U.S. NUCLEAR REGULATORY COMMISSION
REGION I

INSPECTION REPORT

Report No. 030-30947/94-001 Program Code 2200

Docket No. 030-30947 EA No. 94-089

License No. 37-28331-01 Priority 4 Category G

Licensee: Advacare Management Service, Inc.
2 Bala Plaza, Suite IL 52
Philadelphia, Pennsylvania 19004

Facility Name: Advacare Management Service, Inc.

Inspection At: 201 Franklin Avenue, Scranton, Pennsylvania

and

2 Bala Plaza, Suite IL 52, Bala Cynwyd, Pennsylvania

and

301 Oxford Valley Road, Yardley, Pennsylvania

Inspection Conducted: April 26 - 28, 1994

Inspector: Mary Cahill 5/22/94
Mary Cahill, Health Physicist date
Medical Inspection Section
Division of Radiation Safety and Safeguards

Approved by: Jenny M. Johansen 5/27/94
Jenny M. Johansen, Chief date
Medical Inspection Section
Division of Radiation Safety and Safeguards

Inspection Summary: Unannounced safety inspection conducted on April 26-28, 1994 to review the Radiation Safety Program authorized by NRC License No. 37-28331-01 (Inspection Report No. 030-30947/94-001).

Areas Inspected: Organization and scope of the licensed program; radiation safety audits; training and supervision of personnel; personnel monitoring; radiation surveys; survey instruments; dose calibrator quality control; sealed sources; and postings.

Results: Fifteen apparent violations were identified: (1) Failure to perform the annual audit of radiation safety program (Details, Section 3); (2) Failure to train personnel (Details, Section 4); (3) Failure to periodically review the use of licensed materials by physicians working under the supervision of an authorized user (Details, Section 4); (4) Failure to maintain records of radiation exposures of personnel (Details, Section 5); (5) Failure of a nuclear medicine technologist to wear personnel dosimetry while in areas where radioactive materials are used or stored and to wear an extremity exposure monitor at all times during the preparation, assay, and injection of radiopharmaceuticals (Details, Section 5); (6) Failure to evaluate the radiation exposure to a contractor nuclear medicine technologist (Details, Section 5); (7) Failure to perform daily surveys at the end of the day (Details, Section 6); (8) Failure to maintain records of removable contamination in appropriate units and to maintain records of daily ambient radiation surveys and weekly contamination surveys (Details, Section 6); (9) Failure to check survey instruments daily for proper operation (Details, Section 7); (10) Failure to perform appropriate constancy checks of the dose calibrator (Details, Section 8); (11) Failure to perform quarterly linearity checks of the dose calibrator (Details, Section 8); (12) Failure of the RSO to sign records (Details, Sections 8 and 9); (13) Failure to maintain records of receipt and transfer of radioactive material (Details, Section 9); (14) Failure to conduct quarterly physical inventory of all sealed sources (Details, Section 9); and (15) Failure to post required documents (Details, Section 10).

DETAILS

1. Persons Contacted

* Robert Perry, General Manager
* Sandy Young, Operations Manager
* Wayne Arnold, M.D., Radiation Safety Officer
* Jack Olley, Consultant Health Physicist
Mark Liddington, Consultant Health Physicist (by phone)

Scranton office:

Chantel Paris, Office Manager
George Svok, Nuclear Medicine Technologist
Gary Golecki, Nuclear Medicine Technologist (by phone)

Bala Cynwyd office:

Dr. Eisenstadt
Antonia Kist, Nuclear Medicine Technologist

Yardley office:

Angelo Amenta, Nuclear Medicine Technologist
Dr. Furey
Suzanne Rothwell, Nuclear Technologist Manager

*Present at exit interview

2. Organization and Scope of the Licensee Program

Advacare Management Service, Inc., is authorized by License No. 37-28331-01 to possess and use byproduct material for diagnostic nuclear medicine studies. Current use of licensed material is limited to cardiac studies. The Licensee is authorized to use licensed material at seven locations, including Philadelphia (two facilities), Bala Cynwyd, Lancaster, Yardley, and Scranton, Pennsylvania and Vineland, New Jersey. The inspection was limited to the examination of licensed activities at the Scranton, Bala Cynwyd, and Yardley facilities.

