



Types of Records Reviewed During X-Ray Inspections

The **facility** shall maintain the following documentation. These documents will be reviewed for compliance with the regulations at the time of inspection(s). Radiation rule reference in parenthesis ().

- ❖ **For all X-Ray Units**
 - Copy of the plan review (.0603)
 - Copy of the letter of acknowledgement (.0603 (a)(2)(A))
 - Copy of the post installation room(s) survey (.0603)
 - Copy of the Form FDA 2579, FDA Report of Assembly Form**
(.0206) and Federal Part 21 CFR Part 1020

- ❖ **General Documents**
 - Current copy of the Notice of Registration from RPS (.0203) & (.0209)
 - Previous inspections reports and correspondence regarding inspections with RPS (.1002)
 - Current copy** of the State Regulations (2002 latest edition) (.1002)
 - Dosimetry Records for Personnel (.1638 & .1644)
 - Technique charts posted visibly and current for all procedures. Chart should include patient's anatomical size versus technique factors at a given source to image distance (SID). (.0603(a)(1)(C))

- ❖ **Radiation Safety Program**
 - Current copy of the radiation safety program (.1603 and .1636)
 - Reviewed annually by the RSO and signed (.1603)
 - Reviewed annually and when changes occur **by all operators and signed** (.1603)

- ❖ **Posting of Signs**
 - Notice to Employees (.1002)
 - Radiation Caution Signs (.1623 & .1624)

- ❖ **Other Items of Interest**
 - Brand, type and emitting color of film
 - Brand, type and emitting color of screens
 - Film/Screen combination speed
 - Type of processor chemicals (MSDS sheets for chemistry)
 - Type and wattage of safelight in darkroom
 - Type of filter on safelight in darkroom and date last changed
 - Average number of exposures per week
 - Film storage procedures and policy
 - Shielding devices and procedures (lead aprons, gonad and thyroid shielding)
 - Fluoroscopic outputs (if applicable)