U.S. NUCLEAR REGULATORY COMMISSION
REGION I
INSPECTION REPORT

Report No. 030-19953/92-002

Docket No. 030-19953

License No. 20-20592-01 Priority 5 Category E Program Code 03620

Licensee: Creative Biomolecules
35 South Street
Hopkinton, Massachusetts 01748

Inspection Conducted: November 10 and 11, 1992

Inspector: Sheri Arredondo 12/22/92
Sheri Arredondo, Health Physicist date

Inspector: Tara Weidner 12/23/92
Tara L. Weidner, Health Physicist date

Approved by: John D. Kinneman 12·23·92
John D. Kinneman, Chief date
Research, Development, and Decommissioning Section

Inspection Summary: Routine, unannounced, safety inspection conducted November 10 and 11, 1992 (Inspection Report No. 030-19953/92-002)

Areas Inspected: Licensee action on previous violations; organization and scope of licensed activities; training and instruction of employees; radiation protection procedures; receipt and transfer of material; personnel protection - external; personnel protection - internal; effluent control; waste disposal; and posting of notices.

Results: Sixteen apparent violations were observed: individuals working in a restricted area had not been trained (Section 4); radioactive materials were used on work areas that were not clearly identified by use of radioactive caution tape, and these work surfaces were not covered with absorbent pads to contain possible spills (Section 5); radioactive materials were being stored in refrigerators outside of the hot lab (Section 5); waste was stored on bench tops in buckets and allowed to accumulate at work sites (Section 5); laboratories were not posted "Caution, Radioactive Materials" (Section 5); containers did not bear the radiation caution symbol and the words "Caution Radioactive Material" (Section 5); the radiation exposure to individuals was not kept to a minimum (Section 5`, waste buckets were not discarded into the proper drum in the radioactive waste storage room (Section 5); surveys and wipe tests for removable contamination were not performed (Section 5); surveys were not performed following iodinations (Section 5); incoming packages were not wipe tested (Section 6); thyroid monitoring was not performed on all persons involved with iodination procedures within two days after use, and routine monthly thyroid measurements were not performed on all individuals working with greater than 1 millicurie of I-125 (Section 8); the licensee performed iodinations in a fume hood that was not certified (Section 8); quarterly effluent release measurements were not performed (Section 9); waste disposal records do not account for all radioactive material (Section 10); the NRC Form-3 was not posted in a sufficient number of places, and Parts 19 and 20, a copy of the license, and the July 1992 NOV were not posted (Section 11).

DETAILS

1. Persons Contacted

*Charles Cohen, Ph.D., Chairman of the Board and Chief Scientific Officer
*Victor A. Jegede, Ph.D., Vice President of Regulatory Affairs and Quality
*William F. Kusmik, Ph.D., Manager of Quality Control/Bioassay, and Radiation Safety Officer (RSO)
Denny Maratea, Ph.D., Director, Quality Assurance & Quality Control
Ron Johnson, Vice President of Operations
Donald Jin, Ph.D., Scientist, Molecular Biology
Maria Day, Research Associate, Cell Biology
Gail Clifford, Assistant Scientist, Molecular Biology
Neal Bramberg, Maintenance Supervisor

*Denotes those present at exit interview.

2. Licensee Action on Previous Violations

(Open) Inspection No. 92-001, failure to perform required surveys for dose rates and removable contamination at weekly intervals. This is a continuing violation (see Section 5).

3. Organization and Scope of Program

The following information was determined by a review of the license and from statements by the RSO, the Vice President of Regulatory Affairs and Quality, the Director of Quality Assurance & Quality Control, and various researchers, and was verified by observation. Licensed activities are conducted at the licensee's facilities at 35 South Street, Hopkinton, Massachusetts.

The licensee operates a small research and development program which involves approximately fifteen to twenty scientists. The scientific staff, working in three departments (Cell Biology, Molecular Biology, and Protein Chemistry) reports to the Director of Quality Assurance & Quality Control (QA/QC) under the Vice President of Regulatory Affairs and Quality. The Vice Presidents report directly to the Chairman of the Board.

