NUCLEAR MEDICINE INSPECTION REPORT

(includes iodine therapy and manual brachytherapy)

(All reg. references proceeded by SRPAR 0400-20)

Licensee:

Address:

Location of Inspection:

License Number: Priority: Inspection Code

Inspection Date: Previous Inspection Date:

Inspection Overdue: Yes ○ No ○

Inspection Type: Initial ○ Routine ○ Special ○

Inspection: Announced ○ Unannounced ○

In Compliance: Yes ○ No ○ Number of Violations

Accompanying Inspector(s):

Other Accompanying Personnel:

Licensee Participants: (list individuals, including titles)

Inspection:

Exit Interview:

Section I. Interview

1. Organization and Administration

a. Administrator -

b. Department Manager-

c. RSO -

d. Is RSO as listed on license? [07-.13(1)(c)] . . . . . yes ○ no ○

e. Authorized Users (doctors) -

f. Are all Authorized Users as listed on license? [07-.13(1)(b)] . . . . . yes ○ no ○

g. Technicians -

2. Radiation Safety Officer (RSO) Authority and Responsibilities [07-.17]

a. Licensee and RSO has agreement, in writing, granting RSO authority to implement radiation protection program [07-.17(2)] . . . . . yes ○ no ○

b. Licensee shall establish the authority, duties, and responsibilities of RSO in writing. [07-.17(5)] . . . . . yes ○ no ○

c. Records retained of signed RSO written agreement and duties [07-.82(2)] yes ○ no ○

d. Has licensee provided RSO sufficient authority, time, and resources to identify radiation safety problems, and provide and complete corrective actions as necessary. [07-.17(7)] . . . . . yes ○ no ○

3. Misadministrations [05-.145] and Incidents [05-.141]

a. Any reportable misadministrations or incidents? . . . . . yes ○ no ○

b. Records maintained? . . . . . N/A ○ yes ○ no ○

c. Spot check review patient records to check prescribed vs. actual dose? yes ○ no ○

d. Records required under 05-.145(7) contain: . . . . . yes ○ no ○

- ☐ Licensee's name
- ☐ Names of individuals involved
- ☐ Identification of patient (need not be a name)
- ☐ Description of the event
- ☐ Why the event occurred
- ☐ Effect on the patient
- ☐ Actions taken to prevent recurrence
- ☐ Was the individual/patient notified?

e. Remind facility of the definition and reporting requirements for therapeutic misadministration? yes ○ no ○

4. Summary of Licensed Program (Use and Possession)

a. (Check all that apply):

- ☐ Measurements of up-takes, dilutions, and excretions - No imaging [07-.38]
- ☐ Diagnostic imaging and localization studies with unsealed sources - **No written directive** [07-.40]
- ☐ Unsealed sources diagnostic and therapeutic – **Written directive required** [07-.44]
- ☐ Sealed sources for manual brachytherapy [07-.51]
- ☐ Teletherapy [07-.63]

b. Quantity and Identity of Material present at facility:

(1) Does a. and b. above agree with the license? [L.C. 6,8,9,10] . . . yes ○ no ○

c. Number of techs making injections: **d.** Number and Type of scans per month:

e. Are sealed source receipt and disposal records maintained? [10-.26] . . . yes ○ no ○

f. Generator (Molybdenum and Rubidium generators) . . . . . N/A ○ yes ○ no ○

(1) If yes, who supplies it?

(2) Receipt / disposal records on file? . . . . . yes ○ no ○

(3) Radionuclide contaminants tests [07-.41]

i. Moly test performed? (<0.15 µCi Mo-99/mCi Tc-99m) N/A ○ yes ○ no ○

ii. Sr-82 per Rb-82 test? (<0.02 µCi Sr-82/mCi Rb-82) . . N/A ○ yes ○ no ○

iii. Sr-85 per Rb-82 test? (<0.02 µCi Sr-85/mCi Rb-82) . . N/A ○ yes ○ no ○

iv. Records maintained? [07-.41(3)] . . . . . yes ○ no ○

v. Records contain: [07-.95] . . . . . yes ○ no ○

- ☐ Ratio of contaminate to desired radionuclide
- ☐ Ratio in units of microCuries or microGrams / millicuries
- ☐ Time and date of measurement
- ☐ Name of individual making the assessment

g. Name of Pharmacy providing unit doses:

h. Multiple locations of use? [L.C.] . . . . . N/A ○ yes ○ no ○

List the locations:

