#### U.S. NUCLEAR REGULATORY COMMISSION REGION I

Enforcement Conference Report No. 030-30947/94-002

Docket No. 030-30947

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

Program Code 2200

Licensee: Advacare Management Service, Inc.

2 Bala Plaza, Suite IL 52

Philadelphia, Pennsylvania 19004

Facility Name:

Advacare Management Service, Inc.

Enforcement Conference At: Region I, King of Prussia, Pennsylvania

Enforcement Conference Conducted: June 8, 1994

Prepared By:

Mary Cahill, Health Physicist

Medical Inspection Section

Division of Radiation Safety and Safeguards

Approved by:

benny M. Johansen, Chief

Medical Inspection Section

Division of Radiation Safety and Safeguards

6-16-94 date

Enforcement Conference Summary: An open Enforcement Conference was held at the NRC Region I Office in King of Prussia, Pennsylvania on June 8, 1994, to discuss the apparent violations identified during an inspection conducted on April 26-28, 1994 at the Bala Cynwyd, Scranton, and Yardley, Pennsylvania facilities. The causes of the violations and the corrective actions planned or implemented to prevent recurrence of the violations were presented by the licensee. Enforcement options available to the Commission were discussed.

#### **DETAILS**

#### 1. Persons Attending

Advacare Management Service, Inc.

Robert Perry, General Manager Sandy Young, Operations Manager Wayne Arnold, M.D., Radiation Safety Officer Joseph J. Berlandi, General Counsel Walter Robinson, Consultant Health Physicist

#### Nuclear Regulatory Commission

Susan Shankman, Deputy Director, Division of Radiation Safety and Safeguards Jenny M. Johansen, Chief, Medical Inspection Section Karla Smith, Regional Counsel Daniel Holody, Senior Enforcement Specialist Mary Cahill, Health Physicist

#### 2. Conference Summary

On June 8, 1994, Advacare Management Service, Inc. representatives met with NRC representatives in the Region I Office at King of Prussia, Pennsylvania. In an opening statement, the NRC Deputy Director of the Division of Radiation Safety and Safeguards explained the purpose of the open Enforcement Conference.

The licensee's Legal Counsel presented a document (Attachment 1) which he had prepared, with the assistance of other Advacare staff, to respond to each violation and presented the Licensee's overall programmatic and specific corrective actions taken or planned to prevent recurrence of the violations described in NRC Inspection Report No. 030-30947/94-001. This document was a revision to a facsimile received in the Region I office on June 7, 1994 (Attachment 2). Based on review of the document provided by the licensee and the Inspection Report by Conference participants, the following modifications will be made:

1. Section 4 of the Inspection Report describes an apparent violation involving the failure of the licensee to periodically review a Bala Cynwyd physician's use of byproduct material and records kept to reflect that use. In Section B.II of the licensee's document, the licensee contended that the use of radioactive material by a physician not listed on the license was supervised by Dr. Wayne Arnold, contrary to the stated violation. Exhibit E of the Licensee's document included a letter from the Radiation Safety Officer (RSO) stating that the RSO had supervised the physician and "overread" studies performed by the physician. Based on discussions between NRC and Advacare representatives, it was determined that the physician had not

been supervised by the RSO in accordance with 10 CFR 35.25(a)(3), contrary to what had been stated in the licensee's document. The licensee committed to revising the document accordingly.

- 2. Section 5 of the Inspection Report describes an apparent violation regarding the failure to maintain personnel dosimetry reports for Scranton and Bala Cynwyd personnel. With regard to the missing personnel dosimetry records for Scranton personnel, Section C.I(a) of the licensee's document had initially stated that the records referred to in the violation were maintained at the Scranton office. The licensee stated that this statement had been made based on information provided by the Nuclear Medicine Technologist (NMT) at the Scranton office. The licensee's revised statement, after failing in an attempt to obtain the records, indicated that dosimeters were worn, but that the dosimetry vendor indicated that they had not received the badges. The licensee committed to revising this document to indicate that the January and February 1994 dosimetry reports were not maintained by the Scranton office. With regard to the portion of the violation involving failure to maintain dosimetry records for June, July and October 1993 at the Bala Cynwyd office, the licensee provided copies of the missing dosimetry records (Attachment 3) at the Conference. The apparent violation will be modified to delete the reference to failure to maintain dosimetry records at the Bala Cynwyd office.
- 3. Section 5 of the Inspection Report describes an apparent violation involving failure of the NMT at the Bala Cynwyd Office to wear personnel dosimetry (whole body and extremity monitors) in July 1993. The licensee's document stated that spare devices were worn during this period. A signed letter (Exhibit F of Licensee's document) from the NMT also indicated that she wore spare devices during July 1993. With regard to the portion of the violation indicating the failure of the Bala Cynwyd NMT to wear an extremity dosimeter at all times when handling radioactive material, item II. on page 6 of the licensee's document states that the NMT always wears the extremity dosimeter during procedures. However, in Exhibit F of the document, the NMT stated that she, on rare occasions, did not wear an extremity dosimeter. NRC staff stated that the violation would be modified to indicate that the NMT failed to wear an extremity dosimeter in June (the NMT began work at the Bala Cynwyd in June 1993) and July 1993 and on other occasions from August 1993 to March 1994.
- 4. Based on discussions during the conference, the licensee committed to revise Section D.I of the licensee's document to indicate that the violation involving failure to perform daily surveys at the end of the day described in Section 6 of the Inspection report was not self-identified prior to the inspection.

- 5. Based on records of surveys contained in the Exhibit I of the licensee's document, the violation for failure to maintain records of weekly contamination surveys described in Section 6 of the Inspection Report will be modified to delete the portion of the violation regarding maintenance of records at the Yardley office.
- Section D. II of the licensee's document and the violation described in Section 8 of the Inspection Report involving failure to test the dose calibrator for linearity will be modified to indicate that linearity tests of the dose calibrator were not performed the third or fourth quarter of 1994.
- 7. Section 9 of the Inspection Report describes a violation involving the failure to perform a physical inventory of all sealed sources in the possession of the licensee. Section E.II of the licensee's document states that the inventory deficiency was self-identified and corrected by the licensee. A copy of the inventory (Attachment 4) provided by the licensee was incomplete in that a second cesium-137 dose calibrator source possessed by the licensee was not inventoried. In addition, the violation was not self-identified as stated in Section E.II. The licensee committed to revise Section E.II of the licensee's document accordingly.
- 8. Section 10 of the Inspection Report describes a violation regarding failure to post current copies of the regulations in 10 CFR 20, the license, and license conditions, or notice indicating where the documents can be found. Section F.I of the licensee's document states that a notice describing where the documents can be found was posted at each facility. However, at the Conference, subsequent to a description of the documents required to be posted, the licensee stated that all of the required documents were not in their possession. The licensee committed to revise their submittal to include this information. The NRC provided the licensee with copies of information required to be maintained at the licensed facilities on June 9, 1994.
- The licensee indicated they will include the conduct of semi-annual Radiation Safety Committee meetings as an additional corrective action in the revised document.

The Deputy Director requested that the licensee thoroughly review the document to ensure accuracy of information therein and make additional modifications, as appropriate, and submit the revised document to the NRC.

The licensee committed to provide an organizational chart which depicts the licensee's corporate structure and chain of command, and a description of each individual's responsibilities with respect to the Radiation Safety Program. The licensee stated that the revised Document and organization chart would be provided to the NRC within several days.

NRC staff questioned the capability of the RSO to meet his responsibilities for the numerous Advacare facilities and considering his busy cardiology practice. The RSO stated that he had made arrangements for coverage of his cardiology practice so that he would be better able to oversee the licensee's Radiation Safety Program. In addition, Advacare management indicated they intend to request a separate license for New Jersey facilities overseen by a different staff, including RSO.

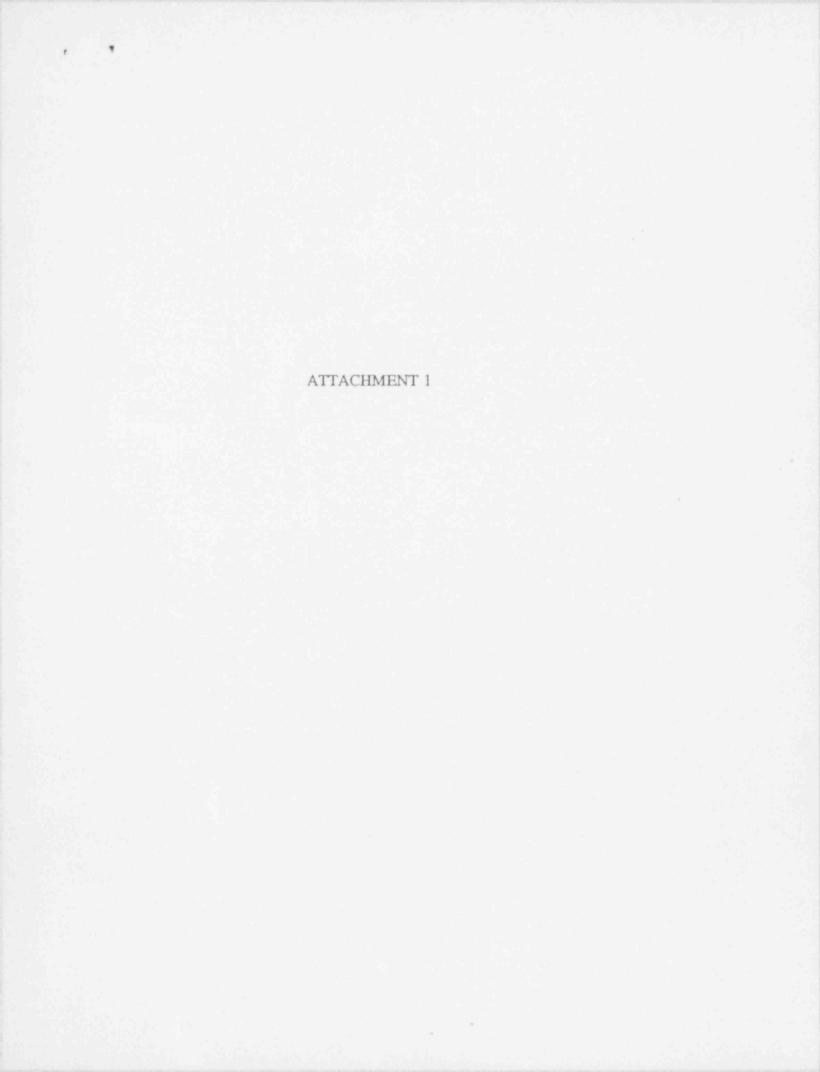
The Enforcement Conference was tape recorded by the NRC. A copy of the recording can be obtained in the NRC Region I Public Document Room.

#### 3.0 Closing

The NRC Senior Enforcement Specialist explained the enforcement procedures and options available to the Commission.

