

APPENDIX A

MEDICAL BROAD-SCOPE INSPECTION RECORD

Region \_\_\_\_

Inspection record No. \_\_\_\_\_

License No. \_\_\_\_\_

Licensee (Name and Address):

Docket No. \_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Location Contact (Authorized Site) Being Inspected:

\_\_\_\_\_

Licensee Contact: \_\_\_\_\_

Telephone No. \_\_\_\_\_

Priority: \_\_\_\_\_ Program Code: \_\_\_\_\_

Date of Last Inspection: \_\_\_\_\_

Date of This Inspection: \_\_\_\_\_

Type of Inspection:                      ( ) Announced                      ( ) Unannounced  
    ( ) Routine                              ( ) Special  
    ( ) Initial

Next Inspection Date \_\_\_\_\_ ( ) Normal ( ) Reduced ( ) Extended

Justification for change in normal inspection frequency:

Summary of Findings and Actions:

- ( ) No violations cited, clear U.S. Nuclear Regulatory Commission (NRC) Form 591 or regional letter issued
- ( ) Non-cited violations
- ( ) Violation(s), Form 591 issued
- ( ) Violation(s), regional letter issued
- ( ) Followup on previous violations

Inspector(s) \_\_\_\_\_  
    (Sign Name)

Date \_\_\_\_\_

\_\_\_\_\_  
    (Print Name)

Approved \_\_\_\_\_

(Sign Name)

Date \_\_\_\_\_

\_\_\_\_\_  
(Print Name)

**PART I-LICENSE, INSPECTION, INCIDENT/EVENT, AND ENFORCEMENT HISTORY**

1. AMENDMENTS AND PROGRAM CHANGES:

[License amendments issued since last inspection; program changes (including major changes in facilities, activities, procedures, or personnel) noted in the license]

<u>AMENDMENT #</u>	<u>DATE</u>	<u>SUBJECT</u>
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2. INSPECTION AND ENFORCEMENT HISTORY:

(Unresolved issues; previous and repeat violations; Confirmatory Action Letters; and orders)

3. INCIDENT/EVENT HISTORY:

(List any incidents, recordable events, or misadministrations reported to NRC since the last inspection. Citing "None" indicates that regional event logs, event files, and the licensing file have no evidence of any incidents or events since the last inspection.)

## PART II - INSPECTION DOCUMENTATION

- \* References that correspond to each inspection documentation topic are in Inspection Procedure 87119, Appendix B, "Medical Broad-Scope Inspection References."

*The inspection documentation part is to be used by the inspector to assist with the performance of the inspection. Note that all areas indicated in this part are not required to be addressed during each inspection. However, for those areas not covered during the inspection, a notation ("Not Reviewed" or "Not Applicable") should be made in each section where applicable.*

*All areas covered during the inspection should be documented in sufficient detail to describe what activities and procedures were observed and/or demonstrated. In addition, the types of records that were reviewed and the time periods covered by those records should be noted. If the licensee demonstrated any practices at your request, describe those demonstrations. The observations and demonstrations you describe in this report, along with measurements and some records review, should substantiate your inspection findings. Attach copies of all licensee documents and records needed to support violations.*

1. **ORGANIZATION AND SCOPE OF PROGRAM:**  
(Management organization; authorities and responsibilities; Radiation Safety Officer (RSO), Radiation Safety Committee (RSC) chairman and members; administrative controls, procedures, and management policies; authorized locations of use; type, quantity and frequency of byproduct material use; staff size; mobile nuclear medicine service; limited distribution of pharmaceuticals; and research involving human subjects)
  
2. **MANAGEMENT OVERSIGHT:**  
[Management support to radiation safety; RSC, RSO; and program audits, including as low as is reasonably achievable (ALARA) reviews]

3. FACILITIES:

[Facilities as described; uses; control of access; engineering controls, ( e.g., ventilation, hoods, filters, etc); irradiators and survey instrument calibrators; maintenance by authorized persons]

4. EQUIPMENT AND INSTRUMENTATION:

(Dose calibrator; instrumentation for assaying alpha- and beta- radionuclides; generators; syringes and vials; survey instruments; 10 CFR Part 21 procedures; and special equipment and instrumentation)

5. MATERIAL RECEIPT, USE, CONTROL, AND TRANSFER:

(Materials and uses authorized; use of radiopharmaceuticals; security and control of licensed materials; and procedures for receipt and transfer of licensed material)

6. THERAPIES:  
(Safety precautions; postings; contamination control; stay times; surveys; release criteria of patients and rooms)



9.     TRAINING AND INSTRUCTIONS TO WORKERS:  
(Interviews and observations of routine work; staff knowledge of all routine activities; 10 CFR Part 20 requirements; therapy training and postulated emergency situations; supervision by authorized users; retraining and periodic training programs; training of ancillary personnel such as housekeeping, security, and maintenance; adequacy of training and instruction)
10.    RADIATION PROTECTION:  
[Radiation protection program with ALARA provisions (worker and general public external and internal exposure control; effluent control); external and internal dosimetry program; exposure evaluations; dose records and reports; and patient release]
11.    RADIOACTIVE WASTE MANAGEMENT:  
(Disposal; effluent pathways and control; storage areas; transfer; packaging, control, and tracking procedures; equipment incinerators, hoods, vents, and compactors; and records)

12. DECOMMISSIONING:  
(Records of radiological conditions; decommissioning plan/schedule; notification requirements; cost estimates; funding methods; financial assurance; and Rule requirements)  
Timeliness

