Washington University in St. Louis

Environmental Health & Safety **Radiation Safety Office**

June 5, 2008

U.S. Nuclear Regulatory Commission
Region III
Nuclear Materials Licensing Section
2443 Warrenville Road, Suite 210
Lisle, Illinois 60532-4352

Attn: Regional Administrator

RE: License No. 24-00167-11
Docket No. 030-02271

Subject: Report of loss of licensed material in accordance with 10 CFR 20.2201

On May 8, 2008 at 4:30 PM CDT, I made a telephone notification to NRC Operations Center concerning loss of two I-125 seeds totaling approximately 1 mCi following a prostate implant procedure at Barnes-Jewish Hospital. I spoke with Jeff Rotton in making this report (Event Number 44194). We learned of the potential loss of this licensed material at approximately 4:30 PM CDT on May 7, 2008, but we were not able to confirm that the two seeds were lost until approximately 8:00 AM on May 8, 2008 when the Authorized User involved with the prostate implant procedure could be interviewed. Initial evaluation of the I-125 seeds was based on the activity of the seeds being ~ 0.370 mCi per seed or ~0.740 mCi total. Therefore, our initial evaluation for the lost I-125 seeds was based on the total activity being greater than 10 times 10 CFR 20 Appendix C quantity, but less than 1,000 times the quantity. We determined during our investigation on May 8 that 0.370 mCi per seed was the apparent activity. Information received on May 8 from the seed manufacturer approximated the contained activity as much as 0.518 mCi per seed, or 1.036 mCi total for the lost seeds (range of 0.962 to 1.036 mCi). Once we determined the activity total may be higher than 1 mCi (1000 times the 10 CFR 20 Appendix C quantity), we prepared to report the loss of licensed material in accordance with 10 CFR 20.2201(a)(1)(i), although our conclusion as to the fate of the I-125 seeds did not indicate that an exposure could result to persons.

This written report is being provided to you in accordance with 10 CFR 20.2201(b).

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Description of Licensed Material

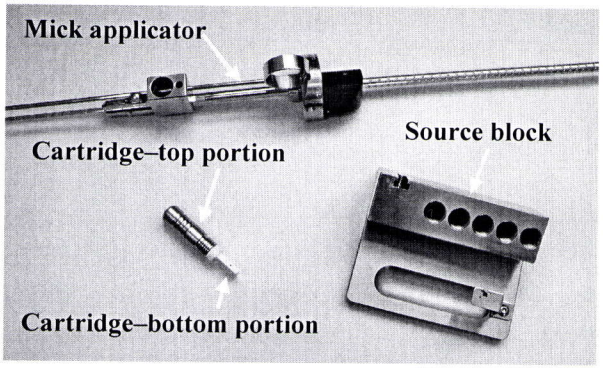
Number of sources –	2
Isotope –	I-125
Manufacturer –	IsoAID, LLC, Florida
Seed model –	Advantage™ I-125 Model No. IAI-125A, Iodine-125 Interstitial Brachytherapy Seed(s)
Sealed Source Registry No. –	FL-1146-S-101-S
Physical form –	I-125 absorbed on a silver rod and encapsulated in a titanium shell
Total source dimension –	Cylinder – 0.8 mm in diameter and 4.5 mm in length
Apparent Activity/source –	~ 0.370 mCi weighted average on the day of administration – manufacturer reported activity range: 0.358 mCi to 0.387 mCi – the apparent activity value is a statistical representation of the range assayed by the manufacturer for seeds in that batch
Contained Activity/source –	~0.4995 mCi median (range ~ 0.481 mCi to ~ 0.518 mCi), based on weighted average – the manufacturer has told us that the ratio of contained activity to apparent activity for this seed model is in the range of 1.3 to 1.4
Total apparent activity –	~ 0.740 mCi
Total contained activity –	~ 0.999 mCi, median (range ~ 0.962 mCi to ~ 1.036 mCi)