#### Attachments:

- Licensee's revised document responding to violations (submitted at June 8, 1994 Enforcement Conference)
- 2. Licensee's original Document responding to violations (telefaxed on June 7, 1994)
- 3. Dosimetry records
- 4. Inventory record



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June 7, 1994

63 Great Road Maynard, MA 01754 508 897 9981 FAX 508 897 7680

Charles W. Hehl, Director Division of Radiation Safety and Safeguards Nuclear Regulatory Commission Region I 476 Allendale Road King of Prussia, PA 19404-1415

RE: NRC Inspection No. 030-30947/94-001

Dear Mr. Hehl:

I am in receipt of your letter and report to Ms. Sandy Young, Operations Manager for AdvaCare Management Services, Inc. in connection with the NRC Safety Inspection of our Scranton, Bala Cynwyd and Yardley, Pennsylvania facilities by Ms. Mary Cahill on April 26-28, 1994. It is my understanding that an enforcement conference has been scheduled for June 8th at 10:00 am at your Region I office in King of Prussia, PA. Attending this conference, on behalf of AdvaCare Management Services, Inc., (AdvaCare) will be the following individuals:

Robert Perry, General Manager Sandy Young, Operations Manager Dr. Wayne Arnold, Radiation Safety Officer Walter L. Robinson, Consulting Radiation Physicist Joseph J. Berlandi, General Counsel

I would like to take this opportunity to thank the Nuclear Regulatory Commission, Division of Radiation Safety and Safeguards for its thorough inspection of our three (3) facilities and prompt report of its findings. AdvaCare has been a licensed provider in Pennsylvania of diagnostic cardiac nuclear medicine (thallium stress tests) since 1989. We take significant pride in our commitment to provide the highest quality of services and equipment and make every effort to ensure compliance with our corporate protocols and Federal and State regulations. As you know, during the past several months we have expanded our facilities to the extent that we presently operate 6 licensed facilities in Pennsylvania and one in New Jersey. In fact, in November of 1993 we opened our Scranton facility and in 1994 we opened our Bustleton and Center City facilities. Notwithstanding this expansion, our full commitment to regulatory and protocol compliance is still resolute. We acknowledge the importance and necessity of full compliance and, within that context, do not consider the findings of apparent

violations stated in your report lightly. We are committed, therefore, to taking the necessary corrective actions to remove any and all existing violations and to provide management oversight to ensure continued compliance.

In preparation of the scheduled conference, I would like to submit the following written responses which are intended to clarify some of the findings which appear to be based upon incomplete or inaccurate information and, more importantly, to describe corrective actions which were either in place at the time of the inspection or have been implemented as a result of the inspection. The overall purpose is to restate our cooperation and commitment to regulatory and protocol compliance.

With the expansion of our licensed facilities, it has become evident that more frequent compliance audits should be performed for each facility, that the exchange of information to and with our Radiation Safety Officer be better documented, and that management oversight be improved to ensure prompt remedial action to compliance issues. In this regard, we have

- Increased the scope of services of our consultant physicist to include a monthly audit of our Scranton, Bala Cynwyd and Lancaster facilities and bi-monthly audits of all other facilities. Walter J. Robinson and Associates will provide these audits and a resulting written report will be provided to our Radiation Safety Officer and to our Nuclear Group Manager.
- (2) Dr. Wayne Arnold, our Radiation Safety Officer, will work closely with our Nuclear Group Manager and our facilities NMT to provide the necessary professional and management oversight to ensure that all compliance violations reported in the audits are promptly corrected and all such actions are appropriately documented.
- Our consulting physicist, Walter Robinson & Associates, with the approval and guidance of our Radiation Safety Officer will continue to provide & annual in-service refresher programs on safety and training to each NMT at each facility. Evidence of such will be documented. He will also continue to make himself available on a day to day basis, if necessary, to address safety related issues.
  - (4) Our Nuclear Group Manager will be responsible, amongst other things, for compliance coordination and management oversight for each facility. The manager will work closely with the NMT

supervisor at each facility and appropriate records will be maintained both at each facility and at the office of the Group Manager.

I believe that the above generally described measures will most assuredly strengthen our compliance and management oversight procedures to avoid future violations.

With reference to specific apparent violations described in your report, I would like to offer the following observations:

## A. Radiation Safety Audits

I. 10 CFR 35.20 (a) "Failure to perform the annual review of the Radiation Safety Program, including a review of operating procedures, in 1992 and 1993."

## (a) Scranton Facility

- (i) <u>Lab Coats</u> All NMT wear lab coats when in those areas requiring lab coats. Please refer to letter from Gary Golecki to Mary Cahill. (Exhibit A)
- (ii) Posting of Documents Our license and notice to employees were, at the time of the inspection, prior to, and currently are posted. The license was posted in the hot lab and notices to employees were posted on the bulletin board. (Exhibit A)
- (iii) Training to Personnel An in-service safety training program is provided to personnel on a received service annual basis for each facility.

> (iv) <u>Deficiencies</u> - January and April 1994 audit deficiencies have been corrected.

#### (b) Bala Cynwyd Facility

- (i) Failure to train an NMT. This NMT was unable to attend the scheduled program due to a prior commitment of a training course provided by General Electric for applications on new equipment. She has of this day received full required training.
- (ii) Response to January 1994
  Audit A copy of the
  written response is
  attached hereto (Exhibit
  B) indicating corrective
  action taken. As noted,
  the response was written
  in the margin of the audit
  report.

## (c) Yardley Facility

- (i) RSO Signing Records This was self identified as indicated in our audits, the RSO has and will sign all required documents as part of his scope of service.
- (ii) Posting of documents The license is posted and
  the Regulations are
  available on site.

## B. Training and Supervision of Personnel

#### I. 10 CFR 35.21 (a)

"Failure to provide annual radiation safety training to personnel in 1992 and 1993."

#### (a) Bala Cynwyd NMT not trained

As reported above, the specific NMT has received the required training.

- (b) No evidence to verify effectiveness of training A certificate will be provided to all NMTs evidencing completion of the training and a test will be given to the NMTs.
- (c) No annual refresher training in 1992 and 1993
  An annual in-service refresher training was provided in September, 1992 and records of the same are maintained at the facility. (Exhibit C) The 1994 meeting was held on April 12th. The attendance list is attached. (Exhibit D)

# II. 10 CFR 35.26(a) (3)

"Failure to periodically review the Bala Cynwyd physician's use of by product material and records kept to reflect that use."

The physician in question, Dr. Eisenstadt, is fully credentialed, however, not currently an authorized user on our license pending submission to and approval of his credentials by the NRC. His scan interpretations have in fact been reviewed by our authorized user, Dr. Wayne Arnold. (Exhibit E)

## C. Personnel Monitoring Program

## 10 CFR 20.2106, 10 CFR 20.401 and 10 CFR 35.21

"Failure to maintain records of radiation exposures for Scranton and Bala Cynwyd personnel."

## (a) Scranton Facility

These records are, in fact, maintained on site.

Unfortunately, our site management, Gary Golecki,
was not in on the day of inspection and the substitute
temporary employee had no knowledge of this.

Badges were worn

#### (b) Bala Cynwyd Facility

All records are forwarded to the RSO for review and signature. The original is sent back to the facility with a copy to the Seranton office. The records were in fact available. Baka legional office.

#### II. 10 CFR 35.21 (a)

"Failure to wear personal monitoring device by NMT at Bala Cynwyd facility"

The specific NMT in question, Antonia Kist, always wears the monitor devices during procedures. On the day of the inspection she was confused by the inspector's question and intended to reply that she did, in fact, remove the device when washing her hands. Please see statement from her in this regard. (Exhibit F)

## III. 10 CFR 20,150 1 (a) and 10 CFR 20.201

"Failure to evaluate radiation exposure of the contractor NMT."

Our policy is to obtain prior 3 month exposure records of a contractor NMT and post the same in the lab and in the individual's badge (Exhibit G). All such records are to be reviewed by the RSO. (Exhibit H) In the instance of Antonia Kist, she commenced work in July, 1993. She wore "spare" badges until the new body and ring badge arrived. The spare badge was returned to Landauer with the July badges and exposure was reported. At no time did she work without monitoring devices. (Exhibit F) }

## D. Radiation Surveys

#### 10 CFR 35.70 (a)

"Failure to conduct surveys at end of the day at Bala Cynwyd facility."

This, indeed, had occurred at the Bala Cynwyd facility. However, it was self identified prior to the inspection and has been corrected accordingly.

#### II. 10 CFR 35.70 (h)

"Failure to maintain records of weekly contamination surveys at Scranton and Yardley facilities."

#### (a) Scranton Facility

Results were recorded in counts per minute rather than disintegrations per minute.

All equipment will be re-calibrated to record properly and inspected during our audits to ensure the same.

(b) Yardley Facility
This facility was operational as of July,
1992. During the period of July 4August 11, 1992 there were nuclear
studies performed and, contamination
surveys prepared. Records are
maintained at the facility, however,
were located in a different binder at the time
(Exhibit I)

## E. Survey Instruments

## I. 10 CFR 35.51 (c)

"Failure to check survey instrument with a dedicated check source each day."

## (a) Bala Cynwyd Facility

A dedicated check source was and, in fact, is still available at this facility. It

appears as though the technician failed to use the instrument on a daily basis during this period. Corrective action has been taken in the form of explicit instructions, to be posted, to all NMTs at all facilities to perform this on a daily basis.

#### (b) Scranton Facility

Same as above.

#### F. Dose Calibrator Quality Control

#### I. 10 CFR 35.21 (a)

"Failure to properly perform constancy checks of the dose calibrator at the Bala Cynwyd facility from January 1, - April 27, 1994."

The RSO and the nuclear group manager will be responsible for ensuring that constancy checks be performed properly. All such checks will be documented by the NMT and periodically reviewed by the RSO and maintained at the facility.

## II. 10 CFR 35.50 (b) (3)

"Failure to properly perform a linearity test of the dose calibrator during third quarter of 1993 at Bala Cynwyd."

It appears that the assay data was collected but not analyzed during this particular period. This was self identified in the January 1994 audit and corrective action was taken. All appropriate procedures are being followed.

## III. 10 CFR 35.50 (e) (3)

"Failure to include signature of RSO on records of dose calibrator linearity tests for 1992 and 1993 at Bala Cynwyd and Yardley facilities."

This was also self identified by an audit and has been corrected. The RSO signs all records accordingly.

#### G. Sealed Sources

#### I. 10 CFR 30.51

"Failure to maintain records at the Scranton and Bala Cynwyd facilities of cesium - 137 dose calibrator source."

(a) Scranton Facility
The calibrator certificate was and still is on site.
However, the transfer record from the manufacturer to us in the incoming package has been misplaced.

#### (b) Bala Cynwyd Facility

Same as (a) above.

## II. 10 CFR 35.59 (9)

"Failure to conduct physical inventory of cesium-137 dose calibrator service at Bala Cynwyd facility during 1st quarter of 1994."

This was self identified and a physical inventory was conducted and record of the same is in the possession of the licensee. Quarterly inventories will continue to be maintained, signed by the RSO, and maintained at the facility.

## III. 10 CFR 35.59

"Failure of RSO to sign records of leak tests."

The RSO has signed records of leak tests for all facilities which shall be maintained at the facility.

#### I. 10 CFR 19.11

"Failure to post current copies of regulations, license, etc."

As of the date of this letter, a notice describing documents and where they may be examined has been posted at each facility. This will be maintained on a current basis. We are also undertaking a major effort to ensure that appropriate records are properly maintained at our main office.

As indicated above, it is not our intention to consider your report lightly. Although a written response is not required, I trust that it will serve as a basis for our discussions at the enforcement hearing. Self identified deficiencies and corrective action has occurred on several of the listed apparent violations. We have also put into effect an enhanced audit program, the creation of a Nuclear Group Manager position to provide management oversight, and improved coordination between the consulting physicist, Nuclear Group Manager and our Radiation Safety Officer.

We are committed to the delivery of quality services and equipment and full compliance with regulations and protocols. I look forward to discussing these issues more fully with you at the hearing.