13. TRANSPORTATION:  
(Quantities and types of licensed material shipped; packaging design requirements; HAZMAT communication procedures; unit dose return; return of sources; procedures for monitoring radiation and contamination levels of packages; HAZMAT training; and records and reports)

14. NOTIFICATIONS AND REPORTS:  
(Theft; loss; incidents; overexposures; change in RSO, authorized user, or nuclear pharmacist; and radiation exposure reports to individuals)



15. POSTING AND LABELING:  
(Notices; license documents; regulations; bulletins and generic information; posting of radiation areas; and labeling of containers of licensed material)
16. INDEPENDENT AND CONFIRMATORY MEASUREMENTS:  
(Areas surveyed; comparison of data with licensee's results and regulations; and instrument type and calibration date)
17. VIOLATIONS, NON-CITED VIOLATIONS (NCVs); AND OTHER SAFETY ISSUES:  
(State requirement and how and when licensee violated the requirement. For NCVs, indicate why the violation was not cited. Attach copies of all licensee documents needed to support violations.)

18. PERSONNEL CONTACTED:  
 [Identify licensee personnel contacted during the inspection (including those individuals contacted by telephone).]

Use the following identification symbols:  
 # Individual(s) present at entrance meeting  
 \* Individual(s) present at exit meeting

19. PERFORMANCE EVALUATION FACTORS (PEFs):

- |    |  |                     |
|----|--|---------------------|
| A. | Lack of senior management involvement with the radiation safety program and/or RSO oversight | ( ) Y ( ) N         |
| B. | RSO too busy with other assignments  | ( ) Y ( ) N         |
| C. | Insufficient staffing  | ( ) Y ( ) N         |
| D. | RSC fails to meet or functions inadequately  | ( ) N/A ( ) Y ( ) N |
| E. | Inadequate consulting services or inadequate audits conducted                                | ( ) N/A ( ) Y ( ) N |

Remarks (consider the above assessment and/or other pertinent PEFs with regard to the licensee's oversight of the radiation safety program):

21. Special Conditions or Issues:  
 (Special license conditions; year-2000 effects of computer software)



APPENDIX A - ATTACHMENT A  
DECOMMISSIONING TIMELINESS INSPECTION ATTACHMENT

Licensee: \_\_\_\_\_

Date of Inspection: \_\_\_\_\_

1. COMPLIANCE WITH DECOMMISSIONING TIMELINESS RULE

(NOTE: Repeat the answers given in Section 12 of the main body of the inspection record. The issues in subsequent sections are dependent on the answers to these questions.)

A. License to conduct a *principal activity* has expired or been revoked. ( ) Y ( ) N

B. Licensee has made a decision to permanently cease *principal activities*, at the entire site, or any separate buildings, or any outdoor areas, including inactive burial grounds. ( ) Y ( ) N

C. A 24-month duration has passed in which no *principal activities* have been conducted under the license at the site, or at any separate buildings, or any outdoor areas, including inactive burial grounds. ( ) Y ( ) N

D. If "Yes" to either A or B or C above:

(1) Identify Site/Bldg/Area: \_\_\_\_\_

(2) Date of occurrence of A, B, or C: \_\_\_\_\_

2. NOTIFICATION REQUIREMENTS

A. Licensee has provided written notification to U.S. Nuclear Regulatory Commission (NRC) within 60 days of the occurrence of 1.A., 1.B., or 1.C., above. ( ) Y ( ) N

If "Yes," date of notification: \_\_\_\_\_

B. If the licensee is requesting to delay initiation of the decommissioning process, the licensee has provided written notification to NRC within 30 days of occurrence of 1.A., 1.B., or 1.C., above ( ) N/A ( ) Y ( ) N

If "Yes," date of notification: \_\_\_\_\_

Basis for Findings:

3. DECOMMISSIONING PLAN/SCHEDULE REQUIREMENTS

- A. Licensee is required to submit a decommissioning plan per 10 CFR 30.36(g), 40.42(g), 70.38(g), or 10 CFR Part 72? ( ) Y ( ) N

If "No" to 3.A., answer the following items B. - F.:

- B. The decommissioning work scope is covered by current license conditions. ( ) Y ( ) N

- C. Decommissioning has been initiated within 60 days of notification to NRC, or NRC has granted a delay. ( ) Y ( ) N

- D. If licensee has initiated decommissioning, give date the decommissioning was initiated:

Initiation date: \_\_\_\_\_

- E. If decommissioning has been completed, it was completed within 24 months of notification of NRC. ( ) N/A ( ) Y ( ) N

- F. If decommissioning is still scheduled to be completed, it is on schedule to be completed within 24 months of notification of NRC. ( ) N/A ( ) Y ( ) N

Basis for Findings:

If "Yes" to 3.A., answer the following items G. - J.:

G. The decommissioning plan has been submitted to NRC within 12 months of notification  Y  N

If "Yes," date of submittal: \_\_\_\_\_

If NRC approved, date of NRC approval: \_\_\_\_\_

H. Has the licensee submitted an alternative schedule request?  Y  N

If "Yes," date of submittal: \_\_\_\_\_

I. If decommissioning has been completed, it was completed within 24 months after approval of the decommissioning plan  N/A  Y  N

J. If decommissioning is still scheduled to be completed, it is on schedule to be completed within 24 months after approval of the decommissioning plan.  N/A  Y  N

Basis for Findings:

Violations identified, if any:

END