The management oversight of the Radiation Safety Program (RSP)is provided by a General Manager and an Operations Manager. The Operations Manager is responsible for handling licensing issues and administrative oversight, including establishing and commencing operations at new office facilities and staffing of all offices. There is also a

nuclear technologist coordinator who is also a Stress Technologist based at the Yardley office. This individual is responsible for coordinating and overseeing nuclear medicine technologist (NMT) activities at all facilities. The Radiation Safety Officer (RSO) for all seven of the facilities is present at the Bala Cynwyd office two times per week. According to several staff interviewed by the inspector, the RSO makes infrequent visits to the other offices. The lack of availability of the RSO was a concern of several staff interviewed. (e.g., The RSO has visited the Yardley facility only four times since it opened in January 1992.)

Prior to January 1994, the Licensee had used the services of a consultant health physicist (Consultant) on an on call basis. There were several concerns raised by NMTs regarding the inaccessibility of the Consultant in or around May 1993. To address these concerns, the Licensee recently retained another Consultant group to provide more reliable services. This group is currently providing services on a quarterly basis for each office. The services include audits of licensed activities, the conduct of inventory and leak tests of sealed sources, review of film badge reports, and dose calibrator linearity and accuracy checks. Although the program has improved in identification of program weaknesses, the effectiveness of management and the RSO in ensuring that corrective actions are prompt and comprehensive to prevent recurrence still appears to be lacking (See the following paragraphs and succeeding sections of this report).

The General Manager, Operations Manager, and RSO stated that they had relied on the previous Consultant and NMTs to ensure that licensed activities were performed in accordance with regulations and license conditions. The inspector informed the Managers and RSO that they were responsible for ensuring compliance with regulations. The inspector determined that the lack of management and RSO oversight of the RSP contributed to the numerous apparent violations identified during the inspection and which are detailed in succeeding sections of this report. The inspector also expressed concern that the increasing number of new facilities being added to the license, which are located over a wide geographical area, appears to have overextended the RSO's and management's ability to provide adequate oversight of licensed activities on a day to day basis at each location authorized by the NRC license. In addition, the inspector expressed concerns that the quarterly services being provided by the Consultant may be insufficient to provide prompt resolutions of regulatory compliance issues (See Section 3). The licensee's managers made a commitment to do what ever was necessary to ensure that the RSP was conducted in accordance with the NRC license conditions and regulations. However, no specific commitments or plans to improve program performance were provided.

3. Radiation Safety Audits

The inspector reviewed written audits of the RSP performed by the new Consultant group in January and April 1994 at the Scranton facility. This facility became operational in November 1993. The audits identified several deficiencies in the RSP.

These included failure to wear lab coats, failure to post the License and 10 CFR Parts 19 and 20 or a notice indicating where the documents could be found, and failure to provide radiation safety training to personnel. The inspector noted that the deficiencies indicated in the January audit were not promptly corrected, as they were also reported in the April audit. A response to the January audit by the NMT did not address the deficiencies described above. Although, the inspector did note at the time of the inspection of this facility on April 26, 1994, that the NMT was wearing a lab coat, the required documents were still not posted or available at the facility.

An audit of the Bala Cynwyd facility was conducted in January 1994. This facility opened in July 1990. The January audit identified numerous deficiencies, including failure to train NMTs. Based on questioning of the NMT, the inspector found that as of April 27, 1994, training had still not been provided to the NMT. The NMT stated that she had been given a video tape, but had not had a chance to view it. She also stated that she was unable to attend a March 1994 training session held by the Consultant for technical personnel from all of the facilities. As was the case with the Scranton facility, the inspector found that all of the deficiencies noted in the audit were not corrected at the time of the inspection. The response to this audit by the Bala Cynwyd NMT could not be located at the time of the inspection.

