

PUBLIC/PDR

030-02670

ST. ELIZABETH HEALTH CENTER  
RADIATION THERAPY

MEMO

34-01131-01

TO: Patricia J. Pelke  
FROM: Shirley Z. Jucius  
RE: Additional Information Requested for Control No. 3C<sup>2</sup>451  
DATE: January 14, 1998

The following is the response to your request for additional information regarding our amendment.

1. We will modify our procedures in the letter dated 10/30/85 to reference the GammaMed 12i device.
2. A copy of our operating procedures is attached to this memo. In addition, a copy of the operating procedures and emergency procedures are supplied to every individual in the department as part of their annual refresher.
3. A copy of the daily checks which we perform is attached.
4. A copy of our monthly safety check which we perform is attached.
5. A copy of our calibration procedure for the device is attached.
6. Maintenance and repair are performed only by the GammaMed 12i manufacturer or individuals specifically licensed by the NRC to perform such services.
7. The GammaMed 12i will be inspected/serviced annually by the manufacturer and records of the inspection/service will be maintained.
8. The source in the GammaMed 12i will be returned to CIS-US. We will retain possession of the unit with its depleted Uranium until some later date. We will apply for an amendment to our license to remove the depleted Uranium at that time.

RECEIVED

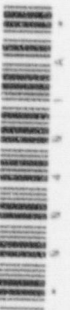
JAN 20 1998  
REGION III

Thank you for your prompt response to our expedited amendment.

9801290082 980114  
PDR ADOCK 03002670  
C PDR

Pm: 1-16-98

Shirley Z Jucius, M.S. JAN 20 1998  
Radiation Safety Officer



ML  
30  
DH

GAMMA MED III  
OPERATIONAL INSTRUCTIONS

1. Unlock and remove the lock at the rear of the source head.
2. Insert the crank into the opening in the source head.
3. Turn on the data display, and then the control console with the key switch. The following signal lamps will demonstrate the operating readiness of the equipment: line, battery, source in container, and the data display.
4. Page 0 first appears when the unit is turned on. This page displays data headings and individual sum times. Pages 1-12 are for the source dwell time positions. Each channel on the source head corresponds to the page that has the same number. Pages are called up in succession by pressing the PAGE button.
5. The DATE button is pushed first. The date is entered numerically using the format - day, month, year. For example, May 4th, 1989 is entered as 040589. The date entered must be correct since this is the date used to accurately adjust the source dwell times for decay of the source.
6. The PATIENT NUMBER button is selected next. This is abbreviated as 'PAT' on the data display screen. The patient numbers are assigned and are found in the log book. This selection can hold up to six digits. This number is for identification purposes only.
7. 'FAK' refers to the Time Automatic Factor and is to be used only with 10 Ci sources. This factor employs the date that was entered and the initial activity of the source when installed and corrects all the irradiation times relative to the decay of a 10 Ci source. Pressing the button displays the activity of the source. (THE DATE ENTERED DURING PROGRAMMING MUST BE CORRECT)
8. The activity is entered automatically after step #7 for documentation purposes only.
9. The Time Factor Manual ('FAK') is not to be used. Since this institution always uses a 10 Ci source, the procedure is to use the Time Factor Automatic.
10. The PROGRAM NUMBER is entered for documentation purposes and is found in the log book.
11. The CYCLE NUMBER is entered next. Any number between 1-99 is possible although cycle 1 is always used at this institution. A page cannot be selected until the cycle number is entered. (IT IS IMPORTANT TO REMEMBER WHEN SELECTING THE CYCLE NUMBER THAT THE NUMBER SELECTED IS MULTIPLIED BY ALL THE SOURCE DWELL TIMES.)



FOR EXAMPLE, IF CYCLE 4 IS SELECTED, THEN ALL THE SOURCE DWELL TIMES THAT WERE PROGRAMMED WILL NOW BE MULTIPLIED BY FOUR TIMES FOR THE IRRADIATION PROCESS.)

12. By pressing the PAGE button, the first page is selected. This is the channel that all source guide tubes are connected to.