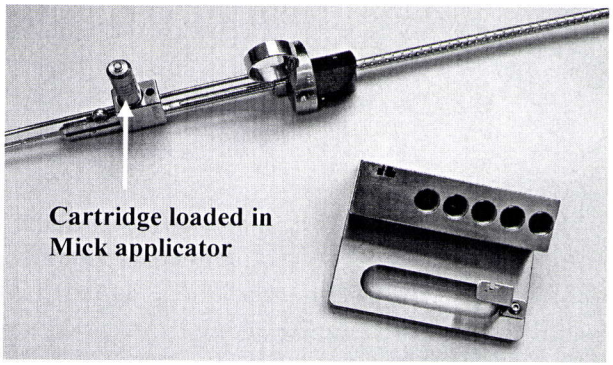
Description of Circumstances

On May 7, 2008, a Radiation Oncology Authorized User (AU) planned to administer additional I-125 seeds to a prostate cancer patient who had originally been treated with I-125 seeds in April 2008. Radiation Oncology staff normally schedule all prostate seed implant procedures on Wednesdays. Radiation Oncology Medical Physics staff ordered 15 I-125 seeds in the manufacturer's preloaded sterile cartridge for use in a TP200 Mick Applicator. The AU planned to implant approximately 9 seeds, and the Medical Physics staff planned to measure the remaining I-125 seeds as part of their normal QA procedure to verify the apparent activity per seed. Normally, Medical Physics staff verify apparent activity of I-125 seeds prior to an implant procedure, but use of a preloaded sterile cartridge requires that this check be done following the procedure.

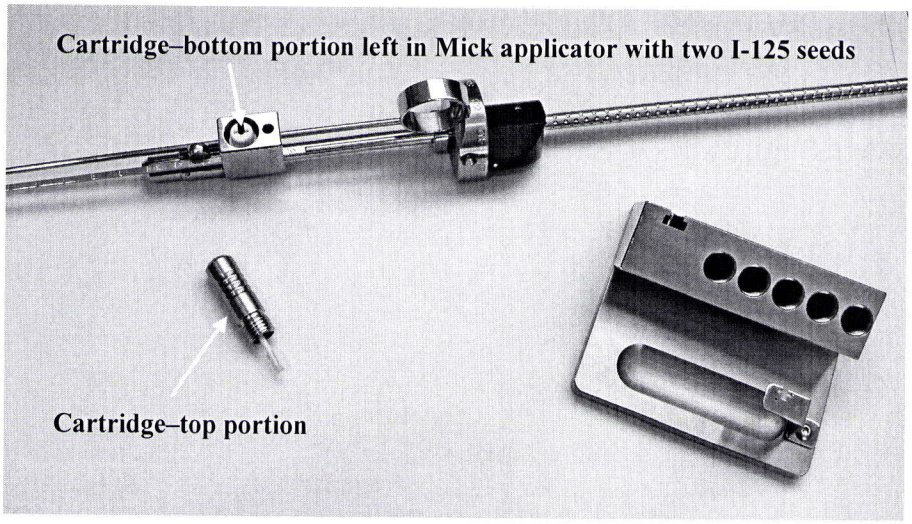
The May 7 brachytherapy procedure took place in an operating room at Barnes-Jewish Hospital (BJH) Center for Advanced Medicine (CAM). The AU was assisted by a Radiation Oncology nurse (RO Nurse) who was being trained in brachytherapy procedures, and a staff member of Radiation Oncology Medical Physics who is in the Medical Physics Residency Program (MP Resident) and had been trained for this procedure by the Lead Brachytherapy Service Medical Physicist. A Radiation Oncology therapist

newly assigned to the Brachytherapy Service observed the RO Nurse to begin learning this procedure, but did not otherwise figure into the loss of the seeds. The AU's final treatment implanted 13 I-125 seeds, and two seeds remained in the cartridge within the Mick applicator. Normally, the AU would remove the cartridge from the Mick applicator, visually verify the presence of the two remaining seeds, and place the cartridge into the source block. In this case, the AU needed to attend to a patient medical condition unrelated to the brachytherapy procedure, and so laid the Mick applicator on the operating table, and the RO Nurse picked it up to retrieve the two seeds and clean the Mick applicator. The MP Resident asked another medical physics resident, who was also trained in this procedure, to come to the OR to pack up the ultrasound equipment used for the implant procedure, and then left to attend a meeting.