5. Training of Personnel [04-.12, 07-.45 & 07-.54] [L.C]

a. Technologists

(1) Received initial and/or annual refresher training in:

i. General rad worker initial radiation training? [04-.12]. . . . . yes ○ no ○

ii. General rad worker refresher training?[L.C.]N/A ○ yes ○ no ○

iii. Training records maintained? [L.C.] . . . N/A ○ yes ○ no ○

(2) Technologists and nurses caring for in-house therapy patients under 07-.45 and .54

i. Working with in house therapy patients [07-.45] N/A ○ yes ○ no ○

ii. Working with in house Brachytherapy patients? [07-.54] N/A ○ yes ○ no ○

iii. Training Records maintained? [07-.96] . . . . . yes ○ no ○

iv. Training records required under 07-.96 contain: . . . . . yes ○ no ○

- ☐ List of topics covered
- ☐ Names of attendees
- ☐ Date of the instruction
- ☐ Names of individuals who provided instruction

(3) Individuals' understanding of current procedures is adequate in: [04-.12]

i. Operating procedures . . . . . yes ○ no ○

ii. Emergency procedures? . . . . . yes ○ no ○

iii. General rules for ALARA? . . . . . yes ○ no ○

(4) Declared Pregnant Worker Training [05-.56, records 05-.135(6)] **N/A** ☐

i. Are workers informed/trained as to policy? . . . . . yes ○ no ○

ii. Are declarations of pregnancy records maintained? . . . . . yes ○ no ○

b. Auxiliary Personnel (janitorial staff, etc.) **N/A** ☐

(1) Received initial training? [04-.12] . . . . . yes ○ no ○

(2) Received annual refresher training? [L.C.] N/A ○ yes ○ no ○

(3) Records maintained? [L.C.] . . . . . N/A ○ yes ○ no ○

Notes:

Section II. Physical Inspection

1. Posting, Labeling, and Procedures [04-.11 & 05-.111 & 05-.113]

a. Are all areas posted appropriately? (CRM, CRA) . . . . . yes ○ no ○

b. Is the lab secure? [05-.100] . . . . . yes ○ no ○

c. Is the storage area secure? [05-.100] . . . . . yes ○ no ○

d. Is RHS 8-3 posted? [04-.11(3)] . . . . . yes ○ no ○

e. Are emergency procedures posted? [04-.11(e)] . . . . . yes ○ no ○

f. Are Lab Rules posted? [04-.11(e)] . . . . . yes ○ no ○

g. Are operating procedures available? [04-.11(e)] . . . . . yes ○ no ○

h. Is a notice stating where to find the license and regulations posted? . . . yes ○ no ○

i. Is the waste labeled CRM? [05-.113] . . . . . yes ○ no ○

j. Are the vials/syringes labeled to identify radioactive drug? [07-.33] . . . . yes ○ no ○

k. Is there food in the RAM fridge? . . . . . N/A ○ yes ○ no ○

l. Does the smoke test show negative pressure? [L.C. ____]N/A ○ yes ○ no ○

m. Is the facility set-up as diagramed in the license? [L.C. ____]N/A ○ yes ○ no ○

n. Does the facility possess a portable survey meter? [L.C.]N/A○ yes○ no○

Notes:

2. Radiation Levels and Contamination Surveys:

	Readings
Background	

License No.
Date

Survey meter(s) used: Model S/N Cal date
Model S/N Cal date

Section III. Record Review

1. Personnel Exposure Records: [05-.135]

a. Supplier:	**b.** Dosimeter Type:
c. Frequency of Exchange:	**d.** Badge Results (in mRem): ↓

