

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED Midwest Bio-Products, Inc. 618 Liberty Street Covington, IN 47932 REPORT NUMBER(S) 12-01		2. NRC/REGIONAL OFFICE Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352	
3. DOCKET NUMBER(S) 030-18424	4. LICENSE NUMBER(S) 13-20477-01	5. DATE(S) OF INSPECTION 6/11/12	

LICENSEE:

The inspection was an examination of the activities conducted under your license as they relate to radiation safety and to compliance with the Nuclear Regulatory Commission (NRC) rules and regulations and the conditions of your license. The inspection consisted of selective examinations of procedures and representative records, interviews with personnel, and observations by the inspector. The inspection findings are as follows:

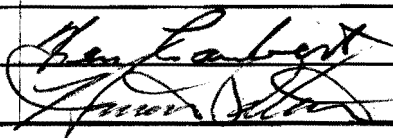
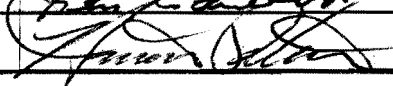
- ✓ 1 Based on the inspection findings, no violations were identified.
- 2 Previous violation(s) closed.
- 3 The violation(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was or is being taken, and the remaining criteria in the NRC Enforcement Policy, to exercise discretion, were satisfied.

Non-cited violation(s) were discussed involving the following requirement(s):

- 4 During this inspection, certain of your activities, as described below and/or attached, were in violation of NRC requirements and are being cited in accordance with NRC Enforcement Policy. This form is a NOTICE OF VIOLATION, which may be subject to posting in accordance with 10 CFR 19.11
(Violations and Corrective Actions)

Statement of Corrective Actions

I hereby state that, within 30 days, the actions described by me to the Inspector will be taken to correct the violations identified. This statement of corrective actions is made in accordance with the requirements of 10 CFR 2.201 (corrective steps already taken, corrective steps which will be taken, date when full compliance will be achieved). I understand that no further written response to NRC will be required, unless specifically requested.

TITLE	PRINTED NAME	SIGNATURE	DATE
LICENSEE'S REPRESENTATIVE			
NRC INSPECTOR	Ken Lambert		6/11/12
BRANCH CHIEF	Pete Peterson		6/20/12

Docket File Information
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6. INSPECTION PROCEDURES USED 87126	7. INSPECTION FOCUS AREAS 03.01 -03.07
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SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S) 3620	2. PRIORITY 5	3. LICENSEE CONTACT Masakazu Miyagi, Ph.D, RSO	4. TELEPHONE NUMBER (812) 235-0696
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Main Office Inspection Next Inspection Date: June 11, 2017
 Field Office Inspection
 Temporary Job Site Inspection

PROGRAM SCOPE

The licensee was a small private biotechnology company involved in research and development of an enzyme used in medical blood testing. The company employs three individuals. The licensee uses H-3 for in vitro assay of DNA synthesis by the enzyme DNA polymerase. The licensee is authorized to possess up to 5 millicuries of H-3. The licensee/owner used licensed material within a dedicated lab within a separate building from the residence. At the time of this inspection, the licensee was only using H-3 2-3 times per year. The licensee purchased H-3 1-2 times per year in 1 millicurie quantities.

OBSERVATIONS AND FINDINGS

The inspection consisted of a tour of the research lab, the radioactive waste storage area, and the material storage areas. The inspector reviewed selected records of package receipts and wipe surveys of the laboratory after H-3 use. The inspector discussed waste disposal practices which included liquid disposal of H-3 through the sanitary sewage system and disposal of solid H-3 waste by incineration. Interviews of licensee staff indicated an adequate knowledge of radiation safety practices.