The RO Nurse incorrectly removed the cartridge from the Mick applicator by unscrewing the top of the cartridge which left the bottom portion of the cartridge and the two I-125 seeds in the Mick applicator. She placed the top portion of the cartridge in the source block and placed the Mick applicator in a tub. She surveyed the patient for release and surveyed areas around the patient and floor to verify no seeds had been dropped. The RO Nurse moved her equipment, including the source block and the tub containing the Mick applicator to the OR decontamination room. There she placed the Mick applicator in a soak basin to clean. The soak basin contained a cleaning solution which was approximately 4-5 inches in depth. She vigorously cleaned the Mick applicator, and moved the seed insertion plunger in and out of the applicator several times to clean the interior. We believe the two I-125 seeds were ejected from the Mick applicator at this point and left in the soak basin. The RO Nurse took the Mick applicator and the source block back to the Radiation Oncology Vault 1 where, at approximately 10:45 AM, she placed the Mick applicator in its case and one of the Radiation Oncology Brachytherapists moved the top portion of the cartridge from the source



block to the seed storage location.

At approximately 4:30 PM, the MP Resident retrieved the cartridge from the seed storage location to make the measurements needed to verify the apparent seed activities. The MP Resident found that only the top portion of the cartridge was present. It was at this point we identified that the two remaining seeds were missing. The effort to locate the missing seeds began immediately.

Probable Disposition of Lost Licensed Material

Based on our investigation, we believe that the two I-125 seeds were inadvertently poured down the drain in the OR decontamination room to the sanitary sewer system when the OR staff emptied the solution from the soak basin into the sink. The soak basin had most likely been emptied and refilled several times by the time the I-125 seeds had been identified as missing.

Exposure Potential

The seed manufacturer reported the weighted average air kerma strength per I-125 seed as 0.47 $\mu Gy\ m^2/hr$ which would be a dose rate of ~ 0.5 mrem/hr at 30 cm from one seed. The low energy x-rays and gammas emitted by I-125 are significantly shielded when the seeds were in the Mick applicator and when the seeds were in the soak basin. The exposure potential to the OR staff who worked around or emptied the soak basin would be insignificant. The seeds were washed into the sanitary sewer system where they would not represent a health and safety hazard because of the 59.41 day half-life for I-125 and because the radioactive iodine was contained in the metal seeds.

Actions Taken to Recover the Lost Material

Upon discovering that the two I-125 seeds were missing, the Chief Radiation Oncology medical physicist (Chief MP), two Radiation Oncology medical physicists, the MP Resident and the other medical physics resident who had helped pack up the ultrasound equipment made an extensive search for the two seeds. The initial search included –

- locating the bottom portion of the cartridge in the Mick applicator, radiation surveys and visual checks of the bottom portion of the cartridge, the Mick applicator, the Mick applicator case and the transfer cart, which were stored in Radiation Oncology Vault 1.

- contacting the RO Nurse at home and discussing her actions in handling and storing the remaining seeds; she still believed that she had returned the two seeds from the OR and that they had been placed in the source storage location, and

- performing radiation surveys and visual checks of the OR room used for the brachytherapy procedure, the path to and from the OR decontamination room, the seed storage location and the transfer cart.

The Chief MP contacted Radiation Safety emergency pager at approximately 6:30 PM May 7, 2008, and the Health Physicist (HP) on emergency response arrived to assist in the search for the seeds. The Chief MP and others briefed the HP on the circumstances they knew at that point, and actions they had taken in searching for the two missing seeds. They took the HP to the various areas they had already searched, and did additional radiation surveys. They decided disposal into the OR trash could be a potential path the seeds may have gone, and learned from BJH Housekeeping staff that the trash from that morning's OR procedures was likely already contained in the compacted trash container at the CAM loading dock. The HP first contacted me, as RSO, at approximately 7:30 PM, and during a follow up call that evening, he and I decided to ask BJH staff to have the trash compactor container held from removal by the vendor which was accomplished. The HP contacted the BJH Environmental Health and Safety Director at approximately 8:30 PM to arrange plans, if necessary, to empty the trash compactor container in the morning to survey the contents for the missing I-125 seeds.

