we can't change in Minnesota 4732 Rule, unless there is a statute change.
 - Currently, under Minnesota Statute 144.121 Certified Registered Nurse Anesthetists is the only APRN qualified to operate x-ray equipment.

Slide ten – Survey Results

- Survey Results
 - Suggestions in areas we can take under consideration for Minnesota 4732 Rule revision.
 - Open for questions.

Slide eleven – Listening Session Ground Rules

- Facilitator Introduction
 - Listening session ground rules.
 - Open for stakeholders to provide comments, suggestions, and topic areas of interest regarding the Minnesota Rule, Chapter 4732.

Slide twelve – Getting Involved

- Getting Involved
 - The x-ray program has 3 communication avenues.
 - Dedicated rule webpage located on the MDH X-ray Unit Website.
 - Rule email on right – Dedicated rule email where you can provide the x-ray program comments regarding the rule.
 - Gov.delivery – Email sign on lower right indicates where you will be able to sign up for the program rule updates – Available in a week.
 - Program will be sending out an email blast to our registrants next week in regards to the x-ray rule page.

Stakeholder's Comments

Radiation Safety/Quality Assurance Program

- Dental exempt for retake and reject analysis.
 - Vet using dental – too much to log.
- Holding rules for human-use and veterinary are not consistent. The human-use are more lenient than veterinary regarding protected hands and body parts in the primary beam and should be as restrictive as veterinary.
- CT Dose Monitoring plan for the future.
 - Do not put in rule as other agencies have this in place.
- 4732.0610 medical events – Fluoroscopic event Skin entrance dose is poor use of words.
 - Should not fall under medical events.
 - Clear up language and move to a different section.
- The department has exempted electron microscopes in the past.
 - Should expand to include x-ray spectroscopy and others devices that are of equal or lesser hazard.
- Utilization log for non-medical is onerous for analytical and cabinet x-ray as dozens of tests are performed per hour.

Quality Control

- Relieve the requirement to keep quality control test evaluation images.
 - CT, lead aprons, etc.
- QC practice evolves rapidly.
 - Language for following manufacturer.
 - Follow a process to align with the medical physicist process.
- More defined regulations for CR/DR quality control requirements. Clarification is necessary for the service providers to provide direction to the regulated community.

Radiation Safety Officer (RSO) & Responsibility

- Training for RSO is a 1-time training.
 - Continuing education stated in rule.

Shielding

- Rule clarification for the use of portable x-ray units. There are requirements for protection of the operator in 4732.0800 based on mA/min. Rules are not clear for shielding requirements for portable x-ray units.

Equipment – Calibrations/Evaluations

- Requirements for calibrations can get dated. Establish rules that are for best practices regarding calibrations.
- kVp check on 2 D pan is not an accurate test.
 - Check at the power source.
 - Non-invasive test in beam is not accurate.
- Definition of calibration refers back to National Institute of Standards and Technology (NIST) traceability of 18 months.
 - More focused definition of calibrations.
 - MDH is 2 years' and NIST is traceable back to 18 months.

Operator Training

- Limited Scope X-ray Operator (LSXO) is a national test; however, MDH does not require continuing education.
 - MDH should establish continuing education requirements for all operators of x-ray equipment.

Operator Qualifications

- Required training for veterinary techs not prescriptive for non-human use.
 - Fluoroscopy
 - Computed Tomography (CT)
- Define the role of the Cardiovascular Tech (CVT).
- Physician Assistant (PA) Agreements copy not required to have on-site and should not be more restrictive than the board of medical practice.
 - Individual sites do not have to have PA agreements on hand.
- 147A.20 Delegation Agreements (PA's) will need to be considered relating to the requirement for the agreement to be kept at the facility and available to the Board upon request. This requirement will stand in the Practice Act unless it changes. All medical services provided by a PA is under the authority of the supervising physician.
- How will MDH be looking to phase out the X-ray Operator?
 - No one can enter this group and would like to see it phased out.
 - Limited Scope X-ray Operator (LMXO) was also mentioned in this comment.
- Address who/what credentials are necessary for a NM tech to perform diagnostic CT scans
 - RT(CT) CNMT
 - CNMT
 - NMTCB – CT