Yours truly,

Joseph J. Berlandi General Counsel



201 Franklin Street 3rd Floor Scranion, PA 18503 717-344-7484 Fux 717-344-7492

Monday, June 6, 1994

Mary Cahill Nuclear Regulatory Commission Region I King of Prussia PA

Dear Ms. Cahill,

I would like to clear up a question that has repeatedly come up. I insist that all personnel that comes in contact with, is working with or in the area that Thallium is used, wears a lab coat. The only time our lab coats come off is when we are on break, on lunch or out in the front office working. I will not tolerate this rule broken by any employee, this has been my policy since day one. There is also the question about the posting of the N R C -3 Form NOTICE TO EMPLOYEES. As you can see from my attached letter date February 11,1994 to Walter L. Robinson & Associates, that was and has been posted in the HOT LAB since our FIRST day of operation.

If you have any other questions please do not hesitate to contact me directly.

Sincerely.

Gary T. Golecki

Administrative Technologist





# WALTER L. ROBINSON & ASSOCIATES

CONSULTANT RADIATION PHYSICISTS

2624 SPRING VALLEY ROAD + LANCASTER, PA 17601 TELEPHONE 717-291-9813 TOLL FREE 800-446-7622

January 22, 1994

Sandy Young Tony Kist 2 Bala Plaza Suite IL 52 Bala Cynwyd, PA 19004

Dear Sandy and Toni:

#### General:

First, Sandy, I would like to say thank you for getting me a copy of your original NRC license and application; however, surely it was inadequately received by the NRC in that form. Surely, there were letters of correspondence that they sent you (deficiency letters) and your response letters. I need these more than what I was given. What I was given was an application for a hospital nuclear medicine department with therapy! Surely, this could not have been acceptable to the NRC. I need all your letters of correspondence to the NRC (including inspection letters and your response) especially those dated: 12-27-88, 5-21-90, 6-21-90, 8-31-90, 5-15,91, 9-5-91, and any subsequent to them. Had I prepared your application, it would have been a letter 3 to 4 pages long with a site diagram for each center.

What you sent me was for a location in Jenkintown, not the four locations in which you currently provide services. I also need all the correspondence and license application from the State Bureau of Rad-Protection (D.E.R.). I would also like a copy of your most recent licenses (NRC and State). I did not get one from either site. Please send this data with Yardley and Scranton directions as soon as possible. I still await a list of names, phone numbers and site responsible parities" for each center.

For your upcoming (by the end of March) NRC license renewal, please have photos taken from two angles (min.) of each hot lab. This will save many words and minimize expediency of inspection, if they have not come by this date. We will submit the pictures with the renewal. Polaroids images are OK.

## Bala Cynwyd Office Status Report:

First, I will reiterate items found at Lancaster that persist here, then I will list site-specific problems areas found.

## Duplicate Areas for Improvement:

Will Resoul 1. I could not find any evidence of R.S.O.-signed documents. Please find form enclosed to improve this deficiency.

2. Missing Records:

A. Leak tests of sealed sources since inception of operations:

FOR 10/97-CONIDNOTFIND DOCUMENTS

LOKED

Data is missing for the dates and sources below:

1) Co-57 flood source (1st date is 4/92, I assume your 1st flood was not purchased before 10/91) S/N 1194/84; C.I.S.; 205 MBq

1/93

8/93

(I did 1/94)

2) Co-57 dose calib. source; S/N 1978/194; C.I.S.; purchased: 2/7/92

Done: 8/93

No data: 8/92

No data: 10/92

2/93

This source is

I could not find this source present! Is it possible you have transported Bala sources to other sites and taken the records along? I would have thought you would have purchased new sources for each new site. Any sources unaccounted for can get you in big trouble with regulatory agencies.

This source

15 Dehind

shield in hot

- 3) Co-57 dose calibrator source; S/N CK992; purchased: 4/8/91 No leak test data at all, but this source is present and used daily!?
- 4.) Cs-137 dose calibrator source; S/N 3063 MA; purchased on 11/1/87! This is its assay date. No leak test data at all, but this source is present and used daily!?
- 5) Cs-137 dose calibrator source; S/N 3890/319

First leak test record was:

Done 4/91

No data: 4/92

10/91

10/92

8/93

Source was not found at Bala site.

- ould not 8/93. If it was purchased before Feb. '93, then it had at least one missing leak test report.
- document 7) A Cs-137 rod source; S/N 13A-101884-0110.106 (10/18/84) was possessed, but only one document on file. Also a Co-57 (0.109 uCi) 7/14/89; S/N 076005-058 source is supposed to be around. I could not (did not) find these?

Shield IN A LEAD CONTAINER WRAPIN LEAD Sourcers

There are serious sealed-source record-keeping problems. As you can see, to me, a mock-inspector, it is apparent you either disposed, lost, sold or transferred sources - minimally without proper documentation. Toni should call me to discuss the location of each of the above sources, plus any other ones she knows about.

dill give To RSO TOSIAN OR WEAR FOR All Tocheck

REMIATION SURVEY

- 3. Film badge records all exposures are low, but there is no evidence that the R.S.O. FSO 105:9N reviews and initials these documents; as a matter of fact, I found one or more still folded Unil fc5+ documents in the form they come out of the envelope. I put these in chronological order for optimal review and comparison purposes. Annual data must be given to all staff badged
  - 4. Quarterly inventories were performed monthly from 3/92 to 9/93, with one missed as recently as 12/93. There was no record prior to 3/92 on site. There was no required "radiation survey" performed on these sealed sources, as required.
  - 5. There have never been radiation surveys behind the hot lab to assure there is no hazard to personnel on the other side. This may not be a license commitment weekly, but some data should be on record. It could be construed as needed weekly by an inspector.
- FRY TO MONITOR Wipe-test records are in d/m, but are being measured on your new Capintec Caprac (a good instrument), but I see no effiencency calculations to assure data is printed out in pure d/m, or if it needs a convertion factor. I will try to contact Janet Barbiere from Capintee to discuss the necessity for this, so we will know how to answer inspectors.

Havepested

- Will REVIED 7. Your staff is not familiar with your whole radiation safety program and commitments.

  Our future in-service and video tops should in the service and video tops should be serviced in the service and video tops should in
  - 8. No back-up dose calibrator or mechanism is present.

HAUROEDEFEE No A.L.A.R.A. binder, all NRC regs., or any PA DER regs. were present for all staff to BANGEL see and read.

10. Your trigger or action levels must be posted or inserted in the front of your het in 50° Th Th, 5 areas, ≤ 2000 d/m for all Tc-99<sup>th</sup> and Tl-201 contamination. WillaskMa wipe-test/survey notebooks; i.e. ≤ 5 mR/hr in restricted areas, ≤ 0.5 mR/hr in unrestricted hot mison To

HAVE ACKNOWLEDGE CHOUSE No evidence of radiation safety/regulatory in-services.

- 12. No caution signs for pregnant or breast-feeding females.
- 13. No evidence of a negative Q.M.P. declaration.

## Site-specific finding (additionally) include:

11- Abje 10 1. Dose calibrator accuracy test data (req'd annually) found only for 7/16/90 and June '93. and DATA

300 548 widely used. This test must be performed for 3 cc. syringes.

MABLE TO 35 Dose calibrator activity linearity tests were performed somewhat regularly since 7/16/90; Find FECOTAS however, the following data was missing:

1) The 2nd, 3rd and 4th qtr. '91 data was

performed were entered. This is not in compliance with the NRC.

2) March '93 data is missing; June '93 data is missing.

- 3) One test was performed two months late in Aug. '93, but the next one was by Toni (now) Jan. '94 to be concurrent with my "sleeve-test" measurements. Therefore, the one that should have been done Sept.-Dec. '93 was missed.
- 4. The radiation survey meter situation is similar to the dose calibrator source situation. I suspect some meters were transferred to other sites instead of geiting new ones for the new sites, since there is data present for meter calibrations, but that meter is not present. There is data for 4 meters with S/N 71976, 72055, 68172, 77523.

Was calibrated semi-annually since 3/90 (only annually req'd!) > S/N 71976

> S/N 72055 Data from 3/90 to 12/91, then no more data.

> S/N 68172 Data from 7/92 to 7/93, then no more data.

➤ S/N 77523 Data only for 10/91

Posting inadequacies

Will have to a) Physician's prescribed dose range should be signed by R.S.O.

Willpist -b) New 10CFR20 should be posted in lieu of old one

will post c) "Caution Radiation Area" sign should be on imaging room door.

6. You should add a "radiation waste storage" area to your weekly survey/wipe records and 31 11 Addcheck this location weekly.

7. Co-57 source vs. Cs-137 source should be used for daily dose calibrator constancy tests.

8. 5 cc. leaded syringe shield needs to be replaced. The leaded glass is broken and ineffective. You may wish to order lead acrylic or new spring-loaded type units (J.R.T. Associates can help).

9. Someone performed a gamma-camera efficiency test, so it could be used for wipe-testing (since it has a computer), but this was not advised by your previous consultant!?

There are probably many more items that I will find as I look more deeply and ask more questions of the staff.

In general, my global recommendations are as we discussed:

- 1. Have the R.S.O. take a more pro-active aggressive role of document signatures, record organization, and visit each site on my 2nd scheduled visit at each site.
- 2. Have the R.S.O. use the "table" that I sent as a reminder of status of documents needing review, signatures and initials. In the future the N.R.C. may not require the R.S.O. to sign the dose calibrator records (proposed new 10 CFR 35 N.R.C. regulations).
- 3. Arrange an in-service (live) for all your administrators, R.S.O., staff technologists to attend from all sites. This in-service to include: a license/regulatory commitment review, a radiation safety program/organizational review, a new regulation synopsis, and a delegation of responsibility discussion. The proposed February evening in-service meeting I can foresee being 6:30 9:30pm on my part, for which there will be an additional visit's billing above our contract. Wednesdays do not suit, I would prefer a Tuesday or Thursday night, except the 10th.

Sincerely,

Walter L. Robinson, M.S., A.B.M.P., and A.B.S.N.M.

Consultant Certified Medical Radiation Health Physicist

annual Radiation Sayety Committee Meeting: Advance Imageoner Mid atlantic Reg Office 2 Bala Plaza Suite IL-17 Bala Cynwyd PA 19004 Conducted by Dr. Woyne anold and Treny Circleselssues discussed - Charges CF. P. 10. 19, 20, 35 went over isotope handling, Spill procedures, Log books, wipe tests, prescription providence (our policy) also went over pregnancy essues, shielding to keep expression. question & answer period post discussion Concerns. I exposure due to Cardiolyte Studio -Scholiling, proper shielding for fre gover employees, Terry ~ In arrold to give inservere to han. Imployeee -Tem Cerrello (physicit stecture) -Ar. Wayne anold MO. Hr. Druce Kornburg MD. Harriet Jams NT John Kivieno NI angelo amento NT Regna Mylin Stress Nurse Surum Rethwell Stress Nance Bob Perry General Marager ..

ADVACARE DIAGNOSTIC

IMAGEAMERICA PHONE: (615) 373-5400 109 WESTPARK DRIVE, SUITE 420 BRENTWOOD, TENNESSEE 37027

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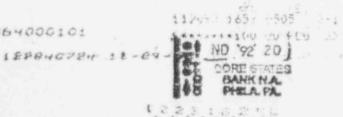
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EXHIBIT D 1 of 5 BALA MEDICAL CENTER Wayne V. Arnold, D.O.