Licensee representatives stated that the bulk of radioisotope use (about 80%) is in the Molecular Biology Department, where radioisotopes are used daily. Most of the remaining radioactive material is used on a regular basis by the Cell Biology Department, with only intermittent use by the Protein Chemistry Department. The Molecular Biology Department uses mostly microcurie quantities of sulfur-35 (S-35) and up to millicurie quantities of phosphorus-32 (P-32). The Cell Biology Department uses millicurie quantities of iodine-125 (I-125) and tritium (H-3). See Attachment 1

for information extracted from the licensee's incoming package receipt log and the licensee's radioactive material sign out record.

The radiation safety program has been coordinated solely by the RSO with no oversight from the Director of QA/QC, the VP of Regulatory Affairs, or the President. The inspectors reached this conclusion based on the fact that only the RSO had access to the radiation safety files and no one else could answer questions concerning the radiation safety program. The RSO specifically stated that he is aware of the requirements of the license but that he has not had sufficient time to perform many of his duties such as conducting routine monthly bioassays, air sampling, coordination of contamination surveys of laboratories, monitoring of incoming packages, inventory controls, and waste disposal.

4. Training and Instruction of Employees

At the time of the inspection it appeared, and licensee representatives stated, that all scientific staff had received the required annual training.

Licensee representatives stated that employees such as administrative staff, clerical and contract cleaning staff (who enter laboratories to pick up clean trash and mop the floors) had not been given training or instruction regarding the storage, transfer, or use of radioactive materials as required by 10 CFR 19.12. The licensee considers the entire facility to be a restricted area because radioactive materials are used in various locations throughout the facility and access to these locations by individuals who have not received the training required by 10 CFR 19.12 is not controlled. Example locations include: the alcove where the gamma counter is located and unshielded radioactive waste buckets are stored; the hot lab which was routinely kept open (until September 1992); and various other laboratories which are unlocked and in which radioactive materials are used or stored.

The finding that individuals working in or frequenting restricted areas, had not been trained is an apparent violation of 10 CFR 19.12.

No additional safety concerns were identified.

5. Radiation Protection Procedures

The inspectors toured the research laboratory areas, observed activities and interviewed several laboratory personnel, and made independent measurements of radiation levels and contamination using the licensee's calibrated Ludlum Model 16 with a NaI detector and a calibrated NRC Eberline Model 120 with a GM detector.

The inspectors observed several areas where radioactive materials were used and

stored on unmarked work surfaces not covered by absorbent pads and several refrigerators where radioactive materials were stored. These practices are contrary to license commitments which require that all radioactive material work surfaces be marked and that only the refrigerator in the hot lab be used for radioactive material storage.

The finding that radioactive materials were used on work areas that were not clearly identified by use of radioactive caution tape, and that these work surfaces were not covered with absorbent pads to contain possible spills, is an apparent violation of License Condition No. 14 which requires that all work areas be clearly identified by use of radioactive caution tape and that work be carried out on absorbent pads.

The finding that radioactive materials were stored in refrigerators outside of the hot lab and not designated for such storage is an apparent violation of License Condition No. 14 which requires that only the refrigerator in the hot lab be used for storage of radioactive material.

One vacant room adjacent to the gamma counter was used to store 2,000 vials which the licensee stated contained a total of about 1 millicurie of I-125; however, this area of the room was not posted with a "Caution, Radioactive Material" sign and work surfaces were not marked. The gamma counter is located in an alcove just beyond the administrative area. This alcove also contained a radioactive waste bucket filled with an absorbent material used for storing liquid waste and an open, small yellow trash bag, both of which did not bear radioactive labels. The inspectors measured about 150,000 counts per minute (cpm) at the surface and 7,000 cpm at three feet above the bucket using a NaI probe. The radiation levels in this immediate area were 1,000 cpm greater than the background of 300 cpm measured using the NaI probe. Another small laboratory which was not posted contained geater than 100 microcuries of I-125 which was used on a surface which was not marked and did not have an absorbent pad, and a radioactive waste bucket which was unlabeled and a refrigerator where radioactive materials were stored which were not labeled.

