

U. S. NUCLEAR REGULATORY COMMISSION

REGION III

Report No. 99990003/89006(DRSS)

General License Registration No. 3494

Docket No. 99990003

Licensee: Chem-Bio Corporation (CBC)
140 E. Ryan Road
Oak Creek, WI 53154

Inspection At: 140 E. Ryan Road
Oak Creek, WI 53154

Inspection Conducted: July 31, 1989

Inspector:

W. J. Sreniawski
D. J. Sreniawski, Chief
Nuclear Materials Safety Section 1

10-20-89
Date

Approved By:

Bruce S. Mallett
Bruce S. Mallett, Ph.D., Chief
Nuclear Materials Safety Branch

10-24-89
Date

Inspection Summary

Inspection on July 31, 1989 (Report No. 99990003/89006(DRSS))

Areas Inspected: This was an announced special safety inspection to review an allegation concerning Chem-Bio Corporation's (CBC's) total inventory of licensed material. The inspection included a review of records, interviews with employees and a tour of the licensee's facility.

Results: The allegation that CBC possessed licensed material in excess of the applicable limit in 10 CFR 31.11(c)(1) was substantiated. One violation was identified (Section 4).

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PDR GA999 EECCHMBC
99990003 PNU

DETAILS

1. Persons Contacted

Robert F. Lipo, Medical Director
David Scherzer, President
Michael Arend, Vice President and General Manager
*Tina Golden, Manager, Clinical Laboratory
*Sharon Heder, Radiation Safety Officer, Second Shift Supervisor
Rochelle Hagen, Staff Technologist

*Present at inspection exit meeting.

2. Licensed Program

CBC was issued NRC specific license No. 48-24625-01 on March 7, 1986, to possess nickel-63 (no single source to exceed 15 millicuries) for use in a Perkin Elmer gas chromatograph(s) for sample analysis. The licensee also has a NRC general license pursuant to 10 CFR 31.11, Registration No. 3494, issued October 17, 1983, to possess a total of no more than 200 μ Ci of iodine-125, iodine-131, selenium-75 and/or iron-59 for use in in vitro clinical or laboratory tests.

CBC is a broad based, full service clinical laboratory performing hematology, microbiology, toxicology RIA, urinalysis and other medical tests. About 10% of their tests involve byproduct material. The use of the radioactive material is controlled by the manager of the Clinical Laboratory.

3. Allegation

CBC was using radioactive material in amounts that were in excess of the limits of their general license; specifically, they have possessed more than 1000 microcuries at a time.

4. Allegation Findings

As a result of an OSHA inspection of the licensee's program on May 2, 1989, the NRC Region III (Chicago) office received a letter from the Department of Labor, Occupational Safety and Health Administration (OSHA) (Chicago) office transmitting an OSHA-90 referral form (#901095455) which contained the allegation (Attachment A). A review of NRC records showed that CBC has a general license to possess up to 200 μ Ci of I-125, I-131, Se-75 and Fe-59 in total.

On May 15, 1989, a Region III NRC inspector phoned CBC and was informed that they currently possessed more than 200 microcuries of iodine-125; however, the licensee committed to return some of their iodine-125 inventory (TSH iodine-125 kits) to their vendor. This would place the licensee below the 200 microcurie possession limit. On May 19, 1989, the CBC Clinical Laboratory Manager phoned the NRC inspector and reported that they were under the 200 microcurie possession limit. A site inspection was performed on

July 31, 1989, by the Chief of the Nuclear Materials Safety Section 1, NRC Region III. During the inspection, the inspector confirmed that CBC had not exceeded their possession limits subsequent to May 19, 1989, and that the licensee returned TSH kits to their vendor as stated. This was determined by a review of licensee inventory records and interviews of a staff technologist who uses the material and the radiation safety officer. Inventory records showed the licensee had previously been ordering iodine-125 once a month in amounts ranging from 100-200 microcuries and that the quantities ordered slowly increased over the last three years to the current levels (since mid-1988) of 800 to 1000 μCi each month. As a result, the licensee was in violation of 10 CFR 31.11(c)(1), which limits their total possession to 200 μCi of iodine-125, iodine-131, selenium-75 and/or iron-59.

The inspector noted that CBC had taken the following steps to ensure future compliance:

- a. Purchases are made each week rather than each month so total inventories are lower; the kits are used in the interim and radioactive waste is disposed of.
- b. The TSH iodine-125 assay which accounted for about 60% of the total amount of material used by the licensee was discontinued and replaced by a non-radioactive analyzer. The replacement employs a fluorescent antibody instead of radioactivity.
- c. Licensee management informed their staff of the requirements to maintain total inventories to less than 200 microcuries.

When questioned as to why CBC had exceeded the possession limit in the past, the Clinical Laboratory Manager stated they had not been aware of the requirements prior to the OSHA inspection. By May 19, 1989, the licensee received a copy of 10 CFR 31 mailed by the Region III office and the requirements were reviewed and understood.

5. Conclusion

The allegation was substantiated; one violation of regulatory requirements was identified. The licensee's immediate and long term corrective actions appear adequate to prevent recurrence.