13. The DISTANCE ('DIS') is now programmed. The distance from the tip of the catheter is entered first and takes up to three digits. The next two digits entered are the distances between the source positions up to two digits. For example, 15cm from the tip of the catheter with 1cm between sources is entered as 15010. All entries are entered in millimeters. An implant at 3cm from the tip with .5cm between sources is entered as 03005. (ON THE DATA DISPLAY LEADING ZEROES ARE NOT SHOWN)

14. POSITION 1 is next and allows for programming of the source dwell times. The dwell time is entered and NEXT POSITION is selected to go through and enter the remaining times.

15. The sum of all individual dwell times is obtained by pressing the CALL TOTAL IRRAD TIME. This is 'SUM' on the data display. This time is the sum of all the individual irradiation times entered on that page for one cycle.

16. The NOMINAL IRRAD TIME is displayed as 'NIT'. For the page it is equal to the 'SUM' time already appearing on the screen.

17. This facility only utilizes page 1, so at this point it is necessary to use the PAGE button to flip through the remaining pages until returning to Page 0.

18. The TOTAL IRRAD TIME appears as 'TOT' on page 0. This time is the 'SUM' time (addition of all the source dwell times) multiplied by the cycle number. Cycle 1 is always used here. Therefore, the 'SUM' time, 'NIT' time, and the 'TOT' time are all the same.

19. The patient and appropriate source guide tubes are hooked up to channel 1. This channel number corresponds with page 1.

20. To initiate the irradiation process, press START and SOURCE IN IRRAD POS simultaneously.

21. The printer begins printing immediately, the START button illuminates, and the SOURCE IN CONTAINER lamp goes out as the source leaves the head.

22. The Primalert radiation monitor and GAMMA MED IN USE lamps go on.

23. The digital counter adds up the actual irradiation time.

NOTE: IT IS IMPOSSIBLE TO ALTER THE PROGRAM DURING THE IRRADIATION

SEQUENCE. IT IS ALWAYS POSSIBLE TO INTERRUPT THE PROGRAM BY PRESSING THE INTERRUPT BUTTON. THIS PROGRAM WILL RESTART BY INITIATING STEP 20. HOWEVER, ONCE THE EMERGENCY BUTTON HAS BEEN PRESSED THE PROGRAM CANNOT BE RESTARTED.

NOTE: TO CLEAR ANY PROGRAM THE CLEAR AND EMERGENCY BUTTONS MUST BE PRESSED SIMULTANEOUSLY.



## EMERGENCY PROCEDURES

### TO INTERRUPT TREATMENT:

1. Press INTERRUPT key (on control console)
2. Press EMERGENCY key (on control console)
3. OPEN DOOR to treatment room not more than 1 inch  
Source must automatically return to safe
4. Press RED EMERGENCY button on Gamma Med trolley

In all cases (1-4) the source returns into the shield located in the gamma med head. The actual treatment time is recorded on the printer and so is the mode of interruption.

### IF THE SOURCE DOES NOT RETURN INTO THE SHIELD

1. YELLOW warning light (Radiation symbol) on console is ON
2. RED LIGHT on control console, source in irradiation position is ON
3. YELLOW warning light on Gamma Med trolley is ON
4. Independent light-Gamma Med/Beam on outside treatment room door is ON

### STEP BY STEP PROCEDURE FOR SOURCE RETURN INTO THE GAMMA MED SHIELD

1. Press EMERGENCY key on control console
2. OPEN DOOR to treatment area not more than 1 inch
3. Press EMERGENCY key on Gamma Med trolley
4. Use HANDCRANK located in the the gamma med head to crank source manually back into the safe.

DO NOT ATTEMPT TO RESTART THE UNIT UNTIL CLEARED BY THE MDICAL PHYSICIST

NOTE: HANDCRANK MUST ALWAYS BE INSERTED INTO THE GAMMA MED HEAD

The handcrank is a "one-way" crank and serves to retract sources only. The source is placed in the proper position (shielded) when all lights are green, the acoustic sound stops, and the light of the 'Gamma Med/Beam On' box located outside the treatment room is in the OFF position.

