Advanced Medical Systems, Inc.
121 North Eagle Street • Geneva, Ohio 44041
(216) 466-4671 TWX 810-4272-183

November 10, 1987

Amend. request

Log... Oct 15
FEE NOT REQUIRED
add'l info - J Madera
10/17/88
3B/3P/3N/2P
addtl info
+ C.N. 84333

Mr. George M. McCann
Nuclear Materials Safety Branch
U.S. Nuclear Regulatory Commission
Region III
799 Roosevelt Road
Glen Ellyn, IL 60137

RE: Amendment Request
License No. 34-19089-01
Control No. ~~84333~~

Dear Mr. McCann:

Please consider these Amendment Requests as supplementary to the AMS Amendment Request dated October 20, 1987.

I. Enclosed are four (4) resumes of individuals in the permanent employ of Advanced Medical Systems.

AMS wishes to have Mr. Robert Jucius named as Radiation Safety Officer for the activities authorized by this License No. 34-19089-01. Mr. Jucius, having extensive training and experience as a Health Physicist, will replace Mr. Howard R. Irwin as named in Condition 11c. of the AMS License.

AMS wishes to have Mr. Howard Irwin, present Radiation Safety Officer, named as an Alternate RSO. Also, AMS wishes that the individuals - Mr. McDermott, Mr. Cox and Mr. Turbett - be named as Alternate Radiation Safety Officers.

Mr. Jucius will be permanently stationed at the London Road facility and lives in the immediate area. However, during his absence such as vacations or company business which may, on occasions, require out-of-town travel, he will be able to designate responsibility to an approved alternate.

II. AMS requests approval of the enclosed Hospital Service Training Program.

Attached is a proposed training plan designed to be sponsored by Advanced Medical Systems for the training of hospital and clinical teletherapy unit users. This plan is intended to provide sufficient training to user personnel which will enable them to conduct minor remedial adjustments and maintenance on or to their C-60 teletherapy units. The training plan also provides the user with the information necessary to identify those areas of service which require the attention of licensed service engineers.

It is AMS' intent to have this training program approved by the USNRC so that AMS may provide the necessary training to users allowing the specific user locations to gain NRC or agreement state approval to conduct the adjustments and remedial service described in the program.

RECEIVED
OCT 05 1988
REGION III

CONTROL NO 86199

9002010371 890119
REG3 LIC30
34-19089-01 PDR

AMS will sponsor the program and provide all necessary documentation to the user personnel and to the NRC. It will be the responsibility of the individual user sites to register their personnel completing this program with the NRC or agreement state.

III. Enclosed for your information is a revised AMS Corporate Organizational Chart which reflects the changes resulting from Amendment Request No. I above. Attached to this organization chart is the resume of Dr. LeRoy Jackopin. As you will note, Dr. Jackopin occupies the one newly-created position as Regulatory Affairs Manager within the ATC corporate structure. However, key contacts for AMS by the USNRC will continue to the the ATC General Manager or the RSO. Matters requiring the attention of the corporate Regulatory Affairs Manager will be referred to him by this administrative staff.

Should you have any questions specific to the organization structure or the Amendment Request listed above, please contact T. Hebert at (216) 466-4671.

Sincerely yours,

Theodore J. Hebert

T.J. HEBERT
General Manager

TJH/mz
Enclosures

CERTIFIED MAIL #P185486084
RETURN RECEIPT REQUESTED

Advanced Medical Systems, Inc.
1020 LONDON ROAD • CLEVELAND, OH 44110

September 29, 1988

U.S. Nuclear Regulatory Commission
Materials Licensing Section
Region III
799 Roosevelt Road
Glen Ellyn, Illinois 60137

Attention: Mr. John R. Madera

Reference: Hospital and Clinical Training Program,
Control No.: 82095

Dear Mr. Madera;

In response to your telephone request for additional information regarding our Hospital and Clinical Training Program what we had submitted August 15, 1988 (Control No.: 82095) the following information is submitted to answer your questions and supplement the submission.

A list of your concerns and our responses are included in the attachment. This information includes updated pages for the Hospital Training Manual.

I look forward to an early authorization for the program. If there are any additional questions or you require additional information please call me at (216) 692-3269.

Sincerely Yours,

Robert A. Jucius

Robert A. Jucius
Health Physicist
Radiation Safety Officer

RAJ/

Enclosure

OCT 4 1988

ENCLOSURE

LIST OF YOUR CONCERNS AND OUR RESPONSES FOR THE ADVANCED MEDICAL SYSTEMS' revised Hospital and Clinical Training Program:

This information includes updated pages for the Hospital Training Manual.

1. Approval -vs- Authorization

   As a representative of the NRC you have explained to us that the NRC does not approve training or other programs. The NRC will assess a program and authorize its use. We will change our terminology to reflect that the program has been authorized by the NRC. Enclosed is a revised cover sheet for the program manual. Any sections in the manual that refers to an approved program will be changed to an authorized program.