The Chief MP, the HP and I decided since we were not yet able to verify with the AU whether the two seeds might have been implanted, that we would resume the search for the missing seeds by interviewing the AU and RO Nurse first thing the next morning (May 8, 2008). Based on what we knew of the apparent activity of the seeds, the uncertainty of whether the seeds were lost, and, if lost, that the likely paths would not result in exposure to a person, I judged we were not required to report the missing seeds to NRC under 10 CFR 20.2201(1)(a)(i) at that time, and decided to conduct further search efforts to locate the two missing seeds in the morning.

Based on interviews with the AU and the RO Nurse during the morning of May 8, 2008, the AU, the Chief MP, the RO Nurse and I decided the I-125 seeds had most likely been lost down the drain in the OR decontamination room. We released the trash compactor container for disposal and evaluated need to search the drain for the I-125 seeds. I decided circumstances did not warrant opening up the sink trap to look for the seeds based on the following facts –

- significant amounts of water and OR wastes had already gone down the drain by the time the seeds had been identified as missing;

- the sink used by the RO Nurse, and perhaps the neighboring sink sharing a common drain, would be taken out of service during a time when several operating rooms were in use; and

- disposal of I-125 seeds to the sanity sewer did not represent a health and safety hazard.

We then focused our efforts toward fully evaluating the causes leading to loss of the seeds and initiating corrective actions.

Measures Taken to Ensure Against Recurrence

The fundamental cause of this event was inadequate training of the RO Nurse which led to her misunderstanding of where the seeds were located in the cartridge and Mick applicator, and not accounting for the two I-125 seeds either visually or by radiation survey. The RO Nurse had previously observed another Radiation Oncology brachytherapist do a similar procedure, but she had not done the procedure herself. The following actions contributed to this fundamental cause by not preventing loss of the seeds or not recognizing more immediately that the seeds were missing –

- The AU was unable due to other medical reasons to complete the procedure to unload the Mick applicator and verify seed count, and the RO Nurse took over completing this task.

- The brachytherapist who assisted the RO Nurse in removing the cartridge top from the source block to the seed storage location did not account for the two I-125 seeds either visually or by radiation survey, and did not recognize that the cartridge she handled was only the top portion of the cartridge.

The Brachytherapy Service Lead Medical Physicist conducted a hands-on training for the Mick applicator and source cartridge on May 8, 2008 with the AU, the RO Nurse, the Chief MP, the MP Resident, the medical physics resident who assisted with the ultrasound equipment, all the brachytherapists, and the newly assigned Radiation Oncology therapist. This training included review of the I-125 prostate implant procedures, responsibilities, and circumstances resulting in loss of the two I-125 seeds. Long term corrective actions taken or planned include –

- Radiation Oncology has established competencies as part of their accredited Physician and Physics Residency Programs (http://radonc.wustl.edu/educationprogram.aspx). Radiation Oncology staff have incorporated these competencies into competency check lists specific for Medical Physics staff and Medical Physics Residents, and for Brachytherapists which are specific for the "ULDR (ultra-low dose rate) Radioactive Seed Permanent Implant Prostate Brachytherapy Procedures." Competency check lists include hands on training with procedure equipment and demonstration of procedure competency during shadowing by another trained individual. Completion of a competency check list for an individual will be used to document his/her training and approval to participate in the procedure without shadowing by another trained individual. Example checklists are provided in Attachment A. All Radiation Workers approved for these procedures will have completed the respective competency check list by June 11, 2008, or will complete the form prior to the next time they participate in a prostate implant.

- Radioactive seed permanent implant prostate brachytherapy procedures have been updated and developed to integrate with the competency check lists, and to emphasize the points when visual and radiation survey seed inventory checks are required. The updated and new procedures are provided in Attachment B.

- In addition to development of the competency check lists, Radiation Oncology staff are evaluating lessons learned from the lost I-125 seeds event for application to other Radiation Oncology procedures involving licensed materials.

While release of two I-125 seeds into the sanitary sewer does not represent a health and safety hazard, we consider our loss of control over these seeds unacceptable in light of our dedication to excellence in patient care, teaching and research. We are committed to learning from this event to correct the causes and missed opportunities leading to the loss, and to preventing future loss of licensed materials.

Please let me know if you need further information or have additional questions concerning this report. My phone number is (314) 362-2988 and my e-mail address is langhors@wustl.edu.