6. Exit Meeting

An exit meeting was held on July 31, 1989, with CBC staff members denoted in Section 1. The apparent violation, the allegation and the licensee's corrective actions were discussed.

U.S. Department of Labor

Occupational Safety and Health Administration
230 South Dearborn Street
Chicago, Illinois 60604




A.B. Davis
Regional Administrator
Nuclear Regulatory Commission
799 Roosevelt Rd.
Glen Ellyn, IL 60137

Dear Mr. Davis:

Enclosed please find an OSHA-90 referral form (#901095455) regarding ChemBio Corporation in Oak Creek, Wisconsin, which was forwarded by our Milwaukee Area Office.

During an industrial hygiene inspection of this establishment, the compliance officer observed potentially hazardous conditions which appear to fall within the jurisdiction of the NRC. I would appreciate it if your office would review the allegations and take whatever action you deem appropriate.

Sincerely,


Michael G. Connors
Regional Administrator

Enclosure

Enclosure Contains
EXEMPT FROM DISCLOSURE INFORMATION
Upon Separation This
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ATTACHMENT A

R44-89-A-0063

1989

4

(10 CFR 2.790 (a))

1. Reporting ID: S28400 2. Previous Activity: Yes [] No [] 3. Referral Number: 901095455

b. Establishment Name: CHEM BIO CORPORATION

a. Site Address: 140 E RYAN RD, OAK CREEK, WI S3154 City Code: 3475 County Code: 079

b. Mailing Address: (Street, City, State, ZIP)

10. Type of Business: CLINICAL LABORATORY 11. Primary SIC: 7391 12. No. of Employees: 250

13. Ownership: a. Private Sector [X] b. Local Government [] c. State Government [] d. Federal Agency/Code []

14. Referred by: a. CSHO [] b. Federal OSHA [X] c. State OSH [] d. Discrimination [] e. Other Federal Agency [] 15. Date Received: f. Consultation [] g. State/Local Government [] h. Media [] i. Other []

16. Source or Contact: TERRY DEMBROWSKI, INDUSTRIAL HYGIENIST, MILWAUKEE AREA OSHA OFFICE, 414-291-3315

17. a. Safety: (1) Imminent Danger [] (2) Serious [] (3) Other [] b. Health: (1) Imminent Danger [] (2) Serious [] (3) Other []

18. Migrant Farmworker Camp []

19. Hazard Description: THE COMPANY IS HANDLING RADIOACTIVE MATERIAL AMOUNTS THAT ARE IN EXCESS OF THE LIMITS OF THEIR GENERAL LICENSE. THEIR RADIOACTIVE MATERIALS LOG INDICATES THAT THE TOTAL AMOUNT OF MATERIAL POSSESSED AT TIMES HAS EXCEED 1000 MICROCURIES

20. a. Send Letter [] b. Date Letter Sent: c. Date Response Due: 21. Supervisor(s) Assigned: a. b.

22. Inspection Planned? [] Yes [] No If Yes, Priority: If No, Reason:

23. Transfer to (Name): NUCLEAR REGULATORY COMMISSION 24. Transfer Date:

25. Transfer to (Category): a. Federal OSHA [] b. State OSH [] c. Other Federal Agency/Code: 6100 d. State/Local Government [] e. Other []

26. Optional Information table with columns: Type, ID, Value, Type, ID, Value. 27. Total Entries

28. Comments

EXEMPT FROM DISCLOSURE

(10 CFR 2.790 (a))

RTT-89A-0063

U.S. Department of Labor

Occupational Safety and Health Administration
230 South Dearborn Street
Chicago, Illinois 60604



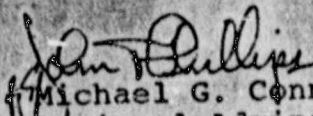
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Regional Administrator

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ATTACHMENT A

R111-89-A-0063

1989

4

301095455

Establishment Name: CHEM BIO CORPORATION

Site Address (Street, City, State, ZIP): 100 E RYAN RD, OAK CREEK, WI 53154

City Code: 3475 County Code: 079

Type of Business: CLINICAL LABORATORY

Ownership: Private Sector

Referred by: Federal OSHA

Source of Contact: TERRY DEMBROWSKI, INDUSTRIAL HYGIENIST, MILWAUKEE AREA OSHA OFFICE, 414-291-3315

17. a. Safety (1) Imminent Danger (2) Serious (3) Other

18. Migrant Farmworker Camp

19. Hazard Description

THE COMPANY IS HANDLING RADIOACTIVE MATERIAL AMOUNTS THAT ARE IN EXCESS OF THE LIMITS OF THEIR GENERAL LICENSE. THEIR RADIOACTIVE MATERIALS LOG INDICATES THAT THE TOTAL AMOUNT OF MATERIAL POSSESSED AT TIMES HAS EXCEED 1000 MICROCURIES

Cont'd

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22. Inspection Planned: Yes No If Yes, Priority: If No, Reason:

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Table with 4 columns: Type, ID, Value, Type, ID, Value. Row 1: Empty. Row 2: Empty. Row 3: Empty. Row 4: Empty. Row 5: Empty.

27. Total Entries

28. Comments

EXEMPT FROM DISCLOSURE