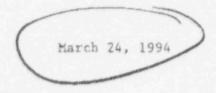
CARDIOLOGY - PERIPHERAL VASCULAR DISEASES

15 NORTH PRESIDENTIAL BLVD. SUFFE 100

BALA CYNWYD, PA 19004

(610) 667-2746 (610) 667-2749 Fax# (610) 667-9420

Sandy: Young, Image America 111 Presidential Blvd. Bala Cynwyd, Pa. 19004



Dear Sandy:

This letter is to smoowne the Radiation Safety Meeting - Semi-Annual to take place on Tuesday evening, April 12, 1994 starting at 6PM. The place is the Starlight Diner, Fogelsville, Pa. I feel the Starlight will provide a very adequate and affordable atmosphere for our Radiation Safety Meeting and is located as a mid-point for the attendees of all our nuclear facilities.

It is located on Route 100 South, Exit 14A off of I-78. Exit 14A is Route 100 South. Phone number of the Starlight is 395-4031 in case any of the attendees need to phone for specific directions.

I look forward to a very successful and productive meeting.

Sincerely,

Wase V. A. ed do Wayne V. Arnold, D.O. Radiation Safety Officer

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Please initial attendance

RSO meeting (mandatory) 4-12-94 Gary Golecki (Scranton) Suzanne Yoder Wood fin - (C-VAZ) Susan Kob (Eval) Scronn Rothwell (Yardley) SIR-Juzanne Ramsey (Bala) SER Angelo Amenta (Yardley) Sheila Beardsly (Bustleton) Sandi Killian (Cval) Russ Mc Connell (Sates rep + account exec (e-ui)) Per - Bot Perry - General Manager -Dr. Wayne Arnold - 1250 Walt Robinson - goup physicist Stell State Sande Killian (WAC) On Warre V Augel 250 palut (deans A M. Hay Toblichi (Scontion) REACHT CHARLES (ALLASSIN Susan Kota ( GUAL) Suganne Toder- Floodfui (LAncaster)

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# PLEASE INITIAL UNDER EACH COLUMN WHEN COMPLETED

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## PLEASE INITIAL UNDER EACH COLUMN WHEN COMPLTED

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Bala Pointe, Suite 109 111 Presidential Boulevard Bala Cynuyd, PA 19004 215 668 8152 FAX 215 668 9850

Charles W. Hehl, Director Division of Radiation Safety and Safeguards U.S. Nuclear Regulatory Commission Region I 475 Allendale Road King of Prussia, PA 19406-1415

June 2, 1994

Dear Mr. Hell,

As Radiation Safety Officer and authorized user for AdvaCare/ImageAmerica operating under NRC license #37-28331-01, I attest that Norman Eisenstadt, M.D. is under my supervision for reading nuclear cardiology studies at our Bala Cynwyd lab. Dr. Eisenstadt's credentials for authorized usership are completed and this preceptorship documentation will be forwarded to the NRC licensing branch for amendment after the resolution of the enforcement hearing scheduled for June 8, 1994.

In my capacity of authorized user and RSO, I have overread Dr. Eisenstadt's studies performed at the Bala Cynwyd lab, and will continue to do so until the Dr. Eisenstadt is approved as a authorized user himself.

Sincerely,

Wayne Arnold, M.D. Radiation Safety Officer EXHIBIT F

## STATEMENT OF ANTONIA KIST, NUCLEAR MEDICINE TECHNOLOGIST

To Whom It May Concern:

I would like to address two cited apparent violations that pertain to my work and my conversations with NRC Inspector Mary Cahill on April 27, 1994.

In Section 5.7 of the letter detailing AdvaCare/ImageAmerica's recent NRC inspection, a cited apparent violation reads:

Failure of 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).

I am the NMT referred to in these incidents and would like to elucidate the circumstances stated above.

When I began work in July 1993 I called Landauer and ordered myself body and ring badges to arrive in the next scheduled shipment. Until their arrival I wore current batch body and ring badges labeled "spare". The "spare labeled badges were returned to Landauer with the rest of the July badges and their reported exposure, which both were M (minimal) was assigned to me. Thus there was no time period that I worked with radioactive materials without personnel monitoring devices.

During the inspection on April 27, 1994 I was continuing to perform patient testing using thallium. Between patients I washed my hands, removing my ring badge to do so. As I was beginning to prepare my next patient unit dose, Inspector Mary Cahill pointed out to me that I was not wearing my ring badge. I replied that I had just removed it to wash my hands and put it in my lab coat pocket, forgetting to put it back on my finger. Inspector Cahill then questioned if I properly wear my ring badge, since my monthly extremity exposures have routinely been M (minimal). I was at that time under considerable stress between a hectic patient schedule and experiencing my first NRC inspection. I told her that I do routinely wear my ring and body badges properly but admitted to forgetting, on very rare occasion, to wear my ring badge on my finger. It seems Inspector Cahill interpreted my honesty, along with my low exposure records, to mean that I fail to wear my ring badge properly on a regular basis. This is not the case. All of our cardiac nuclear medicine technologists who image primarily with thallium receive M (minimal) monthly badge reports regularly, due to the lower energy of thallium and unit dose availability. I feel that my attempt to be sincere and admit human error was taken out context in the inspection report.

antonia Kist RT(N)

Jan Casford MTS Health Care Services, Inc. 1551 Bond Street Suite 109 Naperville, IL 60563-0114

June 1, 1994

Dear Ms. Casford,

This letter is to inform MTS of a procedural update regarding ImageAmerica's personnel dosimetry monitoring program when contracting nuclear medicine technologists from your agency.

Effective immediately, all agency NMTs providing temporary coverage to ImageAmerica accounts must wear radiation badges supplied by ImageAmerica as well as the badges provided by MTS. The temporary NMT must also produce their personnel exposure record for the previous twelve months to be kept on record at the ImageAmerica facility which they cover.

It is my understanding that this procedure is now in place and the applicable technologists are aware of and have complied to this regulation.

We at ImageAmerica thank you for your prompt action in this matter, and for your continued service.

Sincerely,

Kathleen Bousquet, Technical Manager,

Nuclear Medicine

To: Image America Nuclear Medicine Technologists

From: Kathleen Bousquet, Technical Manager,

Date: June 1, 1994

Re: Responsibility of handling radiation badges

At each ImageAmerica lab, one person (a nuclear medicine technologist in all cases) will be responsible for the receipt, distribution, return shipment and report posting of radiation badges. This procedure will have management oversight by the RSO and nuclear group manager, but the responsible party at the individual lab level will be the nuclear medicine technologist. The current list of technologists resonsible for radiation badge handling is listed below. If you have any questions or concerns, please contact me at by pager at 508-722-2351 or Sue Rothwell at 215-930-6689. I look forward to seeing you all on my next visit to sites on June 20-22.

LAB TECHNOLOGIST

Bala Cynwyd Toni Kist

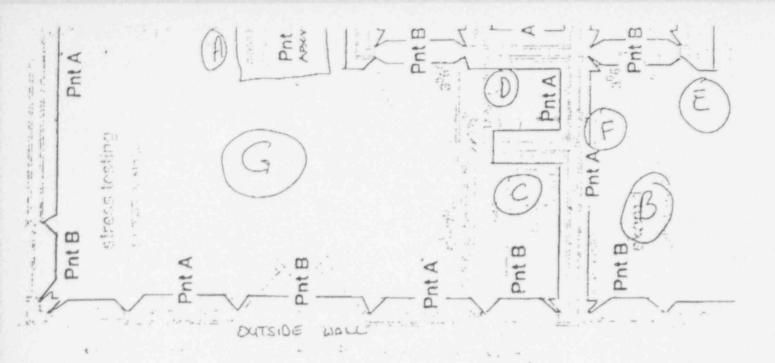
Bustleton Sheila Beardsley

Center City Toni Kist

CVAL Suzanne Woodfin

Scranton Gary Golecki
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## WALTER L. ROBINSON & ASSOCIATES

CONSULTANT RADIATION PHYSICISTS

2624 SPRING VALLEY ROAD . LANCASTER, PA 17601 TELEPHONE 717-291-9813 TOLL FREE 800-446-7622

June 4, 1994

Wayne Arnold, D.O.
Radiation Safety Officer
Bala Pointe
Suite 109
III-Presidential Blvd.
Bala Cynwyd, PA 19004

Dear Dr. Arnold:

I confirm receipt of your letter requesting Walter L. Robinson & Associates to provide more frequent visits to the Pennsylvania ImageAmerica nuclear cardiology sites. At your request, we will continue this frequency of visits until further notice by you, in writing.

We will commence these enhanced services as soon as possible, but not later than July, 1994, as we have a lot of vacation requests to fill in June.

We will visit the Scranton, Bala Cynwyd, and Lancaster facilities monthly, while the Yardley, Bustleton, and Center City facilities will be visited bi-monthly. This is as opposed to the previous quarterly arrangement for all sites.

We will expect a written response to our report for each site, by the nuclear medicine technologist, addressing their corrective actions for each problem found. This report to be sent to me and yourself (R.S.O.) no later than 2 weeks following monthly visit sites and 4 weeks following bi-monthly visit sites.

With this increased frequency of service, we will provide more time for one-on-one in-services and training for all technological staff (or others who come into contact with radioactive materials). The topics to be included as a minimum will include: applicable regulations that pertain to license commitments and conditions, safe storage of radioactive materials, relative and potential hazard of all the radioactive materials used, the radiation safety program with its procedures, radiation safety standard work rules, mechanism for reporting unsafe conditions, emergency response mechanism, staff worker's rights, and posting requirements. The training for technologists prior to assuming duties as a new technologist will be to read my previously-provided "radiation safety program synopsis for this licensee" and the list of frequencies for all record-keeping and other technological radiation safety/regulatory duties. If there are any questions they can call me. I will also be available to them upon my next scheduled visit. I send a post card approximately 30 days prior to the next visit. If the date is totally unacceptable, they will need to call me to reschedule. These post cards will be sent only to

the individual sites, but a list of up-coming dates of visits will be submitted to you, the R.S.O., so that you can coordinate spot visits in conjunction with me as desired.

A certificate will be provided to all technologists who have completed in-service training by us. I recommend that a total of 4 hours be a minimum for each technologist/yr. This should be no problem with the current frequency of services. In-services will also be given at "radiation safety committee meeting assemblages", which are currently planned semiannually.

We have provided each site with a videotape entitled: "A Review of Your Radiation Safety Program". Also, to this end, I have provided a textual handout synopsizing the site's nuclear cardiology radiation safety program, and a post test to be completed by all technologists watching the videotape.