2. Literary Materials

   Specify that students will receive the appropriate literature or reading material to perform maintenance. Clarify that students will be trained only on the equipment that their hospitals have in-house.

   In the section on the Program Purpose we have identified that the students are to be trained only on the equipment at their facility. We have re-written this section so that it is clear and we have included a reference to the material that the students will receive. This section is at the end of the introductory section of the manual.

3. Agreement States

   We were informed that Illinois is now an Agreement State. When this training manual was first developed, Illinois was not an agreement state. Illinois has now been added to the list. We currently have the regulations available for all of the states that we work in including Illinois' latest agreement state regulations. The regulations for all Agreement States will be made available for the students. However, it will also be recommended that the student contact the states directly for copies of their regulations so that they will have direct contact with their licensing agency. Enclosed is an updated page to the manual.

4. Questions relating to information in Examinations.

4.1 The NRC requires at least 50 questions.

Enclosed are copies of questions 22 - 34 for part I of the Radiation Safety Test, and questions 1 - 7 for part II of the Radiation Safety Test. These questions apparently were missed when the manual was copied for submittal to the NRC. Also included are the answers to the part I examination.

4.2 Question 18, part II of the radiation safety quiz is unclear. It reads as follows:

18. You are informed that the source "ON" time has suddenly increased to 4 seconds. What should you do? (Answer = Nothing directly. Advise superiors to contact licensed service organization.)

The question has been reworded to clarify it as follows:

18. You or one of the technologists have been doing routine testing of the shutter open time and have discovered that the time has increased to 4 seconds. What should you do?

4.3 Questions should be included that require the use of calculations using the inverse square law.

Enclosed are three additional questions and revised question 18 to be added to part II of the radiation safety quiz.

5. Tools and Equipment

Enclosed is a list of equipment to be inserted after the introduction in Tab 3.

6. Tab 3, Section 1.9 - Typographical Error.

Enclosed is a revised sheet that corrects the typographical error.

REPLACE and/or ADD in appropriate location before Tab 1.

HOSPITAL AND CLINIC SERVICE
TRAINING PROGRAM

SPONSORED BY
ADVANCED MEDICAL SYSTEMS, INC.

AUTHORIZED BY USNRC

DATE: _____

AUTHORITY: _____

PROGRAM PURPOSE

The training program prepared herein is intended to provide designated individuals in the employ of specific hospital and clinical institutions with adequate training to conduct limited remedial maintenance and adjustments on or to their AMS/Picker Teletherapy Treatment units. It is not intended to provide training to service other systems.

The program has been designed to: 1.) provide training for the conduct of limited remedial maintenance and adjustments by user personnel; 2.) to identify areas of maintenance and repair which should be limited to licensed factory or other NRC-approved service engineers; 3.) to provide the user trainee with adequatecertification and documentation of the training received; 4.) to provide the NRC or agreement state authority with copies of these certificates; and 5.) to instruct the trainee in the procedure for obtaining NRC or agreement state authorization to perform user service on their teletherapy unit.

ESSENTIAL PROGRAM REQUIREMENTS

1. For AMS to provide high quality training using company employees and consultants.

2. For the AMS Program to be authorized by the U.S.N.R.C.

3. For the NRC to approve to the users license the authorization of the trainee to conduct the service described herein based on the merit of satisfactory course completion. This application and approval will be the sole function of the user and the U.S.N.R.C. or agreement state. AMS will provide the necessary course documentation to both the user and U.S.N.R.C. or agreement state.

4. For AMS to provide to the trainee those operators and maintenance manuals necessary for the machine to be serviced.

REPLACE and/or ADD in appropriate location behind tab marked RADIATION SAFETY MANUAL.

STATE REGULATIONS

The U.S.N.R.C. has entered into agreements with 29 states whereby the individual state has assumed the licensing and regulatory functions of the NRC within its borders. These states, called 'Agreement States', are as follows:

Alabama	Idaho	Nebraska	Oregon
Arkansas	Illinois	Nevada	Rhode Island
Arizona	Iowa	New Hampshire	South Carolina
California	Kansas	New Mexico	Tennessee
Colorado	Kentucky	New York	Texas
Florida	Louisiana	North Carolina	Utah
Georgia	Maryland	North Dakota	Washington
	Mississippi		

Basically, each of these states has published its own regulations for the protection of workers and the possession and use of radioactive material. For the most part, these regulations are nearly the same as the NRC regulations. Under reciprocity policies, these states recognize and honor our NRC license; therefore, we do not have to obtain a license from each state.

Certain states charge an annual fee for performing service work within their boundaries. In addition, most states require prior notification of our intention to perform work in their state.

The service technician should be prepared for a visit by a state inspector when doing work in an agreement state.

A summary of the states and their requirements which affect our work follows:

1. Mississippi requires that AMS service engineers have a copy of the state regulations in their possession while working in the state.