An audit was conducted during February 1994 at the Yardley facility which was opened in July 1992. The inspector noted that, according to this audit, only minor deficiencies of a non-regulatory nature were identified at this facility, except for RSO responsibilities such as lack of RSO signature on required records, and required license documents and regulations not at the facility. The response to this audit by the NMT indicated that most deficiencies were corrected. Only deficiencies attributed to RSO responsibilities or to documents originally sent to the Bala Cynwyd facility, such as lack of RSO signature on required records, and required license documents and regulations not at the facility, were not corrected at the time of the inspection.

As describe above, the fact that the license's management and the RSO did not ensure prompt and comprehensive corrective action based on the audit findings of the consultant is indicative of a lack of involvement of the RSO and management in the oversight of the radiation safety program.

The inspector determined that no annual audits of the RSP were conducted in 1992 and 1993 as required by the licensee's ALARA program. 10 CFR 35.20(a) requires that each licensee develop and implement a written radiation protection program that includes provisions for keeping doses ALARA. The Licensee's approved ALARA program is that contained in the application dated December 27, 1988. Item 1.b of the Licensee's ALARA program states that a formal annual review of the radiation safety program will be performed, including reviews of operating procedures and past dose records, inspections, and consultations with the radiation safety staff or outside consultants. Based on interviews with the RSO, the inspector determined that while dose records and

consultations with outside consultants had periodically taken place, reviews of operating procedures had not been performed.

Failure to perform the annual review of the radiation safety program, including a review of operating procedures, in 1992 and 1993, is an apparent violation of 10 CFR 35.20(a).

4. Training and Supervision of Personnel

The inspector interviewed personnel and examined audit records for 1994 to determine the scope of the Licensee's training program and qualifications of personnel who use radioactive material under the Licensee's program.

Based on audit findings discussed in Section 3 of this report, which identified the licensee's failure to train its employees in NRC regulations, and recommendations of the new Consultant, the Licensee took corrective action and held a training session for some technical personnel from the Scranton, Bala Cynwyd, and Yardley facilities in Fogelsburg, Pennsylvania, in March 1994. The RSO also attended this training. According to the NMT interviewed at the Yardley facility, the Consultant provided instruction on pertinent NRC regulations. The Consultant also provided a tape on radiation safety practices to be reviewed by NMTs. However, as discussed in Section 3, an NMT from the Bala Cynwyd facility had not received the training. In addition, the inspector was unable to identify methods or procedures that the licensee uses to verify the effectiveness of training.

The inspector was informed that no annual refresher training had been performed in 1992 and 1993. 10 CFR 35.21 requires that the Licensee, through the RSO, ensure that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements. The Licensee's approved training program, as contained in the application dated December 27, 1988, requires that personnel will receive training before assuming duties with radioactive materials and during annual refresher training in specified subject areas. These subjects include: applicable regulations and license conditions, areas where radioactive material is used or stored, potential hazards associated with radioactive materials in each area the employee will work, appropriate radiation safety procedures, work rules, reporting unsafe conditions, emergency response, worker's rights, and posting requirements.

Failure to provide annual radiation safety training to personnel in 1992 and 1993 is an apparent violation of 10 CFR 35.21(a).

The inspector noted that a physician who was neither listed on the license as an authorized user nor under the supervision of an authorized user listed on the license performed nuclear medicine cardiac studies on patients. 10 CFR 35.25(a)(3) requires

that a licensee that permits the possession, use, or transfer of radioactive material by an individual under the supervision of an authorized user, periodically review the supervised individual's use of byproduct material and the records kept to reflect this use. The inspector interviewed two physicians who performed nuclear medicine cardiac studies but who were not listed as authorized users on the license. The physician from the Yardley office stated that he was supervised by an authorized user listed on the license and that scans were formally interpreted by the authorized user. The physician at the Bala Cynwyd indicated that his use of radioactive material and records reflecting that use (e.g. scan interpretations) had not been reviewed by an authorized user listed on the license.