	Totals for year:		**Totals for year:**		**Totals for year:**		**Totals for year:**		**Totals for year:**	
	WB	**Ring**	**WB**	**Ring**	**WB**	**Ring**	**WB**	**Ring**	**WB**	**Ring**
Ave										
Max										

e. Is every one badged? . . . . . yes ○ no ○

f. Are badges returned on time? . . . . . yes ○ no ○

g. Dose limits maintained? [05-.50] . . . . . yes ○ no ○

h. Exposures estimated for missing badges? . . . . . N/A ○ yes ○ no ○

i. All badge records present? . . . . . yes ○ no ○

j. Control badge maintained in proper area? . . . . . N/A ○ yes ○ no ○

k. Reports reviewed by (name and title):

l. Attempt to obtain employees radiation exposure history from other facilities? [05-.133(1)(b)] . . . . . N/A ○ yes ○ no ○

2. Radiation Safety Committee [07-.17(6)] [L.C.] N/A ☐

a. Do they have a RSC? (if required by 07-.17(6)) . . . . . yes ○ no ○

b. Meetings held at least every 6 months? [07-.17(8)] . . . . . yes ○ no ○

c. Do the minutes show that they are performing their duties? [07-.82(3)] . . yes ○ no ○

3. Internal audits or inspections [05-.40] [L.C.]

a. Audits or inspections are conducted? . . . . . yes ○ no ○

b. Records maintained? [05-.131] . . . . . yes ○ no ○

4. Patient Doses, Assays, and Records [07-.30] [L.C.]

a. Does licensee obtain all patient doses in prepackaged unit doses from a nuclear pharmacy? . . . . . yes ○ no ○

b. Any bulk doses? . . . . . yes ○ no ○

5. Area Surveys [07-.34] [L.C.]

a. Daily contamination surveys where RAM is prepared or used? [07-.34 (1)] yes ○ no ○

b. Daily contamination surveys for generators/bulk doses?[07-.34(5)] NA ○ yes ○ no ○

c. Weekly dose rate level surveys for storage areas? [07-.34 (2)] . . . . . yes ○ no ○

d. Survey action levels established for restricted area:

Area dose rates? [07-.34(4)] Action Level: yes ○ no ○

Area contamination? [07-.34(7)] Action Level: yes ○ no ○

e. Survey action levels established for unrestricted area:

Area dose rates? [L.C.]Action Level: yes ○ no ○

Area contamination? [L.C.]Action Level: yes ○ no ○

f. Are records of all surveys maintained? [07-.91]? yes ○ no ○

g. Records contain:

☐ date of survey ☐ results of survey

☐ instrument used ☐ name of surveyor [07-.91] . . . . . yes ○ no ○

6. Dose Calibrator Calibration [07-.28] [L.C.] N/A ☐

a. Geometric Mean performed? (Installation and/or after maintenance) . . . yes ○ no ○

(1) Date of last test:

(2) Within limits (± 10%*) . . . . . yes ○ no ○

(3) Records maintained? [07-.89] . . . . . yes ○ no ○

b. Annual Accuracy tests performed? . . . . . yes ○ no ○

(1) Dates of tests:

(2) Within limits? (±10%*) . . . . . yes ○ no ○

(3) Records maintained? [07-.89] . . . . . yes ○ no ○

c. Quarterly Linearity performed? . . . . . yes ○ no ○

(1) Dates of tests:

(2) Within limits? (± 10%*) . . . . . yes ○ no ○

(3) Method used:

(4) Records maintained? [07-.89] . . . . . yes ○ no ○

d. Daily Constancy performed? . . . . . yes ○ no ○

(1) Within limits? (± 10%* with a sealed source) . . . . . yes ○ no ○

(2) Records maintained? [07-.89] . . . . . yes ○ no ○

* *These percentages come from the Medical License Application Guide (revised March 2010); license conditions and/or manufacturer recommendations may vary.*

7. Inventory of Sealed Sources [07-.32(5)] [L.C.] N/A ☐

a. Conducted semi-annually? [07-.32(5)] . . . . . yes ○ no ○

b. Records maintained? [07-.111(2)] . . . . . yes ○ no ○

c. Records under 07-.111(2) contain: . . . . . yes ○ no ○

- ☐ Model number
- ☐ Serial number (if one has been assigned)
- ☐ Identity of each source by radionuclide
- ☐ Each source's nominal activity
- ☐ Location of each source
- ☐ Name of individual who performed the inventory

d. Dates of Inventories:

e. Are exempt sources inventoried? [Schedule RHS 8-3 chp.10] . N/A ○ yes ○ no ○

f. Sources in storage secure? (05-.100) . . . . . N/A ○ yes ○ no ○

8. Leak tests [07-.32] [L.C.](sources > 100 µCi gamma/beta, > 10 µCi alpha) N/A ☐

a. Dates/Sources:

b. All Leak test results reported less than 0.005 µCi or <185 Bq? [07-.32(3)] yes ○ no ○

c. Records maintained [07-.111(1)] . . . . . yes ○ no ○

d. Records under 07-.111(1) contain: . . . . . yes ○ no ○

- ☐ Model number
- ☐ Serial number (if one has been assigned)
- ☐ Identity of each source by radionuclide
- ☐ Estimated activity
- ☐ Results of the test
- ☐ Date of the test
- ☐ Name of the individual who performed the test

9. Package Receipt [05-.115] [L.C.]

a. Are written procedures maintained? [05-.115(5)] . . . . . yes ○ no ○

b. Procedures followed (one meter, surface, swipe)? [05-.115] . . . . . yes ○ no ○

c. Surveyor understands action levels (10mR/hr at one meter, 200 mR/hr at surface of package, 2200 dpm per 100 cm^2 swipe)? . . . . . yes ○ no ○

d. Records maintained of receipt survey? [05-.132(1)] . . . . . yes ○ no ○

e. Incoming packages surveyed on time? [05-.115(3)] . . . . . yes ○ no ○

f. Are after hours deliveries secure? [05-.100] . . . . . N/A ☐ yes ○ no ○

g. Where after hours packages maintained?

10. Survey Meter Calibration (annually) [07-.29] [L.C.]

a. Model: S/N: Last Cal Date:

Model: S/N: Last Cal Date:

Model: S/N: Last Cal Date:

b. Current Calibration? [07-.29(1)] . . . . . yes ○ no ○

c. Calibration date affixed to meter? [07-.29(2)(c)] . . . . . yes ○ no ○

d. Calibration records maintained? [07-.29(4)] . . . . . yes ○ no ○

e. Calibration records required by 07-.29(4) contain: [07-.88] . . . . . yes ○ no ○

☐ Model and serial number of the instrument
☐ Date of the calibration
☐ Results of the calibration
☐ Name of the individual who performed the calibration

f. Daily operational check? [L.C.]. . . . . yes ○ no ○

11. Waste Disposal Records [05-.120 and 07-.37] [L.C.] N/A ☐

a. Disposal to sanitary sewer? . . . . . N/A ○ yes ○ no ○

(1) In accordance with 05-.122? . . . . . yes ○ no ○

(2) Records maintained? [05-.137 & 10-.26] . . . . . yes ○ no ○

b. Waste held for decay in storage? [07-.37] . . . . . .N/A ○ yes ○ no ○

(1) Surveys waste at background levels before disposal? [07-.37(1)(a)] yes ○ no ○

(2) Are RAM labels removed / defaced prior to release? [07-.37(1)(b)] yes ○ no ○

(3) Waste disposal records maintained? [07-.94] . . . . . yes ○ no ○

(4) Waste record includes: [07-.94] . . . . . yes ○ no ○

☐ date of disposal
☐ instrument used ☐ background measured
☐ results of survey ☐ name of surveyor

12. Xenon [L.C.] N/A ☐

a. Describe monitoring or evaluation method:

b. Charcoal trap monitored per license? . . . . . yes ○ no ○

c. How often is the trap replaced?

d. Clearance time & emergency procedures posted? . . . . . yes ○ no ○

e. Ventilation rates checked annually for negative pressure? . . . . . yes ○ no ○

13. DTPA [L.C.] N/A ☐

- **a.** Treatment room surveyed for contamination after administration? . . . . . yes ○ no ○
- **b.** Survey records maintained? . . . . . yes ○ no ○
- **c.** How are the used ventilation kits disposed of?