Fluoroscopy

- Explore the definition of a licensed practitioner of the healing arts to include Advanced Practice Registered Nurse (APRN).
- Why would APRN's need to use x-ray fluoroscopy, most physicians are not qualified to use these devices.
- Clarification of levels of operation.
 - One that steps on the pedal and one that wants to step on the pedal.
- Use of hand-held trained operators is not limited to license.
 - Anyone who is trained.
 - Clarification of the hand-held operator.
- The use of fluoroscopy by unsupervised Advanced Practice Registered Nurses (APRN) to perform interventional pain procedures:
 - The current rule appears to prohibit Advanced Practice Nurses from using a fluoroscope without direct physician supervision.
 - The rule does appear to allow APRN's to use a fluoroscope, but not to supervise the use of fluoroscope. We therefore believe that APRN's cannot use a fluoroscope as they are now doing (unsupervised) in a number of pain clinics.
 - Clarify what the statute actually allows APRN's to do and what they cannot do and then enforce the regulations in Minnesota in order to protect public health.
- Overexposure – concerns with potential scope of practice expansion to operators that are not thoroughly trained in radiation safety.
 - Pulled a variety of cases in order to develop an average of fluoroscopy time of radiologists in the Twin Cities:
 - Average fluoroscopy time for 15 different radiologists was 23.5 seconds for epidural steroid transforaminal injections (lumbar).
 - Have seen cases of utilizers taking well over six minutes for the same procedure.

Other program areas – Security Screening

- Further explanation on process for exemptions and adopt a process for evaluating exemptions.
- Develop rule language that can simplify statute/rule changes.
- Too broad an application and an advisory board and focus that inevitably will be (and should be) made up of medical, dental, vet professionals. But security screening needs a separate process for addressing the needs (and potential regulations) for other purpose.
 - Separate screening for security from medical, dental, vet purposes.

Other program areas – Hand Held

- Use of hand-held trained operators is not limited to license.
 - Anyone who is trained.
 - Clarification of the hand-held operator.

- Keep hand-held separate from general x-ray QA as they are very different.
- 4732.0306 unauthorized use.
 - Open access to imaging technology.
 - Vet, forensic
 - Remove or repeal 'A' (4732.0306, subpart A) requirement for variance use especially for dentistry.
- Define what hand-held use is? (FDA)
- No requirement for lead protection.
- Separate the use of this device.
 - Convoluted when mixed with other modalities.
 - Leading edge – More to come as far as technology.
- Dentistry – Is the state involved in this?
 - Where is the state in this process?
 - It seems the dental field is not sure on this.
 - If a customer calls, should we have them contact the state?
 - Any liability with the vendor?

Other program areas – Allied Dental Staff

- Collaborative agreements are being developed just for ordering x-ray exams.
- Recall patients and standing orders language does not coincide with the Board of Dentistry.

Other program areas – Research

- More rules directed to research, XRD, and XRF.
- Rule does not apply when directed under industrial.

Other program areas – Service Providers

- Outstate service providers may have not had a vetting process to ensure they are qualified/trained.
 - Can we have formal vetting process for service providers?
- Consider a fee for service providers and make the service provider company responsible for its staff.

Other program areas – Rule Revision

- Rulemaking for x-ray is extremely complex and in its aggregate would take dozens of hours to discuss. Believe this meeting may highly under represent the concerns and complexity of the rulemaking process.
- Encourage recruiting as we have a mutual obligation to make rules that would work for everyone not just the special interests.
 - Expertise exists out in the professional field.
 - Some individuals have higher obligations based on their expertise.