Failure of the Licensee to periodically review the Bala Cynwyd physician's use of byproduct material and records kept to reflect that use (scan interpretations) is an apparent violation of 10 CFR 35.25(a)(3).

5. Personnel Monitoring Program

Film badges and TLD extremity monitors are obtained from Landauer, Inc. on a monthly basis. The inspector reviewed records of radiation exposures for staff at all three offices. Reports of exposures for January and February 1994 for Scranton personnel were not available at the time of the inspection. An attempt was made by the Office Manager to obtain the records from Landauer at the time of the inspection, but she was informed that the monitors had not been received. At the Bala Cynwyd office, records of radiation exposures were not available for June and July 1993, and October 1993. 10 CFR 20.401 (in effect prior to January 1, 1994) and 10 CFR 20.2106 (effective January 1, 1994) require that records showing the radiation exposures of all individuals for whom personnel monitoring is required under 10 CFR 20.202 or 10 CFR 20.1502 be maintained until the Commission authorizes disposition. 10 CFR 35.21 requires that the Licensee, through the RSO, ensure that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements.

Failure to maintain records of radiation exposures for January and February 1994 for Scranton personnel and for June, July, and October 1993 for Bala Cynwyd personnel is an apparent violation of 10 CFR 20.2106, 10 CFR 20.401 and 10 CFR 35.21.

Based on questioning of the NMT at the Bala Cynwyd facility, the inspector determined that the NMT had not received personnel dosimetry to monitor the NMT's extremity and whole body exposure to radiation until three weeks after beginning work at the facility in July 1993. During this three week period, the NMT handled licensed material and performed nuclear medicine studies on patients.

10 CFR 35.21(a) requires that the licensee, through the Radiation Safety Officer, shall 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. The licensee's approved procedures for the safe use of radioactive material are those contained in Section 10.h of the application dated December 27, 1988. Item 7 of Section 10.h of the safe use procedures requires that personnel monitoring devices be worn at all times while in areas where radioactive materials are used or stored.

The inspector noted that the Bala Cynwyd NMT's extremity exposures were almost always reported as M (minimal). The inspector asked the NMT if she wore her extremity dosimeter during preparation, assay and injection of radiopharmaceuticals. The NMT stated that she sometimes forgot to wear her extremity dosimeter.

Item 8 of Section 10.h of the safe use procedures requires that a finger exposure monitor be worn during the preparation, assay, and injection of radiopharmaceuticals, and when holding patients during procedures.

Failure of the NMT to wear personnel monitoring devices at all times while in areas where radioactive materials are used or stored for three weeks in July 1993, and failure of the same NMT to wear a finger exposure monitor at all times during the preparation, assay, and injection of radiopharmaceuticals, and when holding patients during procedures and from August 1993 to April 1994 is an apparent violation of 10 CFR 35.21(a).

A contractor NMT who worked at the Bala Cynwyd office two days per week beginning in November 1993 was not issued monitors by the Licensee. Although she wore whole body and finger monitors issued by the Agency she worked for, the Licensee did not obtain and review her radiation exposure records. 10 CFR 20.201 (in effect prior to January 1, 1994) and 10 CFR 20. 1501(a) requires that each licensee make such surveys as may be necessary to comply with the regulations in Part 20. As defined in 10 CFR 20.201 (in effect prior to January 1, 1994) and 10 CFR 20.1003, "survey" means an evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal, or presence of radioactive material of other sources of radiation.

Failure of the Licensee to evaluate the radiation exposure of the contractor NMT by issuing monitors to the NMT or by obtaining and reviewing the NMT's exposure records from is an apparent violation of 10 CFR 20.1501(a) and 10 CFR 20.201.

6. Radiation Surveys

The inspector reviewed records of surveys and interviewed NMTs regarding daily and weekly contamination surveys at all three facilities.

Based on these reviews and interviews, the inspector found that surveys at the Bala Cynwyd facility were conducted at the beginning of each day in areas where radioactive

materials were used or stored, rather than at the end of the day as required during the period July 1, 1993 to April 27, 1994. Daily surveys at the other facilities were performed at the end of the day.

