U.S. NUCLEAR REGULATORY COMMISSION

REGION III

Reports No. 030-04214/83-01(DRMS); 033-04215/83-01(DRMS)

Docket Nos. 030-04214; 030-04215

License No. 12-11184-01 Category E Priority III

License No. 12-11184-02G Category E Priority III

Licensee: Kay-Ray, Incorporated
516 West Campus Drive
Arlington Heights, IL 60004

Inspection At: 506 and 516 West Campus Drive
Arlington Heights, IL

Inspection Conducted: April 12 and 13, 1983

Inspector: J. L. Lynch 6-3-83
Radiation Specialist

Reviewed By: D. G. Wiedeman, Chief for 6-9-83
Materials Radiation
Protection Section 1

Approved By: J. R. Miller, Chief 6/9/83
Materials and Safeguards Branch

Inspection Summary

Inspection on April 12 and 13, 1983 (Reports No. 030-04214/83-01(DRMS); 030-04215/83-01(DRMS))
Areas Inspected: Announced, routine inspection of activities conducted under Licenses No. 12-11184-01 and No. 12-11184-02G including reports of apparent overexposures; apparent overexposure analysis, organization; training and instruction to workers; radiological protection procedures; material; facilities; equipment; inventory; receipt and transfer of material; security of material; shipping incidents; personnel monitoring; surveys; leak tests; waste disposal; notifications and reports; posting; and confirmatory measurements. The inspection involved 16 inspector-hours onsite by one NRC inspector.
Results: Of the areas inspected, four items of noncompliance were identified against License No. 12-11184-01: (1) overexposure of Field Service Engineer (Sections 4 and 5); (2) material outside of designated area (Section 10); (3) survey meters not calibrated as required (Section 11); (4) inventory not performed (Section 12).

## DETAILS

1. Persons Contacted

*Leslie R. Axelrod - Vice President - Research and Engineering
*Robert J. Baker - Vice President - Production
*Alan J. Peterson - Radiation Safety Officer (RSO)
Donald R. Freeman - National Manager, Field Engineering Services
Guadalupe Diaz - Source Loader
Anthony Rath - Source Loader

*Attended exit interview on April 13, 1983.

2. Purpose of Inspection

This announced routine inspection was conducted at the licensee's Arlington Heights, Illinois facility on April 12 and 13, 1983. The inspection included a review of the radiation safety program, a specific evaluation of two possible overexposures and reports of leaking sealed sources.

Kay-Ray, Inc. installs sealed sources containing byproduct material in several types of gauging devices which are distributed to general and specific licensees. Gauges are also received at the Kay-Ray facility for repair and maintenance.

3. Inspection History

A. Routine Safety Inspection: February 24-25, 1982.
Results: No items of noncompliance.
*Comments: Apparent extremity overexposure.

B. Special Inspection: February 9, 12 and March 20, 1981.
Results: One item of noncompliance.
*Comments: Apparent overexposure.

C. Special Inspection: May 19, 1980.
Results: Two items of noncompliance.
Comments: Missing gauge with sealed sources.

D. Investigation: December 27-28, 1978 and January 5, 1979.
Results: No items of noncompliance.
*Comments: Apparent overexposure.

E. Inspection: August 15-16, 1978.
Results: One item of noncompliance.

F. Inspection: September 2, 1977.
Results: Three items of noncompliance.

G. Investigation: April 4-5, 1977.
Results: Four items of noncompliance.
*Comments: Apparent overexposure.

H. Inspection: August 18, 1975.
Results: One item of noncompliance.

I. Inspection: July 18, 1973.
Results: Two items of noncompliance.

J. Inspection: July 20, 1972.
Results: Seven items of noncompliance.

*The four previous apparent overexposures reported since 1977 all were attributed to exposures to the dosimetry device only and not to the individuals involved.

4. Reports of Apparent Overexposures

The licensee reported to the Region III office on February 1, 1983, an apparent beta radiation overexposure of 15.240 rem to a Kay-Ray employee (see Attachment A). The employee, a Field Service Engineer, is identified in Attachment E. The exposure was received on the October 1982 film badge and reported to Kay-Ray on January 4, 1983.

