Introduction

The following information is provided for completing a routine compliance inspection of various facilities with X-ray units. It provides instructions for completing the attached inspection form. It is not expressed or implied that successfully completing a form constitutes a thorough inspection. The form merely captures inspection information deemed important and relevant by the Director of the Division of Waste Management and Radiation Control.

Qualified Experts should be knowledgeable with all applicable sections of the Utah Administrative Code, R313. There are a number of regulatory issues which are not listed on the inspection form because the items of noncompliance are rare. All identified items of noncompliance are to be addressed on Exhibit B.

Section 1  General Radiation Safety

Regulations

R313-18-11  Notice to Workers
R313-15-101  Radiation Protection Program
R313-16-225(2)  Radiation Protection Program
R313-15-501  Surveys
R313-16-225(2)  Surveys
R313-15-1103  Survey Records
R313-28-31(3)  Survey Records
R313-28-31  General and Administrative Requirements
R313-28-350  Qualification of Operators

Procedure

1. If the facility has an employee, even someone who does not take X-rays, the Division of Waste Management and Radiation Control form DRC-04 Notice to Employees must be posted. If the registrant does not have a copy, provide them with one and have them post it on their Right to Know board, break room, X-ray suites, etc. A copy may be obtained from the DWMRC website. Request to see their Certificate of Registration. You will need this for Exhibit A of the inspection.

2. A facility with an employee is required to have copies of R313-15 and R313-18. Provide them with copies or if they have Internet access in the office, suggest they visit the DWMRC website for a copy of the regulations. In addition to these two sections, you should recommend that they maintain a copy of sections 12, 14, 16, 28, and 70 of R313. This is NOT a requirement, but you should encourage them to review and maintain these rules.
3. A facility with auxiliary X-ray operators is required to develop, document and implement a radiation protection program. Determine the knowledge employees have about the availability and contents of the radiation protection program. Review the program and offer suggestions in areas they may be lacking information. (Also see item 7.)

The objectives of a program should include provisions: a) that radiation exposures to X-ray unit operators and the general public do not exceed regulatory limits; b) that the program is designed to keep exposures to the X-ray unit operator and the general public “as low as is reasonably achievable” (ALARA); and c) to keep patient exposures to a minimum, consistent with the objectives of the X-ray procedure.

4. The radiation protection program must be reviewed (audited) at intervals not exceeding 12 months. Confirm that this review has occurred and records have been maintained in support of the requirement.

5. A registrant must have surveys completed and records of the information must be kept. Determine that a survey of radiation levels has been performed in accessible areas adjacent to and within rooms where X-ray procedures are conducted and that the results demonstrate that the objectives of the radiation safety program have been met. Evaluate surveys of restricted areas, unrestricted high occupancy areas adjacent to rooms containing stationary X-ray equipment, and shielding records for X-ray rooms.

Note: Surveys may be an evaluation of radiation levels from personnel monitoring records, area radiation measuring devices, or shielding plans along with workload information.

6. You need to determine if personnel monitoring is required. If the answer is yes, determine that the monitoring results and records are compliant with the rules. Observe whether or not personnel are wearing their badge during examinations.

7. Evaluate the registrant’s compliance with the requirements of R313-28-31, General and Administrative Requirements. A registrant with auxiliary X-ray operators is required to create and make available to X-ray operators written safety procedures. Determine the knowledge employees have about the availability and contents of the written safety procedures. Review the procedures and offer suggestions in areas where information may be lacking.

Important items required to be in the procedures include:

Room restrictions - only staff, ancillary personnel, trainees, or individuals needed for the medical procedure are to be in the room where X-ray procedures are performed. If patients are in a room when an X-ray procedure is to be performed and they cannot be removed from the room, instructions on procedures to follow in limiting their exposure to radiation needs to be developed and provided to the X-ray unit operator.

Aprons - individuals in a room when X-ray procedures are performed must be protected from scatter radiation unless it can be shown by using distance as a safety factor that the annual limits will not be exceeded. If a part of an individual, other than the patient, is to be struck by the primary beam, that part must be protected.
Aprons and gloves must be available in sufficient numbers to provide protection to personnel involved in X-ray procedures involving the need to hold a patient.

Holding a patient - instructions must be provided to the X-ray unit operator on how to choose the individual who is to hold a patient when holding a patient is required and what radiation safety practices the “holder” is to follow. This need also applies to holding the film.

Mechanical holding devices - mechanical holding devices must be used when the technique permits. The written procedures must list the individual projections where mechanical holding devices can be utilized.

Personnel monitoring - confirm that, if personnel monitoring is required, the registrant has a policy requiring that individuals wear badges and the procedures include information on where single or multiple badges are to be worn.

Pregnant radiation worker - the registrant must develop a policy concerning a pregnant radiation worker that satisfies the requirements of R313-15-208.

Patient protection - under specific circumstances, gonadal shielding is required. The registrant needs to provide instructions to the X-ray unit operator on when gonadal shielding is to be used and the shielding must meet the radiation attenuation requirements. A safety procedure concerning the potentially pregnant patient needs to be provided to the X-ray unit operator.

Radiographer training - individuals who will be operating X-ray equipment must be instructed in the registrant’s written radiation safety program and the individuals must be qualified in the safe use of the equipment.

8. Evaluate the qualifications of operators of diagnostic X-ray systems. You must confirm that all operators of X-ray equipment are licensed in accordance with the requirements of the Utah Department of Commerce, Division of Occupational and Professional Licensing. Note that there are two circumstances (a person performs services in a dental facility under the supervision of a dentist or a person performs services in a medical facility under the supervision of a podiatric physician) where an exemption from licensure exists.

Determine that the registrant has documented that the operator is trained in the proper choice of technique factors to be used and in the safe and effective operation of the X-ray equipment.

Technique information must be available at the control panel for routine radiographic procedures.

9. The registrant is to utilize procedures and equipment that are designed to minimize patient exposure consistent with the diagnostic objective of the examination. Knowledge of patient exposure is necessary in order to meet this requirement. Confirm that the facility has patient exposure information, consistent with the clinical use conditions, of routine radiographic procedures.
procedures for the standard man. In particular, patient exposure information for fluoroscopic procedures must be readily available and computed tomography dose measurements of the multiple scan average dose must also be available.

It is important to note that there are no regulatory restrictions which limit the exposure a patient may receive for a given procedure. Registrants should strive to minimize unnecessary radiation exposure and to maintain patient exposure to levels which are in keeping with the ALARA concept.

Section 2  X-ray Unit Evaluation

Regulations
R313-28-31(3) Equipment Maintenance and Calibration
R313-16-293 Application for Registration of Inspection Services

Procedure
1. The registrant is to maintain records of calibration, maintenance and modifications performed on each X-ray machine. Check to see that this information has been kept and use it as needed when evaluating the performance of each X-ray unit.

2. Qualified experts are to follow the guidelines for the evaluation of X-ray equipment that have been defined by the Director. You must provide the registrant with documentation which demonstrates that the X-ray equipment satisfies the regulatory standards under clinical use conditions. The registrant must maintain a record of this information to satisfy item 1 above.

Section 3  Inspection Summary

Regulations
R313-16-293 Application for Registration of Inspection Services

Procedure
1. Qualified experts or registrants are required to submit to the Director, within 30 calendar days after completion of an inspection, a written report of compliance or noncompliance. Reports of noncompliance must contain the information listed in R313-16-293(2)(i).

Mail completed inspection form and supporting documents to:

Director
Division of Waste Management
and Radiation Control
P.O. Box 144880
Salt Lake City, Utah  84114-4880