APPENDIX A

RADIOPHARMACY INSPECTION RECORD

Region ___

Inspection record No._____ License No. _____

Licensee (Name & Address): Docket No. _____

_____

_____
_____
_____
_____

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 NRC Form 591 or regional letter issued
( ) Non-cited violations
( ) Violation(s), Form 591 issued
( ) Violation(s), regional letter issued
( ) Follow-up on previous violations

Inspector(s) _____ Date _____
(Sign Name)

_____
(Print Name)

Approved _____ Date _____
(Sign Name)

_____
(Print Name)

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

1. AMENDMENTS AND PROGRAM CHANGES:
(License amendments issued since last inspection, or program changes noted in the license.)

AMENDMENT #	DATE	SUBJECT

2. INSPECTION AND ENFORCEMENT HISTORY:
(Unresolved issues; previous and repeat violations; Confirmatory Action Letters; and orders.)

3. INCIDENT/EVENT HISTORY:
(List any incidents, or events, reported to U.S. Nuclear Regulatory Commission since the last inspection. Citing "None" indicates that regional event logs, event files, NMED, 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 IP 87117, Appendix B, Radiopharmacy Inspection References.

The inspection documentation part is to be used by the inspector to assist with the performance of the inspection. Note that not all areas indicated in this part are 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 organizational structure; Radiation Safety Officer (RSO); type, quantity, and frequency of byproduct material use; staff size; number of facilities served; distribution and redistribution of materials; oversight by Food and Drug Administration/State)

2. MANAGEMENT OVERSIGHT:
(Management support to radiation safety; RSO; authorized nuclear pharmacists and change notifications; supervision of drug preparation by the ANP; program audits or inspections; as low as reasonably achievable (ALARA) reviews; staff coverage)

3. FACILITIES:
(Facilities as described; uses; control of access; fire protection; engineering controls; shielding; ventilation systems; maintenance program)

4. EQUIPMENT AND INSTRUMENTATION:
(Operable and calibrated survey instruments and dosimetry; area and process monitors; maintenance; shielding; generators; procedures; 10 CFR Part 21 procedures; calibration records; fixed radiation monitors)

5. MATERIAL USE, CONTROL, AND TRANSFER:
(Materials and uses authorized; security and control of licensed materials; and procedures for receipt and transfer of licensed material; iodine handling)

6. OPERATING AND EMERGENCY PROCEDURES:
(Procedure development and availability; manufacturer's instruction; emergency preparedness; assistance arrangement with outside agencies)

7. AREA RADIATION SURVEYS :
(Radiological survey locations and frequencies; leak tests; inventories; handling of radioactive materials; protective clothing; personnel monitors; safety precautions in preparation and use of drugs; records and reports; public doses)

8. TRAINING AND INSTRUCTIONS TO WORKERS:
(Training and retraining requirements and documentation; interviews and observations of routine work; staff knowledge of all routine activities; 10 CFR Parts 19 and 20 requirements; emergency response)

9. RADIATION PROTECTION:
(Radiation protection program with ALARA provisions; access control; dosimetry (whole body and extremity); exposure evaluations; dose and survey records and reports; annual notifications to workers; bulletins and other generic communications)

10. DECOMMISSIONING:
(Records relevant to decommissioning; decommissioning plan/schedule; notification requirements; cost estimates; funding methods; financial assurance; Timeliness Rule requirements; changes in radiological conditions since decommissioning plan was submitted)

11. TRANSPORTATION:
(Quantities and types of licensed material shipped; packaging design requirements; shipping papers; hazardous materials (HAZMAT) communication procedures; return of sources; procedures for monitoring radiation and contamination levels of packages; HAZMAT training; and records and reports.)

12. NOTIFICATIONS AND REPORTS:
(Overexposure and misadministration reports; administrative changes in RSO, authorized users, and physicist; reports to individuals)

13. POSTING AND LABELING:
(Notices; license documents; regulations; bulletins and generic information; area postings; and labeling of containers of licensed material)

14. MISADMINISTRATION:
(Review misadministration cases, if any, and ensure appropriate corrective actions were taken.)

15. INDEPENDENT AND CONFIRMATORY MEASUREMENTS:
(Areas, both restricted and unrestricted, surveyed and measurements made; comparison of data with licensee's results and regulations; and instrument type and calibration date)

16. VIOLATIONS, NON-CITED VIOLATIONS, AND OTHER SAFETY ISSUES:
(State requirement and how and when licensee violated the requirement. For non-cited violations, indicate why the violation was not cited. Attach copies of all licensee documents needed to support violations.)

17. 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

18. Special Conditions or Issues:
(Special license conditions; etc.)

PART III - POST- INSPECTION ACTIVITIES

1. DEBRIEF WITH REGIONAL STAFF:
(Post-inspection communication with supervisor, regional licensing staff, Agreement State Officer; and/or State Liaison Officer)

END

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 10, "Decommissioning," 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 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 to 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 to 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