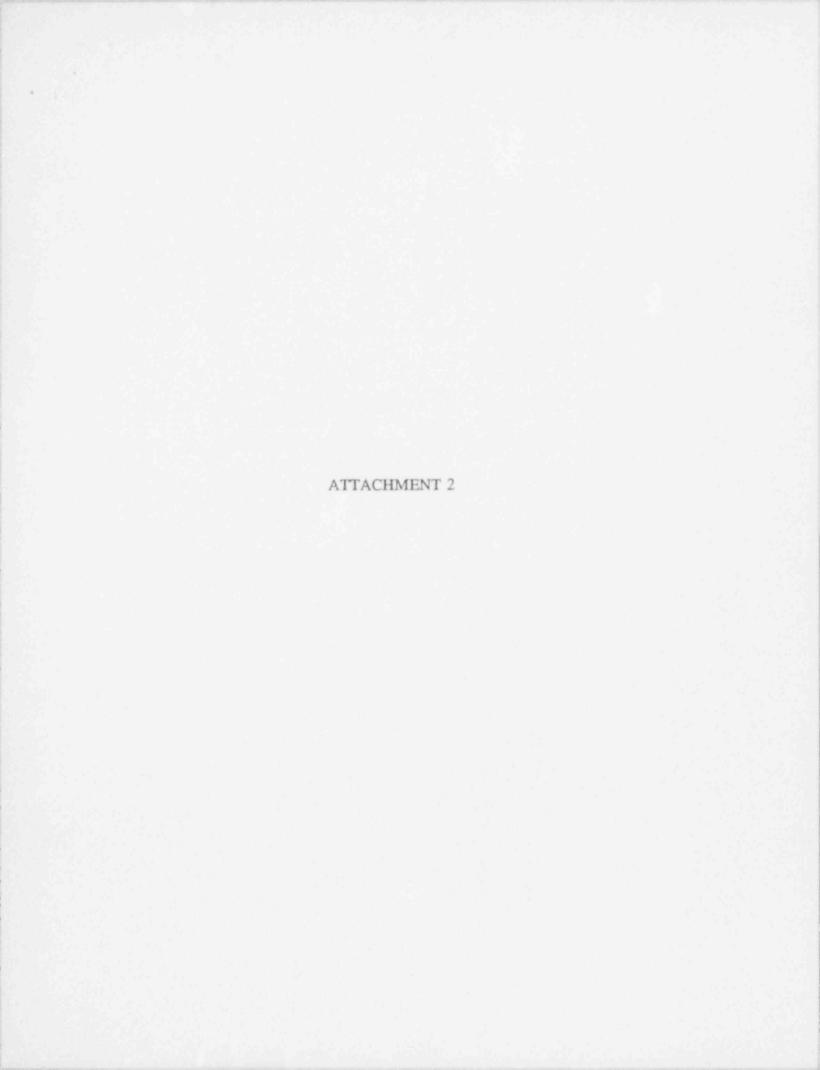
In addition to the above training services now possible due to the increased frequency of services, we will also provide:

- 1. Quarterly Sealed Source Inventories with Radiation Survey
- 2. Sealed Source Leak/Wipe Tests semiannually
- 3. Regulatory Management Audits
  - a) Level 1 (Mock Regulatory Inspection including record review) quarterly
  - b) Level 2 (Follow-up on previously found problem areas) monthly/bi-monthly
- 4. Provide telecommunication connections with you, the R.S.O., and management personnel for any answers or discussions through:
  - a) Voice Mail: 717-291-9813 or 1-800-446-7622
  - b) Fax: 717-291-9813 or 1-800-446-7622
  - c) Pager: 1-800-752-6500 P.I.N. 4334
  - d) Car Phone: 717-940-5493
  - e) Home Phone (Radiation Emergencies Only Please!): 717-397-2569
- Check all radiation detection equipment monthly or bi-monthly for acceptable operation (including dose calibrator, Caprac, and survey meters)
- 6. Assist technologists with dose calibrator activity linearity measurements and there calculations, and record-keeping
- 7. Perform a S.P.E.C.T. gamma camera phantom baseline evaluation for quality control purposes at least once/yr. at each site.
- 8. Check the technologist's Q.C. program for planar and S.P.E.C.T. imaging, with suggestions
- Assist with writing recommended regulatory response letters to inspections, amendments, license renewals for all the Pennsylvania sites.
- 10. Provide telephone consultation assess for all technologists as needed via 800 #

Sincerely

Walter L. Robinson, M.S., A.B.M.P., A.B.S.N.M.

Consultant Certified Radiation Physicist



06/07/94 13:56 \$508 897 7680

## MedAlliance, Inc. IMAGEAMERICA of Massachusetts, Inc.

63 Great Road Maynard, MA 01754-2011 PHONE: 508-897-9981 FAX: 508-897-7680



## FACSIMILE TRANSMITTAL COVER SHEET

ro: Charles W. Herl (Recipient's parce & department)	
FROM: Sender I name & department)  Total number of pages (including cover sheet) 35  MESSAGE:	

If you have any questions or difficulty receiving this transmittal, please call 508-897-0005 ext. 2007. 3050

Notice of Confidentiality: This transmission is intended only for the addressee(s) listed above and may contain information that is confidential and/or legally privileged. If you are not the addressee, any use, disclosure, copying or communication of this transmission is prohibited IF THIS CONTAINS MEDICAL INFORMATION, the recipient of this patient information is prohibited from disclosing this information (including copies) to any party not authorized by the patient. If this message was received in error, please telephone us at 508-897-9981 and we will arrange for the return to us of the original documents at no cost to you.

Image America



63 Great Road Maynard, MA 01754 508 897 9981 FAX 508 897 7680

June 7, 1994

Charles W. Hehl, Director Division of Radiation Safety and Safeguards Nuclear Regulatory Commission Region I 476 Allendale Road King of Prussia, PA 19404-1415

RE: NRC Inspection No. 030-30947/94-001

Dear Mr. Hehl:

I am in receipt of your letter and report to Ms. Sandy Young, Operations Manager for AdvaCare Management Services, Inc. in connection with the NRC Safety Inspection of our Scranton, Bala Cynwyd and Yardley, Pennsylvania facilities by Ms. Mary Cahill on April 26-28, 1994. It is my understanding that an enforcement conference has been scheduled for June 8th at 10:00 am at your Region I office in King of Prussia, PA. Attending this conference, on behalf of AdvaCare Management Services, Inc., (AdvaCare) will be the following individuals:

Robert Perry, General Manager Sandy Young, Operations Manager Dr. Wayne Arnold, Radiation Safety Officer Walter L. Robinson, Consulting Radiation Physicist Joseph J. Berlandi, General Counsel

I would like to take this opportunity to thank the Nuclear Regulatory Commission, Division of Radiation Safety and Safeguards for its thorough inspection of our three (3) facilities and prompt report of its findings. AdvaCare has been a licensed provider in Pennsylvania of diagnostic cardiac nuclear medicine (thallium stress tests) since 1989. We take significant pride in our commitment to provide the highest quality of services and equipment and make every effort to ensure compliance with our corporate protocols and Federal and State regulations. As you know, during the past several months we have expanded our facilities to the extent that we presently operate 6 licensed facilities in Pennsylvania and one in New Jersey. In fact, in November of 1993 we opened our Scranton facility and in 1994 we opened our Bustleton and Center City facilities. Notwithstanding this expansion, our full commitment to regulatory and protocol compliance is still resolute. We acknowledge the importance and necessity of full compliance and, within that context, do not consider the findings of apparent

violations stated in your report lightly. We are committed, therefore, to taking the necessary corrective actions to remove any and all existing violations and to provide management oversight to ensure continued compliance.

In preparation of the scheduled conference, I would like to submit the following written responses which are intended to clarify some of the findings which appear to be based upon incomplete or inaccurate information and, more importantly, to describe corrective actions which were either in place at the time of the inspection or have been implemented as a result of the inspection. The overall purpose is to restate our cooperation and commitment to regulatory and protocol compliance.

With the expansion of our licensed facilities, it has become evident that more frequent compliance audits should be performed for each facility, that the exchange of information to and with our Radiation Safety Officer be better documented, and that management oversight be improved to ensure prompt remedial action to compliance issues. In this regard, we have

- (1) Increased the scope of services of our consultant physicist to include a monthly audit of our Scranton, Bala Cynwyd and Lancaster facilities and bi-monthly audits of all other facilities. Walter J. Robinson and Associates will provide these audits and a resulting written report will be provided to our Radiation Safety Officer and to our Nuclear Group Manager.
- (2) Dr. Wayne Arnold, our Radiation Safety Officer, will work closely with our Nuclear Group Manager and our facilities NMT to provide the necessary professional and management oversight to ensure that all compliance violations reported in the audits are promptly corrected and all such actions are appropriately documented.
- (3) Our consulting physicist, Walter Robinson & Associates, with the approval and guidance of our Radiation Safety Officer will continue to provide bi-annual in-service refresher programs on safety and training to each NMT at each facility. Evidence of such will be documented. He will also continue to make himself available on a day to day basis, if necessary, to address safety related issues.
- (4) Our Nuclear Group Manager will be responsible, amongst other things, for compliance coordination and management oversight for each facility. The manager will work closely with the NMT

> supervisor at each facility and appropriate records will be maintained both at each facility and at the office of the Group Manager.

I believe that the above generally described measures will most assuredly strengthen our compliance and management oversight procedures to avoid future violations.

With reference to specific apparent violations described in your report, I would like to offer the following observations:

#### Radiation Safety Audits A.

I. 10 CFR 35.20 (a)

> "Failure to perform the annual review of the Radiation Safety Program, including a review of operating procedures, in 1992 and 1993."

#### Scranton Facility (a)

- Lab Coats All NMT wear (i) lab coats when in those areas requiring lab coats. Please refer to letter from Gary Golecki to Mary Cahill. (Exhibit A)
- (ii) Posting of Documents -Our license and notice to employees were, at the time of the inspection, prior to, and currently are posted. The license was posted in the hot lab and notices to employees were posted on the bulletin board. (Exhibit A)
- (iii) Training to Personnel - An in-service safety training program is provided to personnel on a semi annual basis for each facility.

> Deficiencies - January and April 1994 audit deficiencies have been corrected.

#### Bala Cynwyd Facility (b)

- Failure to train an NMT. -(i) This NMT was unable to attend the scheduled program due to a prior commitment of a training course provided by General Electric for applications on new equipment. She has of this day received full required training.
- (ii) Response to January 1994 Audit - A copy of the written response is attached hereto (Exhibit B) indicating corrective action taken. As noted, the response was written in the margin of the audit report.

#### (c) Yardley Facility

- (i) RSO Signing Records -This was self identified as indicated in our audits, the RSO has and will sign all required documents as part of his scope of service.
- Posting of documents -(ii) The license is posted and the Regulations are available on site.

#### II. 10 CFR 35.21 (a)

"Failure to provide annual radiation safety training to personnel in 1992 and 1993."

#### (a) Bala Cynwyd NMT not trained

As reported above, the specific NMT has received the required training.

- No evidence to verify effectiveness of training (b) A certificate will be provided to all NMTs evidencing completion of the training and a test will be given to the NMTs.
- No annual refresher training in 1992 and 1993 (c) An annual in-service refresher training was provided in September, 1992 and records of the same are maintained at the facility. (Exhibit C) The 1994 meeting was held on April 12th. The attendance list is attached. (Exhibit D)

#### 111. 10 CFR 35.21 (a) (3)

"Failure to periodically review the Bala Cynwyd physician's use of by product material and records kept to reflect that use."

The physician in question, Dr. Eisenstadt, is fully credentialed, however, not currently an authorized user on our license pending submission to and approval of his credentials by the NRC. His scan interpretations have in fact been reviewed by our authorized user, Dr. Wayne Arnold. (Exhibit E)

#### Personnel Monitoring Program B.

#### 10 CFR 20.2106, 10 CFR 20.401 and 10 CFR 35.21 1.

"Failure to maintain records of radiation exposures for Scranton and Bala Cynwyd personnel."

#### (a) Scranton Facility

These records are, in fact, maintained on site. Unfortunately, our site management, Gary Golecki, was not in on the day of inspection and the substitute temporary employee had no knowledge of this.

#### (b) Bala Cynwyd Facility

All records are forwarded to the RSO for review and signature. The original is sent back to the facility with a copy to the Scranton office. The records were in fact available.

