

CHARLOTTE HUNGERFORD HOSPITAL
540 Litchfield Street
P.O. Box 988
Torrington, CT 06790

October 18, 2006

Br. 1

Nuclear Regulatory Commission
Region I
Nuclear Materials Safety Branch
Division of Radiation Safety and Safeguards
475 Allendale Road
King of Prussia, PA 19406-1415

REFERENCE: License Number: 06-08349-04 Amendment

03009293

To Whom it May Concern:

Please amend our license to include the clinical use of the GammaMed Brachy HDR Seal
Source Device, DR Model: GammaMed 212, GammaMed 232, HDR Certificate: CA-066-S-104
S dated 2/26/03.

RECEIVED
REGION I
2006 OCT 23 11:25

Documentation of the manufacturer's training given to our staff including the authorized user,
authorized medical physicist, and the radiation safety officer is attached

Please let me know if additional information is required. Thank you.

Sincerely,



Daniel McIntyre
President & CEO

Enc: "Gamma Med On-Site Training" documentation

VARIAN
medical systems

BRACHYTHERAPY

***GammaMed System On-Site
Training Course Outline
including
GammaMed Plus***

Notes

- This schedule is intended as a guide and should not be considered as prescriptive. Those for whom the training is intended should therefore feel free to make alterations to this schedule in line with staff availability, or learning requirements. These changes can be made prior to the visit of the instructor, or following a discussion at the commencement of training.
- This training schedule incorporates a checklist covering all essential aspects of the training course. The instructor should check off this list as each aspect is covered and a record made of each person attending each session. Each customer receiving training should then sign to the effect that they have received and understood each training session. Sessions not covered should be crossed out and initialled.
- In order to optimise the Applications training, it is recommended that a complete patient procedure is carried out on the last day of the course. This allows all aspects of the training to be practised and any unforeseen practical problems resolved.
- For those customers with no previous HDR experience, changes to the schedule whereby a patient is treated on the first or second day of this course should be avoided.
- If, for scheduling reasons it is not possible for a patient to be treated, it is recommended that a patient treatment be simulated to meet the same goal of walking the staff through an entire procedure while the instructor is available on-site.
- The staff group for whom the session is primarily intended is indicated for each session describe below. Please note that the staff listed in these groups is based upon that found in a typical Oncology center. Obviously, there will be a large variation in the division of labour from one hospital to the next, and it is left for the individual hospital to decide which staff fall into each group, and therefore which should attend each session.
- The intended duration of each session shown below is approximately half a day. However, this is intended as a guide and some sessions may be of a longer or shorter duration depending on customer requirements.

The staff groups referred to in the schedule below are defined as follows:

Brachytherapy Team

All staff involved in delivery of a brachytherapy treatment e.g. Physician, Technologist, Physicists, Dosimetrists, Oncology Nurses etc.

Operators

All staff who intend to operate the VariSource Afterloader (for clinical or non clinical purposes) e.g. Technologist, Physicists

Physicists

All staff who will be involved in quality assurance procedures, dosimetry measurements and treatment planning e.g. Physicists and Dosimetrists.

Training / Attendee List

Part One: Customer Site Information:

Facility Name	CHARLOTTE HUNGERFORD HOSPITAL		
Street Address	200 KENNEDY DRIVE		
City	TORRINGTON		
State or Prov.	CT	Postal Code	06790
Country	USA		
Phone	(603) 489-6718	Fax	
Date Of Course	OCT. 12-13, 2006		

For the purposes of the training records list below all those receiving GammaMed Applications Training (to any level) along with job function (e.g. Oncologist, Physicist etc.), signature and initials.

	Name	Job Function	Email address	Signature
1.	ABRAHAM KURUVILA	Dosimetrist	Abe.kuruvila@adl.com	
2.	Lee Anne Zager	Physicist	L.Zager@Hungerford.org	
3.	Pamela Ciccarelli	RN	pciccarell@hungerford.org	
4.	Elizabeth Whalen	MD	ewhalen@hungerford.org	
5.	Robert Taylor	RT(T)	rtaylor@hungerford.org	
6.	Mary Jean Thielman APED	APRN	mthielman@midstate-medical.org	
7.	Wendy Fedor	RT(T)	wafedor@yahoo.com	
8.	Sherry Kennardson	RT(T)		
9.	GERALD RANDALL	RSO	radrem@ADL.COM	

Instructor

Name: STAVROS D. PRIONAS, Ph.D.