14. Transportation [10-.30] N/A ☐

- **a.** Licensee makes shipments of RAM? . . . . . yes ○ no ○
- **b.** If so, describe shipment content and method:
- **c.** Shipments
  - **(1)** Authorized packages used? . . . . . yes ○ no ○
  - **(2)** Package type used?
  - **(3)** Packages properly labeled and marked? . . . . . yes ○ no ○
  - **(4)** Packages properly surveyed? . . . . . yes ○ no ○

15. Mobile Nuclear Medicine Service [07-.36] [L.C.] N/A ☐

- **a.** Licensee uses mobile nuclear medicine services? . . . . . yes ○ no ○
- **b.** Licensee operates mobile nuclear medicine services? . . . . . yes ○ no ○
- **c.** Mobile location specified? [07-.36(1)(a)] . . . . . yes ○ no ○
- **d.** Check dose calibrator daily at each location? [07-.36(1)(b)] . . . . . yes ○ no ○
  (at minimum, a daily constancy check)
- **e.** Check survey meters daily at each location? [07-.36(1)(c)] . . . . . yes ○ no ○
- **f.** Survey all areas of use at each location? [07-.36(1)(d)] . . . . . yes ○ no ○
- **g.** Shipping papers and emergency procedures available? [10-.30] . . . . . yes ○ no ○
- **h.** Is RAM delivered to the licensee? [07-.36(2)] . . . . . yes ○ no ○
  - **(1)** If no, does the client have a license to receive RAM? . . . . . yes ○ no ○
- **i.** Does the driver have hazardous material employee training? [10-.30(1)(a)6.] yes ○ no ○
  - **(1)** At least once every three years? . . . . . yes ○ no ○

Notes:

License No.
Date

Section IV. Iodine 131 Therapy [07-.46] [L.C.] N/A ☐

(Note: Rule .46 includes any other radiopharmaceutical that might be used, in addition to I-131)

1. Written Directive Requirements [07-.21]

a. Written procedure available for verifying patient's identity? [07-.21(1) . . . yes ○ no ○

b. Written directive procedure in accordance with 07-.21(2)? . . . . . yes ○ no ○

☐ Verifying the identity of the patient
☐ Verifying that the administration is in accordance with the written directive

c. Copy of written directive from the Authorized User maintained? [07-.20(4)] yes ○ no ○

d. Written directives for Iodine-131 therapy contain:. . . . . yes ○ no ○

☐ Dosage amounts [07-.20(2)(a)]
☐ Authorized user signature and date [07-.20(1)]

2. Inpatient Cases **N/A** ☐

a. Patients placed in private room? [07-.46(1)(a)] . . . . . yes ○ no ○

b. Patient room posted CRM? [07-.46(1)(b)] . . . . . yes ○ no ○

c. Patient room posted CRA? [07-.111(1)] . . . . . yes ○ no ○

d. Visitor instructions posted on door or in patient's file? [07-.46(1)(c)] . . . yes ○ no ○

e. DMP surveys performed in adjacent areas to patient's room? [05-.61] . . yes ○ no ○

(1) Records maintained? [05-.136] . . . . . yes ○ no ○

f. After release, patient room surveyed and free released? [07-.46(1)(d)] . . yes ○ no ○

3. Outpatient Cases **N/A** ☐

a. Release of patients meets 07-.35? . . . . . yes ○ no ○

(1) Records maintained for basis of release? [07-.92] . . . . . yes ○ no ○

b. Written instructions provided to patient? [07-.35(2)] . . . . . yes ○ no ○

(1) Records of instructions given patient? [L.C]. . . . . yes ○ no ○

Notes:

License No.
Date

Section V. Manual Brachytherapy [07-.51 & .52][L.C] N/A ☐

1. Summary of Program

a. Sources on site and containment type (seeds, ribbons, needles, etc.):

b. Types of Procedures:

2. Written Directive Requirements [07-.21]

a. Written procedure available for verifying patient's identity? [07-.21(1) . . . yes ○ no ○

b. Written directive procedure in accordance with 07-.21(2)? . . . . . yes ○ no ○

- ☐ Verifying the identity of the patient
- ☐ Verifying that the administration is in accordance with the written directive

c. Copy of written directive from the Authorized User maintained? [07-.20(4)] yes ○ no ○

d. Written directives for brachytherapy contain: [07-.20(1), (2) and 2(f)] . . . . yes ○ no ○

(1) Before Implantation:

- ☐ Authorized User's name and date ☐ Treatment site
- ☐ Patient name ☐ Radionuclide to be used
- ☐ Dose to be delivered to the patient

(2) After Implantation:

- ☐ Radionuclide used ☐ Number of sources
- ☐ Treatment site ☐ Total source strength
- ☐ Exposure time or total dose to be given

