U.S. NUCLEAR REGULATORY COMMISSION

REGION III

V.A. Edward Hines Jr.,
Medical Center
ATTN: Joan Cummings, M.D.
Director
P.O. Box 5000
Hines, IL 60141

License No. 12-01087-07
Docket No. 030-01391

Report No. 030-01391/94001(DRSS)

License No. 12-01087-07 Category G1 Priority 1

Licensee: V.A. Edward Hines Jr., Medical Center
Hines, IL 60141

Inspection Dates: April 13, 1993

Inspector: Michael F. Weber 4/15/94
Michael F. Weber Date
Materials Inspector

Approved By: John D. Jones 04/25/94
John D. Jones, Acting Chief Date
Nuclear Materials Inspection
Section 2

Inspection Summary

Inspection on April 13, 1994 (Report No. 030-01391/94001(DRSS))
Areas Inspected: This was a special, announced safety inspection conducted to review an April 6, 1994 incident in which a patient received a dose of 10.4 Gray instead of the intended 6 Gray per fraction during a treatment with a high dose rate remote afterloader. The inspection also included a review of the quality management program pertaining to brachytherapy.
Results: Of the areas inspected, no violations of NRC requirements were identified. However, one unresolved issue was identified regarding the definition of a misadministration as it relates to the brachytherapy incident (Section 3).

DETAILS

1. Persons Contacted

+James Jones - Associate Director
*Julie Stark - Assistant Director
*Philip Dobrin, M.D. - Assistant Chief of Staff
*Lawrence Case - Radiation Safety Officer
*Bernard Kelly - Assistant Radiation Safety Officer
Glenn Glasgow, Ph.D. - Radiation Physicist
Leonid Leybovich, Ph.D. - Radiation Physicist

+Present at entrance meeting held April 13, 1994.
*Present at exit meeting held April 13, 1994.

2. Licensed Program

V.A. Edward Hines Jr., Medical Center (V.A. Hines or Licensee) is authorized by License No. 12-01087-07, a medical broad scope license, to use, in part, sealed sources of iridium-192 (Ir-192) in an Isotopen-Technik Dr. Sauerwein GmbH Model GammaMed III high dose rate remote afterloading device (GammaMed HDR) for interstitial and intercavitary treatment of cancer.

3. Brachytherapy Incident

The following is a summary from the interviews held with the Licensee's radiation physicists.

On April 6, 1994, a patient being treated for cancer of the larynx was scheduled to receive the first of two radiation treatments using a GammaMed HDR. Each treatment was to deliver a dose of 6 Gray (Gy), for a total dose of 12 Gy. Some time before the treatment, the radiation therapist correctly entered the treatment parameters into the GammaMed computer. The entry of these parameters was checked by another therapist and a radiation physicist. This check was documented on the licensee's HDR treatment form. At the time of the treatment, the therapist recalled the treatment parameters from the computer, and, by mistake, entered the date in the incorrect format, i.e., 040694 (June 4, 1994) rather than 060494 (April 6, 1994). She then checked the dwell times for each position, which were correct, and started the treatment. During the post-treatment quality assurance check, it was discovered that the treatment time was too long by a factor of 1.74. Further checking revealed that the date had been entered incorrectly, as discussed above. The long treatment time was accounted for by the data entry error (see Appendix A). This resulted in the patient receiving a dose of 10.4 Gy instead of the intended 6 Gy for the first planned treatment. As of the date of the inspection, the radiation oncologist had not yet decided whether to give a second treatment of 1.6 Gy, or to modify the written directive and cease treatment. The licensee notified Region III of this incident on April 8, 1994.

A NRC medical consultant has been contacted to review this incident and provide an opinion on the biological effects expected for the patient.

The incident is still under review by the NRC to determine if a misadministration, as defined in 10 CFR 35.2, occurred (URI 94001/01).

Regarding corrective actions, shortly after the incident, the radiation physics staff held a meeting where the HDR operating procedures, especially the data entry requirements, were reviewed. New, large signs were posted near the HDR console to remind the therapists of these requirements. Also, the HDR treatment form was modified to: (1) require the therapist to write the date in the same format as it must be entered into the computer, and (2) immediately before treatment, require another check of the treatment parameters (this is in addition to the first data entry check which is performed when all the treatment parameters are initially entered into the computer). Moreover, the licensee will begin using a manual, backup timer to check the agreement with the HDR timer.

