

General Information or Other	Event Number: 43301
Rep Org: NEW YORK STATE DEPT. OF HEALTH Licensee: NOT PROVIDED Region: 1 City: State: NY County: License #: NOT PROVIDED Agreement: Y Docket: NRC Notified By: ROBERT DANSEREAU HQ OPS Officer: JEFF ROTTON	Notification Date: 04/13/2007 Notification Time: 15:56 [ET] Event Date: 03/07/2007 Event Time: [EDT] Last Update Date: 04/16/2007
Emergency Class: NON EMERGENCY 10 CFR Section: AGREEMENT STATE	Person (Organization): PAUL KROHN (R1) ABY MOHSENI (FSME)

Event Text

AGREEMENT STATE REPORT - MEDICAL EVENT

The State provided the following information via facsimile:

"A brachytherapy misadministration involving a 31year old female patient with a history of vaginal cancer was reported to NYS DOH BERP on 3/9/07.

"The patient was successfully treated to 5590 cGy to the target volume using external beam (IMRT) therapy and she was to receive 2500-3000 cGy via interstitial brachytherapy with both Cesium-137 and Iridium-192 (seeds in ribbons) sources.

"The medical physicist developed a treatment plan as directed by the authorized user/ radiation oncologist using a commercial treatment planning software application. Eleven ribbons with 8 seeds each and an activity of 1.855 mgRaEq per Ir-192 [3.19 mCi] seed were ordered from Best Industries. Hospital owned Cs-137 sources were selected for use. The medical physicist verified source strength of all sources. The oncologist reviewed and approved the plan. He prescribed a total dose of 2500 cGy to be delivered to the 50 cGy-isodose line for a total treatment time of 50 hours.

"At 2:30 PM on 3/6/07 the sources were placed into the patient. A Syed template was used to place the ribbons and the Cs-137 sources were loaded into a tandem applicator.

"On 3/7/07, late in the morning, the medical physicist performed a manual check of the treatment plan calculations and identified a significant discrepancy - the hand calculations indicated a significantly higher dose rate than what was generated from the treatment planning software. An investigation ensued, which included consultation with the TPS vendor's application specialist. After several hours of investigation it was determined that the original treatment plan was in error, and at 5:30 PM on 3/7/07, after 27 of the intended 50 hour treatment time, the radiation oncologist decided to remove the sources [from the patient].

"Instead of the intended 2500cGy, the patient received an estimated dose of 4590 cGy and the anterior rectal dose was approximately 7300 cGy.

"The licensee provided a written report as required, and DOH staff performed an on-site investigation on 3/21/2007.

"Cause and contributing factors:

- "1. The primary error was the use of an inappropriate Dose Rate Factor in the TPS. The value used corresponded to the DRF for Air Kerma however the source strength entered was in MgRaEq. The physicist should have changed the units of source strength or entered the correct DRF.
- "2. Changing the units of activity in the TPS does not generate a prompt for a new Dose Rate

A/4

Constant.

"3. During the physics review it was determined that acceptance testing of this treatment planning software did not include Iridium-192. The acceptance testing covered Cesium -137 and Iodine -125 seeds which were the only materials being used at the time. If this testing had been performed the physicist would have been more likely to recognize that the treatment planning system does not automatically select the correct dose rate factor when the source strength units are changed.

"4. There was no check of the preplan before the seeds arrived although there was sufficient time (sources ordered 2/27/07). The plan was approved on 3/6/07.

"5. Neither the physicist nor the radiation oncologist had prepared a treatment with Ir-192 in six years and the physicist had not used this particular TPS for Ir-192 implants. It would have been prudent to have an additional review or outside review in order to verify there were no oversights or errors.

"6. The double check was not done until after the day after sources had been implanted. Again while the physicist was observing the minimum requirements of Part 16 it would have been prudent to perform a check of the calculations either prior to the implant or immediately thereafter.

"Corrective action: The policy and procedures have been changed to require a check of calculations for any single fraction brachytherapy treatment to be performed and approved prior to initiation of treatment.

"Patient condition and follow-up: The radiation oncologist disclosed that the patient is at risk for radiation cystitis, rectal proctitis and more importantly, fistula formation between the rectum and the vagina. The patient will be monitored closely over the next year by both her gynecologic oncologist and the radiation oncologist. The patient is currently being treated with broad spectrum antibiotics along with daily treatments in a hyperbaric oxygen chamber."

