U.S. NUCLEAR REGULATORY COMMISSION

REGION III

Report No. 030-02066/90001(DRSS)

Docket No. 030-02066

EA 90-214

License No. 21-07059-01 Category G Priority III

Licensee: Stanley Levy, M.D.
10601 West Seven Mile Road
Detroit, MI 48221

Inspection At: Stanley Levy, M.D.
10601 and 10615 West Seven Mile Road
Detroit, MI 48221

Inspection Conducted: November 15-26, 1990

Inspector: Colleen C. Casey 12/7/90
Colleen C. Casey Date
Radiation Specialist

Reviewed By: Gary L. Shear for 12/7/90
Roy J. Caniano, Chief Date
Nuclear Materials Safety Section 2

Approved By: John A. Grobe 12/7/90
John A. Grobe, Chief Date
Nuclear Materials Safety Branch

Inspection Summary

Inspection on November 15-26, 1990 (Report No. 030-02066/90001(DRSS))
Areas Inspected: This routine, unannounced inspection was conducted to evaluate compliance with Commission rules, regulations and license conditions. The inspection consisted of a review of the licensee's organizational structure and staffing; management controls; personnel exposure monitoring; independent measurements; qualifications and training; materials, facilities and equipment; posting and labeling; radiopharmaceutical dose records; radiation protection procedures; package receipt/surveys; dose calibrator tests; area surveys; airborne radiation protection procedures; and sealed source inventories and leak tests.

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Results: Of the areas inspected, ten apparent violations and one area of concern were identified.

1. Apparent Violations

   a. 10 CFR 30.34(c) and License Condition No. 10 - failure to confine possession and use of byproduct material to the location authorized by the license (Section 6).

   b. 10 CFR 35.21(a) and License Condition No. 16 - failure to ensure that eating and drinking do not take place in areas where radioactive materials are used or stored (Section 7).

   c. 10 CFR 35.21(a) and License Condition No. 16 - failure to test the xenon-133 trap for saturation monthly since August 20, 1990 (Section 11).

   d. 10 CFR 35.53(c) - failure to include the time of measurement and the initials of the individual making the record on radiopharmaceutical dosage records (Section 10).

   e. 10 CFR 30.51(a) - failure to retain records showing receipt of five doses of radiopharmaceuticals (Section 9).

   f. 10 CFR 35.50(b)(2), 35.50(b)(3), 35.50(b)(4) and 35.50(c) - failure to test the dose calibrator for accuracy, linearity and geometrical variation following repairs made on July 18, 1990 (Section 8).

   g. 10 CFR 35.21(a) and License Condition No. 16 - failure to test for removable contamination in the nuclear medicine department using a series of wipe tests and failure to test for removable contamination in the radioimmunoassay laboratory for more than one year (Section 7).

   h. 10 CFR 35.50(e)(2), 35.59(g), 35.59(i) and 35.59(d) - failure of the Radiation Safety Officer to sign records of dose calibrator accuracy tests, sealed source inventories, sealed source ambient surveys and sealed source leak tests (Sections 6 and 12).

   i. 10 CFR 35.50(b)(3) and 35.50(d) - failure to test the dose calibrator for linearity from January 20, 1989 through November 15, 1990 and failure to repair or replace the dose calibrator when accuracy and constancy errors exceeded ten percent (Section 8).

   j. 10 CFR 35.21(a) and License Condition No. 16 - failure to train two radiation workers in appropriate radiation safety procedures, work rules, applicable regu ations and license conditions (Section 13).