After the source has returned to the safe, call radiation protection to check surface readings on the gamma med source head. The reading is not to be more than 2mR/hour on surface.

IF THE SOURCE CANNOT BE CRANKED INTO THE SHIELD:

1. ENTER ROOM, REMOVE source guide tube and applicator from patient and immediately insert it into the lead shield provided within the GammaMed trolley, or the emergency container in the room.
2. REMOVE the patient from treatment room.
3. CLOSE DOOR, POST SIGN ON DOOR - DANGER - DO NOT ENTER.
4. NOTIFY the Radiation Safety Officer:

Shirley Z. Jucius, M.S. Tel. 480-3158 or 3182, 3183  
Tel. (216) 464-0182 or  
(216) 559-0140

5. NOTIFY the chief of Radiation Therapy:

Dr. P. Soleimani Tel. 480-3181 or 3182, 3183  
Tel. 568-7707

6. NOTIFY:

Mick Radio Nuclear Instruments, Inc.  
1470 Outlook Avenue  
Bronx, New York 10465 Tel. (718) 597-3999

**NOTE:** Emergency procedures must be posted in control console area and/or next to the treatment room entrance.

In case of a malfunction of the Primalert Meter (the Primalert malfunctions in the "ON" condition i.e. the "BEAM ON" light stays lit), the operator is to enter the room with the survey meter "ON" to determine if ANY radiation levels are present. If any levels are present, close the door and inform the physician and physicist in attendance. Follow the rest of the Emergency Procedures.

(attach printout to back of this page)

DATE	INITIAL	MON	TUES	WEDS	THURS	FRI	COMMENTS
1. Current date and time coincide with printer							
2. Door Interlock: with source in "on" position and the door is opened: a. Source must retract automatically b. Alarm (acoustic sound) must go on c. Printer must read: DOR-interrupt							
3. Door Interlock: with treatment door open: a. Source can not be activated b. Door light indicator on console must be "on"							
4. Interrupt: during normal interrupt, source retracts in normal mode: a. Interrupt control light is "on" b. When pressing "restart", interrupt light goes off							
5. Primalert							
6. Console/door light							
7. CC TV and intercom							
8. Paper supply in console printer							
9. Ludlum survey meter-check source							
10. Primalert check with dedicated check source							

IF ANY ERRORS OR MALFUNCTIONS OCCUR SAVE THE PRINTOUT AND INFORM THE PHYSICS STAFF BEFORE TREATING ANY PATIENT!



# DAILY PHYSICS QA ON GAMMAMED III

Date	Mon	Tues	Wed	Thur	Fri
1. <u>GamUhr Function Test:</u> a) Enter INCORRECT DATE and key in "TIME FACTOR AUT" "ERROR" MESSAGE MUST FLASH IN DATE FIELD					
b) Enter CORRECT DATE and key in "TIME FACTOR AUT" DAY/MONTH/YEAR and FACTOR must correspond with the current data					
c) Enter complete program without entering "TIME FACTOR AUT" INITIATE START- "ERROR" MESSAGE MUST FLASH IN "FAK" FIELD					
d) Enter INCORRECT FACTOR in "FAK" and INITIATE START "ERROR" MESSAGE MUST FLASH IN "FAK" FIELD					
e) Enter complete program. Enter 77ABAB in "PRO" FIELD (AB = 2 digit program number) Key "PROGRAM AUTO" (print-out) Are DATE/FACTOR and all other treatment parameters correct?					
2. <u>Autoradiograph (using the source position cassette):</u> Kodak V-film, FAK: 50%, AKT: 200%, 1 sec, 10 mm steps, 20 steps (enter program #10 and press "Program Auto") Source position accuracy: within 1 mm					
INITIAL					



# GAMMAMED III HDR - MONTHLY SPOT CHECK

## OUTPUT AND ACTIVITY MEASUREMENT

Electrometer: Keithley 35614 SN: 34489 CF: 1.010 c/Rdg  
Keithley 35617EBS SN: 33215 CF: 0.999 nc/"nc"

