APPENDIX A

MATERIALS PROCESSOR/MANUFACTURER INSPECTION RECORD

	Region	_
Inspection Report No		License No
Licensee (Name and Addre	ess):	Docket No.
_		
-		
-		
- Licensee Contact:		Telephone No.
Priority: Prog	ram Code:	
Date of Last Inspection: Date of This Inspection:		
Type of Inspection:	() Announced () Routine () Initial	() Unannounced () Special
Next Inspection Date	()	Normal () Reduced () Extended
Justification for change in r	normal inspection frequen	icy:
Summary of Findings and A	Actions:	
 () No violations cite regional letter is () Non-cited violation () Violation(s), Form () Violation(s), region () Follow up on presented 	ssued ons (NCVs) m 591 issued onal letter issued	egulatory Commission (NRC) Form 591 or
Inspector(s)	(Sign Name)	Date
	(Print Name)	_
Approved	(Sign Name)	Date
	(Print Name)	_

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

1. <u>AMENDMENTS AND PROGRAM CHANGES</u>:

(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 <u>each</u> inspection. However, for those areas <u>not covered</u> 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)

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)

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3.	FACILITIES: (Facilities as described; uses; control of access; engineering controls; calibration facilities; shielding; air flow)
4.	EQUIPMENT AND INSTRUMENTATION: (Operable survey equipment; shielding devices; procedures; 10 CFR Part 21 procedures; process and storage systems)
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)

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)

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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

(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. <u>NOTIFICATIONS AND REPORTS</u>:

(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)

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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.	<u>DEBRIEF WITH REGIONAL STAFF</u> : (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:			
2.	A. Registered or licensed with U.S. Food and Drug Administration as manufacturer () B. Registered or licensed with State Agency as a drug manufacturer Licensee distributes * sealed sources ()Y()N * alpha and beta emitter()Y()N * generators ()Y()N * photon emitters ()Y()N	-		
Basis	for Findings:			
3. Basis	Observe licensee during first run operations for Findings:	()Y()N		
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 comeasurement and calculation before commercial distribution [10 CFR 32.72(c)]	mbination of		
Basis for Findings:				
6.	License has and uses appropriate shielding to maintain doses ALARA () Y () N		
Basis	for Findings:			

7. Instrumentation Osed to Measure Radioactivi			nemation osed to Measure Radioactivity of Drugs	
		A.	List type of equipment used to assay alpha and beta particles.	
		B. and im	Procedures for instrument use developed plemented [10 CFR 32.72(c)]	() Y () N
		C.	Calibration tests performed before initial use, periodically, and for accuracy, linearity, and geometry dependence, as appropriate	
			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 each day of use [10 CFR 32.72(c)(2); L/C] $$ () Y () N	e beginning of
	Basis 1	or Find	ings:	
	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 1	or Find	ings:	
	10.		ers are knowledgeable of the risks associated with licensed activitien rpical dose rates, contamination, ALI's, etc.)	s (including ()Y()N
Basis for Findings:				
	* The time may be omitted for drugs with a half-life greater than 100 days.			

<u>APPENDIX A - ATTACHMENT B</u> <u>DECOMMISSIONING TIMELINESS INSPECTION</u>

Licens	see:				
Date o	of Inspe	ction: _	<u> </u>		
1.	(NOTE	E: Repo	E WITH DECOMMISSIONING TIMELINESS RULE eat the answers given in Section 12 of the main body of the inspection ssues in subsequent sections are dependent on the answers to these		
	A.	Licens	se to conduct a <i>principal activity</i> <u>has</u> expired or been revoked ()Y()N		
	B.	entire	see <u>has</u> made a decision to permanently cease <i>principal activities</i> , at the site, or at any separate buildings, or at any outdoor areas, including ve burial grounds. () Y () N		
	C.	A 24-month duration has passed in which no <i>principal activities</i> 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	"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.			
		If "Yes	s," date of notification://		
	В.	If the licensee is requesting to delay initiation of the decommissioning process the licensee <u>has</u> 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	s," date of notification://		
Rasis	for Find	linas:			
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3. DECOMMISSIONING PLAN/SCHEDULE REQUIREMENTS Α. 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 If licensee has initiated decommissioning, give date the decommissioning was D. initiated: / / E. If decommissioning has been completed, it was completed within 24 months of notification to NRC. () N/A ()Y () Ν 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()NBasis 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.
	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 Find	ings:
Violations ide	ntified, if any:
	END