NY Event No: NYS-DOH 07-001

* * * UPDATE ON 4/16/2007 AT 1112 FROM FLANNERY (NRC/FSME) VIA E-MAIL TO HUFFMAN * * *

This event has been reviewed and determined to be a reportable medical event.

A "Medical Event" may indicate potential problems in a medical facility's use of radioactive materials. It does not necessarily result in harm to the patient.

Full Report

08/11/2009

Item Number: 070215

Last Updated: 05/15/2008

Narrative:

The licensee reported that a 31-year-old female patient with a history of vaginal cancer was prescribed 2,500 cGy (rad) via interstitial brachytherapy to the 50 cGy (rad) isodose line, but received 4,590 cGy (rad). The patient's anterior rectal dose was approximately 7,300 cGy (rad). The licensee used both Cs-137 and Ir-192 for the treatment. The medical physicist developed a treatment plan as directed by the authorized user/radiation oncologist using a commercial treatment planning software application. The licensee used 11 seed ribbons, each containing eight Ir-192 seeds (Best Industries), with each seed contained an activity of 1.855 mgRaEq or 118 MBq (3.19 mCi). A Syed template was used to place the Ir-192 ribbons and the Cs-137 sources were loaded into a tandem applicator. The treatment was initiated on 3/6/2007. The medical physicist performed a manual check of the treatment plan calculations on 3/7/2007 and identified a significant discrepancy. It was noted that the hand calculations indicated a significantly higher dose rate than what was generated by the treatment planning software. After several hours of investigation, it was determined that the original treatment plan was in error. After 27 hours of the intended 50-hour treatment time, the sources were removed from the patient. The primary error was the use of an inappropriate dose rate factor in the treatment planning software. The value used corresponded to the dose rate factor for air Kerma; however, the source strength was entered in milligram radium equivalent. During the physics review, it was determined that acceptance testing of this treatment planning software did not include Ir-192; the acceptance testing covered only Cs-137 and I-125. There was no check of the preplan prior to obtaining the Ir-192 seeds, although there was sufficient time. Neither the physicist nor the radiation oncologist had prepared a treatment using Ir-192 in six years and the physicist had not used this particular treatment planning software for Ir-192. It would have been prudent to have an additional review or outside review. The double check was not performed until the day after the treatment began. Corrective actions taken by the licensee included changing the policy and procedures to require a check of calculations for any single fraction brachytherapy treatment. The radiation oncologist disclosed that the patient is at risk for radiation cystitis, rectal proctitis, and, more importantly, fistula formation between the rectum and the vagina. The patient will be monitored closely over the next year by both her gynecologic oncologist and the radiation oncologist. The patient was treated with broad spectrum antibiotics along with daily treatments in a hyperbaric oxygen chamber. Department of Health staff performed a reactive inspection on 3/21/2007. Licensee staff was interviewed and radiation therapy quality assurance policies, procedures, and patient records were reviewed. The patient's record was sent for review by a radiation oncologist and medical physicist. Their report identified several issues which the Department of Health will follow-up on.

Event Date: 03/06/2007

Discovery Date: 03/07/2007

Report Date: 03/21/2007

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	NR	Name:	NR
NRC Docket Number:	NA	City:	NR
NRC Program Code:	NA	State:	NY Zip Code: NR
Responsible NRC Region:	1		

Site of Event:

Site Name: NR
State: NY

Additional Involved Party:

License Number:	NA	Name:	NA
NRC Docket Number:	NA	City:	NA
NRC Program Code:	NA	State:	NA Zip Code: NA
Responsible NRC Region:	NA		

Other Information:

NRC Reportable Event:	Y	Abnormal Occurrence:	Y
Agreement State Reportable Event:	Y	Investigation:	N
Atomic Energy Act Material:	Y	NMED Record Complete:	N
Consultant Hired:	N	Event Closed by Region/State:	N

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: HUMAN ERROR

Corrective Actions Information:

Action Number: Corrective Action:

MD2

1 NEW PROCEDURE WRITTEN

Patient Information:

Patient Number: 1

Patient Informed: U Date Informed:

Given:

Therapeutic Procedure: BRACHY, MANUAL IMPLANT

Organ: VAGINA

Radiopharmaceutical: NA

Radionuclide: IR-192 Activity: 280.7 mCi 10385.9 MBq Dose: 4590 rad 45.9 Gy

Intended:

Therapeutic Procedure: BRACHY, MANUAL IMPLANT

Organ: VAGINA

Radiopharmaceutical: NA

Radionuclide: IR-192 Activity: NR mCi NR MBq Dose: 2500 rad 25 Gy

% Dose Exceeds Prescribed: 83.6

% Dose is Less Than Prescribed: NA

Effect on Patient:

Patient Number: 1A

Patient Informed: U Date Informed:

Given:

Therapeutic Procedure: BRACHY, MANUAL IMPLANT

Organ: RECTUM

Radiopharmaceutical: NA

Radionuclide: IR-192 Activity: 280.7 mCi 10385.9 MBq Dose: 7300 rad 73 Gy

Intended:

Therapeutic Procedure: BRACHY, MANUAL IMPLANT

Organ: RECTUM

Radiopharmaceutical: NA

Radionuclide: IR-192 Activity: NR mCi NR MBq Dose: NR rad NR Gy

% Dose Exceeds Prescribed: NR

% Dose is Less Than Prescribed: NA

Effect on Patient:

Source of Radiation:

MD2

Source Number: 1

Source/Radioactive Material: SEALED SOURCE BRACHYTHERAPY

Radionuclide or Voltage (kVp/MeV): IR-192

Manufacturer: BEST INDUSTRIES

Activity: 0.2807 Ci 10.3859 GBq

Model Number: NR

Serial Number: AGGREGATE

Device/Associated Equipment:

MD2

Device Number: 1

Device Name: SEED RIBBON

Model Number: NA

Manufacturer: BEST INDUSTRIES

Serial Number: AGGREGATE

Reporting Requirements:

MD2

Reporting Requirement: 35.3045(a)(1)(i) - Total dose delivered that differs from the prescribed dose by 20% or more; and differs from the prescribed dose by more than 0.05 Sv (5 rem) EDE, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) SDE.

References:

Reference Number:	Entry Date:	Retraction Date:	Coder Initials:	Reference Type:
NYS-DOH 07-001	04/11/2007		DCH	AGREEMENT STATE EVENT REPORT
EN43301	04/17/2007		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
LTR070425	04/30/2007		DCH	NRC LETTER

LTR070608
LTR070626
AS 07-03
ML081300424

06/11/2007
06/27/2007
05/15/2008
05/15/2008

DCH
DCH
RLS
RLS

AGREEMENT STATE LETTER
AGREEMENT STATE LETTER
ABNORMAL OCCURRENCE NUMBER
ABNORMAL OCCURRENCE NUMBER

Event No. NYS-DOH 07-001

A brachytherapy misadministration involving a 31y/o female patient with a history of vaginal cancer was reported to NYS DOH BERP on 3/9/07.

The patient was successfully treated to 5590cGy to the target volume using external beam (IMRT) therapy and she was to receive 2500-3000cGy via interstitial brachytherapy with both Cesium-137 and Iridium-192 (seeds in ribbons) sources

The medical physicist developed a treatment plan as directed by the authorized user/ radiation oncologist using a commercial treatment planning software (TPS) application. Eleven ribbons with 8 seeds each and an activity of 1.855 mgRaEq per Ir-192 seed were ordered from Best Industries. Hospital owned Cs-137 sources were selected for use. The medical physicist verified source strength of all sources. The oncologist reviewed and approved the plan. He prescribed a total dose of 2500 cGy to be delivered to the 50cGy-isodose line for a total treatment time of 50 hours.

At 2:30 PM on 3/6/07 the sources were placed into the patient. A Syed template was used to place the ribbons and the Cs-137 sources were loaded into a tandem applicator.

On 3/7/07, late in the morning, the medical physicist performed a manual check of the treatment plan calculations and identified a significant discrepancy – the hand calculations indicated a significantly higher dose rate than what was generated from the TPS. An investigation ensued, which included consultation with the TPS vendor's application specialist. After several hours of investigation it was determined that the original treatment plan was in error, and at 5:30 PM on 3/7/07, after 27 of the intended 50-hour treatment time, the radiation oncologist decided to remove the sources.

Instead of the intended 2500cGy, the patient received an estimated dose of 4590cGy and the anterior rectal dose was approximately 7300 cGy.

The licensee provided a written report as required, and DOH staff performed an on-site investigation on 3/21/2007.