2. The following states require that AMS certifies that its service personnel have read and understand the state regulations:

   Arizona
   New Mexico
   North Carolina
   South Carolina

A copy of these state's regulations will be issued to each qualified service engineer.

22. To be authorized to perform routine service work of a Cobalt-60 teletherapy system you must be knowledgeable in the radiation protection regulations of the US Nuclear Regulatory Commission or of "Agreement" State in which you perform the licensed activities. T F

23. The "depleted uranium" found in the therapy machines is source material. T F

24. Absorbed dose is the energy imparted to matter by ionizing radiation per unit mass of irradiated material at the place of interest. T F

25. Give an example of a source of external radiation.

_____

26. Give an example of a source of internal radiation.

_____

27. Permanent records of an individual's exposure must be kept by his employer. T F

28. Describe the actions you would take if you found a Cobalt-60 teletherapy room to be contaminated.

_____

_____

_____

_____

29. Different radioisotopes (Co-60, Sr-90, Cs-137, etc.) present different degrees of hazard. T F

30. Radioactive materials for transportation on public highways must be packaged in conformity with U.S. Department of Transportation and the U.S. Nuclear Regulatory Commission Regulations. T F

31. In using radiation detection equipment:

a. "SCANNING" refers to the rapid qualitative survey, usually carried out with sensitive detecting instruments, to locate and determine the extent of a radiation source. T F

32. The Co-60 source inside a teletherapy head is a good example of an internal radiation hazard. T F

33. List 3 important operations that are not authorized by the training that you are receiving.

(1) _____

(2) _____

(3) _____

34. Explain the mechanism which makes the Cobalt machine safe if a malfunction occurs resulting in the source remaining in the "ON" position during a treatment.

_____

_____

_____

_____

_____

_____

Minimum passing grade requires 80% correct answers.

NAME:_____ DATE:_____

PART II

FINAL TEST (RADIATION SAFETY)

1. The activity of a teletherapy source is measured in which of the following units?

   a) Roentgens b) Curies c) Rems d) Rads

2. Cobalt 60 emits which two forms of radiation?

   a) Alpha b) Beta c) X-Ray d) Gamma

3. Is there beta exposure from an encapsulated Cobalt 60 source? Why or why not?

4. The most radiosensitive state in the life of an organism is:

   a) Embryo b) Childhood c) Adolescence d) Adulthood

5. An acute dose of 1 Rem to the whole body may result in:

   a) Significant blood change
   b) Nausea, vomiting
   c) Sterility
   d) No observable effects

6. How often should radiation survey instruments be calibrated?

7. Prior to using a survey instrument to make radiation measurements, what three checks should be made?

15. a) For a teletherapy machine head with the source in the closed position, what is the normal radiation leakage at the surface?

b) What are the average and maximum allowable radiation levels at 1 meter from a teletherapy head?

16. Prior to entering a teletherapy room for service, what steps should you take for the protection of yourself and any assistants?

17. Who is responsible for the radiation safety program at your facility?

18. You or one of the technologists have been doing routine testing of the shutter open time and have discovered that the time has increased to 4 seconds. What should you do?

19. What dose would be obtained if you had to enter a treatment room, travel 12 feet to the machine and close the shutter? You spent a total of 1 minute in the room and the unit was a 80cm unit. The average dose rate was calculated by the hospital Radiation Safety Officer to be 5R/hr.

20. Radiation levels increase as you approach a source of radiation. What is the principle used to calculate the increase in radiation levels and what is the formula?

21. At 1 meter from an unshielded radiation source the levels are 500 mR/hr. What will the radiation levels be if you move 2.5 meters from the unshielded source?

RADIATION SAFETY AND HEALTH PHYSICS OBJECTIVES
MULTI QUESTION TEST

TEST ANSWERS

PART I

1. True
2. True
3. False
4. A) Cobalt-60
5. False
6. False
7. D) Lead
8. True
9. C) As Low As is Reasonably Achievable
10. B) Slowly
11. C) 100mr/hr
12. C) 200mr
13. B) 225mr
14. True
15. False
16. True
17. True
18. C) 125mr
19. a. 1.25
    b. 3
20. B) 1370 dpm
21. True
22. True
23. True
24. True
25. Cobalt Teletherapy
26. Radioactive Iodine injection, Natural K-40
27. True
28. 1) Clear the area
    2) Post the area "Do Not Enter Contaminated"
    3) Notify the Radiation Safety Officer
29. True
30. True
31. True
32. False
33. 1) Change source
    2) Remove collimator
    3) Leak testing of source
34. The unit is equipped with a source emergency drive mechanism which, when held down at the console, will close the source rotor.

FINAL TEST

ANSWERS

PART II

1. b.

2. b., d.

3. No. Beta particles cannot escape the capsule.

4. a.

5. d.

6. 6 months to 1 year, depending on license conditions.

7. Battery, calibration date, meter response.

8. 1250 mRem

9. 10CFR 20 or Agreement state regulations.