3. Accountability Requirements for All Implants

a. After implanting sources in patient, all sources <u>not</u> implanted accounted for? [07-.52(1)] . . . . . yes ○ no ○

(1) Records maintained? [07-.52(3)] . . . . . yes ○ no ○

(2) Records required by 07-.52(3) contain: [07-.97] . . . . . yes ○ no ○

- ☐ Date of survey
- ☐ Results of survey
- ☐ Survey instrument used
- ☐ Name of individual who performed the survey

4. Accountability Requirements for Removal of Temporary Implants **N/A** ☐

a. After removal of sources from patient, is patient surveyed to make sure all sources have been removed? [07-.52(2)] . . . . N/A ○ yes ○ no ○

(1) Records maintained? [07-.52(3)] . . . . . yes ○ no ○

(2) Records required by 07-.53(3) contain: [07-.97] . . . . . yes ○ no ○

- ☐ Date of survey
- ☐ Results of survey
- ☐ Survey instrument used
- ☐ Name of individual who performed the survey

b. Sources immediately returned to storage area after removal from patient? [07-.53(2)] . . . . . N/A ○ yes ○ no ○

5. Records for Temporary Implants Must Contain: **N/A** ☐

a. Upon removal of source from storage: [07-.98(2)(a)] yes ○ no ○

- ☐ Number of sources removed from storage
- ☐ Activity of sources removed from storage
- ☐ Time and date of removal from storage
- ☐ Name of person removing the sources from storage
- ☐ Location of use of sources

b. Upon return of sources to storage [07-.98(2)(b)] yes ○ no ○

- ☐ Number of sources returned to storage
- ☐ Activity of sources returned to storage
- ☐ Time and date of return to storage
- ☐ Name of person returning the sources to storage

6. Records for Permanent Implants Must Contain: **N/A** ☐

a. Upon removal of sources from storage: [07-.98(3)(a)] yes ○ no ○

- ☐ Number of sources removed from storage
- ☐ Activity of sources removed from storage
- ☐ Date of removal from storage
- ☐ Name of person removing the sources from storage

b. After sources are implanted in the patient: [07-.98(3)(b) and (c)] yes ○ no ○

- ☐ Number of sources implanted into the patient
- ☐ Activity of sources implanted into the patient
- ☐ Number of sources NOT implanted into the patient
- ☐ Activity of sources NOT implanted into the patient
- ☐ Date of return to storage of sources NOT implanted in patient
- ☐ Name of person returning sources to storage

License No.
Date

7. Inventory of Brachytherapy Sources **N/A** ☐

a. Inventory conducted semi-annually? [07-.32(5)] . . . . . yes ○ no ○

b. Inventory records maintained? [07-.111] . . . . . yes ○ no ○

c. Inventory record contains: [07-.111] . . . . . yes ○ no ○

- ☐ Model number of each source
- ☐ Serial no. of each source (if one has been assigned)
- ☐ Identity of each source by radionuclide
- ☐ Nominal activity of each source
- ☐ Location of each source
- ☐ Name of individual performing the inventory

d. Dates of Inventories:

8. General Requirements

a. Source storage room posted CRA? [05-.111(1)] . . . . . N/A ○ yes ○ no ○

b. Dose to the Member of the Public (DMP) surveys performed for source storage area? [05-.61] . . . . . N/A ○ yes ○ no ○

(1) Records maintained? [05-.136] . . . . . yes ○ no ○

c. Are all sources calibrated before use? [07-.56] . . . . . N/A ○ yes ○ no ○

(1) Record of each source calibration maintained? [07-.56(4)] . . . . . yes ○ no ○

9. Additional Requirements for Inpatient Cases: [07-.55] **N/A** ☐

a. Patient in private room? [07-.55(1)(a)] . . . . . yes ○ no ○

b. Room posted CRM? [07-.55(1)(b)] . . . . . yes ○ no ○

c. Room posted CRA? [05-.111(1)] . . . . . yes ○ no ○

d. Visitor instructions posted on door or in patient's file? [07-.55(1)(c)] . . . . yes ○ no ○

e. Emergency response equipment available near patient room to be able to handle a dislodged source? [07-.55(2)] . . . . yes ○ no ○

f. DMP surveys performed in adjacent areas to patient's room? [05-.61] . . yes ○ no ○

