AUDIT Definition

“Periodic examination of the radiation safety program... related to the possession, use, storage, transfer, & disposal of licensed material.”

Ref: NUREG-1516 “Management of Radioactive Material Programs at Medical Facilities”

WHY AUDIT?

- Document compliance status
- Self-identify problems
- Implement & assure ALARA

JCAHO STANDARDS

- Medical equipment management plan is implemented (EC.2.7)
  ➤ Review of equipment testing results
  ➤ Deficiency follow-up documented
- Medical equipment is maintained, tested, & inspected (EC.2.13)
  ➤ Performance evaluation at least annually
- Data on important processes & outcomes are collected from quality control activities (PI.3.3.3)
  ➤ QA procedures

MEDICAL RADIATION MANAGEMENT

- Key Responsible Components
  ➤ Executive Management
  ➤ Radiation Safety Committee (RSC)
  ➤ Radiation Safety Officer
### TYPES OF AUDITS

1. **Department/Facility**
   - **Target:** Director/Manager/Authorized User
   - **Frequency:** quarterly

2. **Radiation Safety Program**
   - **Target:** Executive Management
   - **Frequency:** annual

### EFFECTIVE AUDIT COMPONENTS

- **Knowledgeable Auditor**
  - NRC/State regulations
  - License conditions
  - License application
  - Facility-approved policies/procedures
- **Documentation**
  - Findings (+/-)
  - Recommendations (Opportunities for Improvement)

### NM AUDIT AREAS

- Documentation Posting
- Appropriate Signage
- Current Manuals & Procedures
- Records
- Shielding/Protective Equipment

### NM AUDIT AREAS

- Sealed Source Control
- LLRW Disposal
- Equipment QC
- Operational Health Physics
- Radiopharmacy

### POSTED DOCUMENTS

- NRC Form-3
- NRC/State license
- Federal/State regulations
- Emergency (Spill) procedures

### APPROPRIATE SIGNAGE

- Entrance doors
- Storage/transport containers
- Storage areas
- Waste containers
- Sink
- Microwave oven
- Fume hood
### MANUALS/PROCEDURES
- Radiation Safety Manual
- Clinical procedures/dosages/dosimetry
- Current license/registration/authorization
- NRC regulations/State rules
- Facilities described in floor plans
- Periodic (annual) review

### EDUCATION (INSERVICE)
- New workers & annually
- Pregnancy
- Allied medical personnel
  - Nursing
  - Shipping/Receiving
  - Security
  - Housekeeping

### RECORDS
**Surveys**
- Package receipt
- Package transfer/returns
- Radiation levels of admin/prep areas - daily
- Radiation levels of storage areas - weekly
- Removable contam in use/storage - weekly
- Spills

NRC IN 98-18: “Failure to perform adequate NM surveys” [5/13/98]

### SURVEYS
**Documentation**
- Reports
  - Instrument
  - Background
  - Results & corrective actions
  - Correction/conversion factors
  - Initials

### SURVEYS
**Area Trigger (Action) Levels**
- Unrestricted - 0.25 mR/hr
- Restricted - 2.5 mR/hr
- General Trash - Background

### SURVEYS
**Wipe Trigger (Action) Levels**
- Therapy Rooms (35.315) - 200 dpm/100 sq.cm.
- Nuclear Medicine (35.70) - 2000 dpm/100 sq.cm.
- Packages - 6600 dpm/300 sq.cm.
- General
  - Unrestricted - 2200 dpm/100 sq.cm.
  - Restricted - 22000 dpm/100 sq.cm.
- Leak Tests - 5 nCi (11000 dpm)
### PROTECTIVE EQUIPMENT
- Lab coats
- Disposable gloves; absorbent pads
- Functional syringe/vial shields/carriers
- "L" body shield; Pb bricks
- Remote handling tools
- Bedside shields for I-131 Tx
- Adequate storage/work areas

### SEALLED SOURCES
- Inventory all nonexempt sources - qtrly
- Leakage tests every 6 mos.
  - Results: proper units, RSO signature
  - in-house (MDA documentation) vs.
  - commercial service (licensed?)

