U.S. NUCLEAR REGULATORY COMMISSION

REGION III

Reports No. 030-14802/90001(DRSS); 030-14801/90001(DRSS)

Dockets No. 030-14802; 030-14801

Licenses No. 21-18294-01 Category E Priority 3

21-18294-02G Category E Priority 3

Licensee: Leeco Diagnostics, Inc.
24475 W. 10 Mile Road
Southfield, MI 48034

Inspection Conducted: September 26, 1990

Inspector: _____ 10-22-90
J. L. Lynch Date
Radiation Specialist

Reviewed By: _____ 10-22-90
R. J. Caniano, Chief Date
Nuclear Materials Safety
Section 2

Approved By: _____ 10-26-90
J. A. Grobe, Chief Date
Nuclear Materials Safety
Branch

Inspection Summary

Inspection on September 26, 1990 (Reports No. 030-14802/90001(DRSS) and No. 030-14801/90001(DRSS))
Areas Inspected: This was an unannounced special inspection conducted in response to an allegation received by the NRC on July 2, 1990, concerning disposal of radioactive waste into the sewerage system (RIII-90-A-0071). The inspection also included a review of the following program areas: organization; materials, facilities and equipment; training; surveys; security; personnel radiation protection; waste disposal; distribution; posting and labeling; and notifications and reports.
Results: The allegation was not substantiated, however, two apparent violations of NRC requirements were identified (both against License No. 21-18294-01): (1) failure by an individual to wear a TLD ring badge, License Condition No. 14 (Section 11); and (2) performance of iodinations in hoods not equipped with activated charcoal filters, License Condition No. 14 (Section 7).

DETAILS

1. Persons Contacted

*Rod Raynovich, Chief Executive Officer
*Ron Steckel, Vice President for Operations
*Dante Capaldi, Ph.D., Radiation Safety Officer
Steve Scheibel, Chemist
Morris Dubs, Chemist

*Attended exit interview on September 26, 1990.

2. Purpose of Special Inspection

This inspection was initiated in response to an allegation of improper radioactive waste disposal received by the NRC on July 2, 1990. The inspection also included a review of the licensee's research, manufacturing and distribution programs under both licenses.

3. Scope of Program

The 21-18294-01 license authorizes the licensee to perform research and development and to manufacture in vitro RIA kits containing iodine-125 and iron-59. The license also authorizes the use of calibration sources and limited laboratory research involving other isotopes.

Currently, only iodine-125 is used for research and development and in RIA kit manufacturing. An iodine-129 calibration source is used in the bioassay program.

The 21-18294-02G license authorizes distribution of in vitro RIA kits containing iodine-125 and iron-59 to general licensees. Only iodine-125 kits are currently distributed.

The RIA kits (14 types) each contain one or two bottles of iodine-125 tracer solution. Each bottle contains less than 10 microcuries of isotope. Convenience kits may contain additional bottles of tracer.

4. Organization

Rod Raynovich is the CEO, Ron Steckel is the Vice President for Operations with responsibility for licensed materials. Dante Capaldi, Ph.D. is the Director of QA and Regulatory Affairs and is the Radiation Safety Officer (RSO). Dr. Capaldi reports directly to Mr. Steckel. All licensed operations are carried out under Dr. Capaldi's supervision.

The licensee employs James Tomlinson of Medical Physics Consultants, Inc. as a consultant to the program.

5. Inspection History

The last inspection of License No. 21-18294-01 was performed on June 28, 1989. No violations were identified during that inspection.

The 21-18294-01 and 21-18294-02G licenses were inspected on April 25, 1984. Again, no violations were identified.

6. Allegation (RIII-90-A-0071)

An allegation of improper disposal of iodine-125 to the sewerage system was received by the NRC on July 2, 1990. The specific allegation and inspection findings are noted below:

Allegation: On September 27, 1989, Leeco disposed of 1600 microcuries of iodine-125 via the sanitary sewer. According to the alleger, this disposal was in excess of the daily limit of 1360 microcuries set forth in 10 CFR Part 20, by approximately 240 microcuries.

NRC Findings: The licensee routinely disposes of radioactive material solutions to the sewerage system as allowed by 10 CFR 20.303. Disposals are recorded as required by 10 CFR 20.401. 10 CFR 20.303 requires, in part, that daily disposals of iodine-125 labeled solutions to the sewerage system be of concentrations less than 4×10^{-5} microcuries per milliliter. The same regulation also limits the monthly disposal concentrations and the annual total disposal.

The licensee's consultant performed an evaluation on May 18, 1990, to determine the maximum amount of iodine-125 which could be disposed of to the sewerage system while remaining in compliance with 10 CFR 20.303 concentration and total disposal limits. The evaluation (Attachment 1) used the average water release for the 10 Mile Road facility from July 1989 to May 1990. The evaluation, which appears to be adequately performed, limits the daily discharge of iodine-125 to the sewerage system to 1360 microcuries. (Note - This is the same limit referenced by the alleger).

