

APPENDIX A

MATERIALS PROCESSOR/MANUFACTURER INSPECTION RECORD

Region ____

Inspection Report No. _____

License No. _____

Licensee (Name and Address):

Docket No. _____

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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 (NCVs)
- Violation(s), Form 591 issued
- Violation(s), regional letter issued
- Follow up 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, 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 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 87111, Appendix B, "Materials Processor/Manufacturer 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; authorized locations of use, including field offices and temporary job sites; type, quantity, frequency of material use, and affect of human performance issues)
2. **MANAGEMENT OVERSIGHT:**
(Management support to radiation safety; Radiation Safety Committee (RSC); Radiation Safety Officer (RSO); program audits, including annual reviews of program and as low as is reasonably achievable (ALARA) reviews; control by authorized users)

6. AREA RADIATION SURVEYS AND CONTAMINATION CONTROL:
(Radiological surveys; air sampling; leak tests; inventories; handling of radioactive materials; contamination controls; records; and public doses)

7. 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 situations; and supervision by authorized users)

8. RADIATION PROTECTION:
(Radiation protection program with ALARA provisions; external and internal dosimetry; exposure evaluations; dose and survey records and reports; annual notifications to workers; bulletins and other generic communications)

9. RADIOACTIVE WASTE MANAGEMENT:
(Disposal; effluent pathways and control; storage areas; transfer; packaging, control, and tracking procedures; equipment; incinerators, hoods, vents and compactors; license conditions for special disposal method)

10. DECOMMISSIONING:
(Records relevant to decommissioning; decommissioning plan/schedule; notification requirements; cost estimates; funding methods; financial assurance; and 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:
(Reporting and follow up of theft; loss; incidents; overexposures; change in RSO, authorized user; and radiation exposure reports to individuals)

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

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

15. 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.)

16. SOURCE OR DEVICE REVIEW:
(Device registration documents; changes; quality assurance/quality control program. Contact Material Safety Branch (NMSS/IMNS) and supervisor if unregistered equipment is identified.)

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, significant equipment failures, etc.)

PART III - POST- INSPECTION ACTIVITIES

1. REGIONAL FOLLOW UP ON PEFs:

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

End

Attachments:

- A. Radioactive Drug Distributors
- B. Decommissioning Timeliness Inspection

APPENDIX A - ATTACHMENT A
RADIOACTIVE DRUG DISTRIBUTORS

Licensee: _____

Date of Inspection: _____

1. Indicate type of operation:
 - A. Registered or licensed with U.S. Food and Drug Administration as a drug manufacturer ()
 - B. Registered or licensed with State Agency as a drug manufacturer ()
2. Licensee distributes
 - * sealed sources () Y () N
 - * alpha and beta emitter () Y () N
 - * generators () Y () N
 - * photon emitters () Y () N

Basis for Findings:

3. Observe licensee during first run operations () Y () N |

Basis for Findings:

4. Licensee periodically reviews work of supervised individuals preparing drugs, and records kept to reflect work. [License condition (L/C)] () Y () N |

Basis for Findings:

5. Radioactive drugs are measured (assayed) by direct measurement or combination of measurement and calculation before commercial distribution [10 CFR 32.72(c)] () Y () N |

Basis for Findings:

6. License has and uses appropriate shielding to maintain doses ALARA () Y () N |

Basis for Findings:

- | 7. Instrumentation Used to Measure Radioactivity of Drugs
 - A. List type of equipment used to assay alpha and beta particles.
 - B. Procedures for instrument use developed and implemented [10 CFR 32.72(c)] () Y () N
 - C. Calibration tests performed before initial use, periodically, and following repair for accuracy, linearity, and geometry dependence, as appropriate for use of the instrument [10 CFR 32.72(c)(1); L/C] () Y () N
 - D. Adjustment to instrumentation made when necessary [10 CFR 32.72(c)(1); L/C] () Y () N
 - E. Instruments are checked for constancy and proper operation at the beginning of each day of use [10 CFR 32.72(c)(2); L/C] () Y () N

Basis for Findings:

- | 8. Transport radiation shield (on transfers for distribution) labeled with radiation symbol, "CAUTION [or DANGER], RADIOACTIVE MATERIAL," name, and quantity at specified date and time* [10 CFR 32.72(a)(4)(i); L/C] () Y () N
- | 9. Syringes, vials, or other containers labeled with radiation symbol, "CAUTION [or DANGER], RADIOACTIVE MATERIAL," and an identifier to correlate with the information on the transport radiation shield label [10 CFR 32.72(a)(4)(ii); L/C] () Y () N

Basis for Findings:

- | 10. Workers are knowledgeable of the risks associated with licensed activities (including e.g., typical dose rates, contamination, ALI's, etc.) () Y () N

Basis for Findings:

* The time may be omitted for drugs with a half-life greater than 100 days.

APPENDIX A - ATTACHMENT B
DECOMMISSIONING TIMELINESS INSPECTION

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 at any separate buildings, or at 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 the 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); 10 CFR 40.42(g); 10 CFR 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: ___/___/___

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

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 submission: ___ / ___ / ___

If NRC approved, date of NRC approval: ___ / ___ / ___

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

If "Yes," date of submission: ___ / ___ / ___

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