2. Area of Concern

   10 CFR 35.21(a) and 35.21(b) - concern was expressed that the licensee, through the Radiation Safety Officer (RSO), was not adequately ensuring that radiation safety activities were being performed in accordance with

approved procedures and regulatory requirements. In addition, the licensee, through the RSO, had not adequately investigated deviations from approved radiation safety practice and implemented corrective actions as necessary (Section 14)

DETAILS

1. Persons Contacted

Stanley Levy, M.D., Authorized User/Owner, Current RSO
Henry Shevitz, M.D., Authorized User, Former RSO
Byron Baker, Nuclear Medicine Technologist
Rebecca Tungol, Radioimmunoassay Technologist
Mrs. Ellis, Office Manager
Craig Pomish, Michigan Nucleonics
Tracy King, Medical Physics Consultants
Jerome Rock, Attorney, Jacob and Weingarten

A preliminary exit interview was conducted with Dr. Levy on November 15, 1990 and a telephone exit interview was conducted with Dr. Levy on November 26, 1990.

2. Purpose of Inspection

This routine, unannounced inspection was conducted to evaluate compliance with Commission rules, regulations and license conditions. The inspection consisted of a selective review of records, independent measurements, personnel interviews, a review of procedures and observations. The inspector met with Dr. Levy at the close of the site inspection to summarize findings and to discuss the NRC's enforcement options. After a telephone interview with the licensee's radioimmunoassay (RIA) technologist on November 26, 1990, a telephone exit interview was conducted with Dr. Levy on the same day.

3. Organization

Dr. Levy is the owner, Radiation Safety Officer (RSO), and one of two authorized users for the license. Dr. Henry Shevitz is the other authorized user and was named as the RSO until July 30, 1990. Two part-time technologists perform the routine scanning and RIA testing functions, under the supervision of Dr. Levy and Dr. Shevitz.

4. Licensed Program and Enforcement History

NRC Byproduct Material License No. 21-07059-01 was originally issued to Stanley Levy, M.D. and Mervyn Lakin, M.D. on January 10, 1961 and was last renewed in its entirety via Amendment No. 20 on July 30, 1990. The licensed program consists of diagnostic nuclear medicine only. Although therapeutic radiopharmaceuticals are authorized on the license, per 10 CFR 35.300 (excluding thyroid carcinoma), no therapy procedures have been performed in the last two years. The license also authorizes the use of materials identified in 10 CFR 35.100 and 35.200 (diagnostic radiopharmaceuticals) and prepackaged kits described in 10 CFR 31.11 for in vitro tests. No iodine-131 is used for diagnostic imaging nor are generators used. A Syncor radiopharmacy in nearby Ferndale, Michigan supplies unit doses as needed.

The licensee currently performs 16-18 diagnostic studies per month, utilizing primarily technetium-99m related products. One or two xenon-133 ventilation studies are also performed monthly. One part-time technologist performs scans one or two evenings each week, as needed. One part-time technologist performs RIA tests one or two mornings each week, as needed.

The licensee's enforcement history includes an inspection performed on July 10, 1986 when three violations were identified, as follows:

(a) 10 CFR 35.14 - failure to maintain records of leak tests for sealed sources;

(b) License Condition No. 16 - failure to survey/wipe test the RIA laboratory since 1984;

(c) License Condition No. 16 - failure to service or replace the dose calibrator when accuracy and linearity tests indicated error exceeding the five percent limit.

The inspector verified during the current inspection that corrective actions had been taken for the first violation; the remaining two violations were identified as apparent repeat violations during the current inspection.

An inspection on May 12, 1983 identified six violations, as follows:

(a) License Condition No. 16 - failure to test the dose calibrator for accuracy in 1980, 1981, and 1982 and failure to test the dose calibrator for linearity since March 1980;

(b) Condition No. 16 - failure to survey and wipe test packages containing radioactive material since February 25, 1980;

(c) License Condition No. 16 - failure to survey dose preparation/injection areas daily and failure to perform weekly wipe tests since February 25, 1980;

(d) 10 CFR 35.14(e)(1)(i) - failure to test the cesium-137 sealed source for leakage between September 19, 1979 and May 11, 1983;

(e) License Condition No. 16 - failure to calibrate the survey meter between February 1980 and September 1982;

(f) License Condition No. 19 - failure to survey radioactive waste prior to disposal on May 12, 1983.