10 CFR 35.70(a) requires that surveys with a radiation detection survey instrument be conducted at the end of each day of use all areas where radiopharmaceuticals are routinely prepared for use or stored.

Failure to conduct surveys at the end of each day at the Bala Cynwyd facility is an apparent violation of 10 CFR 35.70(a).

The inspector noted that records of weekly contamination surveys at the Scranton facility did not contain the removable contamination in each area expressed in disintegrations per minute per 100 square centimeters. Results were recorded in counts per minute.

Records of daily and weekly surveys performed during the period July 4 to August 11, 1992 were not maintained at the Yardley facility and nuclear medicine studies were performed during this period. The NMT stated that he could not locate any survey records except for package surveys for the July 4 to August 11, 1992 time period when the facility was open and nuclear medicine studies were performed.

10 CFR 35.70(h) requires that records of weekly contamination surveys contain the removable contamination in each area expressed in disintegrations per minute per 100 square centimeters, and that records of daily area and weekly contamination surveys be retained for three years.

Failure to maintain records of weekly contamination surveys at the Scranton office which contained removable contamination results expressed in disintegrations per minute per 100 square centimeters, and failure to maintain records of area and contamination surveys of the Yardley facility for the period July 4, 1993 to August 11, 1993 is an apparent violation of 10 CFR 35.70(h).

7. Survey Instruments

The inspector determined that appropriate survey instruments were available at all three facilities and that the instruments had been calibrated within a year, as required.

The NMT at the Bala Cynwyd facility was unable to demonstrate an operational check of the survey instrument with a dedicated check source. The NMT informed the inspector that she did not check the instrument for proper operation each day of use. The inspector also found that survey instruments had not been checked for proper operation at the Scranton facility from November 29, 1993 to around January 30, 1994 on each day of use.

10 CFR 35.51(c) requires that each survey instrument be checked for proper operation with a dedicated check source each day of use.

Failure to check each survey instrument for proper operation with a dedicated check source each day of use at the Bala Cynwyd from July 1993 to April 27, 1994 and at the Scranton facility from November 29, 1993 to January 30, 1994 is an apparent violation of 10 CFR 35.51(c).

8. Dose Calibrator Quality Control

The inspector reviewed records of constancy, linearity, geometry and accuracy checks of the dose calibrator at each facility.

The inspector found that constancy checks of the dose calibrator at the Bala Cynwyd office were not performed correctly from January 1 to April 27, 1994. The results of assays of long-lived reference sources were not analyzed to make any determination as to the constancy of equipment performance.

10 CFR 35.21(a) requires that the licensee, through the Radiation Safety Officer, shall 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. The licensee's approved procedures for calibrating the dose calibrator are those contained in Section 10.d of the application dated December 27, 1988. Section 10.d states that the dose calibrator will be calibrated in accordance with ANSI Standard N422.1986 entitled "Calibration and Usage of Dose Calibrator Ionization Chambers for the Assay of Radionuclides". Item 4.5.1 of the ANSI Standard states that calibration checks of the dose calibrator using a long-lived reference source shall be performed and logged on each work shift during which the instrument is used and that a determination shall be made that the assay reading is within 10% of the of the anticipated assay.

Failure to make a determination that the assay readings of the long-lived reference sources were in accordance with the anticipated assay is an apparent violation of 10 CFR 35.21(a).

The inspector examined linearity tests of the Bala Cynwyd dose calibrator. The inspector found that although assay data were collected for a linearity test in August 1993, the data were never analyzed to determine if the dose calibrator response was linear. Because the data were not analyzed, the inspector stated that a linearity test of the dose calibrator was not performed the third quarter of 1993. Subsequent tests indicated that the dose calibrator response was linear.

10 CFR 35.50(b)(3) requires that each dose calibrator be tested for linearity upon installation and at least quarterly thereafter.