Sincerely,

Susan M. Langhorst, Ph.D., CHP
Radiation Safety Officer

Cc w/ attachments:
J.M. Michalski
D.A. Low
A.D. Medina
D.A. Lichti
B.D. Backus
B.A. Siegel
L.J. Shapiro
C.W. Goddard

ATTACHMENT A

Included are check lists we have created, as of June 4, 2008, to improve training documentation for Medical Physics staff and Medical Physics residents, and for Radiation Oncology brachytherapists, and specific for ULDR (ultra-low dose rate) Radioactive Seed Permanent Implant Prostate Brachytherapy Procedures. Development of these check lists began soon after the I-125 seeds were lost, and these check lists are provided as examples of our corrective actions. We will continue to evaluate our training documentation needs and may further modify these check lists.

Barnes Jewish Hospital
Washington University School of Medicine
Radiation Oncology Department
Medical Physics Division

Medical Physicist Staff or Resident Credentialing

ULDR Radioactive Seed Permanent Implant Prostate Brachytherapy Procedures

Medical Physicist (staff or resident) Name: _____

Tasks/Cases	Date Completed Case ID	Supervisor Sign-off
Radiation Safety Exam		
Knowledge of Brachytherapy Physics QA Manual/QMP		
Knowledge of Online Documents		
Knowledge of Procedure Specific Procedure Manuals		
Source Characteristics		
Applicators / Equipment Training (Stranded/Needle)		
Applicators / Equipment Training (Mick)		
Ultrasound Unit operation and QA		
Implantation Equipment Use and Setup (US operation and O.R Stepper Setup)		
Treatment Planning System Operation		
Pre plan and Post plan Review and Interpretation		
Seed Ordering and Seed QA procedures (source strength and accountability)		
O.R. / Pre Treatment QA and Prep Procedures (Needle/Box Loading , # Seeds/needle, Mick Appl/Cartridges)		
O.R. Implantation Procedure Training (needle calling, needle tracking, seed tracking)		
O.R. / Post Treatment QA Procedures (surveys and source counts)		
SHADOW CASES		
Intra op Case 1 (Strand seeds /needles)		
Intra op Case 2 (Strand seeds /needles)		
Intra op Case 3 (Strand seeds /needles)		
Intra op Case 4 (Mick applicator)		
Intra op Case 5 (Mick applicator)		

Comments: _____

_____

I have been trained in the above "signed-off" procedures. I understand the operation of the equipments and feel comfortable in independently performing the procedures. I understand that if at any point I become aware that I am requested to perform a procedure that I am not familiar with; I will notify my supervisors before performing the procedure.

Medical Physics Staff/Resident: _____ Date: _____

RADIATION ONCOLOGY AUTHORIZED STAFF

The person above has completed the necessary requirements, commensurate with their tasks, to operate equipment and perform ULDR Radioactive seed Permanent Prostate Implant Brachytherapy Procedures at Barnes-Jewish Hospital/Siteman Cancer Center

Authorized Medical Physicist: _____ Date: _____

Brachytherapy Service Lead Authorized User: _____ Date: _____
Dr. Perry Grigsby, MD, MS

Barnes Jewish Hospital
Washington University School of Medicine
Radiation Oncology Department
Medical Physics Division

Brachytherapy Therapist Credentialing

ULDR Radioactive Seed Permanent Implant Prostate Brachytherapy Procedures

Brachytherapy Therapist Name: _____

Tasks/Cases	Date Completed/ Case ID	Supervisor Sign-off
Radiation Safety Exam		
Knowledge of Brachytherapy Physics QA Manual/QMP		
Knowledge of Online Documents		
Knowledge of Procedure Specific Procedure Manuals		
Source Characteristics		
Applicators / Equipment Training (Stranded/Needle)		
Applicators / Equipment Training (Mick)		
Implantation Equipment Use and Setup (US operation and O.R Stepper Setup, Fluoro Operation)		
Treatment Plan Review and Interpretation		
O.R. / Pre Treatment QA and Prep Procedures (Needle / Box Loading , Count of # Seeds/needle, Mick Applic/Cartridge)		
Misc. O.R. Instruments Operation (seed sterilization)		
O.R. Implantation Procedures (plan calling)		
O.R. / Post Treatment QA Procedures (surveys and source counts)		
SHADOW CASES		
Case 1 (Strands/needles)		
Case 2 (Strand/needles)		
Case 3 (Strands/needles)		
Case 4 (Mick applicator)		
Case5 (Mick applicator)		

Comments: _____

_____

I have been trained in the above "signed-off" procedures. I understand the operation of the equipments and feel comfortable in independently performing the procedures. I understand that if at any point I become aware that I am requested to perform a procedure that I am not familiar with; I will notify my supervisors before performing the procedure.