#### II. 10 CFR 35.21 (a)

"Failure to wear personal monitoring device by NMT at Bala Cynvyd facility"

The specific NMT in question, Antonia Kist, always wears the monitor devices during procedures. On the day of the inspection she was confused by the inspector's question and intended to reply that she aid, in fact, remove the device when washing her hands. Please see statement from her in this regard. (Exhibit F)

#### III. 10 CFR 20.150 1 (a) and 10 CFR 20.201

"Failure to evaluate radiation exposure of the contractor NMT."

Our policy is to obtain prior 3 month exposure records of a contractor NMT and post the same in the lab and in the individual's badge (Exhibit G). All such records are to be reviewed by the RSO. (Exhibit H) In the instance of Antonia Kist, she commenced work in July, 1993. She wore "spare" badges until the new body and ring badge arrived. The spare badge was returned to Landauer with the July badges and exposure was reported. At no time did she work without monitoring devices. (Exhibit F)

#### C. Radiation Surveys

## 10 CFR 35.70 (a)

"Failure to conduct surveys at end of the day at Bala Cynwyd facility."

This, indeed, had occurred at the Bala Cynwyd facility. However, it was self identified prior to the inspection and has been corrected accordingly.

## II. 10 CFR 35.70 (h)

"Failure to maintain records of weekly contamination surveys at Scranton and Yardley facilities."

#### (a) Scranton Facility

Results were recorded in counts per minute rather than disintegrations per minute.

All equipment will be re-calibrated to record properly and inspected during our audits to ensure the same.

(b) Yardley Facility
This facility was operational as of July, 1992. During the period of July 4 - August 11, 1992 there were nuclear studies performed and, contamination surveys prepared. Records are maintained at the facility, however, were located in a different binder. (Exhibit I)

## III. 10 CFR 35.51 (c)

"Failure to check survey instrument with a dedicated check source each day."

## (a) Bala Cynwyd Facility

A dedicated check source was and, in fact, is still available at this facility. It

appears as though the technician failed to use the instrument on a daily basis during this period. Corrective action has been taken in the form of explicit instructions, to be posted, to all NMTs at all facilities to perform this on a daily basis.

#### (b) Scranton Facility

Same as above.

#### D. Dose Calibrator Quality Control

#### 10 CFR 35.21 (a)

"Failure to properly perform constancy checks of the dose calibrator at the Bala Cynwyd facility from January 1, - April 27, 1994."

The RSO and the nuclear group manager will be responsible for ensuring that constancy checks be performed properly. All such checks will be documented by the NMT and periodically reviewed by the RSO and maintained at the facility.

## II. 10 CFR 35.50 (b) (3)

"Failure to properly perform a linearity test of the dose calibrator during third quarter of 1993 at Bala Cynwyd."

It appears that the assay data was collected but not analyzed during this particular period. This was self identified in the January 1994 audit and corrective action was taken. All appropriate procedures are being followed.

## III. 10 CFR 35.50 (e) (3)

"Failure to include signature of RSO on records of dose calibrator linearity tests for 1992 and 1993 at Bala Cynwyd and Yardley facilities."

This was also self identified by an audit and has been corrected. The RSO signs all records accordingly.

#### E. Sealed Sources

#### 10 CFR 30.51

"Failure to maintain records at the Scranton and Bala Cynwyd facilities of cesium - 137 dose calibrator source."

- (a) Scranton Facility
  The calibrator certificate was and still is on site.
  However, the transfer record from the manufacturer to us in the incoming package has been misplaced.
- (b) <u>Bala Cynwyd Facility</u> Same as (a) above.

#### II. 10 CFR 35.59 (9)

"Failure to conduct physical inventory of cesium-137 dose calibrator service at Bala Cynwyd facility during 1st quarter of 1994."

This was self identified and a physical inventory was conducted and record of the same is in the possession of the licensee. Quarterly inventories will continue to be maintained, signed by the RSO, and maintained at the facility.

## m. 10 CFR 35.59

"Failure of RSO to sign records of leak tests."

The RSO has signed records of leak tests for all facilities which shall be maintained at the facility.

## F. Postings

#### I. 10 CFR 19.11

"Failure to post current copies of regulations, license, etc."

As of the date of this letter, a notice describing documents and where they may be examined has been posted at each facility. This will be maintained on a current basis. We are also undertaking a major effort to ensure that appropriate records are properly maintained at our main office.

As indicated above, it is not our intention to consider your report lightly. Although a written response is not required, I trust that it will serve as a basis for our discussions at the enforcement hearing. Self identified deficiencies and corrective action has occurred on several of the listed apparent violations. We have also put into effect an enhanced audit program, the creation of a Nuclear Group Manager position to provide management oversight, and improved coordination between the consulting physicist, Nuclear Group Manager and our Radiation Safety Officer.

We are committed to the delivery of quality services and equipment and full compliance with regulations and protocols. I look forward to discussing these issues more fully with you at the hearing.

Yours truly,

Joseph J. Berlandi General Counsel

EXHIBIT A 1 of 1 Image America



201 Franklin Street 3rd Floor Scranton, PA 18503 717-844-7416 Fuz 717-344-7492

Monday, June 6, 1994

Mary Cahill
Nuclear Regulatory Commission
Region I
King of Prussia PA

Dear Ms. Cahill,

I would like to clear up a question that has repeatedly come up. I insist that all personnel that comes in contact with, is working with or in the greathat Thallium is used, wears a lab coat. The only time our lab coats come off is when we are on break, on lunch or out in the front office working. I will not tolerate this rule broken by any employee, this has been my policy since day one. There is also the question about the posting of the NRC-3 Form MOTICE TO EMPLOYEES. As you can see from my attached letter date February 11,1,34 to Walter L. Robinson & Associates, that was and has been posted in the HOT LAB since our FIRST day of operation.

If you have any other questions please do not hesitate to contact me directly.

Sincerely,

Gery T. Golecki

Administrative Technologist

EXHIBIT B



# WALTER L. ROBINSON & ASSOCIATES CONSULTANT RADIATION PHYSICISTS

2624 SPRING VALLEY ROAD + LANCASTER, PA 17601 TELEPHONE 717-291-9813 TOLL FREE 800-446-7622

January 22, 1994

Sandy Young Tony Kist 2 Bala Plaza Suite IL 52 Bala Cynwyd, PA 19004

Dear Sandy and Toni:

#### General:

First, Sandy, I would like to say thank you for getting me a copy of your original NRC license and application; however, surely it was inadequately received by the NRC in that form. Surely, there were letters of correspondence that they sent you (deficiency letters) and your response letters. I need these more than what I was given. What I was given was an application for a hospital nuclear medicine department with therapy! Surely, this could not have been acceptable to the NRC. I need all your letters of correspondence to the NRC (including inspection letters and your response) especially those dated: 12-27-88, 5-21-90, 6-21-90, 8-31-90, 5-15,91, 9-5-91, and any subsequent to them. Had I prepared your application, it would have been a letter 3 to 4 pages long with a site diagram for each center.

What you sent me was for a location in Jenkintown, not the four locations in which you currently provide services. I also need all the correspondence and license application from the State Bureau of Rad-Protection (D.E.R.). I would also like a copy of your most recent licenses (NRC and State). I did not get one from either site. Please send this data with Yardley and Scranton directions as soon as possible. I still await a list of names, phone numbers and site — "responsible parities" for each center.

For your upcoming (by the end of March) NRC license renewal, please have photos taken from two angles (min.) of each hot lab. This will save many words and minimize expediency of inspection, if they have not come by this date. We will submit the pictures with the renewal. Polaroids images are OK.

## Bala Cynwyd Office Status Report:

First, I will reiterate items found at Lancaster that persist here, then I will list site-specific problems areas found.

1-22-94

## Duplicate Areas for Improvement:

Will Resort 1. I could not find any evidence of R.S.O.-signed documents. Please find form enclosed to improve this deficiency.

LokeD 2. Missing Records:

FOR 10/92 A. Leak tests of scaled sources since inception of operations:

Could NOT FIND

Data is missing for the dates and sources below:

 Co-57 flood source (1st date is 4/92, I assume your 1st flood was not purchased before 10/91) S/N 1194/84; C.I.S.; 205 MBq

Done: 4/92

No data: 10/92

1/93

8/93

(I did 1/94)

2) Co-57 dose calib. source; S/N 1978/194; C.I.S.; purchased: 2/7/92

Done: 8/93

No data: 8/92 2/93

This source is behind Lead TLAB

I could not find this source present! Is it possible you have transported Bala sources to other sites and taken the records along? I would have thought you would have purchased new sources for each new site. Any sources unaccounted for can get you in big trouble with regulatory agencies.

UNAble To LOCATE THESE

- 3) Co-57 dose calibrator source; S/N CK992; purchased: 4/8/91 No leak test data at all, but this source is present and used daily!?
- 4.) Cs-137 dose calibrator source; S/N 3063 MA; purchased on 11/1/87! This is its assay date. No leak test data at all, but this source is present and used daily!?
- Cs-137 dose calibrator source; S/N 3890/319
   First leak test record was;

This source Lead is nehind horte

Done 4/91 No data: 4/92 10/91 10/92 8/93 4/93

Source was not found at Bala site

- 6) Co-57 flood source; S/N 206/2019; 12/31/92, 198 MBq was first leak tested could not 8/93. If it was purchased before Feb. '93, then it had at least one missing leak test report.
- 7) A Cs-137 rod source; S/N 13A-101884-0110.106 (10/18/84) was possessed, but only one document on file. Also a Co-57 (0.109 uCi) 7/14/89; S/N 076005-058 source is supposed to be around. I could not (did not) find these?

BETILD LEAD A LEAD CONTAINER WRAPIN LEAD

#### EXHIBIT B 3 of 5

1-22-94

There are serious sealed-source record-keeping problems. As you can see, to me, a mock-inspector, it is apparent you either disposed, lost, sold or transferred sources - minimally without proper documentation. Toni should call me to discuss the location of each of the above sources, plus any other ones she knows about.

- Will give To (SO TOSIAN Will rest document FOR WEAR FOR 111 Tocheck
- 3. Film badge records all exposures are low, but there is no evidence that the R.S.O. reviews and initials these documents; as a matter of fact, I found one or more still folded in the form they come out of the envelope. I put these in chronological order for optimal review and comparison purposes. Annual data must be given to all staff badged
  - 4. Quarterly inventories were performed monthly from 3/92 to 9/93, with one missed as recently as 12/93. There was no record prior to 3/92 on site. There was no required "radiation survey" performed on these sealed sources, as required.
- RADIATION SURVEY
  - 5. There have never been radiation surveys behind the hot lab to assure there is no hazard to personnel on the other side. This may not be a license commitment weekly, but some data should be on record. It could be construed as needed weekly by an inspector.
    - Wipe-test records are in d/m, but are being measured on your new Capintec Caprac (a good instrument), but I see no efficiencency calculations to assure data is printed out in pure d/m, or if it needs a convertion factor. I will try to contact Janet Barbiere from Capintee to discuss the necessity for this, so we will know how to answer inspectors.
- Your staff is not familiar with your whole radiation safety program and commitments. Our future in-service and video tape should improve this.
- 8. No back-up dose calibrator or mechanism is present.

HAVE OR DEFER BINGEF

No A.L.A.R.A. binder, all NRC regs., or any PA DER regs. were present for all staff to see and read.

10. Your trigger or action levels must be posted or inserted in the front of your hob in 50° Th Sareas, ≤ 2000 d/m for all Tc-99° and Ti-201 contamination. wipe-test/survey notebooks; i.e. ≤ 5 mR/hr in restricted areas, ≤ 0.5 mR/hr in unrestricted HANE ACKNOWN 12. No caution size of radiation safety/regulatory in-services.