The finding that radioactive waste was stored on bench tops in buckets and allowed to accumulate at work sites is an apparent violation of License Condition No. 14, which requires that radioactive waste must not be stored on benches or allowed to accumulate at work sites and that no radioactive waste is to be left out overnight. The finding that radioactive materials were used in areas and laboratories that were not posted, "Caution Radioactive Materials", is an apparent violation of 10 CFR 20.203 (e).

The finding that containers which contained greater than specified amounts of radioactive materials did not bear the radiation caution symbol and the words "Caution Radioactive Material" is an apparent violation of 10 CFR 20.203 (f).

The inspectors measured radiation levels in the hot lab which is used for iodinations. The radiation level at the standing area for work in the fume hood due to the waste bucket was 15,000 cpm with a NaI and 1.2 mR/hr with a GM. The radiation level on top of the bucket was 2,500K cpm with the NaI and 48 mR/hr with the GM. The general radiation levels in the hot lab were 700-1,700 cpm greater than the measured background of 300 cpm.

The finding that the radiation exposure to individuals performing iodinations at the fume hood and next to two radioactive waste barrels was not kept to a minimum is an apparent violation of License Condition No. 14 which requires that exposure to radioactive materials be kept to a minimum.

The RSO stated that up until one month prior to the inspection, the hot lab door was propped open by a waste bucket filled with absorbent materials used to store liquid I-125, P-32, S-35, and H-3 waste. After a complaint by an employee, the RSO moved the waste bucket just inside the doorway next to the fume hood and shut the door to the hot lab. Recently, the waste bucket began to overflow due to a large amount of liquid being absorbed, so the RSO added a second waste bucket next to the original. On November 10, 1992, the inspectors observed the two waste buckets in the hot lab. Also, the inspectors observed that the waste buckets in the hot lab and in other areas in the facility were uncovered and not properly contained to prevent the release of airborne radioactivity.

The finding that a second waste bucket was added because the first bucket was full, instead of discarding the contents of the full waste bucket into the proper drum in the radioactive waste storage room is an apparent violation of License Condition No. 14 which requires that waste containers be discarded into a waste drum in the waste storage facility when full.

The inspectors interviewed several individuals including the RSO concerning wipe tests and surveys performed since June 30, 1992, the date of the last inspection. The information that was gathered is as follows: weekly meter surveys were performed and records were maintained in the Molecular Biology areas; for over a year, wipe tests were not performed in the Molecular Biology areas; meter surveys were not performed in the Cell Biology areas; and since May, 1992 wipe tests were not performed in the Cell Biology areas. In the hot lab, monitoring was not performed after each iodination, as required by licensee's procedures. Monitoring in the Protein Chemistry area and the animal laboratory facility was not reviewed.

The inspectors also toured the waste storage area. The waste barrels are kept in a locked room. However, the barrels were not labeled, and the posting of the room was on the floor in the doorway. Also, one of the barrels was not properly closed causing a radiation level of 70,000 cpm at the surface and 4,000 cpm at a three foot distance using a NaI probe. Monitoring is not being performed in the waste storage

area, as required by licensee procedures.

The finding that surveys and wipe tests for removable contamination were not performed weekly is a violation of License Condition No. 14 which requires that weekly surveys and wipe tests be performed in areas in which use is greater than 200 microcuries. The violation was apparently not corrected following Inspection No. 92-001.

The finding that surveys were not performed following iodinations is an apparent violation of License Condition No. 14 which requires that after every iodination, the area must be surveyed, found acceptable and the results of the survey documented.