A "Management Control" paragraph was included with the Notice of Violation for the May 12, 1983 inspection. In a letter to the NRC dated July 14, 1983, Dr. Levy committed to hiring an independent consulting service, hiring a college-trained nuclear medicine technologist, and monitoring the day to day functions of the department through the Radiation Safety Officer. Violations one and three above were also identified during the inspections performed on July 10, 1986 and November 15-26, 1990.

When questioned by the inspector on November 15, 1990 licensee representatives indicated that no misadministrations, overexposures, incidents, thefts, or losses of material have occurred since the previous inspection on July 10, 1986.

5. Personnel Exposure Monitoring

The licensee provides film whole body badges for the physicians and nuclear medicine technologist (NMT) and a thermoluminescent (TLD) finger badge for the NMT. The badges are obtained from Siemens, an accredited vendor, and are exchanged monthly. The inspector reviewed exposure records from January 1988 through August 19, 1990. The maximum annual whole body dose to a radiation worker was 50 millirem and the maximum cumulative extremity dose, for 1990, was 140 millirem. No exposures exceeding the limits in 10 CFR 20.101(a) were observed.

No violations were identified.

6. Facilities Tour/Independent Measurements

The inspector toured the licensee's facilities and evaluated compliance with respect to security, posting, labeling and radiation level requirements.

The postings required by 10 CFR 19.11 and door/container labels required by 10 CFR 20.203 were observed during the inspection of the nuclear medicine hot lab and imaging room. A refrigerator containing licensed RIA kits bore the appropriate "Caution ..." label. Security of the radioactive material use and storage areas appeared to be adequate in that the areas were either attended by staff or locked.

10 CFR 30.34(c) requires, in part, that each licensee confine his possession and use of byproduct materials to the locations and purposes authorized by the license. Condition 10. of the license requires that licensed material be used only at 10601 West Seven Mile Road, Detroit, Michigan.

On November 15, 1990, during the inspector's facilities' tour, the inspector noted that the hot lab, the RIA lab, and the refrigerator containing the RIA kits were located in the building next door to the clinic, 10615 West Seven Mile Road. Also, the Syncor courier delivered the radiopharmaceutical doses to the hot lab at the 10615 facility. The possession and use of byproduct material at a location not authorized by the license appears to be a violation of 10 CFR 30.34(c) and Condition 10. of the license.

The inspector performed surveys of radiation levels in the hot lab, imaging area and RIA refrigerator and use areas. These surveys were performed with an NRC Xetex 305B G.M. survey meter, NRC No. 009004, calibrated September 24, 1990. Surveys of the shielded waste and sealed source storage area measured a maximum of 0.7 milliroentgen/hour (mR/hr) at the surface of the shielded container holding the cesium-137 source.

The inside of the RIA refrigerator measured a maximum of 0.8 mR/hr at six inches from the kit packages. The RIA use areas and the imaging room, where patients were injected and scanned, measured 0.1 mR/hr, equivalent to background. These measurements appeared to be in reasonable agreement with the licensee's surveys.

One apparent violation was identified.

7. Radiation Protection Procedures/Area Surveys

The inspector interviewed staff and reviewed records to determine compliance with requirements for radiation protection procedures and area surveys.

The licensee's representatives appeared to comply adequately with some of the "Rules For The Safe Use of Radiopharmaceuticals," contained in Item 10.4 of their application dated May 24, 1990, which is referenced by License Condition No. 16. Subitem 5 of these rules, however, prohibits eating, drinking, smoking or the application of cosmetics in any area where radioactive material is used or stored. Subitem 6 of these rules prohibits storage of food, drink or personal effects in areas where radioactive material is used or stored. On November 15, 1990 the inspector observed loaves of bread and beverage containers stored in the room where the RIA kits were used and stored. An individual was observed preparing lunch in a microwave oven in this area also. A licensee representative said that food and drink was routinely consumed in the room. (A refrigerator used for storing food was located in the back of the room, near the hot lab. No radioactive materials were observed by the inspector in this refrigerator. Also, no food or drink was observed by the inspector inside the refrigerator containing the RIA kits.)