On March 8, 1983, Kay-Ray again reported to the NRC an apparent overexposure (see Attachment B). The December 1982 film badge results indicated that the same Field Service Engineer (herein referred to as "the subject") also exceeded the limits for whole body gamma exposure during the fourth quarter of 1982. The results received by Kay-Ray from the dosimetry service on February 9, 1983, indicated an overexposure of 1.260 rem.

The subject wore the October film badge from October 25 to December 9, 1982. He was issued the badge approximately 10 days late and returned the badge 25 days late due to out of town travel. The November film badge was worn by the subject on December 9 only, with minimal exposure reported. The film badge issued in December was in his possession from December 10 to January 24, 1983. This badge was returned late by about two weeks.

The subject was also issued TLD ring badges monthly for extremity exposure detection. The TLD ring issued in October 1982 was lost by the subject and thus not available for processing.

The November TLD ring, like the monthly film badge, was worn only one day, December 9, with minimal exposure recorded. The December TLD ring was in the subject's possession from December 10 to January 21, 1983. Approximately one week after receiving his January film badge and TLD ring, the subject terminated employment with Kay-Ray. These badges have not yet been returned to Kay-Ray even after repeated requests to do so.

During the October film badge period, the subject installed and performed wipe tests on source heads containing either cesium-137 or radium-226. The subject had no knowledge of working with or near any sources of beta radiation.

Mr. Alan Peterson, Radiation Safety Officer, conducted an investigation to determine if the beta exposure could be explained. The details of this investigation are included in the Apparent Overexposure Analysis section of this report.

No violations were identified.

5. Apparent Overexposure Analysis

After receiving the dosimetry reports indicating the possible overexposures, Kay-Ray instituted an investigation into events of that time period. Attempts were made to contact the subject who had moved out of state upon termination of employment with Kay-Ray. At this time, the subject would not communicate with Kay-Ray other than one brief telephone conversation. A registered letter was sent by Kay-Ray to the subject on February 22, 1983, requesting answers to specific questions about the overexposure incidents (see Attachment C). The letter was received but not answered. A number of telephone calls also went unanswered until April 19, 1983, when the subject had a telephone conversation with Mr. Peterson. On April 20, the Region III inspector telephoned the subject at his place of employment.

During this conversation the subject stated that the badges were not intentionally exposed by himself or others. He also repeated that he was not aware of working with or in the vicinity of any beta radiation gauges while the October 1982 badge was worn. The subject believed that his badges were not dropped or set on any gauge or radiation source. Concerning the gamma exposure, the subject said that his October badge was in his tool box in close proximity to a 10 microcurie cesium-137 check source for a period of four days. As calculated by Kay-Ray, this action may have exposed the film badge to approximately 115 millirem gamma exposure but would in itself not account for the overexposure.

The subject also related to the RSO that during the period of the December film badge, he removed the dust cover from a gauge and then noticed that the source shutter was in the open position. The gauge contained a 0.5 curie cesium-137 source. It may be possible that the subject received a significant exposure from this incident and it may account for a portion of the 660 mrem received by the badge during that period.

The December TLD ring badge worn by the subject recorded an extremity exposure of 2.490 rem gamma radiation. This figure is consistent with the whole body gamma exposure of 0.660 rem for the badging period. The subject was informed that if his October TLD ring badge is found in the future he should return it for evaluation and comparison with that month's film badge.

Immediately after receiving the film badge report with the beta overexposure, Kay-Ray requested that the dosimetry service do a reevaluation of the film. The service, R. S. Landauer Co. performed another evaluation of the film with identical findings. In a telephone conversation between Ms. J. McDonald of R. S. Landauer Co. and the Region III inspector, a detailed explanation of the findings was given. Ms. McDonald stated that the exposure was unlike a gamma or x-ray exposure (including low energy x-rays). The film emulsion density changes indicated a beta source, probably small in size and at close range. The badge was not damaged in any way or processed incorrectly.

As part of the Kay-Ray investigation into the apparent beta overexposure, the RSO called each of the facilities in which the subject worked while wearing the October film badge. None of the 14 facilities contacted admitted having any beta radiation gauges or sources.