(1) Records maintained? [05-.136] In patient's file? [L.C.] yes ○ no ○

g. After release, patient room surveyed and free released? [07-.46(1)(d)] . . yes ○ no ○

License No.
Date

10. Additional Requirements for Outpatient Cases: [07-.35] **N/A** ☐

a. Release of patients meets 07-.35? . . . . . yes ○ no ○

(1) Records maintained for basis of release? [07-.35(3)] . . . . . yes ○ no ○

b. Written instructions provided to patient? [07-.35(2)] . . . . . yes ○ no ○

(1) Records of instructions given patient? . . . . . yes ○ no ○
[07-.35(4) for breastfeeding patients; for all others, L.C.]

Notes:

Section VI. General Inspection Requirements

1. Non-Standard requirements **N/A** ☐

2. Incidents, Overexposures, Theft or Loss, Equipment Malfunction **N/A** ☐
[05-.140 & 05-.141] (Those not described elsewhere should be reported here)

3. General Observations

License No.
Date

4. Inspection History (violations from previous inspections)

License Condition or Reg. Requirement	Violation	Corrective Action Taken (y/n)	Status

5. Exit Interview/non-compliance summary

License Condition or Reg. Requirement	Violation	1-Immediate Hazard 2-Serious 3-Non-serious	Corrective Action Taken (y/n)

License No.
Date

NOTES

NOTES

License No.
Date

Records to Review

___License

___Dose Calibrator QA/QC:

- ___Daily Constancy
- ___Quarterly Linearity
- ___Annual Accuracy
- ___Geometric Mean

___Radiation Safety Committee Meetings (semi-annually)

___Sealed source inventory (6 months)

___Survey instrument calibrations (annually)

___Receipt records

___Disposal records

___Sanitary Sewer Release records

___Xenon surveys after each use

___Tc99m DTPA surveys after each use

___Daily Contamination surveys

___Weekly Wipe tests surveys

___Waste disposal records

___Employee bioassays

___Leak tests of sealed sources (6 months)

___Patient dose assay records

___Xenon trap survey

___Xenon trap change out records

___Personnel monitoring records

___Misadministrations

___Declared Pregnant Workers training

___State Regulations

___Operating Procedures (lab rules)

___Emergency procedures

___Employee Training

License No.
Date

Regulation Bibliography Nuclear Medicine

(all reg. references proceeded by SRPAR 400-20-)

Chapter 4

04-.11 Posting of Notice to Employees
04-.12 Instruction to Workers

Chapter 5

05-.40 Radiation Protection Programs
05-.50 Occupational Dose Limits for Adults
05-.56 Dose to an Embryo/Fetus
05-.61 Compliance with Dose Limits for Individual Members of the Public
05-.100 Security of Stored Material
05-.111 Posting Requirements
05-.113 Labeling Containers
05-.115 Procedures for Receiving and Opening Packages
05-.120 General Disposal Requirements
05-.122 Disposal by release into Sanitary Sewer
05-.131 Records of Radiation Protection Program
05-.132 Records of Surveys
05-.133 Determination of Prior Occupational Dose
05-.135 Records of Individual Monitoring Results
05-.136 Records of Dose to Individual Members of the Public
05-.137 Records of Waste Disposal
05-.140 Reports of Theft or Loss of Licensed Material
05-.141 Notification of Incidents
05-.145 Notifications, Records and Reports of Misadministration