One unresolved item was identified.

4. Quality Management Program (QMP)

The inspector performed a review of the licensee's QMP (HDR section only). Since the last inspection, nine HDR treatments have been performed. For each treatment, the written directive was prepared as required. A patient's identity was verified by asking the patient his/her name, and by comparing the individual with a photograph of the patient which is kept in the patient's chart. The treatment plans were formulated to deliver the prescribed dose as listed on the written directive, and were always checked by a second individual prior to treatment. The treatment planning was performed in accordance with the manufacturer's instructions and planning atlas. The entry of the treatment parameters into the computer was checked by a second individual prior to treatment. After the treatment, a check is performed to assure that the treatment was delivered as planned, to within ±10%. The incident described above was the only example of an unintended deviation from the written directive. As discussed already, this deviation was immediately identified, and the licensee took prompt and effective actions to prevent recurrence. The incident and the corrective actions were thoroughly documented (see Appendix B).

No violations of NRC requirements were identified.

5. Exit Meeting

An exit meeting was held at the conclusion of the inspection with those individuals identified in Section 1 of this report. A summary of the inspection was discussed. The licensee did not identify as proprietary any of the materials provided to or reviewed by the inspectors.

APPENDIX A

Iridium-192 (Ir-192) has a half-life ($\tau_{1/2}$) of 73.83 days. On February 2, 1994, the activity (A) of the Ir-192 source was 9.9 Curies (Ci). The activity of a radioactive sample at time τ is calculated from

$$A(\tau) = A(0)\ e^{-\frac{\ln 2}{\tau_{1/2}}(\tau)} .$$

where A(0) is the initial activity. Thus, on April 6, 1994, 63 days later, the activity was 5.48 Ci, since

$$A(63) = 9.9\ Ci\ \ e^{-\frac{\ln 2}{73.83}(63)} = 5.48\ Ci.$$

On June 4, 1994, 122 days later, the activity would be 3.15 Ci, since

$$A(122) = 9.9\ Ci\ \ e^{-\frac{\ln 2}{73.83}(122)} = 3.15\ Ci.$$

The treatment time would be increased by a factor of 1.74, since

$$\frac{5.48}{3.15} = 1.74 .$$

APPENDIX B

00/001/001A
cc 001AS - Larry Casey

-1- Date: April 11, 1994

PRELIMINARY NOTIFICATION OF EVENT OR UNUSUAL OCCURRENCE PNO-III-94-22

This preliminary notification constitutes EARLY notice of events of POSSIBLE safety or public interest significance. The information is as initially received without verification or evaluation, and is basically all that is known by the Region III staff on this date.

Facility
Veterans Affairs Medical Center
Hines, IL 60141

License No. 12-01087-07
Docket No. 030-01391

Licensee Emergency Classification
General Emergency
Site Area Emergency
Alert
Unusual Event
X Not Applicable

Subject: RADIATION THERAPY ERROR

On April 8, 1994, the licensee informed Region III (Chicago) that an error had occurred during the radiation treatment of a patient using a Gamma Med II HDR unit and an iridium-192 sealed source. The patient was scheduled to receive a series of two treatments of 600 rads (6 gray) for a total dose of 1,200 rads (12 gray). Because of an error in the treatment parameters, the patient received 1,000 rads (10 gray) in the first treatment on April 7, 1994.

On April 6, 1994, during treatment planning, the licensee entered the wrong date into the HDR unit. The date, "4-6-94," was incorrectly entered as "6-4-94." The treatment time is based on the computed strength of the iridium-192 source. Since the iridium-192 source with a 74-day halflife would have a lower strength on 6-4-94, the HDR unit increased the calculated treatment time resulting in the greater than intended dose.

The licensee intends to modify the written directive for the treatment to compensate for the error. For the second treatment, the dose will be 200 rads (2 gray). Therefore, the patient will receive the intended total dose.

Region III will conduct a special inspection this week to evaluate the circumstances surrounding the error. An NRC medical consultant has also been contacted regarding the case.