Brachytherapy RTT: _____ Date: _____

RADIATION ONCOLOGY AUTHORIZED STAFF

The person above has completed the necessary requirements, commensurate with their tasks, to operate equipment and perform ULDR Radioactive seed Permanent Prostate Implant Brachytherapy Procedures at Barnes-Jewish Hospital/Siteman Cancer Center

Authorized Medical Physicist: _____ Date: _____

Brachytherapy Service Lead Authorized User: _____ Date: _____
Dr. Perry Grigsby, MD, MS

ATTACHMENT B

Included are the following procedures updated or created as part of our corrective actions:

- "BRACHYTHERAPY AND RADIOPHARMACEUTICAL QUALITY ASSURANCE MANUAL, PERMANENT IMPLANT PROSTATE QUALITY ASSURANCE" (updated June 4, 2008) – This QA protocol was updated to clarify needle/applicator preparation (see section I. D.1.d.) and add training and experience requirements for approval or authorizations of individuals responsible for portions of these therapy procedures (see section I.E.).

- "Prostate Brachytherapy Logistics" (June 4, 2008) – This procedure was created to give a set of steps assigned to different groups of individuals for pre- and post-implant actions.

- "Mick Applicator and Cartridge Use Procedure in the Operating Room" (June 4, 2008) – This procedure was created to give a set of steps assigned to different individuals for OR implant actions.

Development of these updated and new procedures began soon after the I-125 seeds were lost, and these procedures are provided as examples of our corrective actions. We will continue to evaluate our procedural needs and may further modify these procedures.

Barnes-Jewish Hospital/Siteman Cancer Center
Washington University School of Medicine
Radiation Oncology Department
Medical Physics Division

BRACHYTHERAPY AND RADIOPHARMACEUTICAL QUALITY ASSURANCE MANUAL

PERMANENT IMPLANT PROSTATE QUALITY ASSURANCE

Revision: 6/4/2008

I. Permanent Implant Prostate Quality Assurance

- A. General Aspects of Permanent Prostate Brachytherapy Quality Assurance
  1. Positional Accuracy
  2. Source Strength Accuracy
  3. Temporal Accuracy
  4. Radiation Safety
  5. Dose Calculation Accuracy
- B. Commissioning, Acceptance Testing
  1. Sources
  2. Computer-Assisted Treatment Planning Systems
- C. Annual Review(s)
  1. Calibration Instrumentation
  2. Treatment Planning System
  3. Ultrasound Machine
  4. Fluoroscopic C-Arm
- D. Treatment Specific QA and Procedures
  1. Pre-Treatment Preparation
  2. Implant
  3. Post-Implant Plan
- E. Training and Experience

I. Permanent Implant Prostate Quality Assurance

Like the HDR and LDR QA protocols, this protocol focuses on the following physical accuracy endpoints:

A. General Aspects of Permanent Prostate Brachytherapy Quality Assurance

1. Positional Accuracy: A positional accuracy criterion of ± 2 mm **should** be utilized and is known to be achievable in the following domains: alignment of implant template with ultrasound machine screen grid, spacing of the sources in needles. Accuracy of needle positioning relative to patient anatomy and to pre implant plan can not be easily quantified and varies with individual patients and needles from 1-10 mm. Ultrasound images, fluoroscopic images, reference markers, and physical measurements **should** be used for guidance in needle placement. At the beginning of each implant day, alignment of implant template with ultrasound machine screen grid **shall** be verified. For each implant, source arrangement in needles **shall** be verified against the treatment plan using a needle autoradiograph. Alignment of the ultrasound images grid with the computer treatment planning system template **should** be within 0.5 mm.
2. Source Strength Accuracy: Prior to clinical use, supplied vendor source strength values **shall** be empirically verified against NIST-traceable sealed-source air-kerma strength calibration standards. At least 10% of sources shall be surveyed. Each institution **shall** acquire NIST or ADCL calibrations for each type of source or isotope clinically used. Calibration of a clinical source **shall** consist of intercomparing it with the corresponding source standard in an instrument (usually a re-entrant ion chamber) the response of which is proportional to air-kerma strength of the given source. Since I-125 interstitial sources are short lived, the constancy of the intercomparison instrument must be monitored using a long-lived source such as Cs-137. The physicist **shall** transfer the NIST calibration from the source standard to clinical sources of the same type with an accuracy of 2%. Tolerances for accepting the vendor calibration are 3% when averaged over a group of nominally identical sources and 5% for individual sources. It is the physicist's responsibility to resolve discrepancies of 5% or more between vendor and institutional calibrations.
3. Timer Accuracy: Does not apply to permanent implants.
4. Radiation Safety: Exposures to the general public and employees **must** adhere to the limits set forth in 10 CFR part 20. Other requirements pertaining to posting, training, documentation, source inventory, instrument calibration, etc. **must** adhere to 10 CFR part

35 requirements and individual license commitments. Exposure level at 1 m from every patient **shall** be measured prior to patient release and recorded on the Patient Survey form (Prostate Implant Forms Appendix). Following the implant, a complete survey of operating room and supplies used for the procedure **shall** be performed. Permanent implant patients may be released from confinement with no restrictions if the total dose equivalent to any other individual is not likely to exceed 500 mR. This determination will be made by measuring the exposure rate at 1 m using a calibrated ion chamber survey meter. Per 10 CFR 35.75(c), the basis of release must be documented. If the dose equivalent to any individual is likely to exceed 100 mR, the patient must be provided with oral and written instructions.

5. Dose Calculation Accuracy: Dose computation programs used in computer-assisted treatment planning **should** have an accuracy of 2%. This is interpreted to mean, that given known input values (AAPM TG43 type dosimetry data), doses calculated by the program **should** agree within 2% with independent values obtained by manual calculations, the published literature, or an independent computer program. For single sources, doses on the transverse axis at distances less than 5 mm may have errors of 3%. Deviations from these accuracy limits **shall** be discussed with the Chief of Brachytherapy Physics and the responsible radiation oncologist.

B. Commissioning, Acceptance Testing

1. Sources

   a. Before initiating clinical use of new sources model, the following **shall** be performed:

      i. Appropriate published dosimetry data for the source **shall** be reviewed and any differences from previously used source model identified.

      ii. All differences **shall** be reviewed with the implant physician and possible clinical consequences **shall** be evaluated.

      iii. Vendor calibrations **shall** be verified according to the guidelines described above, which implies that the NIST traceable calibration source **should** be obtained.

   b. Sources **shall be** logged into the permanent inventory records with signatures.

   c. Appropriate data (AAPM TG43 type dosimetry data) consistent with recommendations of the current literature must be entered into the RTP system to facilitate computer-assisted dose calculation. The results must be verified using point-dose estimates (not isodose curve position) against independent calculations or published dosimetry data. Requirements of the algorithm, dimensions and

composition of source components, expected clinical utilization and national protocol requirements (e.g. RTOG) must be taken into account in generating 3D single-source dose matrices and dose volume histograms.

d. Source Strength Calibration Device

i. Source positioning jigs **should** be constructed to eliminate significant (> 1 %) variations in instrument response due to positioning variations.

ii. Precision of repeated readings **shall** be verified. Generally, the range of readings when repeated with the same source **should** be no more than ±1 %. Drift of instrument response with time **must** be measured. If its response varies by more than 1% from session-to-session, each reading **should** be normalized to the expected response from a long-lived source of known strength.

iii. Linearity (or ion recombination corrections) **shall** be verified over the entire source-strength range that the physicist expects to encounter in clinical practice. The leakage **should** be measured and if necessary, subtracted from each reading. For a fixed position in the calibrator and type of source, the response of the instrument **should** be linear within 2%.