12. No caution signs for pregnant or breast-feeding females.

HAVEFESTED

13. No evidence of a negative Q.M.P. declaration.

## Site-specific finding (additionally) include:

Unableto FIND DATA

1. Dose calibrator accuracy test data (reg'd annually) found only for 7/16/90 and June '93.

EXHIBIT B 4 of 5

1-2294

Willuse. 2. Dose calibrator geometry test performed only on 10 cc. vial, yet 3 cc. syringes are most 3cc 5yr 19 widely used. This test must be performed for 3 cc. syringes.

UNAble To 35 Dose calibrator activity linearity tests were performed somewhat regularly since 7/16/90;

The 2nd, 3rd and 4th our '91 data

performed were entered. This is not in compliance with the NRC.

2) March '93 data is missing; June '93 data is missing.

- 3) One test was performed two months late in Aug. '93, but the next one was by Toni (now) Jan. '94 to be concurrent with my "sleeve-test" measurements. Therefore, the one that should have been done Sept-Dec. '93 was missed.
- 4. The radiation survey meter situation is similar to the dose calibrator source situation. I suspect some meters were transferred to other sites instead of getting new ones for the new sites, since there is data present for meter calibrations, but that meter is not present. There is data for 4 meters with S/N 71976, 72055, 68172, 77523.

> S/N 71976 Was calibrated semi-annually since 3/90 (only annually req'd!)

➣ S/N 72055 Data from 3/90 to 12/91, then no more data.

> S/N 68172 Data from 7/92 to 7/93, then no more data.

> S/N 77523 Data only for 10/91

5. Posting inadequacies

Will have To a) Physician's prescribed dose range should be signed by R.S.O.

Willpist b) New 10CFR20 should be posted in lieu of old one

will post c) "Caution Radiation Area" sign should be on imaging room door.

will Add - 6. You should add a "radiation waste storage" area to your weekly survey/wipe records and check this location weekly check this location weekly.

15 dONE 1914

7. Co-57 source vs. Cs-137 source should be used for daily dose calibrator constancy tests.

Willber

- 8. 5 cc. leaded syringe shield needs to be replaced. The leaded glass is broken and ineffective. You may wish to order lead acrylic or new spring-loaded type units (J.R.T. Associates can help).
- 9. Someone performed a gamma-camera efficiency test, so it could be used for wipe-testing (since it has a computer), but this was not advised by your previous consultant!?

There are probably many more items that I will find as I look more deeply and ask more questions of the staff.

In general, my global recommendations are as we discussed:

EXHIBIT B 5 of 5 1-22-77

- 1. Have the R.S.O. take a more pro-active aggressive role of document signatures, record organization, and visit each site on my 2nd scheduled visit at each site.
- 2. Have the R.S.O. use the "table" that I sent as a reminder of status of documents needing review, signatures and initials. In the future the N.R.C. may not require the R.S.O. to sign the dose calibrator records (proposed new 10 CFR 35 N.R.C. regulations).
- 3. Arrange an in-service (live) for all your administrators, R.S.O., staff technologists to attend from all sites. This in-service to include: a license/regulatory commitment review, a radiation safety program/organizational review, a new regulation synopsis, and a delegation of responsibility discussion. The proposed February evening in-service meeting I can foresee being 6:30 9:30pm on my part, for which there will be an additional visit's billing above our contract. Wednesdays do not suit, I would prefer a Tuesday or Thursday night, except the 10th.

Sincerely,

Walter L. Robinson, M.S., A.B.M.P., and A.B.S.N.M. Consultant Certified Medical Radiation Health Physicist

EXHIBIT (

annual Radiation Sujety Committee Meeting: advacase Imageonen Mid atlantic Reg Office 2 Bala Plaza Scrite IL-17 Bala Cynwyd PA 19004 Conducted by An Wayne and Teny Cinello alssues discussed - Charges CFR-10-19, 20,35 went over esotope handling, Spill procedures, Desk Keeping, NRC segs + inspection procedures (our policy) also went over pregnancy essues, shielding to keep exposent, question & answer period post discussion Concerns. A exposure due to Cardiolyte Studies scholuling, proper shielding for pregnistenployues. anthoused users up dated on Lisence, Terry . D. arrold to give inservereto have. Imployees attender Teni Cerello (physicit-+ lecture) -A. Wayne anold Mo. Dr. Druce Kornburg MD Harriet Jama NT John Milieno NI angelo amento NT Regna Myin Stress Nurse Syrung Rothwell StresNus Bob Perry General Marager

EXHIBIT C 2 of 2

ADVACARE DIAGNOSTIC

IMAGEAMERICA PHONE: (615) 373-5400 109 WESTPARK DRIVE, SUITE 420 BRENTWOOD, TENNESSEE 37027

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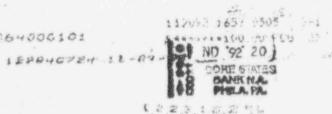
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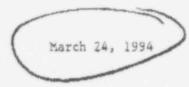
1 of 5

## BALA MEDICAL CENTER Wayne V. Arnold, D.O.

CARDIOLOGY - PERIPHERAL VASCULAR DISEASES

15 NORTH PRESIDENTIAL BLVD. SUITE 100 BALA CYNWYD, PA 19004 (610) 667-2746 (610) 667-2749 Fax# (610) 667-9420

Sandy: Young. Image America 111 Presidential Blvd. Bala Cynwyd, Pa. 19004



Dear Sandy:

This letter is to amonume the Radiation Safety Meeting - Semi-Annual to take place on Tuesday evening, April 12, 1994 starting at 6PM. The place is the Starlight Diner, Fogelsville, Pa. I feel the Starlight will provide a very adequate and affordable atmosphere for our Radiation Safety Meeting and is located as a mid-point for the attendees of all our nuclear facilities.

It is located on Route 100 South, Exit 14A off of I-78. Exit 14A is Route 100 South. Phone number of the Starlight is 395-4031 in case any of the attendees need to phone for specific directions.

I look forward to a very successful and productive meeting.

Sincerely,

Wayne V. Arnold, D.O. Radiation Safety Officer

WVA: S

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2 of 5

please initial attendance

RSO meeting (Mandatry) 4-12-94 Gary Golecki (Scranton) Suzanne Yoder Wood fin - (C-VAL) Susan Kob (Eval) Scrann Rothwell (Yardley) Juzanne Kamsey (Bala) SER Angelo Amenta (Yardley) Sheila Beardsly (Bustleton) Sandi Killian (Cval)
Russ Mc Connell (Sales rep + account exce (C-val)) Bot Perry - General Managen -Dr. Wayne Arnold - 1250. Walt Robin Son grup physicist Stein Sithakh Sattethy See. Sande Killian (COAC) On Wane V Angle RSO I forbutt Geam Al M. / Scounton) REACHT CHARLES (OUR BASIN Susan Lots ( GUAL) Suganne Toder- Floodfui (LANCASTER)

CVAL

## PLEASE INITIAL UNDER EACH COLUMN WHEN COMPLETED

	Viewing Radiation Safety Tapes	Synopsis of New 10CFR20 Regulatory Changes	Newsletter 12/17/93
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S. Woodfin	Fried.	540 54	547, 94
S. McGurl	5-m	5m	514 277-94
P. Lynch	2-1794	2-17-94	2-17-94
S. Kob	5.128bl 2-25-94	5 : KDD- 2-25 -94	3-165 2-25-94
C. Pezon	- 118/51/	cump = 121/94	cup 2/21/9+

4 of 5

(Yardley)

## PLEASE INITIAL UNDER EACH COLUMN WHEN COMPLTED

Tech Name	Viewing Radiation Safety Tapes	Synopsis of New 10CFR20 Regulatory Changes	Newletter Date:	
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· Bala Location

# PLEASE INITIAL UNDER EACH COLUMN WHEN COMPLTED

Tech Name Viewing Rad Safety Tapes		Newletter Date:	
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EXHIBIT E

Image America



Bala Poinm, Suite 109 111 Presidential Boulowed Bala Cynwyd, PA 19004 215 668 8152 FAX 215 668 9850

Charles W. Hehl, Director
Division of Radiation Safety and Safeguards
U.S. Nuclear Regulatory Commission
Region I
475 Allendale Road
King of Prussia, PA 19406-1415

June 2, 1994

Dear Mr. Held,

As Radiation Safety Officer and authorized user for AdvaCare/ImageAmerica operating under NRC license #37-28331-01, I attest that Norman Eisenstadt, M.D. is under my supervision for reading nuclear cardiology studies at our Bala Cynwyd lab. Dr. Eisenstadt's credentials for authorized usership are completed and this preceptorship documentation will be forwarded to the NRC licensing branch for amendment after the resolution of the enforcement hearing scheduled for June 8, 1994.

In my capacity of authorized user and RSO, I have overread Dr. Eisenstadt's studies performed at the Bala Cynwyd lab, and will continue to do so until the Dr. Eisenstadt is approved as a authorized user himself.

Sincerely,

Wayne Amold, M.D. Radiation Safety Officer EXHIBIT F 1 of 1

#### STATEMENT OF ANTONIA KIST, NUCLEAR MEDICINE TECHNOLOGIST

To Whom It May Concern:

I would like to address two cited apparent violations that pertain to my work and my conversations with NRC Inspector Mary Cahill on April 27, 1994.

In Section 5.7 of the letter detailing AdvaCare/ImageAmerica's recent NRC inspection, a cited apparent violation reads:

Failure of 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).

I am the NMT referred to in these incidents and would like to elucidate the circumstances stated above.

When I began work in July 1993 I called Landauer and ordered myself body and ring badges to arrive in the next scheduled shipment. Until their arrival I wore current batch body and ring badges labeled "spare". The "spare labeled badges were returned to Landauer with the rest of the July badges and their reported exposure, which both were M (minimal) was assigned to me. Thus there was no time period that I worked with radioactive materials without personnel monitoring devices.

During the inspection on April 27, 1994 I was continuing to perform patient testing using thallium. Between patients I washed my hands, removing my ring badge to do so. As I was beginning to prepare my next patient unit dose, Inspector Mary Cahill pointed out to me that I was not wearing my ring badge. I replied that I had just removed it to wash my hands and put it in my lab coat pocket, forgetting to put it back on my finger. Inspector Cahill then questioned if I properly wear my ring badge, since my monthly extremity exposures have routinely been M (minimal). I was at that time under considerable stress between a hectic patient schedule and experiencing my first NRC inspection. I told her that I do routinely wear my ring and body badges properly but admitted to forgetting, on very rare occasion, to wear my ring badge on my finger. It seems Inspector Cahill interpreted my honesty, along with my low exposure records, to mean that I fail to wear my ring badge properly on a regular basis. This is not the case. All of our cardiac nuclear medicine technologists who image primarily with thallium receive M (minimal) monthly badge reports regularly, due to the lower energy of thallium and unit dose availability. I feel that my attempt to be sincere and admit human error was taken out context in the inspection report.

Intonia Kist RT(N)

EXHIBIT G 1 of 1

> Jan Casford MTS Health Care Services, Inc. 1551 Bond Street Suite 109 Naperville, IL 60563-0114

June 1, 1994

Dear Ms. Casford,

This letter is to inform MTS of a procedural update regarding ImageAmerica's personnel dosimetry monitoring program when contracting nuclear medicine technologists from your agency.

Effective immediately, all agency NMTs providing temporary coverage to ImageAmerica accounts must wear radiation badges supplied by ImageAmerica as well as the badges provided by MTS. The temporary NMT must also produce their personnel exposure record for the previous twelve months to be kept on record at the ImageAmerica facility which they cover.