The State of Illinois has been informed. (Illinois is an Agreement State but federal facilities remain under NRC jurisdiction.) The information in this preliminary notification has been reviewed with licensee management.

Region III was notified of this event on April 8, 1994. This information is current as of 1:00 p.m. on April 11, 1994.

CONTACT:

Thomas Young
708/829-9835

Roy Caniano
708/829-9804

April 6, 1994

REPORT

of an error that occurred during irradiation of a patient with the Gamma-Med IIi HDR remote afterloading unit.

Patient name: [redacted] SSN: [redacted]
Treatment site: Supraglottic larynx
Treatment date: April 6, 1994

According to the treatment plan, the radiation therapist Ms. Reynolds keyed into the Gamma-Med computer the treatment parameters, which were verified by another radiation therapist, Ms. Johnson, and by the radiation physicist, Dr. Leybovich, and stored in the Gamma-Med computer.

However, when Ms. Johnson recalled the treatment parameters from the computer memory, she inadvertently keyed in a wrong date, 4.06.94* (June 4, 1994) instead of the correct date, 6.04.94* (April 6, 1994). She checked the dwell times for each position and the total time which were correct, and started the treatment.

Because the Gamma-Med computer adjusts the FAK and AKT parameters automaticly, these factors have been changed by the computer according to the wrong date. These parameters are used by the treatment computer to modify the planned (keyed) treatment time according to the source decay. Thus, the treatment computer used a greater modifying factor (3.17) instead of the required modifying factor (1.83).

This resulted in administration to the patient a dose of 10.39 Gy instead of planned 6.0 Gy per fraction (6.0 Gy x (3.17/1.83)= 10.39 Gy). However, the total prescribed dose (12.0 Gy in two fractions) was not exceeded because the error occurred during administration of the first fraction.

Leonid Leybovich

Leonid B. Leybovich, Ph.D.
Assistant Professor

NB: Filed w/52
Karry Lane - R80 - ✓
S. Lulla, M.D. - R&C Committee
4-8-94

*The Gamma-Med treatment computer uses a European notation.

Note: I believe this constitutes a recordable event as the last fraction has not been given. Dr. Reddy will see the patient again in two weeks, examination for tumor regressing and decide then about giving the 1.16 Gy. Glenn P. Glazer, M.D. 4-8-94

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(708) 531-3930

Edward Hines V.A. Hospital
Mail Route #114-B
Dept. of Radiotherapy
Hines, IL 60141
(708) 343-7200

L/H: 4 YEAR: 94 NUMBER:

SOCIAL SECURITY NUMBER [redacted]

[redacted]
PATIENT'S NAME - LAST, FIRST, MIDDLE

Reddy / Paulino
RADIOTHERAPIST

DATE	DIAGNOSIS	AGE	SEX	RACE
Apr. 6, 1994	Squamous cell carcinoma of supraglottic larynx	[redacted]	[redacted]	[redacted]

PLACE TREATMENT TAPE HERE! ↓

TREATMENT PLANNING:

PRESCRIPTION BY: A Paulino

DATE: 4/6/94

BILLING CODES:

_____ 77781 - 1 to 4 source positions/catheters
_____ 77782 - 5 to 8 source positions/catheters
_____ 77783 - 9 to 12 source positions/catheters
_____ 77784 - over 12 source positions/catheters

PRESCRIBED DOSE (Gy) 12 Gy at 10 in tissue (mm) DOSE/FRACTION 6 (Gy)

NUMBER OF FRACTIONS 2 NUMBER OF WEEKS 2 TREATMENT NUMBER 1 OF 2

INITIAL DATE OF ACTIVITY	TREATMENT DATE	ELAPSED DAYS	CURRENT ACTIVITY BY CHART
Feb. 2, 1994	April 6, 1994	63	.5536 × 9.9 Ci = 5.48 Ci

INITIAL ACTIVITY 9.9 Ci FAK TODAY 183 % AKT TODAY 54 %

PATIENT NUMBER [redacted] APPLICATOR Esophageal (in 8 mm tube) NO. OF CYCLES 1 PROGRAM STORED 9