10. Any area, access to which is controlled for the purposes of protection of individuals from exposure to radiation or radioactive materials.

11. These areas contain no critical body organs.

12. Time, distance, shielding.

13. Cobalt 60, higher energy (approximately 2 times Cs^{137}).

14. 6000 Rads/hour.

15a. 15-100 mR/hour, depending on source size and shielding material.

15b. 2mR/hour, 10mR/hour.

16. Carry and use a survey instrument, verify that shutter is off, take possession of shutter control key.

17. Individuals name, RSO.

18. Nothing directly. Advise superiors to contact licensed service organization.

19. 5R/hr x 1000mR/R x 1hr/60min x 1min = 83.3mR.

20. The inverse Square Law, $I_1 = I \times X/X$ where I=the dose at the new distance I = the original dose, X = the new distance and X = the original distance.

21. I = 500 x 1 /2.5 - 80 mr/hr

REPLACE and/or ADD in appropriate location BEHIND TAB 3.

TOOL LISTING - ALL UNITS

THE FOLLOWING TOOLS ARE RECOMMENDED FOR GRADUATES TO HAVE AVAILABLE FOR USE WHEN PERFORMING MAINTENANCE:

DVM - Beckman 310 or Equal (digital volt meter)

Screwdrivers,
- Slotted - 3/32" x 2", 1/8" x 4"
- 1/8 x 8", 3/16" x 4", 1/4" x 1-1/4"
- (Stubby), 1/4" x 4", 5/16" x 6"
- Phillips - #0 x 2", #1 x 3"
- #2 x 1-5/16" (Stubby), #2 x 4"
- Screwholding, Slotted and Phillips
- Offset, Slotted and Phillips

Handle for Nutdriver-Hex-Spline Blades, 3"
Handle for Nutdriver-Hex-Spline Blades, 4"
Nutdriver Blades, 3/16"-1/2", 9 pcs.
Hex Driver Blades, .050"-3/16", 9 pcs.
Spline Driver Blades, .048"-.096", 6 pcs.
Extension for Above Blades, 4"
Nutstarter, Fits Nut Sizes 2 thru 6
Ignition Wrench Set, 8 pcs.
Socket Set, 1/4" Drive, 9 Sockets, Ratchet, Spinner, 2 Extensions and Case, 14 pcs.
Hex Key Set, Short Arm, 7 pcs.
Adjustable Wrench, 4"
Adjustable Wrench, 8"
Groove Joint Utility Pliers, 10"
Diagonal Cutters, 5"
Miniature Cutters, 4"
Miniature Chain Nose Pliers, 4"
Long Nose with Side Cutter, 6"
1/2" Allen Wrench
Wire Stripper/Cutter with Adjustable Stop
Crimping Tool with Bolt Cutter, and Wire Stripper
Tweezers, Reverse Action
Tweezers, Non-Magnetic, Stainless
Knife, Electrician's Multi-Purpose
Scissors, Electrician's Type
Hammer, Ball Pein 4 oz Head
Center Punch, 1/4"
Drive Pins, 1/16" and 1/8"
Pocket Scribe
Soldering Iron, 25W with Tip
Solder Pack
Solder Aid, Brush/Flor
Solder Braids
Flat Mill File
Rule, 6" Stainless with Wire Gauge
Feeler Gauge, 15 Blades
Alignment Tools, Set of two Multi-Purpose
Penlight with Batteries
Inspection Mirror, Dental Type
Adhesive, General Purpose

STUDY AIDS

Tab 3

1. AMS Teletherapy Hospital Maintenance Course Outlines and Personal Notes.

2. Unit Operations Manuals A, B, C, D

3. Electrical Schematic 200070 and T61 Series.

4. Equipment (Teletherapy Units) and Basic Components.

Rotational Units	C-9 C-8 & C-4 *
Vertical Units	V-9 & V-4
Components	C-9 Couch C-8 Couch
Collimators	3706 3347
Control Console	VG-8 200422

Note: Study Aid #4 will be used throughout the Laboratory Exercises portion of the training.

1.9 C-ARM DRIVE SPROCKET

Remove the left-hand shroud from the Stand and note the location of the sprocket mounting bolts. (Ten 5/8 x 18 socket-head screws)

Rotate the C-arm in the SLOW speed mode until a mounting bolt is accessible through the opening above the upper diagonal brace on the left-hand side of the Stand. Mark this screw with a crayon or chalk.