A complete report of the Kay-Ray investigation is included in Attachment D to this report.

One area of difficulty in analyzing the apparent overexposure lies in the fact that film badges at Kay-Ray are not exchanged monthly as designed. As an example, the subject's October 1982 film badge was in his possession for one and one half months. If the badge had been turned in for processing within the monthly wearing period, results would have been available in early December rather than in January. If a high exposure was evident, precautions could have been taken immediately and one overexposure may have been avoided. The shorter wearing period would also help pinpoint the time and location of a particular exposure.

The method used to exchange film badges at Kay-Ray sometimes inhibits prompt assessment of possible exposures. Badges are exchanged by field service personnel when they return to the Kay-Ray facility in Arlington Heights. If their schedule keeps them out beyond the scheduled change date, the badges in possession are worn until they return to the office.

In conclusion, it is conceivable that the subject may have actually been exposed to the reported gamma doses if basic safety measures were not observed. Incidents such as those related by the subject also may have contributed significantly to the overexposure.

The beta overexposure is not as easily explained. A beta radiation source capable of producing the overexposure has not yet been found. The dosimetry service has ruled out other types of radiation exposures and processing errors. Thus, we conclude that the badge may have been exposed to beta radiation but the possible source of that exposure is unknown. The 15.240 rem beta radiation exposure is considered unexplained. The thorough investigation by Kay-Ray, Inc. yielded no probable cause of the exposure and therefore it will not be considered an item of noncompliance against License No. 12-11184-01.

The apparent exposure to an individual of 1.260 rem gamma radiation appears to be valid or at least possible under the circumstances. This

occupational dose is in excess of the quarterly limit of 1.250 rem stipulated in 10 CFR 20.101(a). The licensee, operating under License No. 12-11184-01, is in noncompliance with 10 CFR 20.101(a).

One violation was identified.

6. Organization

Jack G. Crump - President
John Crump - Vice President - Sales and Marketing
Leslie R. Axelrod - Vice President - Research and Engineering
Robert J. Baker - Vice President - Production
Alan J. Peterson - Radiation Safety Officer
Donald R. Freeman - National Manager - Field Engineering Services

No violations were identified.

7. Training and Instruction to Workers

All personnel are required to read a paper entitled "Radiation at Kay-Ray" and sign a statement indicating they have done so. General production workers also are instructed in basic radiation safety.

Field Engineering Services (F.E.S.) personnel are required to attend Kay-Ray's five day Radiation Safety School.

Source loaders receive all of the above training in addition to specialized training in source loading procedures.

10 CFR 19.12 requirements governing instruction to workers are satisfied.

Several employees, including the overexposure subject were interviewed in regard to the licensee's training program. All employees appeared knowledgeable of radiation safety procedures and all were satisfied with the Kay-Ray training program.

No violations were identified.

8. Radiological Protection Procedures

The licensee's basic radiation safety program is described in the Kay-Ray, Inc. Radiation Safety Manual. The manual was last revised in June 1980. The licensee is committed to the requirements in this manual in addition to those specified in license conditions, other licensee referenced documents, and NRC regulations.

No violations were identified.

9. Material

License No. 12-11184-01 authorizes use and/or possession of byproduct material for research, development, production, testing, distribution,

demonstration and servicing of gauging equipment. Authorization is also given to perform leak tests on sources and devices, to store material prior to disposal and to calibrate radiation survey and measuring instruments.

License No. 12-11184-02G authorizes distribution of devices containing byproduct material to generally licensed persons.

A review of procedures and records indicates material is used, possessed and distributed in accordance with the conditions of each license.

No violations were identified.

10. Facilities

The Kay-Ray production facilities and Field Engineering Services (F.E.S.) are located at 506 West Campus Drive, Arlington Heights, IL. The production facility includes a source storage room, with two 5 foot deep by 3 foot diameter concrete pits. These pits allow greater shielding and distance from high strength and high energy sources. The inner walls of the storage room are lined with bricks and sheet lead to reduce radiation levels outside the room.

Next to the storage room is the source loading area. Here sources are transferred between containers and loaded into source heads. A vacuum system is employed in the source transfer process. Sources are loaded into gauge source heads with long handled tools. The individuals performing this task stand behind a thick lead body shield with leaded glass for optical protection while viewing the operation.