Chamber: NEL Chamber #2 Model #2571 SN: 1328 Nx =  $4.7724 \times 10^9$  R/c  
for Ir-192 (chamber wall + build-up)

Calibration Applicator: 3 mm tandem

Temp: \_\_\_\_\_ °C Pressure: \_\_\_\_\_ mm Hg CTP =  $\frac{273 + \text{Temp}}{273 + 22} \times \frac{760}{\text{Pressure}}$  = \_\_\_\_\_

Source to chamber distance: 0.20 meter

FAK = 100% AKT = 100% With Build-up Cap

## TIMER ERROR:

120 second reading (B): \_\_\_\_\_, \_\_\_\_\_, \_\_\_\_\_  $\bar{B}$  = \_\_\_\_\_

3 x 40 second reading (A): \_\_\_\_\_, \_\_\_\_\_, \_\_\_\_\_  $\bar{A}$  = \_\_\_\_\_  
(by interrupt)

Timer Error =  $\frac{120 (\bar{A} - \bar{B})}{3\bar{B} - \bar{A}}$  =  $\frac{120 ( \quad - \quad )}{(3 \times \quad) - \quad}$  = \_\_\_\_\_ sec

EXPOSURE RATE @ 1 Meter =  $\frac{3600 \times \bar{B} \times N_x \times CTP \times (0.2)^2 \times CF}{120 + \text{timer error}}$

EXPOSURE RATE =  $\frac{3600 \times 0.04 \times \quad \times 10^9 \times \quad}{120 + \quad}$   
= \_\_\_\_\_ R/hr @ 1 meter

ACTIVITY =  $\frac{\text{Exposure rate}}{\text{Exposure rate constant}} = \frac{\quad \text{R/hr @ 1 m}}{0.462 \text{ R/hr-Ci@1m}}$  = \_\_\_\_\_ Ci

## COMPARISON OF EXPECTED AND MEASURED ACTIVITY

Activity at last calibration (Ao) = \_\_\_\_\_ Ci Date \_\_\_\_\_

Activity decayed to today's date \_\_\_\_\_ T = \_\_\_\_\_ days

$T_{1/2} = 74$  days

$-0.6931 (T) / (T_{1/2}) = \quad$  Ci

A = AoE

Difference =  $\frac{\text{Measured Activity}}{\text{Anticipated Activity}} = \frac{\quad \text{Ci}}{\quad \text{Ci}} = \quad$

GammaMed III activity shown on the monitor

AKT = \_\_\_\_\_ = \_\_\_\_\_ Ci

GMMONCK October 1995

# GAMMAMED 111 HDR - MONTHLY SPOT CHECK

## SAFETY CHECKS

YES

NO

1. Door Interlock: With the source in "on" position and the door is opened.
  - a. Source must retract immediately \_\_\_\_\_
  - b. Alarm (accoustic sound) must go on \_\_\_\_\_
  - c. Printer must read: DOR - interrupt \_\_\_\_\_
2. Door Interlock: With treatment door open
  - a. Source can not be activated \_\_\_\_\_
  - b. Door light indicator on console must be "on" \_\_\_\_\_
3. Interrupt: During normal interrupt, source retracts in normal mode.
  - a. Interrupt control light is "on" \_\_\_\_\_
  - b. When pressing "restart", interrupt light goes off \_\_\_\_\_
4. Source guide tube:
  - a. Without the source guide tube properly attached, the source can not be activated \_\_\_\_\_
  - b. Source guide tube light indicator on control console must be "on" \_\_\_\_\_
5. Emergency source retraction:
  - a. When pressing the emergency source button, source must retract in rapid mode \_\_\_\_\_
  - b. Printer reads: NOT \_\_\_\_\_
  - c. Program remains on screen \_\_\_\_\_
6. Primalert observed during irradiation:
  - functions properly? \_\_\_\_\_
  - Battery pack - functions properly? \_\_\_\_\_
7. Primalert checked with dedicated check source - functions properly? \_\_\_\_\_
8. Ludlum survey meter checked with check source - functions properly? \_\_\_\_\_