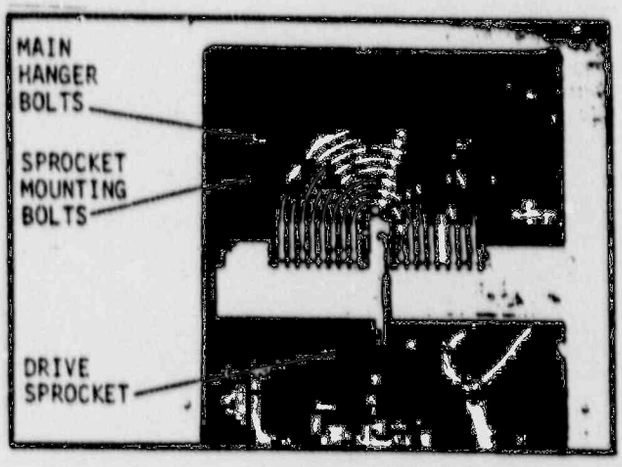
With a 1/2" allen wrench, partially torque the screw. When each of the mounting bolts has been partially torqued, continue the rotation procedure and final-torque each bolt to 240 Ft.-Lbs. (33 Kg-m). (80 Lbs. with a three-foot extension or 120 Lbs. with a two-foot extension.)

Lecture Notes

1.10 STAND TO C-ARM BOLTS

These bolts are accessible through the ten holes in the large C-arm drive sprocket. Proceed as above to torque each bolt to 240 Ft.-Lbs. (33Kg-m)

Lecture Notes



GENERAL TEST

ANSWERS

FINAL TEST PART I

1. False

2. 300lb.

3. b.

4. 20cm

5. ± 2mm

6. 120 VAC 50/60HZ 105VAC - 125 VAC)

7. Emergency Hand Wheel
Emergency Switch
Shutter Return Spring

8. By adjusting its bracket mounting screws and setting the cross hair a known distance. (± 2mm total)

9. Located left side of yoke, these switches limit head tilt travel to within mechanical limits allowable by assoc. wiring. (i.e. out 90° through in 20°).

10a. 6.3 VAC
10b. 2HVDC

11. 1/8"

12a. 240 ft-lbs.
12b. 420 ft-lbs.

13. False.

14. Vary the rotational speed of the gantry from 40°/min through 400°/min.

15. Oils from skin will shorten their life.

16. Illuminate a field that will represent the radiation field during treatment.

17. Physicist. Actual relationship of light to radiation fields.

18. The amount of mechanical activation the switch exhibits AFTER the electrical switching has occurred.

19. In gantry stand just behind ratiotra speed control.
(The actuator is fastened to the main rot. sprocket)

20. False.

21. 55 to 100 cm.

GENERAL TEST

ANSWERS

FINAL TEST PART 1

(Page 2)

22. False

23. Stand. Reverse motor rotation.

24. RE12; Tab switch #23 must be actuated. (Switch located under gantry anglescale tabs).

25. RE6, RE7

26. F8

27. Source is in full on position

28. Upon power-up. Never, AMS has discontinued use of Halo Switch Circuitry.

29. Head tilt off center. (mercury switches in action)

30. RE2; Timer set to desired time.
Door closed.
Any one Zonegard condition met.
met Halo circuit energized.

31. Key switch.

32. a.

33. Distance from source to isocenter.

34. By finding isocenter.

35. c.

36. Head end is lighten by 10 to 25 lbs.

37. Infinite in either direction.

GENERAL TEST

ANSWERS

V UNITS ONLY
(Final Test Part 3)

1. Glazed brake pads.

2. Tighten yoke brake pads.

3. Bad rotor bearings
slipping V-belt
low motor voltage
bad shutter return spring

4. 80 lbs.

5. Head - up, down
Head - in, out (tilt)
Yoke - right, left (rotate)

6. Press the emergency bar to close the shutter in an emergency. Press and hold in to power the source while closed, using the shutter motor.

7. By adjusting the tension in the shutter drive.

8. Whitmore Wire Rope Spray.

9. True.

10. True.

GENERAL TEST

ANSWERS

C-8 & C-4 UNITS ONLY
Final Test Part 4

1. 3347D

2. To provide a record of the actual exposure time in case of an emergency situation.

3. No.

4. No.

5. LUBRI PLATE.

6. 120VAC 20 Amps 50/60HZ
1 phase (105VAC to 125 VAC)

7. Treatment over pre-set arcs or areas while the C-arm is rotating. The source comes on or off depending on how the index tabs are set at the gantry center.

8. Manual.

9. Provides a mechanical method of locking a shutter.
Rotor in the OFF position.

10. Press the emergency bar and hold it depressed.

CONVERSATION RECORD

TIME 1:20 (P) DATE 9/15/88

TYPE
☐ VISIT ☐ CONFERENCE ☒ TELEPHONE
☐ INCOMING ☒ OUTGOING

Location of Visit/Conference:

NAME OF PERSON(S) CONTACTED OR IN CONTACT WITH YOU	ORGANIZATION (Office, dept., bureau, etc.)	TELEPHONE NO.
Donna-Beth Howe	HQ.	

ROUTING

NAME/SYMBOL	INT

SUBJECT

Dr. White & AMS

SUMMARY

1. Accept Charlie Rose course for 200 hrs didactic training. - HQ did not act quick enough. Course has been given for 8-10 yrs and accepted.
2. Send course to Donna-Beth Howe for Technical assistance and she will forward to FDA for evaluation. (AMS service course).