Failure to perform a linearity test of the dose calibrator during the third quarter of 1993 is an apparent violation of 10 CFR 35.50(b)(3).

The inspector noted that records of linearity tests of the dose calibrators performed during 1994 included the signature of the RSO. Records of linearity tests performed in 1992 and 1993 at the Bala Cynwyd and Yardley facilities did not include the signature of the RSO. This appears to be another example of lack of RSO oversight of the RSP.

10 CFR 35.50(e)(3) requires that records of dose calibrator linearity tests include the signature of the radiation safety officer.

Failure to include the signature of the RSO on records of dose calibrator linearity tests performed in 1992 and 1993 at the Bala Cynwyd and Yardley facilities is an apparent violation of 10 CFR 35.50(e)(3).

9. Sealed Sources

The inspector examined records of leak tests and inventories of sealed sources at all of the facilities.

The inspector asked to see records of receipt of the cesium-137 dose calibrator source at the Scranton facility. At the time of the inspection the record of receipt of this source could not be found.

The inspector found that the origin of a cesium-137 source at the Bala Cynwyd facility was not known. The NMT speculated the source was brought to the Bala Cynwyd facility prior to July 1993 from a nuclear medicine facility in Philadelphia that had closed. No record of transfer of the cesium-137 source could be found.

10 CFR 30.51 requires that records of receipt of radioactive material be maintained for as long as the material is possessed and that records of transfer of radioactive material be maintained for three years after each transfer.

Failure to maintain a record of receipt of the cesium-137 dose calibrator source at the Scranton facility and of the transfer of a cesium-137 dose calibrator source to the Bala Cynwyd facility is an apparent violation of 10 CFR 30.51.

The inspector found that there was a cesium-137 source that had not been included on the January 1994 inventory at the Bala Cynwyd facility. 10 CFR 35.59(g) requires that a quarterly physical inventory be conducted of all sealed sources in the possession of the licensee.

Failure to conduct a physical inventory of the cesium-137 dose calibrator source at the Bala Cynwyd facility during the first quarter of 1994 is an apparent violation of 10 CFR 35.59(g).

The inspector noted that a number of records of leak tests and inventory for 1992 and 1993 at the Bala Cynwyd facility did not include the signature of the RSO. This appears to be another example of lack of RSO oversight of the RSP. 10 CFR 35.59 requires that records of inventories and leak tests of sealed sources include the signature of the radiation safety officer.

Failure to include the signature of the RSO on records of leak tests and inventories for 1993 is an apparent violation of 10 CFR 35.59.

10. Postings

The inspector noted that none of the facilities had a current copy of the License. The December 27, 1988 application was only found at the Scranton facility, but was not posted nor was a notice describing the document and where it could be examined posted in the facility. In addition, none of the facilities had copies of the revised 10 CFR Part 20.

10 CFR 19.11 requires that each licensee post current copies of the regulations in 10 CFR Part 20, the license, license conditions, or documents incorporated into a license by reference, and amendments thereto, and the operating procedures applicable to licensed activities or a notice which describes the document and states where it may be examined, in a sufficient number of places to permit individuals engaged in licensed activities to review them.

Failure to post current copies of the regulations in 10 CFR Part 20, the license, license conditions, or documents incorporated into the license by reference, and amendments thereto, and the operating procedures applicable to licensed activities or a notice which describes the document and states where it may be examined, at the Bala Cynwyd, Scranton, and Yardley facilities is an apparent violation of 10 CFR 19.11.

The inspector noted that the transfer of documents from the main office in Philadelphia to other facilities was a significant weakness in the Licensee's program. In addition, maintenance of appropriate records is a weakness at the main office.

11. Exit Interview

At the conclusion of the inspection at the Bala Cynwyd and Scranton facilities on April 27, 1994, the inspector met with the Licensee's representatives designated in Section 1 of this report. The inspector summarized the scope and findings of the inspection. Following the inspection at the Yardley facility on April 28, 1994, the inspector discussed the findings of that inspection with the Operations Manager by phone.