OTHERS

- |   | YES   | NO    |
|---|-------|-------|
| 1. Length Gauge:  |       |       |
| Indicates that all source guide tubes are accurate length.  | _____ | _____ |
| 2. Source position accuracy: When source guide tube is attached to source STEP VIEWER, the source must reach the distal point.<br>Acceptable tolerance: within 1 mm |       |       |
| a. In needle (TOP) - Channel 12   | _____ | _____ |
| b. In 3 mm tandem (MIDDLE) - Channel 6  | _____ | _____ |
| c. In glass channel (BOTTOM) - Channel 1  | _____ | _____ |
| 3. Timer functions properly   | _____ | _____ |
| 4. Console/door light functions properly?   | _____ | _____ |
| 5. CC TV and intercom functions properly?   | _____ | _____ |
| 6. Paper supply in the console printer - OK?  | _____ | _____ |
| 7. Review daily QA book - OK?   | _____ | _____ |
| 8. Auto radiograph - Kodak V film, FAK: 50%,<br>AKT: 200%, 1 sec, 10 mm steps, 10 steps OK?   | _____ | _____ |
| 9. Back-up battery<br>Tested per manufacturer's instructions - OK?  | _____ | _____ |
| 10. GAMUHR card functions properly?   | _____ | _____ |

\_\_\_\_\_  
DATE

\_\_\_\_\_  
RADIATION PHYSICIST

# GAMMAMED 111 HDR - Ir-192 SOURCE CALIBRATION

Electrometer: Keithley 35614 SN: 34489 CF: 1.010 c/Rdg  
Keithley 35617EBS SN: 33215 CF: 0.999 nc/"nc"

Chamber: NEL Chamber #2 Model #2571 SN: 1328 Nx =  $4.7724 \times 10^9$  R/c  
for Ir-192 (chamber wall + build-up)

Calibration Applicator: 3 mm tandem

Temp: \_\_\_\_\_ °C Pressure: \_\_\_\_\_ mm Hg CTP =  $\frac{273 + \text{Temp}}{273 + 22} \times \frac{760}{\text{Pressure}}$  = \_\_\_\_\_

Source to chamber distance: 0.20 meter

FAK = 100% AKT = 100% With Build-up Cap

## TIMER ERROR:

120 second reading (B): \_\_\_\_\_, \_\_\_\_\_, \_\_\_\_\_  $\bar{B}$  = \_\_\_\_\_

3 x 40 second reading (A): \_\_\_\_\_, \_\_\_\_\_, \_\_\_\_\_  $\bar{A}$  = \_\_\_\_\_  
(by interrupt)

Timer Error =  $\frac{120 (\bar{A} - \bar{B})}{3\bar{B} - \bar{A}}$  =  $\frac{120 ( \quad - \quad )}{(3 \times \quad) - \quad}$  = \_\_\_\_\_ sec

EXPOSURE RATE @ 1 Meter =  $\frac{3600 \times \bar{B} \times \text{Nx} \times \text{CTP} \times (0.2)^2 \times \text{CF}}{120 + \text{timer error}}$

EXPOSURE RATE =  $\frac{3600 \times 0.04 \times \quad \times 10^9}{120 + \quad}$   
= \_\_\_\_\_ R/hr @ 1 meter

ACTIVITY =  $\frac{\text{Exposure rate}}{\text{Exposure rate constant}} = \frac{\quad \text{R/hr @ 1 m}}{0.462 \text{ R/hr-Ci@1m}}$  = \_\_\_\_\_ Ci

MANUFACTURER'S STATED ACTIVITY = \_\_\_\_\_ Ci on \_\_\_\_\_

DIFFERENCE =  $\frac{\text{Mfr. stated activity}}{\text{Measured activity}} = \frac{\quad}{\quad} = \quad \%$

Factor to set FAK =  $\frac{10 \text{ Ci}}{\text{Measured act. in Ci}} \times 100 = \frac{10 \text{ Ci}}{\quad \text{Ci}} = \quad$  as of \_\_\_\_\_

Measurement performed by: \_\_\_\_\_ Date \_\_\_\_\_