Sewerage disposal records were reviewed from May 1989 to the day of the inspection. According to the RSO, no sewerage disposals occurred between May 1989 and September 27, 1989. The iodination laboratory was moved to the 10 Mile Road facility during that time period.

The sewerage disposal records for September 27, 1989, identify that 680 microcuries of iodine-125 labeled tracer chemicals were disposed of. This quantity is significantly less than the 1600 microcuries that was alleged to have been disposed on that date. The RSO and technical staff stated, that to the best of their knowledge, no additional sewerage disposals, to those recorded, were performed on September 27, 1989.

A review of records since that date indicates that sewerage disposals have been performed on an irregular frequency, increasing to an almost daily frequency in September 1990. The records indicate that all disposals have involved less than 1360 microcuries of iodine-125 per day. The records also show compliance with the monthly and annual disposal limitations.

The allegation was not substantiated, and no violations or NRC requirements were identified.

7. Materials, Facilities and Instruments

The licensee moved most of its operations to the 10 Mile Road facility from the Evergreen Road site in May 1989. The iodination laboratory was moved 1-2 months later. The Evergreen facility closeout was submitted to the NRC in October 1989.

Radioactive material was never used at the 20712 Robinson, Farmington Hills address which was deleted from the license in May 1990.

Iodine-125 is received in millicurie quantities on a biweekly standing order. The material is tagged to tracer chemicals via iodinations which are performed in fume hoods.

The RSO stated that the current iodine-125 inventory is less than the 200 millicurie possession limit. He is working on a system to closely monitor the amount of isotopes on hand in research, manufacturing, product storage and waste areas. An amendment request has been made to increase the possession limit to 1 curie. This increase allows for business increases and allows for onsite storage of waste in view of the Midwest Waste Compact difficulties which have resulted in suspension of commercial radioactive waste disposal for Michigan licensees.

An Eberline MS-3 scaler with a low energy gamma probe (LEG-1) is used to perform thyroid counts on employees. Two Bicron 2000 pancake GM instruments are used in the radiation safety program. The instruments are calibrated annually, as required, by the licensee's consultant.

During the inspection, it was identified that the licensee removed the activated charcoal filters from the iodination fume hoods in approximately July 1989. The licensee's March 26, 1986 letter to the NRC referenced in License Condition No. 14 requires, however, that all iodinations take place in large flow hoods with continuous flow indicators and activated charcoal filters.

The licensee evaluated the facility air effluent in June 1989 and concluded that charcoal filters were not necessary as the radioactive effluent from the roof exhaust (without charcoal filters) was well below

NRC concentration limits. An amendment to the license was not requested, however, and therefore an NRC evaluation of the change was not performed. The performance of iodinations using iodine-125 in hoods not equipped with activated charcoal filters constitutes an apparent violation of License Condition No. 14. The RSO was not aware that an amendment was needed for this type of equipment change.

The licensee's evaluation of the roof exhaust concentrations appears to be adequate suggesting that the quantities of iodine-125 released from the facility are not significant. The RSO stated that he would submit the effluent data to the NRC for a full review when responding to this apparent violation.

One apparent violation of NRC requirements was identified.

8. Training

The licensee conducts a semiannual training session for all Leeco employees. In addition, specific position training is given to those individuals who handle or work near radioactive materials. The RSO stated that improvements presently being made to the program will provide him with periodic updates of employees who are due for required training.

No violations of NRC requirements were identified.

9. Surveys

A review of survey records revealed no significant radiation level or contamination problems. Surveys are documented as required by 10 CFR 20.401.

Survey instruments are used continuously during iodinations to alarm chemists of increased radiation levels.

Biweekly radiation surveys and wipe tests are performed of the entire facility by a technician. Results are sent to the RSO for evaluation. Contaminated areas are cleaned and resurveyed in a prompt manner.

All incoming packages of radioactive material are surveyed and wipe tested. Packages leaving the facility, including products, are surveyed prior to shipment as required by the license.

No violations of NRC requirements were identified.

10. Security

Research and production laboratories, product storage areas and waste areas appear to be secured as required by 10 CFR 20.207.

No violations of NRC requirements were identified.

11. Personnel Radiation Protection-External

Leeco monitors personnel radiation exposure with film badges and TLD ring badges supplied by Siemens. Badges are exchanged on a monthly frequency and reports are promptly reviewed by the RSO.

The maximum annual whole-body exposure in 1989 and 1990 was 490 millirem. The maximum extremity exposure for the same period was 260 millirem.

During the inspection, an individual was observed performing an iodination using millicurie quantities of iodine-125. While the individual was wearing a film badge, he was not wearing a TLD ring. When confronted with the absence of the TLD, the individual stated that he forgot to wear it for the procedure, but he normally does wear a TLD during iodinations. The individual was wearing one pair of disposable gloves and no eye protection during the iodination.