### WASTE MANAGEMENT/EFFLUENTS
- Segregate waste types: RAM/sharps/biohazard
- Decay-in-storage records
  - Deface labels per 10 CFR 20.1904
    - [NRC IN 97-03,2/20/97]
- Sewer limits, if applicable
- Xenon: trap checks monthly
  - Room/hood exhaust rates - 6 mos
    - posted evacuation times

### QUALITY CONTROL
Program to assure all scintillation equipment functions properly
- Gamma cameras
- Uptake probe/well-counter
  - procedures & action levels
  - counting efficiencies (cpm → dpm)
  - MDA for bioassay/leakage tests

### OPERATIONAL HEALTH PHYSICS
- Cleanliness
- Personnel monitoring (badge) reports
- Adequate survey meters for work (β ?)
  - calibrated - annual
  - functional & check source reading
- Emergency (Spill) supplies/kit
- Performance based inquiries
- Security

### SECURITY
“failure to secure, or maintain surveillance over radioactive materials…”
- Level of violations tied to aggregate 10 CFR Part 20, Appendix C quantities
  - Level III violation: 1 mCi I-131
**RADIOPHARMACY**
- Moly-99 breakthrough
- Dose calibrator tests
  - constancy - beginning of each day of use
  - linearity - quarterly
  - accuracy with 2 sources - annual
  - geometry - installation
- Syringe/vial labeling
- Biohazard (laminar flow) hood certified - annual
- Track dosage: patient ↔ source

**RADIOPHARMACEUTICAL THERAPY**
- Inpatient Tx records
  - Posted precautions
  - Patient & area radiation levels
  - Room discharge monitoring
- I-131 bioassay
- Patient ALARA instruction for all Tx types
- "QMP" documentation

**QUALITY MANAGEMENT PROGRAM**

**General**
"...program to provide high confidence...material will be administered as directed by the authorized user."

- Written policies & procedures
- Workers familiar with QMP
- Submitted to NRC
- Workers familiar with licensee’s QMP

**Specifics**
- Written directive prior to administration
- Patient ID by at least 2 methods
- Administration follows directive
- Identify, evaluate, & correct unintended deviations
- Review QMP at least every 12 months
  - All recordable events & misadministration
  - Representative sample of administrations

**PROGRAM AUDIT**
- Radiation Safety Committee
- Annual Report to Management of Program
- Corrective Actions

**RADIATION SAFETY COMMITTEE**

**Minutes**
- RSC Members meet Part 35/License conditions
- Informs Management & members
- Documents compliance to outside agencies
- Contents:
  - Dates
  - Attendance/Absence
  - Summary discussion
  - Actions with voting results
**PROGRAM AUDIT**
Report to Management

- Summary of RSC actions
- Users approved by RSC/NRC
- Personnel monitoring ALARA review
  - Annual monitoring reports to workers
- RAM inventory compliance (Possession limits)

**PROGRAM AUDIT**
Report to Management

- Document air emissions TEDE < 10 mrem (EPA) - [NRC IN 97-04, 2/24/97]
- Incidents/major spills
- "QMP" records review:
  - Recordable events
  - Misadministrations
- Medication errors

REQUEST RESPONSE!!

**CORRECTIVE ACTIONS**

- Self identify citations in best interest

- Must promptly correct with root cause analysis
  - Level IV → "noncited" violation w/o enforcement action
  - NRC IN 96-28, 5/1/96

- Response regardless dept or program audit

**CORRECTIVE ACTIONS**

- NRC Revised Enforcement Policy
  - Focus on current performance
  - Focus efforts on licensees with multiple actions in short time
  - Prompt comprehensive action important

  Ref: Fed Reg 5/13/98
## PROPOSED REVISION

**10 CFR 35**

**AAPM**

Nashville, TN

Ralph P. Lieto, MS

Henry Ford Hospital

Detroit, MI

## BACKGROUND

- Federal Register Notice: 8/13/98
- Part 35 Working Draft of Final Rule 4/30/99

- Regulations are:
  - performance based (minimize prescriptive)
  - risk based
  - eliminate license conditions - codify or delete