Signature / Initials: S.D.P.

GammaMed Training Outline

Preparation - System inventory (if not already performed by Installation Engineer)

The Applications Specialist and one member of staff check off all system components, applicators and accessories against a copy of the original order.

Ensure that a copy of each of the Afterloader and planning system manuals, as appropriate is available.

Ensure that the system has been adequately and neatly installed

Instructors Initials: S.D.P.

Attendees Initials: LA

Session 1 - Team

General discussion

Discus the intended uses of the Afterloader, how the work will be divided between staff disciplines, how the training will be scheduled.

Afterloader component identification and terminology

Physically identify each component of the Afterloader and provide a brief description of its function.

Control PC / Printer

Control Console (making specific reference to its role as a status / error indicator, key switches)

Junction box

Afterloader (trolley, control panel, key switches, elevator, emergency hand crank, foot brake)

Location of emergency stop and reset buttons

Emergency container and accessories

Instructors Initials: S.D.P.

Attendees Initials: LA

GammaMed Plus Training Course Outline

Afterloader System Operation Overview

Describe the basic operation of each component with particular emphasis on safety features and wire tracking concepts and emergency situations.

Source wire construction and cycle limitation.

Dummy / Active wire concept (applicator end test)

Wire position within machine

Wire tracking (light barriers, incremental encoder)

Wire drive assembly (wheel drive mechanism)

Key switches (source lock key, battery key)

Emergency retract operation

Emergency back-up systems (on-board battery, GM tube).

Instructors Initials: *S.D.P.*

Attendees Initials: *ETR*

Emergency Procedures

Describe and discuss in depth, correct emergency procedures in the full range of possible failure situations.

Emphasis the importance of having locally written emergency procedures bases on the type of treatments practised.

Emphasis the importance of regularly rehearsing the emergency procedures.

Describe the emergency equipment to be kept available during the procedure.

Discuss the requirement to have both a Physicist and Physician physically present during a procedure each having clearly defined responsibilities. Also discuss the idea of having a person responsible for note taking and time keeping during an emergency.

Importance of position of Afterloader relative to room entrance i.e. allow easy access to the rear of the machine).

Importance of position of emergency recovery equipment within room, i.e. ensure easy access when ever a treatment is in progress.

System safety checks and emergency recovery processes as described in the flow diagram contained within the emergency procedures section of the Users Manual (include reference to the status of the system alarms for each failure mode and possible recovery methods i.e. manual retract handle or manual recovery).

Describe recovery procedure if manual retract handle is not indicated. Include the options of removing the applicator from the patient.

Instructors Initials: S.D.P.

Attendees Initials: L.A.

Applicators

Demonstrate the use and special features of all applicators held on-site.

Demonstrate the correct assembly of all applicators held by customer.

Discuss the sterilization of these applicators and the possibility of re-use.

Demonstrate the correct use of the measurement wire and emphasis the importance of its regular use to check the length of applicator / catheter assemblies.

Discuss the use of a dead space at the tip of applicators to prevent the source colliding with the applicator.

Discuss the fix length technique (1.3m) of the GM afterloaders

Explain the applicator-end-test in channels 1-19

Instructors Initials: S.D.P.

Attendees Initials: L.A.

Connection of Catheters / Applicators to the Afterloader

Show how to prepare the machine for use.

Demonstrate correct use of the Transfer Tube Connections and its connection into the indexer, showing also ways in which incorrect connection can occur.

Discuss the importance of correct placement of Afterloader relative to patient (i.e. keep catheters as straight as possible).

Instructors Initials: S.D.P.

Attendees Initials: L.A.

