RADIATION SAFETY AUDITS IN NUCLEAR MEDICINE

AAPM Continuing Education
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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"

AUDIT
Definition

"...deliberate examination of the program to determine if it is effective. The audit is an integral part of any quality assurance effort..."

Ref: NCRP Report No. 127 "Operational Radiation Safety Program"

WHY AUDIT?

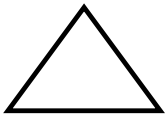
- Document compliance status
- Self-identify problems
- Implement & assure ALARA

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

SEALED 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 breakthru
- 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

QUALITY MANAGEMENT PROGRAM 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

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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 [>5nCi(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

TRAINING & EXPERIENCE

- 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

MEDICAL EVENTS

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