The source loading area and the entrance to the storage room are enclosed by chainlink fencing with a lockable door to control access. This door is kept locked at all times except when authorized persons enter or leave the area. The fence is posted with "Caution, Radiation Area" signs.

A manual roller conveyor runs from the storage room through the source loading and monitoring areas to the loading dock in the attached garage. Source heads may be moved on the conveyor rather than being carried by hand from one operation to another.

In the assembly, packaging and shipping areas, empty and loaded source heads sit on the floor ready for the next operational phase.

Procedures stated in a license referenced letter to the NRC dated June 24, 1980, require certain precautions be taken with loaded source heads.

The letter states that "all loaded source heads not being worked on will be stored in one or two barricaded or roped-off areas." Also, "all designated storage areas will bear the applicable radiation warning signs."

During the inspection, it was found that approximately 25 loaded source heads were located in areas that were not barricaded or roped-off with appropriate radiation warning signs. These devices were located in the holding and shipping areas of the facility. It was also noted in one instance that a Kay-Ray employee was performing maintenance on an empty source housing while kneeling near several loaded source heads. The radiation levels from the loaded source heads were approximately 2.0 mR/hr at the place the employee was working.

The failure to keep loaded source heads in a posted storage area that is barricaded or roped-off constitutes noncompliance with License No. 12-11184-01, License Condition No. 16.

The Research and Engineering facilities are located next door at 516 West Campus Drive. Only small amounts of byproduct material are possessed for research, development and testing.

One violation was identified.

11. Equipment

The licensee uses a variety of survey instruments and area monitors in the radiation safety program.

The source loading area is continuously monitored with an ionization chamber. The output is displayed and is recorded on a paper tape chart recorder. The recorded paper tapes are kept in a logbook in chronological order and are examined daily for general trends in radiation levels.

The Kay-Ray, Inc. Radiation Safety Manual requires that the survey meter used for weekly surveys shall be calibrated every three months. Also, the application dated December 29, 1977 and referenced in License No. 12-11184-01 requires that all meters shall be checked by the RSO every six months on the calibration test range.

The survey meters used in the Kay-Ray facility are calibrated semiannually by Health Physics Associates, Inc. None of the in-house survey meters are calibrated on a three month basis or checked on the test range. Six (6) survey meters used at job sites by Field Engineering Services personnel are not calibrated routinely but are supposed to be checked semiannually on the test range by the individuals to whom the meters are assigned. Records are not maintained of these checks nor does the department manager ensure that the checks are performed.

The licensee failed to calibrate the survey meters used for weekly surveys on a three month basis and failed to perform and record results of test range calibration checks on all survey meters.

This constitutes noncompliance with License No. 12-11184-01, License Condition No. 16.

One violation was identified.

12. Inventory

The Kay-Ray, Inc. Radiation Safety Manual states that two types of inventories of sealed sources will be performed. The first is a monthly cycle count in which source capsules in stock are compared to the perpetual inventory. This is performed at the end of every month and any discrepancies are investigated immediately.

The other inventory required is a daily curiage inventory. It is designed to keep track of all sources in the Kay-Ray facility, including those returned for repair or disposal. In the past, the inventory was being performed with daily updates of the total number of curies in the facility. In April 1982, it became obvious that the curie totals were inaccurate. The inventory curiage totals were much smaller than the actual number of curies of byproduct material at Kay-Ray. The inventory was discontinued at this time and has not been reestablished to date. When the inventory was being performed, cross checks with the monthly cycle count were not made. This sort of check may have indicated the source of inaccuracies in the daily inventory. The failure to perform a daily curiage inventory constitutes noncompliance with License No. 12-11184-01, License Condition No. 16.

The current inventory (as of 3/31/83) shows the following quantities of material in sealed sources at the Kay-Ray facility.

| | Storage (Ci) | In Process (Ci) | Returns (Ci) | Total (Ci) |
|---|---|---|---|---|
| cesium-137 | 97.731 | 19.810 | 53.045 | 170.586 |
| americium-241 | 2.800 | 0.500 | 0.500 | 3.800 |
| cobalt-60 | 0.050 | -0- | -0- | 0.050 |
| californium-252 | -0- | -0- | -0- | -0- |

Quantities of byproduct material possessed are within the limits as specified in the licenses.