Session 2 - Operators

Control Software GammaWin

Discuss the different fields of the main screen (Patient-, Irradiation Time-, Date&Time-, Device-, Indexcr-, Source Position-, Dwell time- and Status field)

Discuss the nominal dwell time concept of GM afterloader devices

Discuss and demonstrate the step size and offset adjustments (with practical test of the offset adjustment)

Introduce the main functions of the program (Treatment menu – creating a treatment plan, open, edit, save, delete; Edit menu – cut, copy, paste of positions and channels; Options menu – configure)

Instructors Initials: *S.D.P.*

Attendees Initials: *KAZ*

Creating test plans for the routine check

Practice programming a delivery of simple treatments.

Create new treatment file.

Demonstrate manual programming of the Afterloader. Create a plan with at least 2 channels and several source stopping positions.

Transfer of data and control.

Explain the hand over of the treatment control to the afterloader device (Start treatment).

Demonstrate the various on screen status indicators shown during treatment.

Demonstrate treatment interruption and termination.

Describe the data shown on the Patient History File printed output

Emphasise the importance of checking correct treatment termination prior to room entry i.e. printout shows treatment complete without errors, no errors on Control Console and independent radiation alarm is clear.

Import of treatment files

Explain the possibility of data file transfer via floppy or network.

Fractionation

Explain and discuss the fractionation of treatments with GammaWin (edit function).

Instructors Initials: *S.D.P.*

Attendees Initials: *KAZ*

Session 3 - Physics

Source strength calibration

Describe in detail the procedure for source strength calibration

Importance of regular instrument calibration and QA checks.

Electrometer / chamber set-up and acclimatisation

Electrometer operation and zeroing procedure

Connecting the catheter to the chamber insert and the importance of using a plastic tipped catheter vs. a metal tip.

Measurement of temperature and pressure.

Importance of finding the chamber "Sweet Spot" and how to set up a GammaWin file to achieve this.

Calibration readings (modes of the electrometer)

Explain the expected discrepancy between Manufacturers and site measured source strength i.e. specification = $\pm 5\%$, although expected results would be approximately $\pm 1.5\%$

Instructors Initials: *S.D.P.*

Attendees Initials: *LA*

QA forms and checks

Describe the various QA checks that should be performed by the user and how the QA forms can be used to keep a record of these.

Describe each test listed on the QA forms and make suggestions as to the frequency of these tests.

With the customer set up the forms for Periodic, Treatment and Source Exchange days.

Demonstrate how each test may be performed.

Demonstrate the Source Decay table and how this may be used to check source calibration prior to treatment. Also, describe other ways in which this test may be performed through the use of spreadsheets.

Position Verification Tests

Discuss the frequency of tests and show how these may be set up for Periodic,

Treatment and Source Exchange days.

Discuss the expected accuracy of the wire positional calibration and the importance of Service intervention in the case of this exceeding the machine specification.

Instructors Initials: S.D.P.

Attendees Initials: [Signature]

GammaMed 3/24 A/L On-Site Operations Class

Sign-in Sheet

Institution: Charlotte Hungerford Hospital

Institution: Dept. of Radiation Oncology

Address: 200 Kennedy Drive

Address: Torrington, CT 06790

Date: October 10, 2006.

Day: Monday Tuesday Wednesday Thursday Friday

Time: 8:00' A.M.

No	NAME (Please Print)	Time In	Time Out
1	Lee Anne Zanger, M.S.	~ 8:30' A.M.	5:00' p.m.
2	Abraham Kururilla, CMD	~ 8:15' A.M.	↓
3	Dr. Elizabeth Whalen	~ 8:30' A.M.	
4	John Morrison (VMS - Instructor)	~ 9:20' A.M.	
5	S.D.P. (VMS)	~ 8:00' A.M.	5:00' p.m.

Note: All participants must document their log in and log out times.

- 1) BV 7.3.10 (MammoSite) - John Morrison.
- 2) -w Admin. Task.
Lunch/chinese ~ 12:30' - 1:30' p.m.

GammaMed 3/24 A/L On-Site Operations Class

Sign-in Sheet

Institution: Charlotte Hungerford Hospital

Institution: Dept. of Radiation Oncology

Address: 200 Kennedy Drive

Address: Torrington, CT 06790

Date: October 11, 2006.

Day: Monday Tuesday ~~Wednesday~~ Thursday Friday

Time: 8:00 A.M.