Cause and contributing factors:

1. The primary error was the use of an inappropriate Dose Rate Factor (DRF) in the TPS. The value used corresponded to the DRF for Air Kerma however the source strength entered was in MgRaEq. The physicist should have changed the units of source strength or entered the correct DRF.
2. Changing the units of activity in the TPS does not generate a prompt for a new Dose Rate Constant

3. During the physics review it was determined that acceptance testing of this treatment planning software did not include Iridium-192. The acceptance testing covered cesium 137 and Iodine 125 seeds which were the only materials being used at the time. If this testing had been performed the physicist would have been more likely to recognize that the treatment planning system does not automatically select the correct dose rate factor when the source strength units are changed.
4. There was no check of the preplan before the seeds arrived although there was sufficient time (sources ordered 2/27/07 and the plan was approved on 3/6/07).
5. Neither the physicist nor the radiation oncologist had prepared a treatment with Ir-192 in six years and the physicist had not used this particular TPS for Ir-192 implants. It would have been prudent to have an additional review or outside review in order to verify there were no oversights or errors.
6. The double check was not done until the day after sources had been implanted. Again while the physicist was observing the minimum requirements of Part 16 it would have been prudent to perform a check of the calculations either prior to the implant or immediately thereafter.

Corrective action: The policy and procedures have been changed to require a check of calculations for any single fraction brachytherapy treatment to be performed and approved prior to initiation of treatment.

Patient condition and follow-up.

The radiation oncologist disclosed that the patient is at risk for radiation cystitis, rectal proctitis and more importantly, fistula formation between the rectum and the vagina. The patient will be monitored closely over the next year by both her gynecologic oncologist and the radiation oncologist. The patient is currently being treated with broad spectrum antibiotics along with daily treatments in a hyperbaric oxygen chamber.

Violations:

A notice of violations is pending final review. It is likely that the licensee will be cited for failure to perform acceptance testing of the TPS for Ir-192.

NYS law prohibits disclosure of facility identifiers thus the name of the facility cannot be provided. However, there is no record of any similar brachytherapy medical event for this licensee.

Thomas W
Smith/SMITW/CC01/INEEL/
US

04/25/2007 08:18 AM

To Dante C Huntsman/DHUN/CC01/INEEL/US@INEL

cc

bcc

Subject Fw: FYI: 070215 Potential AO - medical event

----- Forwarded by Thomas W Smith/SMITW/CC01/INEEL/US on 04/25/2007 08:18 AM -----



"Angela McIntosh"
<ARM@nrc.gov>

04/24/2007 06:53 AM

To "Robert L Sant" <Robert.Sant@inl.gov>, "Thomas W Smith"
<Thomas.Smith@inl.gov>, "Michele Burgess"
<MLB5@nrc.gov>

cc "Blake Rice" <BBR2@nrc.gov>, "Cinthya Roman-Cuevas"
<CIR1@nrc.gov>, "Cynthia Flannery" <CMF@nrc.gov>,
"Gregory Morell" <GKM@nrc.gov>

Subject Re: FYI: 070215 Potential AO - medical event

Michele, Robert and Tom: thanks for the information below. However, I'd like to raise an issue that I hope one of you can answer.

The Event Notice (EN) report contained 2 pieces of information that is not included in the NMED abstract. The more important piece is the expected risk and the effects to the patient, which, according to the EN, the radiation oncologist said was radiation cystitis, rectal proctitis, and, "more importantly, fistula formation between the rectum and the vagina." The EN stated that the patient is being treated with broad spectrum antibiotics along with daily treatments in a hyperbaric oxygen chamber, and the patient will be monitored closely over the next year by both her gynecologic oncologist and the radiation oncologist.

The other piece of information that I perceive as somewhat less important but perhaps should also be included is the fact that the medical physicist used a commercial treatment planning software application to develop a treatment plan as directed by the authorized user and radiation oncologist.

My question is, is there any reason to not include these two pieces of information?

Angela

>>> Michele Burgess 4/24/2007 7:01 AM >>>

FYI - INL has marked NMED 070215 as a P AO.