License Condition No. 14 (August 31, 1978 application) requires that film badges and TLD ring badges be worn at all times when working with radioactive materials. The failure to wear a TLD ring badge when handling millicurie quantities of iodine-125 constitutes an apparent violation of License Condition No. 14.

The RSO stated that he will review the use of TLD rings in the facility to determine why ring badge exposures are generally less than whole-body exposures. The RSO also indicated that he would evaluate the procedure which allows the performance of iodinations by an individual while wearing only one pair of disposable gloves and no eye protection.

One apparent violation of NRC requirements was identified.

12. Personnel Radiation Protection-Internal

Bioassays are performed quarterly on all personnel handling iodine-125. Thyroids are counted on the Eberline system detailed in Section 7. None of the individuals had uptakes which resulted in doses greater than allowable annual doses or 10 CFR Part 20 concentration limits.

No violations of NRC requirements were identified.

13. Waste Disposal

As described in Section 6, liquid radioactive waste appears to be disposed of in accordance with 10 CFR 20.303. The liquid waste is soluble, meets daily, monthly and annual concentration limits.

Air effluent evaluations have been performed by the licensee. The radioactive effluent from the roof exhaust appears to be within 10 CFR 20.106 concentration limits.

Commercial disposal of radioactive waste is suspended due to the current problems which the Midwest Waste Compact is experiencing. The last shipment occurred in September 1990. The licensee plans to expand its decay-in-storage program to alleviate problems generated by the suspension.

No violations of NRC requirements were identified.

14. Distribution

The licensee distributes RIA in vitro kits to General Licensees under the authorization of the 21-18294-02G license and in accordance with 10 CFR 32.71.

Several thousand iodine-125 RIA kits are distributed monthly. Customers' registration certificates or specific licenses are maintained on file at Leeco and are reviewed prior to shipment.

Product labels and package inserts for several types of RIA kits were reviewed for conformance with 10 CFR 32.71 requirements.

No violations of NRC requirements were identified.

15. Posting and Labeling

A walkthrough inspection of the Leeco facility identified compliance with NRC requirements. Restricted areas were properly posted as required by 10 CFR 20.203. Packages, drums and other containers were also labeled as required.

Form NRC-3 notices and documents describing the location of 10 CFR Parts 19 and 20 were posted in the facility.

No violations of NRC requirements were identified.

16. Notifications and Reports

No exposures in excess of 10 CFR Part 20 limits were identified. No thefts, losses of licensed material or significant incidents were reported during the inspection period.

No violations of NRC requirements were identified.

17. Independent Measurements

Radiation measurements were performed with the licensee's Bicron 2000 pancake GM. Radiation levels in restricted areas appeared acceptable and were in good agreement with previously performed licensee surveys.

No violations of NRC requirements were identified.

18. Exit Interview

An exit interview was conducted at the Leeco facility on September 26, 1990. Licensee attendance at this meeting is detailed in Section 1 of this report. Licensee representatives were informed of NRC inspection findings, apparent violations and NRC enforcement policies. No written material was left with the licensee. The licensee indicated that no proprietary information is included in this report.

Attachment 1: Leeco Liquid Disposal Calculations

ATTACHMENT 1

Medical Physics Consultants, Inc.

LIQUID RADIOACTIVE WASTE DISPOSAL

Leeco Diagnostics, Inc. 18 May 1990 Iodine-125

* Water Usage (08 July 1989 - 09 May 1990): 3.66 E5 c.ft.

  ((3.66 E5 c.ft)/(305 days))(28.32 l/c.ft.) = 3.40 E4 l/day

* Average Daily Water Release = 3.4 E4 l
  = 3.4 E7 ml

* Max. Permissible Conc. (MPC) I-125 in water = 4.0 E-5 uCi/ml (10 CFR 20 303 (b)(1))

* Daily Disposal = (4.0 E-5 uCi/ml)(3.4 E7 ml) = 1.36 E3 uCi

1360 uCi of I-125 may be disposed in sanitary sewerage DAILY.

The efficiency factor for the gamma counter is approximately 1.25 dpm/cpm.

To determine the activity of the sample to be disposed of:

1. Count a one (1) ml sample of the solution for one (1) minute (cpm).
2. Subtract the background (cpm).
3. Multiply by the volume of solution (in ml).
4. Multiply by efficiency factor (1.25 dpm/cpm).
5. Divide by 2.2 E6 (2,200,000).

$$\text{Activity (uCi)} = \frac{(\text{count (cpm)} - \text{Bkg (cpm)})}{1\ \text{ml}}(\text{solution (ml)})\left(\frac{1.25\ \text{dpm}}{1.0\ \text{cpm}}\right)\left(\frac{1\ \text{uCi}}{2.2\ \text{E6 dpm}}\right)$$

James A. Tomlinson

James A. Tomlinson, M.S.
Medical Physicist