ACTION REQUIRED

NAME OF PERSON DOCUMENTING CONVERSATION	SIGNATURE	DATE
	J. R. Mod	9/15/88

ACTION TAKEN

SIGNATURE	TITLE	DATE

CONVERSATION RECORD

TIME

DATE 9/13/88

TYPE ☐ VISIT ☐ CONFERENCE ☒ TELEPHONE ☐ INCOMING ☒ OUTGOING

Location of Visit/Conference:

ROUTING	
NAME/SYMBOL	INT

NAME OF PERSON(S) CONTACTED OR IN CONTACT WITH	ORGANIZATION (Office, dept., bureau, etc.)	TELEPHONE NO.
* Steve Baggett	HQ	8-492-0637
Thomas Rich		Bag 8-492-0542

SUBJECT

1. AMS Training Course CN 82095
2. Noresing, Inc. CN 85005

SUMMARY

1. AMS - [redacted] 3. US Steel (IPIS unit)

a.) We have received response from AMS to def. letter and have question on sham - need to submit 50 questions at least on rad. protection including inverse square law.

b.) We have also requested from AMS a response to your concerns as outlined on memo dated July 06, 1988.

c.) AMS was contacted by telephone and has 30 days to respond.

* d.) We contacted Steve Lewis at OGC and asked him if he saw any problem with issuing amendment. He stated that he didn't see any problem but suggested we contacted NMSS in case their legal counsel saw a problem from a policy standpoint. (over)

ACTION REQUIRED

NAME OF PERSON DOCUMENTING CONVERSATION	SIGNATURE	DATE
	J R Mach	

ACTION TAKEN

SIGNATURE	TITLE	DATE

Will it be necessary to submit the package to OGC and if so why? - as long as Lewis said there is no problem - go ahead and issue.

2. NORESIN, Inc.

a.) what is status on the device review for this licensee? - Baggett will check → almost ready.

~~3. [illegible]~~

3. U.S. Steel (Tips) Lon Morgan → [redacted]
Baggett will check and call back.

Baggett saw no problem in our review of AMS Training Course.

CONVERSATION RECORD

TIME

DATE 9/9/88

TYPE

☐ VISIT ☐ CONFERENCE ☒ TELEPHONE

☐ INCOMING ☒ OUTGOING

Location of Visit/Conference:

ROUTING	
NAME/SYMBOL	INT

NAME OF PERSON(S) CONTACTED OR IN CONTACT WITH YOU	ORGANIZATION (Office, dept., bureau, etc.)	TELEPHONE NO.
Donna-Beth Howe	HQ	8-492-0636

SUBJECT

AMS. CN 82095
FDA role in amendment.

SUMMARY

I. Do we need to coordinate with FDA in order to issue amendment for training course to perform minor maintenance and repairs on Teletherapy units, if so why? Dr. Howe will contact FDA and inform them of the AMS request and will get back to us with their concerns.

ACTION REQUIRED

NAME OF PERSON DOCUMENTING CONVERSATION	SIGNATURE	DATE
	J P Mad	9/9/88

ACTION TAKEN

SIGNATURE	TITLE	DATE

50271-101

U.S. GPO: 1988-201-760/80190

(40231) CONVERSATION RECORD

OPTIONAL FORM 271 (12-76)
DEPARTMENT OF DEFENSE

CONVERSATION RECORD

TIME 2 30 (P) | DATE 9/8/88

TYPE: ☐ VISIT ☐ CONFERENCE ☒ TELEPHONE ☐ INCOMING ☒ OUTGOING

Location of Visit/Conference:

NAME OF PERSON(S) CONTACTED OR IN CONTACT WITH YOU	ORGANIZATION (Office, dept., bureau, etc.)	TELEPHONE NO.
T.J. Hebert	AMS	216/466-4671

ROUTING

NAME/SYMBOL	INT

SUBJECT

* Donna Ely Response to CN 82095 Def. Letter dated 6/6/88

SUMMARY

① General Exam - Need 50 questions dealing with Radiation Safety Fundamentals including problems involving the inverse square law. Include correct answers.

② Explain that NRC does not approve training courses - only assesses them for adequacy.

③ Availability of current Agreement State Regulations for students.

④ Clarify question 18 on Rad Safety Orig.

⑤ Update Agreement State list to include Illinois, etc.

⑥ Typo correction Tab 3 Section 1.9 "Left-ahdn" should be left-hand?

⑦ Need a list/section of equipment and tools

ACTION REQUIRED

NAME OF PERSON DOCUMENTING CONVERSATION	SIGNATURE	DATE

ACTION TAKEN

SIGNATURE	TITLE	DATE

CONVERSATION RECORD

TIME | DATE

TYPE

☐ VISIT ☐ CONFERENCE ☐ TELEPHONE

☐ INCOMING ☐ OUTGOING

Location of Visit/Conference:

NAME OF PERSON(S) CONTACTED OR IN CONTACT WITH YOU	ORGANIZATION (Office, dept., bureau, etc.)	TELEPHONE NO.