The licensee reported that a 31-year-old female patient, with a history of vaginal cancer, was prescribed 2,500 cGy (rad) via interstitial brachytherapy to the 50 cGy (rad) isodose line, but received 4,590 cGy (rad). The patient's anterior rectal dose was approximately 7,300 cGy (rad). The licensee used both

Cs-137 and Ir-192 for the treatment. The licensee used 11 seed ribbons, each containing eight Ir-192 seeds (Best Industries), and each seed contained an activity of 1.855 mgRaEq or 118 MBq (3.19 mCi). A Syed template had been used to place the Ir-192 ribbons and the Cs-137 sources were loaded into a tandem applicator. The treatment was initiated on 3/6/2007. The medical physicist performed a manual check of the treatment plan calculations on 3/7/2007 and identified a significant discrepancy. It was noted that the hand calculations indicated a significantly higher dose rate than what was generated by the treatment planning software. After several hours of investigation, it was determined that the original treatment plan was in error. After 27 of the intended 50-hour treatment time, the sources were removed from the patient. The primary error was the use of an inappropriate dose rate factor in the treatment planning software. The value used corresponded to the dose rate factor for air Kerma; however, the source strength was entered in Ra mg-Eq. During the physics review, it was determined that acceptance testing of this treatment planning software did not include Ir-192. The acceptance testing covered only Cs-137 and I-125. There was no check of the preplan prior to obtaining the Ir-192 seeds, although there was sufficient time. Neither the physicist nor the radiation oncologist had prepared a treatment using Ir-192 in six years, and the physicist had not used this particular treatment planning software for Ir-192. It would have been prudent to have an additional review or outside review. The double check was not performed until the day after the treatment began. Corrective actions taken by the licensee included changing the policy and procedures to require a check of calculations for any single fraction brachytherapy treatment.



"Robert E. Dansereau"
 <red07@health.state.ny.us>
 06/08/2007 05:52 AM

To Dante.Huntsman@inl.gov, mlb5@nrc.gov
 cc "Stephen M. Gavitt" <smg03@health.state.ny.us>, GMISKIN@health.nyc.gov
 bcc

Subject Fw: Information request for NMED item 070215

As indicated in the original report of this event to the US NRC, we cannot release any identifying information for a facility/licensee involved in a medical event. Such information is protected.

Robert E. Dansereau
 Chief, Radioactive Materials Section
 Bureau of Environmental Radiation Protection
 NYS Department of Health - Rm 530
 547 River Street
 Troy, NY 12180-2216
 Phone (518)402-7590
 FAX (518)402-7585
 red07@health.state.ny.us

----- Forwarded by Stephen M. Gavitt/BERP/DEP/CEH/OPH/DOH on 06/07/2007 03:35 PM -----

"Gene Miskin"
 <GMiskin@health.nyc.gov>

06/07/2007 03:34 PM

"Stephen M. Gavitt"
 <smg03@health.state.ny.us>

To

cc

Subject

FW: Information request for NMED item 070215

Steve-I'm not sure this is ours so forwarding to you in case this was one of yours.

From: Dante C Huntsman [mailto:Dante.Huntsman@inl.gov]
 Sent: Thursday, June 07, 2007 3:25 PM
 To: Gene Miskin
 Cc: mlb5@nrc.gov
 Subject: Information request for NMED item 070215

We need additional information to complete the NMED record (identified below) associated with an event report that you submitted to NMED. The additional information is needed to meet the minimum requirements of STP

Procedure SA-300 (available at the NRC/STP web site, www.hsrdoornl.gov/nrc/home.html). In order to promptly complete the NMED record, we request a reply at your earliest convenience, but no later than 60 days from the date of this request.

NMED Item No.: 070215
State Event No.: NYS-DOH 07-001
Licensee/Reporting Party: NR
License Number: NR
Event Date: 3/6/2007

ADDITIONAL INFORMATION REQUESTED

Gene, I was not sure who to direct this information request to and I know that this information is usually not provided, but I still needed to ask per our procedures.

What was the city of the licensee's/company's residence?
What was the license number?
What was the licensee's/company's name?

Thank you for your help,

Dante Huntsman
NMED Project
Dante.Huntsman@inl.gov

The New York City Department of Health & Mental Hygiene is now offering information important for the health of all New Yorkers. To sign up for these new and valuable updates, log-on to our website at <http://www.nyc.gov/health/email> and select the NYC DOHMH updates you'd like to receive.

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"Robert E. Dansereau"
<red07@health.state.ny.us>
06/26/2007 09:56 AM

To Dante.Huntsman@inl.gov, mlb5@nrc.gov, JJK@nrc.gov
cc
bcc

Subject NMED item 070215 - update

History

This message has been replied to.