10 CFR 35.21(a) requires that the licensee, through the Radiation Safety Officer, ensure that radiation safety activities are being performed in accordance with approved procedures. The licensee's procedures for safe use of radiopharmaceuticals are described in the application dated May 24, 1990 and were approved by License Condition No. 16.

The licensee's storage and consumption of food and drink in areas where radioactive materials are used and stored appears to be a violation of 10 CFR 35.21(a) and certain commitments made in the application dated May 24, 1990, referenced by License Condition No. 16.

As the licensee usually uses licensed material only one day per week, the licensee performs ambient exposure rate surveys and wipe tests once a week in the hot lab and injection/imaging areas, in accordance with 10 CFR 35.70 and the license conditions. The application dated May 24, 1990, Item 10.12, "Area Survey Procedures," subitem 5, requires that surveys for removable contamination consist of a series of wipes which will be assayed using a procedure sufficiently sensitive to detect 2000 disintegrations per minute (dpm) or lower. Subitem 3 of this procedure requires that laboratory areas where each process involves less than 200 microcuries (uCi) of byproduct material be surveyed monthly for ambient exposure rates and

removable contamination. In discussing these procedures with licensee representatives, the inspector learned that the nuclear medicine wipe tests have been performed with only a single wipe to test all the areas of use in the hot lab and injection/imaging areas. It was also learned that the RIA lab, which involves use of less than 200 uCi of byproduct material, had not been surveyed for ambient exposure rates and removable contamination in more than one year. The inspector's review of survey records identified no contamination problems in the nuclear medicine areas and the inspector's surveys in the RIA lab did not identify any obvious contamination or radiation level problems. The failure to perform wipe tests using a series of wipes and the failure to survey the RIA lab for ambient exposure rates and removable contamination appears to be a violation of 10 CFR 35.21(a) and certain commitments made in the application dated May 24, 1990, referenced by License Condition No. 16.

The violation concerning failure to survey the RIA lab monthly for ambient exposure rates and removable contamination is an apparent repeat violation as it was identified during the inspection conducted on July 10, 1986.

Two apparent violations were identified.

8. Dose Calibrator Tests/Survey Meter Calibrations

The inspector reviewed selected records and interviewed licensee representatives to determine compliance with requirements for survey meter calibrations and dose calibrator tests, including accuracy, constancy, linearity and geometrical variation.

The licensee's survey meter, a Bicron 2000, was being calibrated off-site by their consultants on November 15, 1990. The licensee was using a calibrated loaner survey meter, also a Bicron 2000, provided by their consultants. The loaner survey meter appeared to be operational when checked by the inspector. A review of records identified no problems with the licensee's calibrations of survey instruments for 1988 and 1989.

The licensee has a Capintec CRC-6 dose calibrator that is tested for accuracy by the licensee's consultants during their quarterly audits. The consultant's audit reports dated December 1, 1989, January 30, 1990, and May 24, 1990 indicated that the dose calibrator's accuracy tests exceeded the ten percent error allowed by 10 CFR 35.50(d). On July 18, 1990, Craig Pomish of Michigan Nucleonics replaced the potentiometer in the dose calibrator during an on-site repair visit. On July 23, 1990 the licensee's consultants identified an error of 13.96% for the dose calibrator accuracy test.

10 CFR 35.50(b)(3), 35.50(b)(4) and 35.50(c) require, in part, that each dose calibrator be tested for linearity and geometrical variation upon installation and, as appropriate, following repair. The licensee did not test the dose calibrator for linearity and geometrical variation following the repair and reinstallation of the dose calibrator on July 18, 1990, although patient studies resumed. The licensee's failure to test the

dose calibrator for linearity and geometrical variation following repair appears to be a violation of 10 CFR 35.50(b)(3), 35.50(b)(4) and 35.50(c).