It is my understanding that this procedure is now in place and the applicable technologists are aware of and have complied to this regulation.

We at ImageAmerica thank you for your prompt action in this matter, and for your continued service.

Kathleen Bousquet, Technical Manager,

lex Bousquet

Nuclear Medicine

To:

Image America Nuclear Medicine Technologists

From: Kathleen Bousquet, Technical Manager

Date:

June 1, 1994

Re:

Responsibility of handling radiation badges

At each ImageAmerica lab, one person (a nuclear medicine technologist in all cases) will be responsible for the receipt, distribution, return shipment and report posting of radiation badges. This procedure will have management oversight by the RSO and nuclear group manager, but the responsible party at the individual lab level will be the nuclear medicine technologist. The current list of technologists resonsible for radiation badge handling is listed below. If you have any questions or concerns, please contact me at by pager at 508-722-2351 or Sue Rothwell at 215-930-6689. I look forward to seeing you all on my next visit to sites on June 20-22.

LAB

TECHNOLOGIST

Bala Cynwyd

Toni Kist

Bustleton

Sheila Beardsley

Center City

Toni Kist

CVAL

Suzanne Woodfin

Scranton

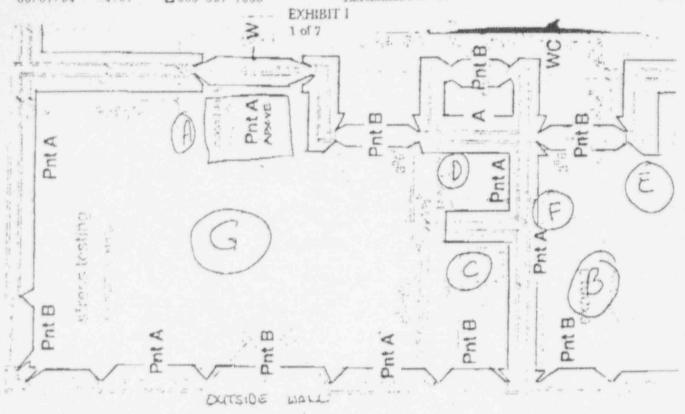
Gary Golecki

Vineland

Linda Warner

Yardley

Angelo Amenta



### Area Survey and Wipe Test

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TRIGGER LEVELS, above which require decontamination and R.S.O. notification: Restricted Area: 5.0 mR/hr, 20,000 dpm/100 sq. cm. Unrestricted Area: 0.5 mR/hr, 2,000 dpm

EXHIBIT I 2 of 7

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EXHIBIT I

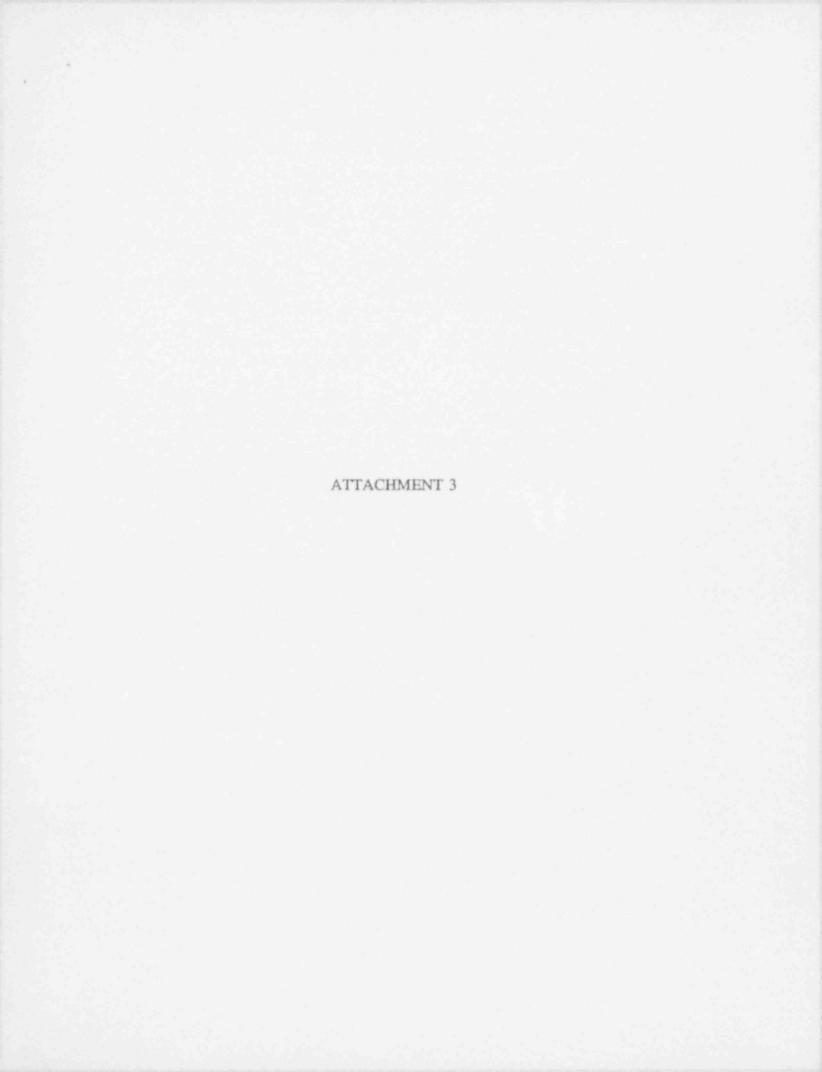
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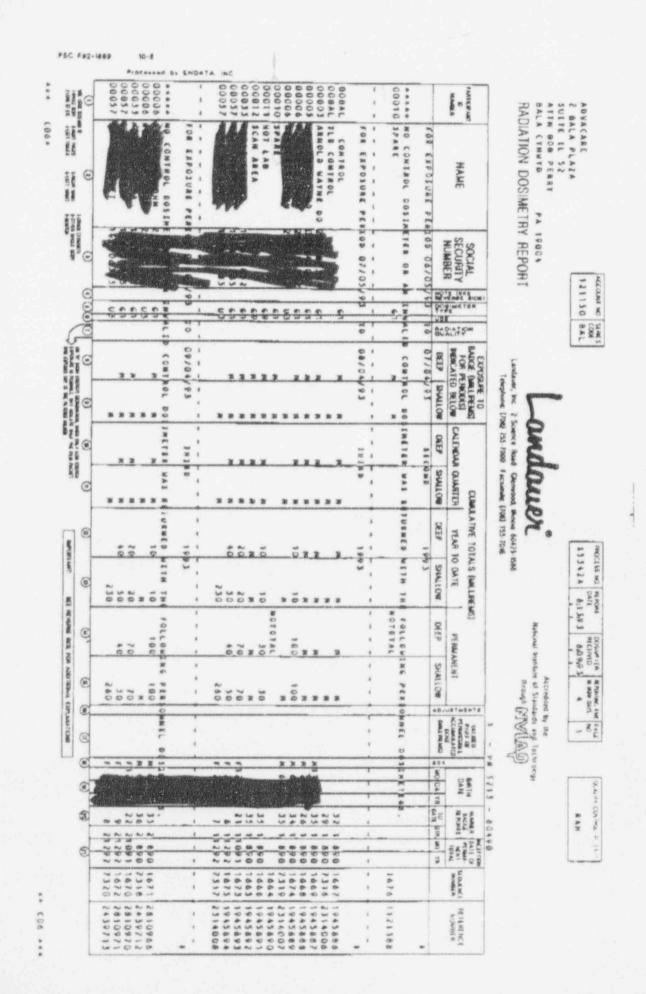
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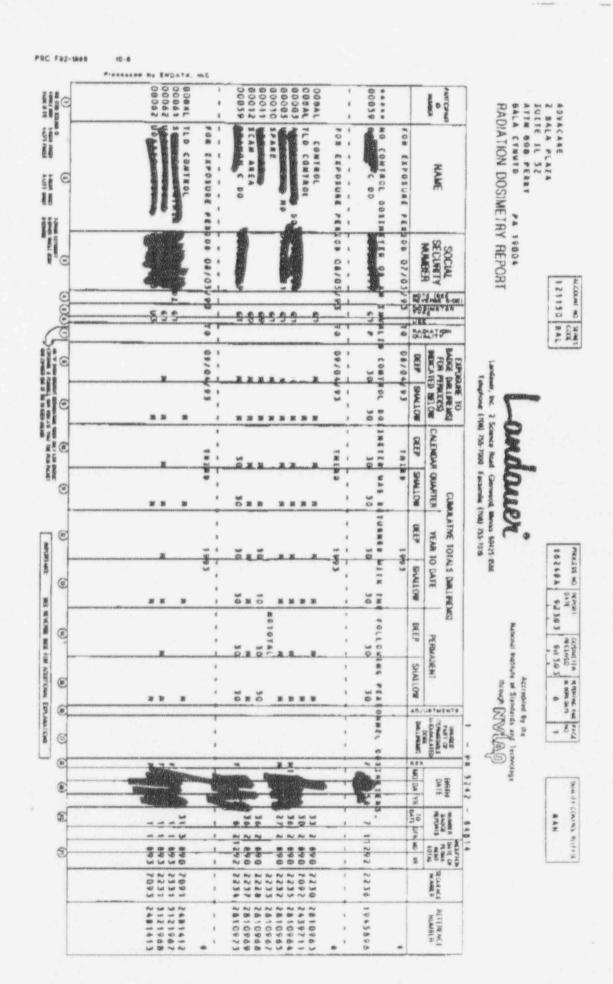
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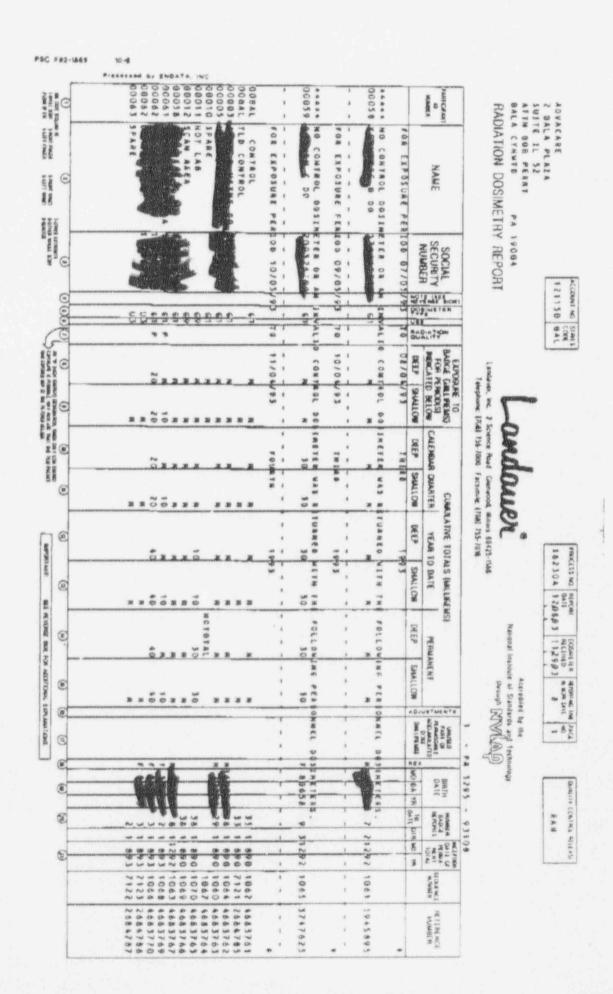
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ATTACHMENT 4

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