CHANNEL NO. 1 OF 1 SKIP-STEP 80 mm IRRADIATED LENGTH 70 mm

TIME SET (seconds):

Position 01 56
Position 02 21
Position 03 28
Position 04 25
Position 05 25
Position 06 28
Position 07 21
Position 08 56
Position 09 _____ / 260 sec
Position 10 _____

Position 11 _____
Position 19 _____
Position 20 _____

TOTAL CHANNEL TIME SET 260 sec

TOTAL TIME-SUM OF ALL CHANNELS _____

RECEIVED APR 8 1994

PLANNED BY: Leonid Leybovich CONFIRMED BEFORE TREATMENT BY: [signature] M.S.

DATA ENTRY AND TREATMENT BY: M. Reynolds R.T. DATA CONFIRMED BEFORE TREATMENT BY: [signature] R.T.

TOTAL TIME SET 260 × FAK TODAY 1.83 = REAL USE TIME DELIVERED 47578 sec

FROM PRINT OUT, TOTAL TIME SET 260 × FAK TODAY 3.17 = REAL USE TIME DELIVERED 824 sec

EXPOSURE RATE ON THE PATIENT SURFACE AFTER TREATMENT = 0.01 MR/HR

SURVEY METER USED: Ludlum Model 3 SN: 25910 SURVEYED BY: Leonid Leybovich

~~TO WITHIN 10%, THIS TREATMENT WAS DELIVERED AS PLANNED.~~ Since the wrong date, 4.06.94 was keyed in instead of 6.04.94 (European notation), the patient received 10.39 Gy instead of planned 6.0 Gy

SIGNATURE Leonid Leybovich DATE 4/7/94

REVISED: 12-92/RCK

To: All Staff With Gamma Med Responsibilities

Fm: Glenn P. Glasgow, Ph.D. GPG

Dt: 4-12-94

Re: Revision in QA Procedures For Gamma Med Patients

Two items require revision in our QA procedures for the Gamma Med.

(1) We had an incident last week in which, in recalling a stored program, the date was inadvertently entered incorrectly. April 6, 1994 (6.04.94) was entered as June 4, 1994 (4.06.94). While we performed all established QA checks as the treatment parameters were entered into the computer and stored, when the program was recalled the displayed dwell times were checked, but the operator failed to check a second time the displayed FACTOR and ACTIVITY values, which were now displayed for June 4 rather than for April 6.

We need to perform a through check of all displayed parameters for each treatment immediately before pressing the START button. I am designing a new form that will allow explicit check-off of each parameter not only at the time of entry but also at the time of recall for stored programs.

(2) We have also discovered, during some QA testing, that it is possible to make an error, probably without realizing it, in entering the data for pre-stepping. In the blank marked SKIP-STEP, recall that to set a pre-step distance of 40 mm with a step distance of 2 mm, the proper entry is DIS: 4002. However, if you enter this as DIS: 402, omitting a zero, the unit will interpret this as a 4 mm skip with a 2 mm step. Hence, it is very important to enter this correctly. The computer will not accept leading zeros. Hence, if you entered 0402 for a 4 mm skip with a 2 mm step, the computer will not accept these values.

Likely clinical values are skips of integer millimeters, e.g., 10 mm, 20 mm, with steps of either 5 mm or 10 mm steps. These are properly entered as Dis: 1005, 1010, 2005, 2010.

If there are no skips, the proper entries are 5, 10, 15, 20 for steps of 5 mm, 10 mm, 15 mm, and 20 mm respectively.

(3) Regarding actions to take to help us recognize if we have some error that we fail to recognize, I am obtaining an external timer with an alarm. We will be developing some procedures to use this timer as an additional safety check mechanism.

(4) I will review these new procedures with you at a short conference that I will schedule later this week.

GPG
4-13-94

INSTRUCTIONS FOR ENTERING A PROGRAM INTO MEMORY AND RECALLING A PROGRAM

GENERAL POINTS:

*Only 23 programs may be stored in memory.

*Each program can contain up to 12 pages or channels.

*Dwell times must not exceed four digits.

*Position distances and number of cycles are limited to two digits.

*Total irradiation time is limited to six digits.