10 CFR 35.50(b)(3) requires, in part, that a licensee test each dose calibrator for linearity upon installation and at least quarterly thereafter. However, during the period January 20, 1989 through November 15, 1990, the licensee failed to test the dose calibrator for linearity. 10 CFR 35.50(d) requires, in part, that a licensee repair or replace the dose calibrator if the accuracy or constancy error exceeds 10%. However, accuracy test records for the dose calibrator dated September 27, 1988, July 13, 1989, May 24, 1990, and July 23, 1990 indicated error exceeding 10% and the dose calibrator was not repaired or replaced. In addition, constancy records dated January 9, 1990, July 3, 1990, October 29, 1990 and November 13, 1990 indicated error exceeding 10% and the dose calibrator was not repaired or replaced. On November 15, 1990, the inspector personally performed a constancy test on the licensee's dose calibrator using a sealed source containing 155 uCi of cesium-137. The inspector's measurement was 133 uCi, taking background into account. This result is (-)14% in error. The licensee's failure to test the dose calibrator for linearity from January 20, 1989 through November 15, 1990 and the failure to repair or replace the dose calibrator when the accuracy and constancy errors exceeded 10% appears to be a violation of 10 CFR 35.50(b)(3) and 35.50(d).

During the inspector's review of the licensee's audits on November 15, 1990, it appeared that there were problems with the calibration of the dose calibrator, as discussed above. When the inspector identified the constancy test error of (-)14%, she contacted the Region III office and, after discussing the matter with Dr. Levy, a Confirmatory Action Letter (CAL) was sent to Dr. Levy on November 16, 1990, to ensure that a calibrated dose calibrator was obtained before resuming patient studies.

Based on the licensee's use of unit doses of radiopharmaceuticals only and a review of unit dose records by the inspector, it does not appear that any misadministrations occurred as a result of the problems with the dose calibrator.

10 CFR 35.50(e)(2) requires the signature of the RSO on records of dose calibrator accuracy test. However, the accuracy test dated May 24, 1990 lacks the signature of the licensee's RSO. The failure of the RSO to sign the accuracy test dated May 24, 1990 appears to be a violation of 10 CFR 35.50(e)(2).

The violation concerning failure to repair or replace the dose calibrator when the accuracy tests indicated error exceeding regulatory limits is an apparent repeat violation as it was identified during the inspection conducted on July 10, 1986.

The violation concerning failure to perform linearity tests on a quarterly frequency for a period in excess of one year is an apparent repeat violation as it was identified during the inspection conducted May 12, 1983.

Three apparent violations were identified.

9. Radioactive Package Receipt and Monitoring

The licensee receives unit doses of radiopharmaceuticals on an "as needed" basis from a local radiopharmacy, Syncor, Ferndale, Michigan. The Syncor courier delivers the licensee's packages during the day only when the building that the hot lab is located in is attended. The courier unlocks the hot lab, drops off the package, picks up any returned packages and locks the hot lab again. A review of package receipt and monitoring records and interviews with personnel identified no problems, with one exception. 10 CFR 30.51(a) requires, in part, that each licensee keep records showing the receipt of byproduct material. However, on August 17, 1989, June 5, 1990, July 10, 1990, September 27, 1990, and November 5, 1990 the licensee did not keep records showing the receipt of byproduct material for unit doses of radiopharmaceuticals. The failure to keep records showing the receipt of byproduct material for unit doses of radiopharmaceuticals appears to be a violation of 10 CFR 30.51(a).

One apparent violation was identified.