Two edits/corrections are needed in the event narrative as follows:

1) There is a typo about midway in the text - says Ra mg eq, should be mg Ra eq.

2) Corrective actions taken by the licensee included changing the policy and procedures to require a check of calculations for any single fraction brachytherapy treatment plan prior to initiating treatment.

UPDATES:

DOH Staff performed a reactive inspection/investigation on March 21, 2007. The radiation oncologists/AUs, AMP, risk management and administrative staff were interviewed, and radiation therapy quality assurance policies, procedures and records, and the patient's medical record were reviewed. Two items of noncompliance regarding the event were cited. Failure to perform acceptance testing on the treatment planning system for iridium 192 and failure to report the event to DOH and the referring physician within the timeframe required by regulation. The facility was fined \$2000 for each of these violations.

The patient's medical record was sent for review by a radiation oncologist and medical physicist. The reviewers' report identified several issues which DOH will follow-up on with the licensee. Based on their review it appears that the event meets the AO threshold for medical events as outlined in FSME-06-095. Specifically, Appendix A, III, C, 1. b and 2. a.

Robert E. Dansereau
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Event Detail - Abnormal Occurrence

ITEM #: 070215 AO #: AS 07-03 AO REPORT: NUREG-0090, Vol. 30
TITLE: Medical Event in New York
NAME: Unspecified Licensee
DATE: 03/07/2007 CITY: Unspecified Facility STATE: NY

Criteria:

Criteria III.C.1 .b and III.C.2.a, "For Medical Licensees," of Appendix A to this report states, in part, that a medical event that results in a dose that is equal to or greater than 10 Gy (1,000 rad) to any tissue or organ (other than the lens of the eye, the gonads, or a major portion of the bone marrow), and represents either a dose or dosage that is at least 50 percent greater than that prescribed, shall be considered for reporting as an AO.

Nature and Probable Consequences:

The licensee reported a brachytherapy medical event to the New York State Department of Health. The event involved a 31-year-old female patient with a history of vaginal cancer. The treatment involved the use of both cesium-137 and iridium-192 seeds. Each ribbon contained 8 seeds with an activity of 1.855 milligram radium equivalent (118 MBq or 3.19 mCi). The patient was to be administered a total dose of 25 Gy (2,500 rad) via interstitial brachytherapy, to be delivered to the 0.5 Gy (50 rad) isodose line for a total treatment time of 50 hours.

On March 6, 2007, the iridium-192 seeds and the cesium-137 seeds were placed into the patient. Late in the morning of March 7, 2007, the medical physicist performed a manual check of the treatment plan calculations, and discovered that the hand calculations indicated a significantly higher dose rate than was generated using the treatment planning software. The ensuing investigation revealed that the original treatment plan was in error. On March 7, 2007, after 27 hours of treatment, the seeds were removed from the patient.

The patient received an estimated dose of 45.9 Gy (4,590 rad) to the treatment site, rather than the intended 25 Gy (2,500 rad). The rectal dose was 73 Gy (7,300 rad). The radiation oncologist disclosed that the patient is at risk for radiation cystitis, rectal proctitis, and more importantly, fistula formation between the rectum and the vagina. The patient and the referring physician were informed of this event. The patient will be monitored closely over the next year by both her gynecologic oncologist and the radiation oncologist. The patient is being treated with broad spectrum antibiotics, along with daily treatments in a hyperbaric oxygen chamber.

Cause:

The primary cause was the use of an inappropriate Dose Rate Factor (DRF) in the treatment planning system. The value used corresponded to the DRF for air kerma, however, the seed strength entered was in milligram radium equivalent. Other causes and contributing factors included failure to check the treatment pre-plan before the seeds arrived although there was time to do so; failure to double-check the calculations either prior to the implant or shortly thereafter; use of a treatment planning system that underwent acceptance testing for cesium-137 and iodine-125, but not iridium-192; and lack of recent experience preparing a treatment plan using iridium-192. Neither the physicist nor the radiation oncologist had prepared a treatment plan using iridium-192 in 6 years.

Licensee Action

The licensee changed its policy and procedures to require a check of calculations for any single-fraction brachytherapy treatment.

NRC Action

Other Agency Action

The State plans to follow-up on the licensee's implementation of their new procedures during the next scheduled inspection.