No	NAME (Please Print)	Time In	Time Out
1	Abraham Kuruvilla	8:00 AM	12:15 pm
2	Lee Ann	~8:30' A.M.	
3	John	~9:05' A.M.	
4	S.D.P.	8:00' A.M.	∇

Note: All participants must document their log in and log out times.

BY 7.3.10 - John Morrison.
 Mammo Site 2
 Vag. Cyl.

GammaMed 3/24 A/L On-Site Operations Class

Sign-in Sheet

Institution: Charlotte Hungerford Hospital

Institution: Dept. of Radiation Oncology

Address: 200 Kennedy Drive

Address: Torrington, CT 06790

Date: October ~~12~~, 2006.

Day: Monday Tuesday Wednesday Thursday Friday

Time: 1:30 p.m.

No	NAME (Please Print)	Time In	Time Out
1	Lee Ann	1:30' p.m.	5:00' p.m.
2	John	1:30' p.m.	↓
3	Abraham	~1:30' p.m.	
4	S.D.P.	1:30' p.m.	

Note: All participants must document their log in and log out times.

GammaMed 3/24 A/L On-Site Operations Class

Sign-in Sheet

Institution: Charlotte Hungerford Hospital

Institution: Dept. of Radiation Oncology

Address: 200 Kennedy Drive

Address: Torrington, CT 06790

Date: October 12, 2006.

Day: Monday Tuesday Wednesday Thursday Friday

Time: 8:00 A.M.

No	NAME (Please Print)	Time In	Time Out
1	Sherry Kennerson	~ 8:30' A.M.	12:30' p.m.
2	L. Jedy Fedor		
3	Mary Jean Threlman APRN		
4	Robert Taylor		
5	Elizabeth Whalen MD		
6	B. Ciccarelli RN		
7	Lee Anne Zarger		
8	Abraham Korovilla	↓	↓

Note: All participants must document their log in and log out times.

GammaMed 3/24 A/L On-Site Operations Class

Sign-in Sheet

Institution: Charlotte Hungerford Hospital

Institution: Dept. of Radiation Oncology

Address: 200 Kennedy Drive

Address: Torrington, CT 06790

Date: October 12, 2006.

Day: Monday Tuesday Wednesday **Thursday** Friday

Time: 1:15' p.m.

No	NAME (Please Print)	Time In	Time Out
1	GERALD G. RANDALL	1:45 PM	5:30' p.m.
2	Sherry Kennerson	≈ 1:30' p.m.	4:30' p.m.
3	Jenny Fedor		4:30' p.m.
4	Robert Taylor		4:30' p.m.
5	Bob Ciccach		4:30' p.m.
6	LeeAnne Zager		5:30' p.m.
7	Elizabeth M. Whalen MD		5:00' p.m.
8	Abraham Korovilla, CMD		5:00' p.m.
9	Mary Jean Thielman APRN	↓	4:30' p.m.

Note: All participants must document their log in and log out times.

GammaMed 3/24 A/L On-Site Operations Class

Sign-in Sheet

Institution: Charlotte Hungerford Hospital

Institution: Dept. of Radiation Oncology

Address: 200 Kennedy Drive

Address: Torrington, CT 06790

Date: October 13, 2006.

Day: Monday Tuesday Wednesday Thursday Friday

Time:

No	NAME (Please Print)	Time In	Time Out
1	Abraham Kurvika cmo	8:00 AM	~ 5:00' p.m.
2	Lee Anne Zager	8:30 AM	~ 5:00' p.m.
3	Dr. Whalen	~ 2:00' p.m.	~ 4:30' p.m.
4	Sherry Kennerson	~ 2:30' p.m.	~ 4:30' p.m.

Note: All participants must document their log in and log out times.



This is to acknowledge the receipt of your letter/application dated

10/19/2006, and to inform you that the initial processing which includes an administrative review has been performed.

Amendment 06-08349-04 There were no administrative omissions. Your application was assigned to a technical reviewer. Please note that the technical review may identify additional omissions or require additional information.

Please provide to this office within 30 days of your receipt of this card

A copy of your action has been forwarded to our License Fee & Accounts Receivable Branch, who will contact you separately if there is a fee issue involved.

Your action has been assigned **Mail Control Number** 139610.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.