*Skip distances are limited to three digits

ENTERING A PROGRAM INTO MEMORY:

1. Enter the desired program following the general instructions for keying in a program. Check the accuracy of the program before entering into memory.

2. At the end of keying in data, you will be on page "0". Assign a desired number to the program, e.g., 1, 2, 3 ... 11, etc. However, under **PROGRAM NO.**, enter this program number as a **DOUBLE ENTRY** with a "0" separating the entries, if it is a single digit number. For example, Program 1 will be entered as **Program No.** 101, Program 11 as **Program No.** 1111.

3. Press **PROGRAM AUTOMATIC**. The program is now stored in memory.

4. Record information about program in the *"Program Log Book"*.

RECALLING A STORED PROGRAM:

1. Enter the heading data specific for your treatment date. For example, Date [REMEMBER Day-Month-Year], Patient No.,

2. With the console **"ON"** and in the "READY" mode, i.e., ready to have data entered, enter the desired program number on page 0 under **Program No.**, e.g., 1, 2, 3 ... 11. (NOTE: Do not use double entry when retrieving programs. Identify from the Log Book, the stored program number you desire to execute.

3. Press PROGRAM AUTOMATIC. **"FAK"** will clear to 0. The total time will be displayed. Verify the Total Time setting per log book. Press Time Factor Auto. The ACT and FAK must be for the current date. Press Page No., number 1 should appear next to *"Page"* on the monitor. Have a second operator, physicist, dosimetrist, or physician cross-check the data recalled from storage. Go through all remaining pages and have a second person cross-check the data (if any). When return to 0 page, have a second person cross-check ACT and FAK.

4. Press **START** and **SOURCE IN IRRADIATION POS** simultaneously to execute treatment. As program runs, observe data display screen to verify that proper page number, stepping distance, position numbers, and dwell times are being executed.

REMEMBER — REMEMBER

ENTER THE DATES IN THE EUROPEAN NOTATION:

DAY - MONTH - YEAR

For example: April 6, 1994 is entered as

060494

4-13-94

GPL
4-13-9

PRESCRIPTION-TREATMENT FORM CHECKLIST PROCEDURES

Please note the changes made in our Prescription/Treatment Form.

(1) Please note that the treatment date, near the center of the form, has been labelled to clearly denote the european format of month-day-year, for entry into the computer. It is imperative that this format be used to enter the date into the computer. Boxes have been added for entering these dates.

(2) Please note that the skip-step data entry has also been clearly labelled and that boxes have been added for entering these numbers. For example, if NO skip distance is to be used, and only a step, enter the step distance, in millimeters. The computer will not accept leading zeros. Hence, 5 mm will be entered in the last box as 5; 10 mm will be entered in the last two boxes as 1 0.

If a skip distance is planned, e.g., 120 mm, with a 10 mm step, enter in the five boxes as 1 2 0 1 0. If a 20 mm skip is planned, with a 10 mm step, do not use the first box and enter data in the last four boxes as 2 0 1 0. Do not us a leading 0 in the first box. If the plan is a 20 mm skip with 5 mm steps, this will be entered as 2 0 0 5 in the last four boxes.

(3) Check boxes have been added to the form for the use of those actually checking work. After the dwell times have been entered by the dosimetrist/physicists (following a second check of this work by a second individual), radiation therapist #1 will key the parameters into the computer under the supervision of radiation therapist #2. Therapist #2 will physically check the appropriate first row of boxes. Now, there are often delays in the actual treatment. If the entered parameters are NOT stored, I still want a check, using the second row of boxes, by a member of the physics/dosimetry staff IMMEDIATELY before treatment. Note there is a new signature line for this check. If the data is STORED, perform this third check AFTER the data is recalled, but IMMEDIATELY before treatment. Be certain to physically check each parameter to make sure that no errors have been made during the recall of the stored program.

(4) Near the bottom of the page, use the date line after the "Surveyed By" line to date the page immediately after treatment. Use the last date line to indicate the date that any additional work is done after treatment to validate the conclusion that the treatment was delivered correctly to within 10%.

