

LICENSE NO: 06-13514-01

DOCKET NO. (s) 30-06891

PAGE _____ OF _____

ATTACHED

- Appendix A
- Appendix B
- Appendix C
- Memo

INSPECTION REPORT NO. 84-01
Becton-Dickinson Company
Route 7 and Grace Way
North Canaan, Connecticut 06018

LICENSEE CONTACT: Wm. Case, RSO Telephone No: 203-824-5487

LICENSE NO: 06-13514-01 CATEGORY E3 PRIORITY: 1

CATEGORY _____ PRIORITY: _____

CATEGORY _____ PRIORITY: _____

INSPECTION DATE (s): 12/12/84 TYPE OF INSPECTION: SPECIAL ANNOUNCED
 ROUTINE UNANNOUNCED
 DAYSHIFT
 OTHER

SUMMARY OF FINDINGS AND ACTION

- NO NONCOMPLIANCE, CLEAR 591 ISSUED
- NO NONCOMPLIANCE, LETTER
- NONCOMPLIANCE, APPENDIX A
- ACTION ON PREVIOUS NONCOMPLIANCE, APPENDIX B
- NONCOMPLIANCE, 591 ISSUED
- SUPPLEMENTAL INFO, APPENDIX C

RECOMMENDATIONS
SEE BASIS IN APPENDIX C

CHANGE CATEGORY TO: _____ CHANGE PRIORITY TO: _____
 NEXT INSPECTION DATE: 12-85

PERSONS CONTACTED

Wm Case, RSO
Richard Crooks, Manager of Bacteriological Sterilization Services
* Andrew Rowjohn, Plant Manager
Frank Dowd, Coordinator Installation & Services AECH

* Exit Interview
 INSPECTOR: C. Rowe 12-18-84

APPROVED: J. Kineman 12/20/84

INSPECTION PLAN AND REPORT NUMBER _____ Page _____ of _____

Plan Approved: _____ Date: _____

Licensee: _____ License No. _____

Inspection Items	Scheduled for Inspection	Post Inspection Status	Module No.
Management Meeting - Entrance and Exit Interviews (Required)			30703B
Program Requirements, MC 2850 (Required)			77710B
Followup on Noncompliance and Deviations			92702B
Independent Inspection Effort (Required)			92706B
Transportation			86740B

INSPECTION REPORT NUMBER _____

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77710B - Irradiator

AREAS INSPECTED AND FINDINGS

Licensee: _____ License No: _____ Amendment No: _____

INSPECTION ITEMS	CRITERIA	FINDING
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1. Organization

Lic Cond _____

Management organization?
Radiation protection organization?
Scope of program?
NOTES & REMARKS:

*RSD reports to Manager of
Bacteriological Services who report
to Plant Manager
Currently 2 shifts with one
qualified operator each shift*

2. Licensee Internal Audits

Lic Cond _____ C

Scope and frequency?
Management controls?
NOTES & REMARKS:

*Audits by manager documented
RSD in area daily but not
documented*

3. Training and Instructions to Employees

Lic Cond _____ C

Training program, scope and frequency, retraining?
Required tests administered; scores satisfactory?
Instructions to workers?
NOTES & REMARKS:

19.12
*Records of training reviewed
5 day training course planned for 7 employees to qualify
them for operator status. Anticipate 3 shift operation
with two operators each shift.*

4. Radiation Protection Procedures

Lic Cond _____ C

Operating & emergency procedures implemented?
Security?
NOTES & REMARKS:

20.207

AREAS INSPECTED AND FINDINGS

Licensee: _____ License No: _____ Amendment No: _____

INSPECTION ITEM	CRITERIA	FINDING
<u>5. Materials, Facilities and Instruments</u>		
Authorized uses and quantities?	Lic Cond _____	<u>C</u>
Restricted areas, posting requirements?	20.203	
Survey instruments & dosimeters; operable, properly calibrated?	Lic Cond _____	
Independent area radiation monitor?		
Survey meter used on entering HRA?		
NOTES & REMARKS:	<i>Source replacement being conducted by AECL at time of inspection - new source loading will be 1.299 million Curies</i>	
<u>6. Receipt and Transfer of Materials</u>		
Procedures implemented, adequate?	20.205, 71.51	<u>C</u>
Transfer of byproduct material?	30.41	
Control of source material, SNM?	40.51, 40.64, 70.42, 70.51, 70.53, 70.54	
Records of receipt, transfer, storage, survey and monitoring?	30.51	
NOTES & REMARKS:	<i>AECL ships to AECL at site & return to Canada paperwork reviewed S.N.</i>	
<u>7. Control of High Radiation Area</u>		
Interlocks, tests, entry control?	20.203(c)(6)	<u>C</u>
Action if entry control device fails?		
Device to prevent source exposure with individual in chamber?		
Level control for liquid shield?		
Source exposure procedure?		
Control of portals (continuous irradiator)?		
NOTES & REMARKS:		