10. Radiopharmaceutical Dosages

The inspector reviewed records showing radiopharmaceutical unit doses procured from Syncor from 1989 and 1990. These records consist primarily of the paper Syncor slips, on which Syncor imprinted and typed a variety of data for each dose, pasted in a logbook. The NMT wrote the patient name and other pertinent information in the logbook on the Syncor slips. 10 CFR 35.53(a) and (b) require, in part, that the licensee measure the activity of each radiopharmaceutical dosage before medical use. 10 CFR 35.53(c) requires, in part, that records of the measurement of radiopharmaceutical dosages contain the date and time of the measurement and the initials of the individual who made the record. The inspector noted that the time of measurement was not recorded for radiopharmaceutical dosages of byproduct material on August 17, 1989, September 28, 1989, October 5, 1989, June 5, 1990 and July 10, 1990. In addition, the individual who made the records of measurement failed to record his initials. The failure to record the time of measurement and the NMT's initials appears to be a violation of 10 CFR 35.53(c).

One apparent violation was identified.

11. Airborne Radiation Protection Procedures

The only potentially airborne contaminant used by the licensee is xenon-133, a noble gas used for ventilation studies. The licensee's consultants appear to have checked the ventilation rates at six month intervals to verify negative pressure exists in the area where the xenon is used. The consultants have also posted the clearance time and safety procedures to be followed in the event of a xenon spill. 10 CFR 35.21(a) requires that the licensee, through the RSO, ensure that radiation safety activities are being performed in accordance with approved procedures. The licensee's procedures for air concentration control of xenon-133 are described in the application dated May 24, 1990, and were approved by License Condition

No. 16. The application dated May 24, 1990, Item 10.13, "Procedures for Air Concentration Control of Xenon-133," describes the licensee's method for testing the trap for saturation and specifies that the trap be tested once each month in which the system is used. The licensee's consultants noted in their audit report dated April 25, 1989 that the licensee had stopped monitoring the xenon trap in December 1988 and reminded them that they must monitor the trap once a month when they do xenon studies. A review of records and interviews with personnel revealed that the licensee did resume monitoring the trap but another audit report dated July 23, 1990 indicated that the trap had not been monitored since April 19, 1990 and again reminded the licensee to resume trap monitoring. As of November 15, 1990, the licensee had not monitored the trap since August 20, 1990 and the system was used in October 1990 and on November 13, 1990. The inspector asked the NMT when the trap had last been replaced with fresh activated charcoal and the NMT indicated that the trap had not been changed in the six years that he had worked for the licensee. The failure to monitor the xenon trap for saturation monthly appears to be a violation of 10 CFR 35.21(a) and certain commitments made in the application dated May 24, 1990, referenced by License Condition No. 16.

One apparent violation was identified.

12. Sealed Source Inventory and Leak Tests

The licensee possesses a sealed source containing 155 uCi of cesium-137, as authorized by 10 CFR 35.57, for testing the dose calibrator. The licensee's consultants have performed the quarterly inventories and six month leak tests, as required by 10 CFR 35.59. In the course of performing its required "day of use" area surveys, the licensee has surveyed the sealed source storage area, in accordance with 10 CFR 35.59(h). 10 CFR 35.59(g) requires the signature of the RSO on records of sealed source inventories. 10 CFR 35.59(i) requires the signature of the RSO on records of sealed source ambient surveys. 10 CFR 35.59(d) requires the signature of the RSO on records of sealed source leak tests. The licensee's consultants, in their audit report dated January 30, 1990, reminded the licensee to have the RSO sign the sealed source leak test and inventory records, as it had not been done for the past two years. Every quarterly audit report contained a "tickler" paragraph addressing the requirements to have certain records signed by the RSO. During a review of records on November 15, 1990, the inspector noted that certain records did lack the signature of the RSO, including the sealed source inventories performed September 27,1988, November 14, 1989, January 30, 1990, May 24, 1990 and July 23, 1990; the leak test performed May 24, 1990; and all sealed source ambient surveys performed since the inception of the requirement on April 1, 1987. The failure to have the RSO sign records of sealed source inventories, leak tests and ambient surveys appears to be a violation of 10 CFR 35.59(g), 35.59(i) and 35.59(d).

