Wednesday, August 3, 2016

Preparing for an Inspection of Medical X-Ray Machines

PLEASE NOTE - INSPECTORS WILL NOW ARRIVE UNANNOUNCED! ● It will be necessary to have your employee operate the x-ray unit(s) during the inspection. Time for the inspection is approximately: 20-30 minutes for routine radiographic units. ● Review of paperwork will take approximately 1 hour depending on the number of units and the complexity of the inspection. ● Approximately 10 minutes must be allowed for an exit summation at the end of the inspection. This should be with the Radiation Safety Officer (RSO) or with the highest level of management available. ● The inspection check list was sent to you as a courtesy to help you prepare for the inspection. It is not all inclusive and does not eliminate your responsibility to read the applicable rules in preparation for the inspection.

PLEASE HAVE THE FOLLOWING RECORDS AVAILABLE FOR REVIEW:

- Current Certificate of Registration.
- Personnel monitoring – records of radiation badge reports.
- Dose to the public surveys.
- Operating and Safety Procedures – for your facility, signed by all operators and your RSO.
- "The Rules" – 25 TAC §289 – Applicable to your Certificate of Registration. Via office internet or you may also print a hard copy.
- Prior Notices of Violation - and your Response Letters to each notice if applicable
- Credentials – must be available, for all individuals who operate the x-ray unit(s), in hard copy or electronic format.
- Notice to Employees – the Notice must be posted.
- **Equipment Performance Evaluations (EPE), Conducted by Jones X-Ray and our Physicist,** Including: The last 3 previous EPE results for each x-ray unit (if applicable). Maximum required intervals: Medical and Chiropractic units every 2 years; Podiatry every 4 years; Fluoroscopy, CT and Therapy Units are not to exceed 14 months.
- **X-ray Image Processing – records of compliance or QA/QC. Call Jones X-Ray.** for digital acquisition systems. QA/QC protocols for digital systems need to be established by the manufacturer or registrant. Rule Reference for this is 25TAC §289.227(r).
- Documentation showing the dose limits to the public are not exceeded.
- Annual evaluations of protective devices and a record of those evaluations.
- Records of film processing or digital equipment maintenance.
- Inventory of X-ray units – annual inventory must be created and maintained by you. It must include the manufacturer's name, model number, serial number and room number for each x-ray unit.
- Receipt of Purchase – or FDA 2579 (pink copy) Report of Assembly. Transfer or Disposal forms for all units if applicable.

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PLEASE KEEP A COPY IN YOUR X-RAY FILE AND POST IN X-RAY ROOM CONTROL BOOTH