

Radiation Safety Practices Community Hospital System (NRC State)

OUTLINE

1. Radiation Protection Program
2. Radiation Safety Audits
3. Medical Events
4. Radioactive Source Security

Overview of St. Luke's Health System, Boise Idaho

- **Facilities**
 - # of Hospitals (large) = 6
 - # of Hospitals (small) = 4
 - # of Cancer Centers = 5
 - # of Linear Accelerators = 8
 - # of Nuclear Medicine Departments = 9
 - # of Use Area Addresses on License = 14
- **Licensed Activities**
 - Therapeutic: HDR, LDR (seeds), Ra-223, Y-90, I-131
 - Diagnostic: Nuclear Medicine, Nuclear Cardiology
 - Security-related high-activity source: Blood Irradiator (Cs-137)
- **Staff**
 - # of Employees = 8,800
 - Largest employer in the state of Idaho
 - Comparisons:
 - Micron Technology = 8,000
 - Mountain Home Air Force Base = 5,200
 - Boise State University = 4,800

1. Radiation Protection Program

- **Regulation**
 - 10 CFR 20.1101 “Radiation Protection Programs”
 - Each licensee shall develop, document, and implement a radiation protection program commensurate with the scope and extent of licensed activities and sufficient to ensure compliance with the provisions of this part.
 - The licensee shall use, to the extent practical, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are as low as is reasonably achievable (ALARA).
- **Resource**
 - NUREG 1556, Vol 9, Rev 2 “Consolidated Guidance About Materials Licenses”.

1. Radiation Protection Program

RECOMMENDED CONTENTS

- **Purpose**
 - To ensure that all activities involving the use of ionizing radiation are performed in such a way as to protect individuals from unnecessary radiation exposure.
- **Management Commitment**
 - Management is committed to keeping radiation doses as low as reasonably achievable (ALARA). St. Luke’s Health System conducts an annual review of its Radiation Protection Program.
- **Annual Audit**
 - St. Luke’s Health System conducts an annual review of its Radiation Protection Program.

1. Radiation Protection Program

RECOMMENDED CONTENTS

- **ALARA Program / Personnel Monitoring**
 - All individuals who are occupationally exposed to ionizing radiation and are likely to receive 10% of the occupationally exposed limit of 5000 mrem per year are issued a whole-body dosimeter that is processed on a monthly or quarterly basis.
 - The Radiation Safety Officer reviews radiation monitoring reports to ensure compliance with 10 CFR 20.1201. Any exposure above 375 mrem per quarter is noted and investigated.
 - St. Luke's Health System establishes and implements procedures to achieve occupational and public doses as low as reasonably achievable (ALARA).
- **Personnel Training**
 - Initial and annual training is provided to radiation workers. Instruction includes the ALARA program, radiation monitoring, exposure limits, applicable regulations, protection from exposure to radiation, emergency procedures and other relevant radiation safety topics.

1. Radiation Protection Program

RECOMMENDED CONTENTS

- **Responsibilities of the Radiation Safety Officer**
 - The Radiation Safety Officer (RSO) is responsible for ensuring that radiation safety activities are performed in accordance with approved procedures and regulatory requirements. The RSO acts in a supervisory capacity in all aspects of the St. Luke's radiation protection activities, including personnel monitoring, maintenance of records, audits, policy development, receipt and disposal, and radiation safety training.
- **Responsibilities of the Radiation Safety Committee**
 - The Radiation Safety Committee (RSC) ensures that use of radioactive material is conducted in a safe manner and in accordance with NRC regulations and the conditions of the license. The RSC holds quarterly meetings to review all radiation safety activities. The RSC ensures that all individuals who work with or in the vicinity of ionizing radiation have sufficient training and experience to enable them to perform their duties safely.

1. Radiation Protection Program

RECOMMENDED CONTENTS

- **Radioactive Source Security**
 - St. Luke's Health System has a written security plan specific to its facilities and operations and written procedures for implementing the plan. Radioactive sources are secured appropriate to their category. Access is restricted to authorized individuals, whose names are documented.
- **Radiation Emergency Plan**
 - St. Luke's Health System maintains a radiation emergency plan in the event of a major event requiring immediate attention to protect individuals from exposure to ionizing radiation.
- **Quality Assurance**
 - Quality assurance procedures are performed to ensure safe handling of radioactive materials and proper surveys, monitoring and calibrations. These activities include ...

2. Radiation Safety Audits

- **Regulation**
 - Review the Radiation Protection Program:
 - Content
 - Implementation
- **Purpose**
 - Ensure compliance with regulations
 - Ensure compliance with license conditions
 - Ensure doses are ALARA
- **Responsibilities**
 - Management: audit is performed annually
 - RSO: audit is documented and reported
 - RSO or designee: performance of the audit

2. Radiation Safety Audits

REGULATION

- **Regulation**
 - 10 CFR 20.1101 “Radiation Protection Programs”
 - Each licensee shall develop, document, and implement a radiation protection program commensurate with the scope and extent of licensed activities and sufficient to ensure compliance with the provisions of this part.