ROUTING

NAME/SYMBOL	INT

SUBJECT

CN 82095 Con't

SUMMARY

needed by the students in order to perform their own maintenance operations. Need to be specified in manual.

8. Specifically state that students will receive the appropriate manuals etc. to perform maintenance and repair operations on their own equipment.

ACTION REQUIRED

30 days to respond, refer to CN 82095

NAME OF PERSON DOCUMENTING CONVERSATION	SIGNATURE	DATE
	J. L. K. Mader	9/8/88

ACTION TAKEN

SIGNATURE	TITLE	DATE

CONVERSATION RECORD

TIME: 10:51 am | DATE: 6 Sept 88

TYPE: ☐ VISIT ☐ CONFERENCE ☒ TELEPHONE ☐ INCOMING ☒ OUTGOING

Location of Visit/Conference:

NAME OF PERSON(S) CONTACTED OR IN CONTACT WITH YOU	ORGANIZATION (Office, dept., bureau, etc.)	TELEPHONE NO.
Steve Lewis	OGC	482-1537

SUBJECT: Re: AMS Training Program for Hospital Clients

ROUTING	
NAME/SYMBOL	INT

SUMMARY

Lewis knows of nothing which would preclude issuance of AMS's proposed training program.

STIS Recommend that we check with NMSS & OGC; Bob Fonzo

ACTION REQUIRED

NAME OF PERSON DOCUMENTING CONVERSATION	SIGNATURE	DATE

ACTION TAKEN

SIGNATURE	TITLE	DATE

Advanced Medical Systems, Inc.
121 North Eagle Street • Geneva, Ohio 44041
(216) 466-4671 TWX 810-4272-183

August 15, 1988

Materials Licensing Section
U.S. Nuclear Regulatory Commission
Region III
799 Roosevelt Road
Glen Ellyn, Illinois 60137

Attention: Mr. John R. Madera

Dear Mr. Madera:

Enclosed are two copies of Advanced Medical Systems' revised Hospital and Clinic Training Program. Please remove the entire original (1987 submission) from your binders and insert the revised copies included in this package. Retain only the schematic #200070 in the rear binder jacket from the original manual.

Included in this revised manual are all of the changes and revisions suggested in your June 6, 1988 letter to Advanced Medical Systems. Please note that the types of Remedial Maintenance and adjustments graduates may perform are marked in the troubleshooting section of Tab 3 and were part of the original 1987 manual.

Should you have any questions regarding the content of this revised manual, please call me at 216-466-4671.

Sincerely,

Theador Hebert

THEADOR J. HEBERT
General Manager
ATC Medical Group

TJH/dsj

Encl.

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

CN 82095

JUL 0 6 1988

MEMORANDUM FOR: George M. McCann, Chief
Materials Licensing Section, RIII

FROM: Vandy L. Miller, Chief
Medical, Academic, and Commercial Use Safety Branch, IMNS

SUBJECT: TAR - ADVANCED MEDICAL SYSTEMS TRAINING PROGRAM

We have reviewed your Technical Assistance Request dated June 3, 1988 concerning a request from Advanced Medical Systems, Inc., (AMS) to approve a Hospital Service Training Program for AMS/Picker teletherapy treatment units. A deficiency letter had already been sent by John Madera to AMS requesting more information regarding the training program. It would have been more appropriate to ask for our review and comments before a deficiency letter was sent to AMS as it may now be necessary to send a second deficiency letter.

However, the TAR has been reviewed by members of the MACUB staff and we are forwarding our comments regarding the AMS proposed training plan. In a telephone conversation on June 28, 1988, between F. St. Mary of my staff and John Madera it was determined that we should forward our comments to you and, upon receipt of an AMS response to your deficiency letter, RIII will decide what action to take after consultation with Headquarters.

Our comments are as follows:

1. Upon receipt of an AMS response to your deficiency letter we will obtain OGC comments regarding the AMS request.

2. FDA should be asked if they have an interest in the information a manufacturer is telling its customers. This request should be coordinated through Donna-Beth Howe, Ph.D., of my staff.

3. NRC cannot approve a training program as requested in the AMS Essential Program Requirements, Item 2.

4. Do we need curricula vitae from Laney Hill, Ed DeRosa, Terry Kellhofer, and Curtis Perry?

5. Tab 2., Question 9: Does AMS have a set of Agreement State regulations in order to know which section is applicable for each state?

6. Tab 2., Question 14: This question should require the dose rate at a distance other than one meter be determined by the student in order to demonstrate ability to use the inverse square law.

7. Tab 2., Question 18: This test question is not understood. Please clarify.

JUL 1 1 1988

8. Page 35: Illinois should be added to the list of Agreement States.

9. Note before Tab 3: Has AMS walked through these techniques/instructions to see if they will work? It appears that they have not. Also, the word "emergency" seems to be inappropriate. More appropriate might be: "If the techniques and instructions outlined in this course do not work, secure the source and room, and call AMS."