6. Receipt and Transfer of Material

The RSO stated that all incoming packages containing radioactive material are delivered to the loading dock where each is received by a worker who then brings the packages to the hot lab. The RSO opens each package, performs a wipe test, logs it into the incoming package log book and stores it in the refrigerator in the hot lab. The users maintain another log, called the radioactive material sign-out sheet, which contains the date that material is signed in or out, the amount, the isotope, the amount remaining, and the initials of the user. Upon examination of these logs, the inspectors observed that only about half of the incoming packages listed on the radioactive sign-out sheet corresponded to entries in the RSO's incoming package log book (see Attachment 1). Upon presenting this information to the RSO, he concluded that packages entered in the sign-out log, but not the incoming package log, must have come in when he was not available, and that those packages had not been wipe tested.

The findings that incoming packages were not wipe tested upon receipt is an apparent violation of License Condition No. 14 which requires that all incoming packages be wipe tested.

No additional safety concerns were identified.

7. Personnel Protection - External

Film badge records from June 1992 to October 1992 were reviewed by the inspectors and found to be complete. Approximately twenty people are badged. Those individuals working with P-32 wear ring badges as well as whole body badges. All doses were minimal, with an occasional reading of 10-20 mrem. The RSO stated that he reviews the results monthly, and investigates any results above normal.

No safety concerns were identified.

8. Personnel Protection - Internal

Iodinations are performed in a mini-hood within the fume hood located in the hot lab. Licensee records since July 1992 were reviewed and indicated that iodinations were performed on September 28, October 5, October 14, and October 28, 1992. Each iodination involved 1.5 to 3.5 millicuries of I-125. Bioassay records indicate that during this time period a thyroid scan was only performed on August 19, 1992. Also, according to the RSO, no routine monthly thyroid scans were performed.

The fume hood located in the hot lab where iodinations were performed was checked for air flow by a certification contractor on September 9, 1992 and an inadequate face velocity, stated by the licensee, of about 75 linear feet per minute (lfm) was found. On September 30, 1992 a new motor was delivered and the maintenance staff installed this motor to the fume hood shortly after that date. On November 12, 1992, the fume hood was retested by the contractor, but the air flow was still less than 100 lfm.

The finding that thyroid monitoring was not performed on all persons involved with iodination procedures within two days after use and that routine monthly thyroid measurements were not performed on all individuals routinely working with greater than 1 millicurie of I-125 is an apparent violation of License Condition No. 14 which requires that thyroid counts be taken on all persons involved with iodination procedures within two days and routine monthly thyroid measurements be conducted for all individuals routinely working with greater than one millicurie of I-125.

The finding that the licensee performed iodinations in a fume hood that was not certified as having a flow rate of at least 100 lfm is an apparent violation of License Condition No. 14 which requires that all iodinations be performed in validated hoods with an appropriate face velocity.

9. Effluent Control

The licensee has an air pump hooked up to two filter samplers, each placed on the floor of the fume hood on either side of the mini-hood. These samplers are at least one foot below the exhaust of the mini-hood. The air in the mini-hood goes through a charcoal trap and exhausts into the main fume hood exhaust duct and out to the atmosphere. During an iodination procedure, the I-125 released would not be sampled by the two charcoal filters on the floor of the hood because the air exhausted from the mini-hood is higher than the samplers. Thus, this is an inadequate survey to assure that air released to unrestricted areas complies with requirements for airborne radioactivity. Also, the RSO stated that quarterly effluent release monitoring has not been done since July.

While no effluent release measurements were made, the technique planned for measuring airborne radioactivity in the effluent from the iodination hood was inadequate and is a safety concern.

The finding that quarterly effluent release measurements were not performed is an apparent violation of License Condition No. 14 which requires that the licensee perform quarterly effluent release measurements.