What does “this part” mean?

- PART 20 - STANDARDS FOR PROTECTION AGAINST RADIATION
 - contains 15 subparts and 83 sections
- The Audit should include all NRC regulations

2. Radiation Safety Audits

LICENSE

- **Examples of “scope of licensed activities”**
 - Posting: “The licensee shall post each radiation area with a conspicuous sign or signs bearing the radiation symbol and the words “CAUTION, RADIATION AREA” (10 CFR 20.1902).
 - Sealed sources: “A licensee shall test the source for leakage at intervals not to exceed 6 months” (10 CFR 35.67).
 - Fetal dose: “The licensee shall ensure that the dose equivalent to the embryo/fetus during the entire pregnancy, due to the occupational exposure of a declared pregnant woman, does not exceed 0.5 rem” (10 CFR 20.1208)
 - Survey records: “Each licensee shall maintain records showing the results of surveys and calibrations” (10 CFR 20.2103)
 - RSO responsibilities: “The licensee shall ensure that radiation safety activities are being performed in accordance with regulatory requirements” (10 CFR 35.24).

2. Radiation Safety Audits

RECOMMENDED CONTENTS

- **Model Medical Licensee Audit** (NUREG 1556, Vol 9, Rev 2 “Consolidated Guidance About Materials Licenses”, Appendix L)
 - Audit History
 - Were previous audits conducted annually [20.1101]?
 - Were records of previous audits maintained [20.2102]?
 - Were any deficiencies identified during previous audit?
 - Were corrective actions taken? (Look for repeated deficiencies).
 - Organization and Scope of Program
 - Is RSO fulfilling all duties [35.24]?
 - Are all locations listed on license?
 - Licensed Material
 - Isotope, chemical form, quantity and use as authorized?
 - Are the actual uses of medical devices consistent with the authorized uses listed on the license?
 - Training, Retraining, And Instructions to Workers
 - Have workers been provided with required instructions [19.12, 35.27, 35.310, 35.410, 35.610]?
 - *Etc - roughly 400 questions contained in this audit template*

2. Radiation Safety Audits

RECOMMENDED CONTENTS

- **Template – St. Luke’s Health System**
 - NRC License contents: authorized users, locations, materials, etc
 - Most recent NRC inspection: results, violations, action plans, etc
 - Radiation signage and postings
 - Radiation Safety Officer: credentials, activities, etc
 - Radiation Safety Committee: meeting minutes, issues, etc
 - Calibrations: survey meters, ion chambers, electrometers, etc
 - Surveys/wipes, Inventory/Leak Tests, Dose Calibrator QA
 - Review of radiation monitoring records
 - Review of Radiation Protection Program
 - Review of internal audits
 - Documentation of all required activities
 - *Etc – several more sections and details for above items*

3. Medical Events

- **Regulation**
 - 10 CFR 35.3045 “Report of a Medical Event”
 - A licensee shall report any event, except for an event that results from patient intervention, in which the administration of byproduct material or radiation from byproduct material results in:
 - A dose that differs from the prescribed dose or dose that would have resulted from the prescribed dosage by more than 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin; and
 - » The total dose delivered differs from the prescribed dose by 20 percent or more
 - » The total dosage delivered differs from the prescribed dosage by 20 percent or more or falls outside the prescribed dosage range; or
 - » The total dosage delivered differs from the prescribed dosage by 20 percent or more or falls outside the prescribed dosage range; or

3. Medical Events

- **Regulation**
 - 10 CFR 35.3045 “Report of a Medical Event”
 - Report any event ... which ... results in:
 - A dose that exceeds 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin from any of the following
 - » An administration of a wrong radioactive drug containing byproduct material
 - » An administration of a radioactive drug containing byproduct material by the wrong route of administration
 - » An administration of a dose or dosage to the wrong individual or human research subject
 - » An administration of a dose or dosage delivered by the wrong mode of treatment; or
 - » A leaking sealed source

3. Medical Events

- **Regulation**
 - 10 CFR 35.3045 “Report of a Medical Event”
 - Report any event ... which ... results in/from:
 - A dose to the skin or an organ or tissue other than the treatment site that exceeds by 0.5 Sv (50 rem) to an organ or tissue and 50 percent or more of the dose expected from the administration defined in the written directive (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site
 - Intervention of a patient or human research subject in which the administration of byproduct material or radiation from byproduct material results or will result in unintended permanent functional damage to an organ or a physiological system, as determined by a physician

3. Medical Events

WRITTEN REPORT

- **The written report must include**
 - The licensee’s name
 - The name of the prescribing physician
 - A brief description of the event
 - Why the event occurred
 - The effect, if any, on the patient
 - Actions, if any, that have been taken or are planned to prevent a recurrence
 - Certification that the licensee notified the patient
 - Or guardian / responsible relative
 - And if not notified, explain why not
 - Do not include: patient’s name or other information