One violation was identified.

13. Staff Qualifications and Training

The qualifications and training for the NMT and the RIA technologist were reviewed by the inspector primarily through interviews conducted with each individual.

10 CFR 35.21(a) requires that the licensee, through the RSO, ensure that radiation safety activities are being performed in accordance with approved procedures. The licensee's procedures for training personnel who work with or in the vicinity of radioactive material are described in the application dated May 24, 1990 and were approved by License Condition No. 16 of Amendment No. 20, dated July 30, 1990, which supersedes License Condition No. 16 of Amendment No. 19, dated May 17, 1985, and Item 12, "Personnel Training Program," of the referenced application dated February 12, 1985. The application dated May 24, 1990, Item 8.1, "Personnel Training Program," requires, in part, that all radiation workers and ancillary personnel whose duties require them to work in the vicinity of radioactive material receive instruction in certain topics and at specified frequency:

a. Before assuming duties with, or in the vicinity of radioactive materials.

b. During annual refresher training.

c. Whenever there is a significant change in duties, regulations, or in the terms of the license.

Item 8.1 further requires that the instruction include, among other topics:

a. Applicable regulations and license conditions.

b. Appropriate radiation safety procedures.

c. The licensee's in-house work rules.

Item 8.1 states that documentation will be kept on hand for review of the list of topics covered, the date of the instruction, and the names of those attending.

The NMT has been employed by the licensee for the last six years, since 1984. His qualifications for NMT employment consist primarily of on-the-job training, as he is not registered with either the American Registry of Radiologic Technologists (ARRT) or the Nuclear Medicine Technologist Certification Board (NMTCB). The NMT currently works for the licensee one or two evenings per week, as he is employed full-time at a different facility during the day. The RIA technologist has worked for the licensee for 19 years and she has performed the RIA tests for the last 16 years. She, too, has another day job and works for the licensee during the mornings only. When questioned by the inspector, neither technologist appeared to be knowledgeable about applicable provisions in

10 CFR 19, 20, 30, 31 and 35; the license conditions; and certain work rules and radiation safety procedures, including requirements pertaining to area surveys, eating and drinking in areas where radioactive materials are used and calibration requirements for the dose calibrator. When asked by the inspector about how often they have personal contact with the licensee (RSO), both technologists indicated that such contact was infrequent. The inspector asked if they had received training in these areas where their knowledge appeared to be deficient and they indicated that, for the most part, they had not. The NMT, in particular, was usually not present during the quarterly consultant audits, due to his part-time, evening work schedule for the licensee. No records of training were available during the inspection on November 15, 1990. Since the previous inspection on July 10, 1986, two significant changes had occurred that affected the licensed program: revised Part 35 went into effect on April 1, 1987 and the license was renewed on July 30, 1990, incorporating many new procedural requirements based on revised Part 35 and the newly revised Regulatory Guide 10.8, dated August 1987. In addition to the required annual training, the staff should have also been trained in revised Part 35 and the new license, when they went into effect. It appears that this training has not been performed. The failure to train two radiation workers in appropriate radiation safety procedures, in-house work rules, and applicable regulations and license conditions appears to be a violation of License Condition No. 16 of Amendment No. 19, 10 CFR 35.21(a) and License Condition No.16 of Amendment No. 20.

One apparent violation was identified.

14. Management Oversight For the Radiation Safety Program

Management oversight for the radiation safety program is exercised through the RSO and the two authorized users.

The licensee contracts with a local firm, Medical Physics Consultants (MPC) of Ann Arbor, Michigan, to assist them in completing tasks associated with the radiation safety program. MPC visits the licensee on a quarterly basis and conducts an audit of the radiation safety program in addition to performing routine tasks. Audits performed by MPC on April 25, 1989, November 14, 1989, January 30, 1990, May 24, 1990, and July 23, 1990 identified some of the violations described in this report, as noted.

