

Shabason, Leonard Ph.D.

p-6

From: Shabason, Leonard Ph.D.
Sent: Monday, September 10, 2007 2:06 PM
To: 'Penny Lanzisera'
Subject: RE: Additional Information to Support Clinical Use, MailControlNo. 140850

37-06864-06
0301563

I will fax copies later this afternoon. The daily timer test will be done for over a minute. This is almost a necessity since the "measured" time is dependent on the observer's reaction time.

-----Original Message-----

From: Penny Lanzisera [mailto:PAN@nrc.gov]
Sent: Monday, September 10, 2007 1:23 PM
To: Shabason, Leonard Ph.D.
Subject: RE: Additional Information to Support Clinical Use, MailControlNo. 140850

Please sign and fax the below information. Also, for timer accuracy done daily, clarify if the test is performed over 1 minute. Thanks, Penny. P.S.- No need to fax the SSDR.

Fax Number 610-337-5269.
Mail Control Number 140850

>>> "Shabason, Leonard Ph.D." <Shabasol@pahosp.com> 09/10/2007 1:12 PM
>>>

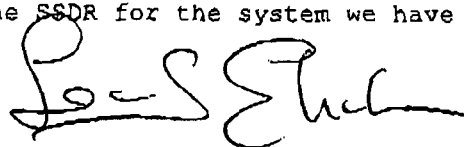
Part of the daily QA check will be confirm that opening the treatment room door will force the system to retract the source. The daily QA check will also confirm that the lights on the control unit will be confirmed to read as specified by the manufacturer. The timer check will be performed to exceed the time out for any clinical application. The timer will be check manually with a stopwatch and the corrected linearity will be checked with at least one measurement point exceeding the maximum estimated treatment time (approximately 20 minutes).

Dr. Lustig and Mr. Etemadnia will not be participating in and HDR procedures at Pennsylvania Hospital.

Please let me know if you require a more formal response (e.g.. a fax of this email).

I am attaching a copy of the SSDR for the system we have at Pennsylvania Hospital.

Leonard Shabason, Ph.D.
Radiation Oncology
Pennsylvania Hospital
800 Spruce Street
Philadelphia, PA 19107

 9/10/07

(215) 829-3865
(215) 829-5424 FAX
shabasol@pahosp.com
shabason@xrt.upenn.edu

-----Original Message-----

From: Penny Lanzisera [mailto:PAN@nrc.gov]
Sent: Monday, September 10, 2007 10:58 AM
To: Shabason, Leonard Ph.D.
Subject: Additional Information to Support Clinical Use, Mail ControlNo. 140850

License No. 37-06864-06

140850

Docket No. 030-15163
Mail Control No. 140850

Dr. Shabason,

Please respond to this email in writing indicating: (i) the duration of time over which timer accuracy is measured; and confirming that (i) the door interlock causes the source to retract when the door is pushed open; and (ii) the lights on the treatment console are confirmed as operational during the daily checks. Additionally, please indicate whether Mr. Etemadnia and Dr. Lustig should be approved for HDR use, and if so, submit confirmation of their vendor training.

You may reply to my attention via fax to 610-337-5269. Please refer to mail control number 140850.

Penny Lanzisera
Senior Health Physicist
US NRC, Region 1

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Shabason, Leonard Ph.D.

From: Shabason, Leonard Ph.D.
Sent: Monday, September 10, 2007 1:12 PM
To: 'Penny Lanzisera'
Subject: RE: Additional Information to Support Clinical Use, Mail ControlNo. 140850

Attachments: SSD GammaMedplus 3-24 MS May 18 2004.pdf



SSD GammaMedplus
3-24 MS May ...

Part of the daily QA check will be confirm that opening the treatment room door will force the system to retract the source. The daily QA check will also confirm that the lights on the control unit will be confirmed to read as specified by the manufacturer. The timer check will be performed to exceed the time out for any clinical application. The timer will be check manually with a stopwatch and the corrected linearity will be checked with at least one measurement point exceeding the maximum estimated treatment time (approximately 20 minutes).

Dr. Lustig and Mr. Etemadnia will not be participating in and HDR procedures at Pennsylvania Hospital.

Please let me know if you require a more formal response (e.g.. a fax of this email).

I am attaching a copy of the SSDR for the system we have at Pennsylvania Hospital.

Leonard Shabason, Ph.D.
Radiation Oncology
Pennsylvania Hospital
800 Spruce Street
Philadelphia, PA 19107

Leonard Shabason 9/10/07

(215) 829-3865
(215) 829-5424 FAX
shabasol@pahosp.com
shabason@xrt.upenn.edu

-----Original Message-----

From: Penny Lanzisera [mailto:PAN@nrc.gov]
Sent: Monday, September 10, 2007 10:58 AM
To: Shabason, Leonard Ph.D.
Subject: Additional Information to Support Clinical Use, Mail ControlNo. 140850

License No. 37-06864-06
Docket No. 030-15163
Mail Control No. 140850

Dr. Shabason,

Please respond to this email in writing indicating: (i) the duration of time over which timer accuracy is measured; and confirming that (i) the door interlock causes the source to retract when the door is pushed open; and (ii) the lights on the treatment console are confirmed as operational during the daily checks. Additionally, please indicate whether Mr. Etemadnia and Dr. Lustig should be approved for HDR use, and if so, submit confirmation of their vendor training.

You may reply to my attention via fax to 610-337-5269. Please refer to mail control

number 140850.

Penny Lanzisera
Senior Health Physicist
US NRC, Region 1

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICENo.: CA-1080-D-103-SDATE: May 18, 2004PAGE 1 of 16

(Supercedes NR-0220-D-122-S)

DEVICE TYPE: Brachytherapy HDR Remote AfterloaderMODEL: GammaMed (and plus and plus 3/24), MammoSourceDISTRIBUTOR:Varian Medical Systems, Inc.
3100 Hansen Way
Palo Alto, CA 94304MANUFACTURER:Varian Medical Systems Haan, GmbH
Bergische Strasse 16
D-42781 Haan
GermanySEALED SOURCE
MODEL DESIGNATION:

GammaMed 232

ISOTOPE:

Iridium-192

MAXIMUM ACTIVITY:

15 Curies (555 GBq) +/- 5%

LEAK TEST FREQUENCY:

6 Months

PRINCIPAL USE:

(V) General Medical Use

CUSTOM DEVICE:YES _____ No X

Shabason, Leonard Ph.D.

From: Shabason, Leonard Ph.D.
Sent: Monday, September 10, 2007 12:53 PM
To: 'Penny Lanzisera'
Subject: RE: Unit type

It is the MammoSource - the single channel system which is a modification of the standard Varian GammaMed system. It is FDA 510K K040541 if that is any help to you. It only differs from the other version by having a turret with only one channel rather than the more standard configuration of 3 or 24 active channels.

Please let me know if you need additional information. I believe the details on the unit were submitted earlier when we requested permission to possess the unit and the iridium HDR source.

Leonard Shabason, Ph.D.
Radiation Oncology
Pennsylvania Hospital
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Philadelphia, PA 19107

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shabason@xrt.upenn.edu

Leonard Shabason
9/10/07

-----Original Message-----

From: Penny Lanzisera [mailto:LAN@nrc.gov]
Sent: Monday, September 10, 2007 11:10 AM
To: Shabason, Leonard Ph.D.
Subject: Unit type

Dr. Shabason,

Also, please confirm the unit type installed (e.g., Plus or Plus 3/24?). Thanks,

Penny Lanzisera
US NRC, Region 1