3. Medical Events

NOTIFICATION DEADLINES

- **Notification to the NRC**
 - By phone:
 - No later than the next calendar day
 - To the NRC Operations Center
 - In writing (written report):
 - Within 15 days (after discovery of the event)
 - To the appropriate NRC Regional Office
- **Notification to the Physician**
 - No later than 24 hours (after discovery of the event)
- **Notification to the Patient**
 - No later than 24 hours (after discovery of the event), unless:
 - Physician chooses to notify the patient
 - Physician decides that telling the patient would be harmful

3. Medical Events

INTERNAL REPORTING/ACTION - ROOT CAUSE ANALYSIS

- **St. Luke's "RCA Process Form"**
 - RECOGNIZE: WHAT IS THE PROBLEM? (compare to what should be happening)
 - DEFINE: IMMEDIATE ACTION (actions to happen right now to reduce risk/harm if problem occurs again)
 - DEFINE: HOW BIG IS THE PROBLEM/SCOPE? (background, frequency, location)
 - ANALYZE: GO MAP WHAT HAPPENED AND IDENTIFY POTENTIAL CAUSES (Current State Map; What is Actually Happening)
 - DETERMINE: WHY DID IT HAPPEN? (problem solve potential cause(s))
 - IDENTIFY SOLUTIONS: GO MAP NEW PROCESS RECOMMENDATIONS (remap the current process into the ideal process)
 - TEST AND IMPLEMENT PROCESS CHANGES (confirm successful implementation of actions from Action Items Form)

4. Radioactive Source Security

REGULATION – 10 CFR 37

- **Security Plan**
 - 37.43: “develop a written security plan specific to its facilities and operations”
- **Local Law Enforcement**
 - 37.45: “coordinate, to the extent practicable, with an LLEA for responding to threats to the licensee's facility”
- **Maintenance / Testing**
 - 37.51: “implement a maintenance and testing program to ensure that intrusion alarms, associated communication systems, and other physical components of the systems used to secure or detect unauthorized access to radioactive material are maintained in operable condition”
- **Written Procedures**
 - 37.23: “develop, implement, and maintain written procedures for implementing the access authorization program”

4. Radioactive Source Security

REGULATION – 10 CFR 37

- **Security Zones**
 - 37.47: “ensure that all aggregated category 1 and category 2 quantities of radioactive material are used or stored within licensee established security zones”
- **Monitoring / Detection**
 - 37.45: “establish and maintain the capability to continuously monitor and detect without delay all unauthorized entries into its security zones”
- **Review**
 - 37.33: “ensure that access authorization programs are reviewed to confirm compliance, at least annually”
- **Training**
 - 37.23: “Individuals shall complete the security training before being allowed unescorted access to category 1 or category 2 quantities of radioactive material”

4. Radioactive Source Security

REQUIREMENTS – SECURITY PLAN

- **Security Plan/Program**
 - Must be a written plan
 - Must describe the measures used to meet the regulation
 - Must identify items to meet the regulation:
 - Security resources
 - Equipment
 - Technology
 - Must be reviewed annually:
 - Content
 - Implementation
 - Identify any noncompliance
 - Take corrective actions

4. Radioactive Source Security

REQUIREMENTS – PROCEDURES

- **Policies and Procedures**
 - Must be written
 - Goal is to limit access to authorized individuals only:
 - Category 1 and Category 2 radioactive materials
 - Must maintain a list of authorized individuals:
 - Unescorted access to security zones
 - Access to the Security Plan
 - Access to the Procedures
 - Must control access to the Security Plan:
 - Authorized individuals
 - Must be reviewed annually

4. Radioactive Source Security

DEFINITION OF CATEGORIES 1 & 2

- **Radioactive Materials – Category 1 & Category 2 Thresholds**
 - Cs-137
 - Category 2 threshold = 27 Ci
 - Category 1 threshold = 2700 Ci
 - Ir-192
 - Category 2 threshold = 21.6 Ci
 - Category 1 threshold = 2160 Ci
 - Cs-137 blood irradiator is Category 1 (> 2700 Ci)
 - Ir-192 HDR afterloader is not Category 2 (< 21.6 Ci):
 - As long as you don't store 3 sources, for instance, in the same area
 - This would be unusual, but possible

4. Radioactive Source Security

REQUIREMENTS – TRAINING

- **Personnel Training**
 - Conduct training to ensure that employees:
 - Possess and maintain:
 - Knowledge
 - Skills
 - Abilities
 - To carry out their assigned duties and responsibilities effectively
 - Must include instruction in the following areas:
 - Security program
 - Report any condition that may result in a violation
 - Report any theft (actual or attempted)
 - Proper response to security alarms
 - Refresher training “not to exceed 12 months”

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... and don't forget August 21st if you're in the path ...