777108 - Irradiator

AREAS INSPECTED AND FINDINGS

Licensee: _____ License No: _____ Amendment No: _____

INSPECTION ITEM	CRITERIA	FINDING
<u>8. Transportation</u>		
Management controls, audits?		<u>C</u>
Selection of packaging?	49 CFR 173.393-5, 10 CFR 71	
Preparation of packages for shipment?	49 CFR 172, 173	
Filling, loading, closing, liquids?	49 CFR 172, 300	
Markings & labelling?	49 CFR 172.403, 402	
Monitoring?	49 CFR 173.393	
Shipping papers, loading & placarding of vehicles?	49 CFR 172.200	
Reports of incidents?		
Examination of packages?		
NOTES & REMARKS:		
<u>9. Personnel Protection- External</u>		
Personnel monitoring control; minimize exposures, control of accumulated dose?	20.101, 20.102, 20.202	<u>C</u>
Surveys conducted, adequate?	20.201	
Records of monitoring, surveys, disposals?	20.401, Lic Cond _____	
Levels in unrestricted areas?	20.1, 20.105	
NOTES & REMARKS:		
<u>10. Personnel Protection - Internal</u>		
Airborne concentrations in restricted areas?	20.103 N/A	<u>C</u>
Exposure of minors?	20.104 ✓	
Posting of airborne radioactivity areas?	20.203 N/A	
Survey, monitoring, bioassay requirements; records?	20.201, 20.401 N/A	
Leak tests of sealed sources?	Lic Cond _____ ✓	
NOTES & REMARKS:		

AREAS INSPECTED AND FINDINGS

Licensee: _____ License No: _____ Amendment No: _____

INSPECTION ITEM	CRITERIA	FINDING
<u>11. Effluent Control, Waste Disposal</u>		
Release of effluents?	20.106	<u>N/A</u>
Waste disposal, proper packaging for shipment?	20.301, 20.303, 20.304, 20.305	
Procedures, records?	20.401, Lic Cond _____	
NOTES & REMARKS:		
<u>12. Shipping, Shipping Incidents</u>		
Procedures for pickup, receipt, monitoring of packages?	20.205(b) & (c)	<u>C</u>
Incidents, reports, corrective actions?	49 CFR 170-189	<i>None</i>
NOTES & REMARKS:		
<u>13. Notifications and Reports</u>		
To individuals?	19.13	<u>C</u>
Overexposures, excessive levels & concentrations, incidents?	20.403, 20.405	
Personnel exposures and monitoring, termination reports?	20.407, 20.408	
Theft or loss of licensed material?	20.402	
NOTES & REMARKS: <i>Minimal exposure per vendor report 30 mR max per year</i>		
<u>14. Posting of Notices</u>		
Part 20, license & documents, procedures, notice of violations?	19.11(a)	<u>C</u>
NRC-3?	19.11(c)	
NOTES & REMARKS:		

AREAS INSPECTED AND FINDINGS

Licensee: _____ License No: _____ Amendment No: _____

INSPECTION ITEM	CRITERIA	FINDING
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15. <u>Environmental Monitoring Program</u>	Lic Cond _____	<u>N/A</u>
Implementation of program, scope and frequency as required?		
Records maintained, reviewed by management?		
NOTES & REMARKS:		

16. <u>Emergency Preparedness</u>	Lic Cond _____	<u>C</u>
Procedures available for incidents and accidents?		
Training for personnel; coordination with supporting groups and agencies?		
NOTES & REMARKS:		

17. <u>Other License Conditions</u>		<u>C</u>
NOTES & REMARKS:		

18. <u>Confirmatory Measurements</u>		<u>Not Done</u>
Licensee's surveys verified on sampling basis?	20.105, 20.201	
Analysis of pool water sample?		
NOTES & REMARKS:		

NRC Instrument: _____ Calibration Due Date: _____

19. <u>Independent Inspection Effort</u>		<u>C</u>
<i>Discussions with RSO Observation of source loading</i>		
NOTES & REMARKS:		

INSPECTION REPORT NUMBER _____

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APPENDIX A - DOCUMENTATION OF NONCOMPLIANCE

Licensee: _____ License No: _____

Reference	Basis for noncompliance
Report item _____ 10 CFR _____ Lic Cond _____ Type n/c _____	
Report item _____ 10 CFR _____ Lic Cond _____ Type n/c _____	
Report item _____ 10 CFR _____ Lic Cond _____ Type n/c _____	
Report item _____ 10 CFR _____ Lic Cond _____ Type n/c _____	
Report item _____ 10 CFR _____ Lic Cond _____ Type n/c _____	
Report item _____ 10 CFR _____ Lic Cond _____ Type n/c _____	

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APPENDIX C - SUPPLEMENTARY INFORMATION

Licensee: _____

License No: _____

-
- Uncorrected/repeated noncompliance
 - Unusual occurrence, conditions, etc
 - Basis for change of Category or Priority

- Unresolved items
- Inspector's comments

DATE	6/24/85
TIME	<input type="checkbox"/> A.M. <input type="checkbox"/> P.M.

TELEPHONE OR VERBAL CONVERSATION RECORD

INCOMING CALL OUTGOING CALL VISIT

PERSON CALLING <i>John Doe</i>	OFFICE/ADDRESS <i>RI</i>	PHONE NUMBER	EXTENSION
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PERSON CALLED <i>Bill Case</i>	OFFICE/ADDRESS <i>B&D</i>	PHONE NUMBER <i>203/824-5487</i>	EXTENSION
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CONVERSATION

SUBJECT *Review of irradiation / defecing letter dated 6/3/85*

SUMMARY

Need a commitment from B&D for

- 1) that they are not by passing Fail Safe Systems (even for maintenance purposes)*
- 2) Using AECL 40 hr training course*
- 3) Using AECL instructor to provide training*

Will send in organization chart

Discussed the responsible individual will have to be physical present whenever the irradiation is in question.

ML10

"OFFICIAL RECORD COPY"

REFERRED TO:

ACTION REQUESTED

ACTION TAKEN

ADVISE ME OF ACTION TAKEN.

INITIALS

DATE

INITIALS

DATE