

NRC – INSPECTION FOCUS ELEMENTS

The following items are the key “focus” issues to be considered in all routine Nuclear Regulatory Commission (NRC) inspections of Medical Material Licensees. These routine unannounced inspections for hospital imaging & localization authorized use are to be expected at least every three (3) years and possibly every five (5) years if the licensee has a “good performance” record for previous inspections. Licensees with High Dose Remote (HDR) Brachytherapy to include vascular brachytherapy authorized use will be inspected every year. With a “good performance” history this may be extended to every two (2) years.

Each inspection’s extent and depth will be determined by the outcome of compliance with the focus elements noted below, plus the potential risks of approved licensed activities. If the focus element inspection outcomes are not desirable, then an “increased inspection effort” will follow, to include root cause analysis. Tactics will include reviews of policies and procedures and additional interviews and direct observations of staff work activities.

NRC inspectors are required to base compliance on direct observation of work activities, interviews with workers, demonstrations by appropriate workers in the performance of regulated tasks, independent measurement of radiation conditions and where appropriate review of selected records.

1. SECURITY AND CONTROL OF LICENSED MATERIAL

Items to be considered:

- Adequate & authorized facilities
- Adequate equipment & instrumentation & use
- Radioactive material inventory & accounting system
- Security and control mechanisms
- Receipt, transfer, shipment of licensed material
- Waste storage and disposal of licensed material
- Effluents & Derived Air Concentration (DAC) calculations
- Compliance with 10 CFR 20.1801 and 20.1802
- Written Directives, Medical Events
- Posting and labeling
- Compliance with 10 CFR 35.75 “Patient Release”

2. SHIELDING OF LICENSED MATERIAL

Items to be considered:

- Review and observe proper shielding of Licensed Materials
- Review Leak tests

3. COMPREHENSIVE SAFETY MEASURES

Items to be considered:

- Evaluate the potential of other industrial safety hazards that could compromise safe use and storage of licensed material.
- Evaluate controls to minimize risk from other hazardous materials

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4. RADIATION DOSIMETRY PROGRAM

Items to be considered: Evaluate radiation protection program per 20.1101
Review occupational radiation exposure records
Note personnel dosimeters
Review Bioassays - Internal dosimetry per 20.1501

5. RADIATION INSTRUMENTATION AND SURVEYS

Items to be considered: Evaluate instruments, equipment & use
Note proper equipment usage and distribution
Area radiation & removable contamination surveys

6. RADIATION SAFETY TRAINING AND PRACTICES

Items to be considered: Access staff knowledge and empowerment to properly implement the following:
General training, ie.10 CFR 19.12
Operating and emergency procedures
Nursing instruction for non-released patients
Observe proper use and availability of protective clothing

7. MANAGEMENT OVERSIGHT

Items to be considered: Review licensee management organization & scope of program
Evaluate radiation protection program administration i.e. RSO and RSC
Verified review of audits records (i.e. MPC Reports)
Self-identified violations & corrective actions
Evaluate authorized users and uses
Financial assurance & decommissioning
Decommissioning timeliness
Communication of NRC information
Review notifications and reports to the NRC
Review special license conditions
Review research involving human subjects