One violation was identified.

13. Receipt and Transfer of Material

Kay-Ray receives special form packages containing new sealed sources from suppliers and used sources from customers. Records of receipt are maintained for all incoming packages. Radiation surveys are performed on each package received but only those levels in excess of the limits in 10 CFR 20.205 and surveys of packages containing more than 20 curies of material are recorded.

After receipt, the sources are transferred from the shipping container to a storage container. A Kay-Ray identification number is given to each source capsule and entered into a logbook with the manufacturer's source number and leak test information. Identification tags remain with each source until that source is shipped from Kay-Ray.

After assembly, the loaded source heads are packaged for shipment to customers. The transport index is measured and the applicable labeling is affixed to the package. During the inspection, approximately 20 transport indexes were verified by the inspector.

Packages are moved to the loading dock in the garage for truck transport. Kay-Ray prepares the bill of lading and gives one copy to the truck driver and sends another copy to the customer.

Gauging devices with sealed sources are transferred to specific licensees under the authorization of License No. 12-11184-01 and to general licensees under License No. 12-11184-02G.

A verification to ensure that a customer is licensed to receive the byproduct material is performed prior to each shipment.

No violations were identified.

14. Security of Material

All licensed material is secured against unauthorized removal. The facility is constantly supervised during working hours and securely locked at other times. The buildings have electronic security systems designed to alert a security agency and the police if unauthorized entry is attempted.

No theft or loss of byproduct material has occurred since the last inspection.

No violations were identified.

15. Shipping Incidents

No shipping incidents have occurred since the previous inspection.

A sampling of packages awaiting shipment were inspected for proper packaging and labeling. All packages appeared to be in compliance with applicable regulations and license conditions.

No violations were identified.

16. Personnel Monitoring

Evaluation of personnel radiation exposures are made with film badges and TLD's supplied by R. S. Landauer, Jr. Co., Inc. and with pocket dosimeters supplied by Dosimeter Corporation of America.

Personnel monitoring devices are issued to personnel in accordance with 10 CFR 20.202.

Individuals who perform source loading wear two film badges (one processed weekly, the other monthly), a pocket dosimeter, a TLD ring badge, and a TLD badge worn on the glasses, all processed weekly. Other employees wear a monthly film badge and in some cases a monthly TLD ring badge.

Pocket dosimeters are read and recharged on a weekly basis. Exposures are recorded in a logbook. A sampling of these results were compared to film badge readings for the same period of time and appeared to correspond favorably.

Film badge and TLD exposure records for all personnel were reviewed for the period January 1982 through February 1983. The highest quarterly exposures recorded during this period are as follows:

film badges - *1,260 millirem whole body gamma
-*15,240 millirem whole body beta
ring TLD - 14,170 millirem extremity gamma
glasses TLD - 420 millirem w.b. lens of eyes gamma

*These two exposures are discussed in the Reports of Apparent Overexposures Section of this report.

NRC-4 forms are maintained for only two Kay-Ray employees. Both the chief source loader and an individual working in Quality Control have their previous exposure histories recorded on this form.

The extremity exposures received by source loading personnel are usually quite high. On occasion they approach the limits set in 10 CFR 20.101. It was suggested to the licensee that alternative handling methods be reviewed as to keep employee exposures as low as reasonably achievable.

No violations were identified.

17. Surveys

Radiation surveys are performed weekly of the entire Kay-Ray facility using an Eberline E-120 survey instrument. Weekly surveys satisfy the requirements as stated in the Radiation Safety Manual. Surveys include measurement of radiation levels in the production, storage, shipping, holding, laboratory and office areas. Results are recorded and copies are distributed to the Radiation Safety Officer and other management personnel.

Continuous monitoring of the source loading area is discussed in the Equipment section of this report.

Wipe tests for the detection of radioactive contamination are performed approximately monthly in production areas. If contamination is found, the area is decontaminated to background levels.