GAMMA MED HDR BRACHYTHERAPY PLANNING & TREATMENT RECORD

4-14-94
GPG

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2160 South First Ave.
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Mail Route #114-B
Dept. of Radiotherapy
Hines, IL 60141
(708) 343-7200

L/H: _____ YEAR: _____ NUMBER: _____

SOCIAL SECURITY NUMBER _____

PATIENT'S NAME - LAST, FIRST, MIDDLE _____ RADIOTHERAPIST _____

DATE	DIAGNOSIS	AGE	SEX	RACE

TREATMENT PLANNING:

PRESCRIPTION BY: _____

DATE: _____

BILLING CODES:
_____ 77781 - 1 to 4 source positions/catheters
_____ 77782 - 5 to 8 source positions/catheters
_____ 77783 - 9 to 12 source positions/catheters
_____ 77784 - over 12 source positions/catheters

PLACE TREAT--MENT TAPE HERE!

PRESCRIBED DOSE (Gy) _____ at _____ (mm) DOSE/FRACTION _____ (Gy)

NUMBER OF FRACTIONS _____ NUMBER OF WEEKS _____ TREATMENT NUMBER _____ OF _____

INITIAL DATE OF ACTIVITY	TREATMENT DATE DAY	MONTH	YEAR		ELAPSED DAYS	CURRENT BY CHART
_____	☐☐	☐☐	☐☐	☐☐	_____	_____

INITIAL ACTIVITY _____ FAK TODAY _____ % ☐☐ AKT TODAY _____ % ☐☐

PATIENT NUMBER _____ APPLICATOR _____ NO. OF CYCLES _____ ☐☐ PROGRAM STORED _____

CHANNEL NO. _____ OF _____ ☐☐ SKIP ☐☐☐ STEP ☐☐☐ ☐☐ mm IRRADIATED LENGTH _____ mm ☐☐

TIME SET (seconds):

Position 01 _____	☐☐	Position 11 _____	☐☐
Position 02 _____	☐☐	Position 12 _____	☐☐
Position 03 _____	☐☐	Position 13 _____	☐☐
Position 04 _____	☐☐	Position 14 _____	☐☐
Position 05 _____	☐☐	Position 15 _____	☐☐
Position 06 _____	☐☐	Position 16 _____	☐☐
Position 07 _____	☐☐	Position 17 _____	☐☐
Position 08 _____	☐☐	Position 18 _____	☐☐
Position 09 _____	☐☐	Position 19 _____	☐☐
Position 10 _____	☐☐	Position 20 _____	☐☐

TOTAL TIME-SUM OF ALL CHANNELS _____ ☐☐ TOTAL CHANNEL TIME SET _____ ☐☐

PLANNED BY: _____ CONFIRMED BEFORE TREATMENT BY: _____

DATA ENTRY BY: _____ DATA ENTRY CONFIRMED BY: _____

DATA PARAMETER CONFIRMED IMMEDIATELY BEFORE TREATMENT BY: _____

TOTAL TIME SET _____ × FAK TODAY _____ = REAL USE TIME DELIVERED _____

FROM PRINT OUT, TOTAL TIME SET _____ × FAK TODAY _____ = REAL USE TIME DELIVERED _____

EXPOSURE RATE ON THE PATIENT SURFACE AFTER TREATMENT = _____

SURVEY METER USED: _____ SN: _____ SURVEYED BY: _____ DATE: _____

TO WITHIN 10%, THIS TREATMENT WAS DELIVERED, AS PLANNED.

SIGNATURE _____ DATE _____

REVISED:
4-12-94GG

GPG
4-13-94

GAMMA MED BACK-UP TIMER CALCULATIONS

Patient's Name - Last, First, Middle

INITIAL DATE OF ACTIVITY	TREATMENT DATE DAY	MONTH	YEAR	ELAPSED DAYS	CURRENT ACTIVITY BY CHART
_____				_____	_____

INITIAL ACTIVITY_____ FAK TODAY_____% AKT TODAY_____%

PLANNED TIME POSITION 1_____ × FAK Today_____ = REAL TIME POSITION 1_____

Calculated By:_____ Date:_____

Note: The back-up timer should be set by someone other than radiation therapist. The Physicists or dosimetrists performing the parameter check immediately before treatment should set the clock. However, the radiation therapist operator will start the clock.