Chapter 7

07-.05 Definitions
07-.13 License Amendments
07-.17 Authority and Responsibilities for the Radiation Protection Program
07-.20 Written Directives
07-.21 Procedures for Administrations Requiring a Written Directive
07-.28 Possession, Use, and Calibration of Instruments Used to Measure the Activity of Unsealed Radioactive Material
07-.29 Calibration of Survey Instruments
07-.30 Determination of Dosages of Unsealed Radioactive Material for Medical Use
07-.32 Requirements for Possession of Sealed Sources and Brachytherapy Sources
07-.33 Labeling of Vials and Syringes
07-.34 Surveys of Ambient Radiation Dose Rate and Contamination
07-.35 Release of Individuals Containing Radioactive Drugs or Implants
07-.36 Provision of Mobile Medical Service
07-.37 Decay in Storage
07-.38 Use of Unsealed Radioactive Material for Uptake, Dilution, and Excretion Studies for Which a Written Directive is Not Required
07-.40 Use of Unsealed Radioactive Material for Imaging and Localization Studies for Which a Written Directive is Not Required
07-.41 Radionuclide Contaminants
07-.44 Use of Unsealed Radioactive Material for Which a Written Directive is Required
07-.45 Safety Instruction
07-.51 Use of Sealed Sources for Manual Brachytherapy
07-.52 Surveys After Source Implant and Removal
07-.53 Brachytherapy Source Accountability
07-.54 Safety Instruction
07-.55 Safety Precautions for Patients Receiving Brachytherapy
Units
07-.82 Records of Authority and Responsibilities for Radiation Protection Programs
07-.88 Records of Radiation Survey Instrument Calibration
07-.89 Records of Dosages of Unsealed Radioactive Material for Medical Use
07-.91 Records of Surveys for Ambient Radiation Exposure Rate
07-.94 Records of Decay in Storage
07-.96 Records of Safety Instruction and Training
07-.98 Records of Brachytherapy Source Accountability
07-.111 Records of Leak Tests and Inventory of Sealed Sources and Brachytherapy Sources

Chapter 10

10-.26 Records
10-.30 Packaging and Transport of Radioactive Material

License No.
Date

Nuclear Medicine Inspection Report Index (for Field form)

Cover page

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1. Organization and Administration
2. RSO Authority and Responsibilities
3. Misadministration's
4. Summary of Licensed Program
5. Training of Personnel

Section II **Physical Inspection**
1. Posting, Labeling and Procedures
2. Radiation Levels and Contamination Surveys

Section III **Record Review**
1. Personnel Exposure Records
2. Radiation Safety Committee
3. Internal Audits
4. Patient Doses, Assays and Records
5. Area Surveys
6. Dose Calibrator
7. Inventory of Sealed Sources
8. Leak Tests
9. Package Receipt
10. Survey Meter Calibration
11. Waste Disposal
12. Xenon
13. DTPA
14. Transportation
15. Mobile Nuclear Medicine Services

Records to Review

Regulation Bibliography

Section IV **Iodine Therapy**
1. Written Directive Requirements
2. Inpatient Cases
3. Outpatient Cases

Section V **Manual Brachytherapy**
1. Summary of Program
2. Written Directive Requirements
3. Accountability Requirements for All Implants
4. Accountability Requirements for Temporary Implants
5. Records for Temporary Implants
6. Records for Permanent Implants
7. Inventory of Brachytherapy
8. General Requirements
9. Additional Requirements for Inpatient Cases
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Section VI **General Inspection Requirements**
1. Non Standard Requirements
2. Incidents
3. General Observations
4. Inspection History
5. Exit Interview

License No.
Date

Revisions

1 I and E section review changes

2 Add Section III, questions 17c and 17d to misadministration section 12/5/12

3 Revise misadministration section 12/6/12

4 All Sections color highlighted in box

Moved misadministration part to Section I. 3

Iodine therapy changed to a separate section (Section IV)

Manual brachytherapy changed to a separate section (Section V)

Section I.3., "Summary of licensed program" moved to Section I.4

Section I.4, "Training of Personnel", moved to Section I.5.

Section I.5, add "General rad worker refresher training" and "Training maintained" questions.

Section I.5(2), added "… and nurses caring for in-house therapy patients under 07-.45 and .54"

Section I.5(b)(2), added "Received annual refresher training? [L.C.___] . N/A____ yes____ no____"

Section I.5(b)(3), added "Records maintained? [L.C.____] . . . N/A____ yes____ no____"

Section III.5, added distinction between restricted and unrestricted area surveys. Added unrestricted area dose rates surveys, contamination surveys and actions levels of each.

Section V.1, added Summary of Program.

Section V.2.d, changed format and added "patient name"

Section V.8, added General Requirements subsection (taking questions from other subsections)

Section V.8, added "Are all sources calibrated before use? [07-.56]" question and records

Section V.9.f, added add "In patient's file? [L.C.____]"

5 Highlighted questions (July 1, 2017)

Insert yes no boxes and dialog boxes