10. Tab 3, Sections 1.2, 1.4, 1.7, 1.9, 1.12: These sections do not appear to give the trainee enough written data or diagrams to identify these components.

11. Tab 3, Section 1.9: "ahdn" needs to be identified.

12. An equipment, tools, and supplies need list should be generated and placed in the manual so that the person doing the service has the proper tools available.

13. The trouble shooting section should only list what can be done by a graduate of the program. A generic statement can then be made about any factory service required.

If you have any questions, please contact me at FTS 492-3418 or Francis St. Mary at FTS 492-0611.

Vandy L. Miller, Chief
Medical, Academic, and Commercial
Use Safety Branch
Division of Industrial and
Medical Nuclear Safety, NMSS

JUN 0 6 1988

Advanced Medical Systems, Inc.
ATTN: T. J. Hebert
General Manager
121 North Eagle Street
Geneva, OH 44041

Gentlemen:

In order to complete our review of your request in Section II of your letter dated November 10, 1987, for a hospital and clinic training program for the conduct of limited maintenance and adjustments by user personnel on their AMS/Picker teletherapy treatment units, we will need additional information on the following:

1. Testing

Your testing program consists of an 18 question final quiz on Radiation Safety and a 20 question general quiz on the C-9 unit only. We typically require at least 50 questions on a final exam covering the material taught in a course, including emergency procedures. An 80 percent passing grade is acceptable. You need to augment your training program as follows:

a. Additional questions should be added to your quizzes, including questions on emergency procedures and on all of the teletherapy units covered in your training program.

b. The final exam should include a practical test covering the operations which a successful graduate would be expected to perform. Submit an outline for a practical exam. These questions may be included in the total number of questions for the final exam.

c. Describe the minimum passing grade which may be achieved on your final exam.

2. Types of Remedial Maintenance and Adjustments Graduates May Perform

Describe the types of maintenance and adjustments which may be performed by graduates of your training program. Also, describe the types of maintenance and adjustments which should be referred to qualified licensed technicians.

3. Hands on Training

Describe in greater detail the type of hands on training which will be given to your students. This type of training should cover the types of operations which they will be expected to perform at their institutions, including emergency procedures. Also, specify the time allotted to this practical type training.

4. Daily Service Log

Please provide a copy of your daily service log given to your graduates in order to maintain a record of types of service performed, when it was performed, authorization, a safety check prior to release for normal use, and authorization for release.

5. Safety Rules

Please submit a copy of the safety rules to be followed by training course graduates while performing service.

6. Unit Specifi[illegible]ning

Please desc[illegible]ne different courses provided by your training program. Specificall[illegible]cribe how your training program is divided into instructi[illegible]ocks for the different types of teletherapy units offered by your [illegible] or training program. Describe the mechanism for determini[illegible]ne type of training that will be provided to your customer (i.e., unit specific as needed).

We will continue our review of your application upon receipt of this information. Please reply in duplicate, within 30 days, and refer to Control Number 82095.

If you have any questions or require clarification on any of the information stated above, you may contact us at (312) 790-5625.

Sincerely,

Original Signed By
John R. Madera
Materials Licensing Section

RIII

Madera/pd
6/ /88

CONVERSATION RECORD

TIME: 12 00 N | DATE: 6/1/88

TYPE: ☐ VISIT ☐ CONFERENCE ☒ TELEPHONE ☐ INCOMING ☒ OUTGOING

Location of Visit/Conference:

NAME OF PERSON(S) CONTACTED OR IN CONTACT WITH YOU	ORGANIZATION (Office, dept., bureau, etc.)	TELEPHONE NO.
T. J. Hebert	AMS	216/466-467

ROUTING

NAME/SYMBOL	INT

SUBJECT: Hospital and Clinic Training Program
CN 82095

SUMMARY

① Discussed with Ms. Hebert the AMS training course and outlined the deficiencies in program.
② Discussed the possibility of AMS providing to licensees, which have techs trained by AMS to perform the services described in their program, with a maintenance work sheet which outlines the type of job requested, date and time the H.P. and/or RSO was notified of service, date and time service was performed, date and time a full check of safety functions by Dosp. Med. H.R and/or RSO was performed. etc.
③ AMS should provide graduate with a Rad protection check list which could be posted.
a) Survey meter properly Cal. & functions.
b.) Dosimetery equipment (Dosimeter & Film badge) properly checked & worn.

ACTION REQUIRED

(over)

NAME OF PERSON DOCUMENTING CONVERSATION	SIGNATURE	DATE
	J Mad	6/1/88

ACTION TAKEN

SIGNATURE	TITLE	DATE

c. Area signs posted - cautioning other techs that work is being performed on unit.

d. Check to make sure unit is off and panel key is removed.

e. Survey area prior and after work performance.

(etc.)