## INSPECTION & ENFORCEMENT

- Licensee develops procedures; not submitted to NRC as license condition
- NUREG-1556 as model procedure document
- Shift from records to procedures review
- Possible inspection actions:
  - review dose records
  - review internal audits
  - confirmatory surveys
  - worker interviews
  - review procedures followed/implemented

## SUPERVISION

- Require instruction of supervised workers
  - Radiation protection procedures
  - Written directive procedures
  - Regulations & license conditions

- Supervised workers required to follow instruction

## SURVEYS

- Document ambient exposure rate where RAM prepared or used *for written directive* - end of each day of use

- Otherwise meet Part 20 for:
  - Contamination Surveys
  - Radiation Level Surveys
  - Handling of Volatiles & Gases
  - Possession of Survey Instruments

## SEALED SOURCE

- Sealed source inventory - semiannual
DOSE CALIBRATORS

- Term “dose calibrator” → “instrument to measure activity”
- Dosage must be w/in ±20% OR prescribed range
- QC tests of manufacturer or national standards
- Allows decay correction of prepared unit dosages

RADIOPHARMACY

- Delete 10 half-lives rule for decay-in-storage waste
- Mo-99 breakthru test for 1st elution only
- Bioassay requirements dropped
  - meet Part 20 only

PATIENT RELEASE

- Revises 10CFR20.1301
  - Patients that cannot be released
  - Permit 0.5 rem to visitors
  - Itemized safety instructions + CFR 19.12
- Monitoring & recording visitor doses not required
- Maintains Part 35.75 for therapy patient release
  - Major concern of Agreement States
- NRC recognizes:
  - possibility of receiving 1.0 rem
  - visitor may be pregnant

QUALITY MANAGEMENT PROGRAM

- Replace “misadministration” with “medical event”
- Dropped recordable events
- Replaced with program that has “high confidence”:
  - identifying patient
  - requires written directives
  - verifies dose/dosage per written directive
  - checks manual & computer calcs
  - verifies computer calcs entered to device
- Patient notification unchanged

RADIATION SAFETY COMMITTEE

- Not required for diagnostic only licensee
- Not required for single therapy type licensee
- Must have RSC if ≥ 2 types of use requiring written directive
- Membership:
  - RSO
  - Management rep
  - Nursing rep
  - Each type of use permitted

REPORTS

- Medical Events
  - Intervention by patient not reportable
- Dose to embryo/fetus/nursing child > 5 rem
  - unless approved in advance by auth user
  - must be unintended exposure to mother
- Leaking sources [>SnCl(185 Bq)]
**TRAINING & EXPERIENCE**

- **AUTHORIZED USER**
  - Certified by NRC recognized board;
  - OR
  - Structured program = didactic + supervised practical experience
    - Focus is rad safety activities not clinical
  - Signed preceptor competent to function independently
  - Received w/in 7 yrs or continuing educ

- **RADIATION SAFETY OFFICER**
  - Certified by NRC recognized board;
  - OR
  - Structured program = 200 hrs didactic + 1 yr FTE supervised training under RSO; &
  - Preceptor signs competent to function alone;
  - OR
  - Authorized user/nuc pharmacist/med physicist + experience with licensed types of use

**MEDICAL EVENTS**

- 5 rem EDE or 50 rem organ/tissue/skin AND
  - wrong radiopharmaceutical
  - wrong route of administration
  - wrong individual
  - wrong treatment mode
  - leaking sealed source

- 5 rem EDE or 50 rem organ/tissue/skin AND
  - total dose $\geq 20\%$ of prescribed OR
  - total dosage $\geq 20\%$ of prescribed OR
  - total dosage $>\text{prescribed range OR}$
  - single fractionated dose $\geq 50\%$ of prescribed
- $>50\text{ rem to wrong organ/tissue}$ & $\text{dose expected from directive} > 50\%$ (except seeds)
- Any patient intervention causing unintended permanent functional damage