10 CFR 35.21(a) requires, in part, that the licensee, through the RSO, ensure that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the daily operation of the licensee's byproduct material program. 10 CFR 35.21(b) requires, in part, that the licensee's RSO investigate deviations from approved radiation safety practice and implement corrective action as necessary. The inspector expressed concern that, since the date of previous inspection, July 10, 1986, the licensee, through the RSO, has not adequately ensured that radiation safety activities were being performed in accordance with approved procedures and regulatory requirements in the routine operation of the licensee's byproduct

material program. This failure to exercise adequate management oversight appears to be the root cause of the violations currently identified. The licensee's RSO also did not identify and investigate deviations from approved radiation safety practice and implement corrective action as necessary, even after problem areas were brought to his attention by the consultants. The inspector also expressed concern that the licensee had failed to implement satisfactory corrective actions for violations identified during two previous inspections, relating to the dose calibrator and the performance of area surveys/wipe tests. Evidence of these problems includes insufficient attention devoted to the dose calibrator accuracy and linearity tests and RIA lab and nuclear medicine surveys, such that errors and deviations from approved practice were not identified, investigated, and corrective actions implemented. The failure of the RSO to sign certain records, as required, and to heed the warnings and reminders provided by his consultants appears to be a contributing factor to the degradation of the radiation safety program.

10 CFR 35.25(b) states that a licensee that supervises an individual is responsible for the acts and omissions of the supervised individual.

The inspector expressed concern that, since the previous inspection on July 10, 1986, the licensee has not adequately instructed supervised individuals in the principles of radiation safety appropriate to each individual's use of byproduct material and periodically reviewed the supervised individual's use of byproduct material and the records kept to reflect this use. Evidence of these problems is that two supervised individuals were unfamiliar with the regulations in 10 CFR 35 and the license conditions with respect to the use of licensed material.

One area of concern was identified.

15. Exit Interview

A preliminary exit interview was conducted on-site with Dr. Levy on November 15, 1990 and a telephone exit interview was conducted with Dr. Levy on November 26, 1990, at the conclusion of the inspection. The apparent violations and area of concern were discussed as well as the NRC enforcement policy and the Confirmatory Action Letter issued by NRC to Dr. Levy on November 16, 1990, regarding replacement or repair of his dose calibrator before resuming patient studies. No proprietary information, as described in 10 CFR 2.790, was identified by the licensee to the inspector.

On November 26, 1990, Region III determined that the violations identified during the inspection warranted holding an enforcement conference with the licensee. During the telephone exit interview with Dr. Levy on November 26, 1990, Dr. Levy and Dr. Shevitz were invited to attend an enforcement conference in the Region III office to discuss the apparent violations, their planned corrective actions and NRC's enforcement options. On November 27, 1990, Dr. Levy and his attorney, Mr. Rock, contacted Region III and declined the invitation to the planned enforcement conference. Mr. Rock stated that he had spoken with Dr. Levy

and Dr. Levy wished to terminate his license with NRC at this time, provided he could obtain a general license registration certificate in order to continue his RIA tests for patients. Dr. Levy assured NRC that he had not resumed nuclear medicine patient studies and that he would not resume them. On November 29, 1990, a telephone conference call was conducted between Dr. Levy and Mr. Rock and Mr. John Grobe and other members of the Region III staff to discuss, in detail, Dr. Levy's intentions to terminate the license. During this call, Mr. Rock stated that he and Dr. Levy planned to meet with the MPC consultants on November 29, 1990 to coordinate the tasks associated with termination of the specific license, including the authorized transfer of the sealed source, performance of the close-out survey, and completion of the Form NRC 314. Mr. Rock agreed to submit the termination request promptly upon the receipt of Dr. Levy's general license registration certificate.