10. Waste Disposal

The licensee collects liquid waste by pouring it into buckets filled with absorbent material which are then brought to the waste storage room for final storage. Two large waste buckets were located in the hot lab and various other unlabeled buckets of radioactive waste were found throughout the facility as explained in Section 5. The licensee maintains an aqueous liquid waste log where material placed in the two large buckets in the waste room is to be entered. The licensee collects solid waste in small plastic yellow bags that are not labeled. These bags are brought to the hot lab where they are compacted in a Kenmore trash compactor and then put into the waste storage room. The licensee keeps a log where radioactive material disposed in solid waste is to be entered. The inspectors reviewed the liquid and solid waste logs and determined that not all of the waste was entered into the logs. In September and October of 1992 8 millicuries of I-125 were used and only 1.025 millicuries was accounted for in both the solid and liquid waste records. Thus, about 7 millicuries of I-125 was not accounted for in the waste records. The finding that not all radioactive material is accounted for in waste disposal records is an apparent violation of 10 CFR 30.51.

11. Posting of Notices

The NRC Form-3 was found posted in the hot lab and in one other lab. Other postings, such as Parts 19 and 20, and a copy of the license were not found, nor did this licensee post the July 29, 1992 Notice of Violation (NOV) which involved radiological working conditions. Licensee employees working with licensed material in a number of areas other than the hot lab and some employees working with radioactive material never enter the hot lab.

The finding that the NRC Form-3 was not posted in a sufficient number of places, that Parts 19 and 20, a copy of the license and the July 1992 NOV were not posted is an apparent violation of 10 CFR 19.11.

12. Exit Interview

The inspection findings were discussed with the individuals indicated in Section 1.

Based on the findings of the inspection, a Confirmatory Action Letter (CAL) dated November 12, 1992 was issued. Subsequent to this CAL, an amendment to the CAL was issued on November 19, 1992. Additional information was obtained from the licensee by facsimile on November 12, 16, 17, and 20, 1992.

Attachment 1

Creative Biomolecules, Inc.

	Incoming Package Receipts		RAM logged in the RAM Sign Out Sheet
H-3	07/28/92 (5 mCi) 09/14/92 (5 mCi)	H-3	09/25/92 (5mCi) 09/14/92 (5 mCi)
I-125	08/28/92 (1.5 μCi) 09/01/92 (10 μCi) 09/10/92 (5 mCi) 09/22/92 (50 μCi) 10/10/92 (2 μCi)	I-125	09/10/92 (5 mCi) 10/14/92 (5 mCi) 09/23/92 (50 μCi)
S-35	08/20/92 (750 μCi) 09/02/92 (750 μCi) 09/21/92 (5 mCi) 09/23/92 (750 μCi)	S-35	09/22/92 (5 mCi) 08/17/92 (750 μCi) 09/02/92 (750 μCi) 09/23/92 (750 μCi) 10/16/92 (750 μCi) 11/04/92 (750 μCi)
P-32	07/31/92 (1.5 mCi) 08/20/92 (1.5 mCi) 08/28/92 (1.5 mCi)	P-32	07/02/92 (1.5 mCi) 08/20/92 (1.5 mCi) 08/28/92 (1.5 mCi) 09/25/92 (1.5 mCi) 10/15/92 (.5 mCi) 10/29/92 (1.5 mCi)

SYNOPSIS

On December 23, 1992, the Office of Investigations, U.S. Nuclear Regulatory Commission (NRC) initiated an investigation to determine if NRC required wipe test records had been falsified at Creative BioMolecules, Inc. (CBM), a materials licensee, Hopkinton, Massachusetts. This investigation was also to determine if the corporation radiation safety officer (RSO) had provided false or misleading oral information regarding a fume hood to NRC technical personnel during an inspection of CBM on November 10-11, 1992. During the investigation, a third matter was identified that suggested that the RSO may have furnished false or misleading information in a written document, dated September 21, 1992, to the NRC.

On the basis of the evidence developed during the investigation and lacking direct testimony from the RSO, the following allegations were substantiated:

1. The RSO intentionally and deliberately directed an employee to falsify NRC required wipe test records.
2. The RSO made false or misleading statements to an NRC inspector.
3. The RSO intentionally and deliberately provided false or misleading information to the NRC in a letter, dated September 21, 1992, in response to a notice of violation.