RI - DNMS Licensee Event Report
Disposition

Licensee: Cardinal Health NPS

Event Description: Return of waste from Stericycle to pharmacy

License No: ~~04-26507-1MD~~ Docket No: ~~030-33959~~ MLER-RI: 2006-005

Event Date: 12/14/05 Report Date: 12/15/05 HQ Ops Event #:

1. REPORTING REQUIREMENT LN 34-29200-01 MD DN 030-36973 *

- [ ] 10 CFR 20.1906 Package Contamination
- [ ] 10 CFR 20.2201 Theft or Loss
- [ ] 10 CFR 20.2203 30 Day Report
- [X] Other Return of hospital waste which contained RAM
- [ ] 10 CFR 30.50 Report
- [ ] 10 CFR 35.3045 Medical Event
- [ ] License Condition

2. REGION I RESPONSE

- [ ] Immediate Site Inspection — Inspector/Date
- [ ] Special Inspection — Inspector/Date
- [X] Telephone Inquiry — Inspector/Date: Richard W. McKinley, 1/31/06
- [ ] Preliminary Notification/Report
- [ ] Information Entered in RI Log
- [ ] Report Referred To:
- [ ] Daily Report
- [X] Review at Next Inspection

3. REPORT EVALUATION

- [X] Description of Event
- [X] Levels of RAM Involved
- [X] Cause of Event
- [X] Corrective Actions
- [ ] Calculations Adequate
- [ ] Additional Information Requested from Licensee

4. MANAGEMENT DIRECTIVE 8.3 EVALUATION

- [ ] Release w/Exposure > Limits
- [ ] Repeated Inadequate Control
- [ ] Exposure 5x Limits
- [ ] Potential Fatality
- [ ] Deliberate Misuse w/Exposure > Limits
- [ ] Pkging Failure>10 rads/hr or Contamination>1000x Limits
- [ ] Large# Indivs w/Exp>Limits or Medical Deterministic Effects
- [ ] Unique Circumstances or Safeguards Concerns

If any of the above are involved:

- [ ] Considered Need for IIT
- [ ] Considered Need for AIT

Decision/Made By/Date:

5. MANAGEMENT DIRECTIVE 8.10 EVALUATION (additional evaluation for medical events only)

- [ ] Timeliness - Inspection Meets Requirements (5 days for overdose / 10 days for underdose)
- [ ] Medical Consultant Used-Name of Consultant/Date of Report:
- [ ] Medical Consultant Determined Event Directly Contributed to Fatality
- [ ] Device Failure with Possible Adverse Generic Implications
- [ ] HQ or Contractor Support Required to Evaluate Consequences

* Note: LN 04-26507-01 was terminated on 6/28/2005

6. SPECIAL INSTRUCTIONS OR COMMENTS

Following Next Routine Inspection

- [ ] Non-Public
- [X] Public-SISP REVIEW COMPLETE

Inspector Signature: Richard W. McKinley Date: 2/1/06

Branch Chief Initials: Date: 3/23/6

Location of File: G:\Reference\Blank Forms\LER FORM.wpd

Rev. 02/25/05