In addition to these surveys, each source head is surveyed after loading, for excessive radiation levels due to defective construction or improperly matched components.

No violations were identified.

18. Leak Tests

Leak testing of sealed sources is performed as required by the license conditions. All sources in the Kay-Ray inventory are tested for leakage semiannually unless a source is in storage. If a source is in storage for a period greater than six months, it is leak tested upon removal from storage.

All sealed sources distributed under Licenses No. 12-11184-01 and No. 12-11184-02G are accompanied by leak test information and results.

During the inspection, the NRC inspector reviewed three reports submitted by Kay-Ray involving possible leaking sealed sources. The incidents were reported to the NRC in letters dated March 31, June 28, and October 28, 1982. In each case, source heads were returned to Kay-Ray by customers for repair or disposal. The standard procedure for such returns is to perform a leak test on the source capsule before removing it from the housing. These tests indicated that contamination in excess of 0.005 microcurie was present on the source capsules. These sources are now in storage awaiting disposal along with previously identified leaking capsules.

Nineteen leaking source capsules have been found by Kay-Ray to date. Seventeen of these were manufactured by the now defunct General Radioisotope Products (GRP), and two by New England Nuclear (NEN). Most of the leaking GRP sources originated from two shipments received in 1975. New use of any source capsules contained in those shipments has been discontinued. Approximately 2,500 GRP capsules distributed by Kay-Ray are still used by customers.

It should be noted that the excessive levels of contamination were found on the source capsules and in the source cavities, not on the outer surface of the source heads.

Kay-Ray has proposed a study by an outside laboratory to determine the cause of the source capsule leakage. A laboratory was contacted, and negotiations have been initiated. It is expected that the study will begin this year.

No violations were identified.

19. Waste Disposal

Radioactive waste has not been shipped from the facility since April 1981. The licensee is planning a waste shipment later this year. Included in this shipment will be some of the sources previously found to be leaking.

No violations were identified.

20. Notifications and Reports

The licensee notified the Region III office in writing of the apparent overexposures within 30 days after receiving the film badge reports from the dosimetry service as required by 10 CFR 20.405.

The licensee considered the apparent beta overexposure to be to the skin of the whole body as was indicated in the film badge report. Therefore, an earlier notification was not required by 10 CFR 20.403 unless the exposure exceeded 30 rem.

In accordance with License Condition No. 17 of License No. 12-11184-02G, Kay-Ray reports quarterly to the NRC, all transfers of devices to general licensees under that license.

The State of Illinois Department of Nuclear Safety was notified of the two possible overexposures and the ongoing inspection.

No violations were identified.

21. Posting

Posting of radiation caution signs in the facility appeared to be adequate except as indicated in the Facilities section of this report.

An NRC-3, "Notice to Employees," Parts 19 and 20, and other documents were posted as required by 10 CFR 19.11

No violations were identified.

22. Confirmatory Measurements

Independent measurements of radiation levels in the facility were made with an Eberline Model E-520, Serial No. 9576, survey instrument. The instrument was last calibrated on March 19, 1983.

The highest levels measured were inside the storage room. There levels read from 15 mR/hr to a maximum of 50 mR/hr. On the outside walls of the storage room levels were at background (<0.05 mR/hr).

The source loading area ranged from 0.5 to 1.5 mR/hr when loading operations were not in progress.

Holding and shipping areas showed readings between 0.5 and 2.5 mR/hr except in very close proximity to loaded source heads where radiation levels were greater.

On the outside wall of the production area, readings were generally at background levels with the exception of an area outside one of the windows. The levels at the window were elevated due to loaded source

heads sitting on the conveyor just inside. Maximum levels were measured at 1.0 mR/hr, and as the source heads were moved along the conveyor, levels returned to background.

No violations were identified.

23. Exit Interview

An exit interview was held at the Kay-Ray, Inc. facility on April 13, 1983. The licensee representatives in attendance are indicated in the Persons Contacted section of this report. The apparent items of non-compliance and other recommendations were discussed as well as the NRC policy regarding possible escalated enforcement.

The inspection was concluded on May 9, 1983, subsequent to the submission of a report by the licensee regarding the validity of the possible beta radiation overexposure.