iv. The instrument response/unit air-kerma strength for each source type used clinically must be measured. These factors are obtained by placing sources, that have been calibrated in terms of air-kerma strength by an ADCL or NIST, in the calibration position and noting the reading. These measurements **should** be repeated several times over a 2-4 week period to assess precision of the calibration transfer. Ideally one scale (mCi) **should** be used for all isotopes with varying correction factors. A procedure for easily verifying instrument response using a long-lived source of known strength must be developed.

v. NIST-traceable calibration **shall** be obtained every 2 years. This interval can be lengthened to four years if the calibration is verified relative to an instrument (RPC or another ROC affiliate) having a more current calibration.

2. Computer-Assisted Treatment Planning Systems

Prior to clinical implementation, recently acquired or updated computer treatment planning systems **shall** be subjected to the appropriate subset of accuracy/function tests listed in the table:

Function	Benchmark Data	Frequency
Verify geometric accuracy of I/O peripherals: digitizer, CT or ultrasound interface, and plotter	Digitize/plot pattern of known geometry. For CT/US, image and reconstruct phantom implant.	Initially, annually
Verify input parameters for all precalculated single-source arrays	Published recommendations, source vendor's mechanical drawings	Initially, annually
Verify point calculations for all source files	Published dose-rate tables, Manual calculations or output of independent RTP	Initially, annually New software version or source changes
Accuracy of single-source Isodoses	Point source output	Initially New software version
Accuracy of multiple-source isodose contouring	Point source data for symmetric source arrays	Initially New software version
Consistency of printed plan documentation	Assumed input parameters	Every clinical use
Accuracy of co-ordinate reconstruction	CT phantom with known catheter geometry	Initially New software version
Dose volume histogram	Use phantom of known dimensions	Initially New software version
Optimization software	Run series of test cases based upon idealized implant geometries of various sizes. Develop a sense of what optimization does to an implant compared to uniform loading before trying it on patients	Initially. Spot check when software changes by duplicating old cases
Overall system test	Run series of standardized plans to globally test all clinically-used features	Initially New software version Annually

A report on implementation/commissioning of a new treatment planning system, software version, source model or type **shall** be submitted to Director of Physics. The report **should** include results and supporting data for all tests, procedures and forms, relevant references, and should identify any possible changes in clinical practice.

C. Annual Review(s)

The responsible brachytherapy physicist **shall** perform an annual QA review which **shall** include the tests outlined below. The form of the report **shall** consist of a brief summary describing the test outcomes, acquisition of any new reviewable equipment, any deviations from stated QA criteria and any corrective actions. Each test (accept calibrator QA) **should** be documented on the appropriate form which **should** be appended to the report and **shall** be submitted to the Physics Chief for review.

1. Calibration Instrumentation

   Review of calibration instrumentation, **should** be performed as a part of general brachytherapy annual quality assurance.

2. Treatment Planning System

   Computer point-dose calculations **shall** be compared to manual or independent computer calculations (stating technique or reference). Input data **should** be verified, followed by comparison of doses at several points. For example, points transverse to the source **should** be compared from 5 mm to 50 mm with no difference >3%. Standard benchmark implant plans **should** be run and checked for accuracy. Geometric accuracy of peripheral 1/0 devices **should** be checked.

3. Ultrasound Machine

   The functionality, accuracy, and image quality of the ultrasound machine **shall** be evaluated on monthly basis (Prostate Implant Forms Appendix). Tests **should** be based on the alignment calibration phantom and Nuclear Associates ultrasound imaging quality assurance phantom.

4. Fluoroscopic C-Arm

   The annual quality assurance for the C-arm is performed as a part of the general brachytherapy quality assurance. The review evaluates positional accuracy of the device as well as imaging performance.

D. Treatment Specific QA and Procedures

1. Pre-Treatment Preparation

   a. Volume Study and the Written Directive

      At least ten days prior to implant, an ultrasound volume study of the prostate **should** be performed. During the study, transverse images of the prostate, spaced 5 mm apart, **shall** be recorded on the VHS tape and/or CD and also printed using the

ultrasound machine heat transfer printer. The scans **should** include patient name and ID number. The entire prostate **should** be contoured and the image containing information about the total prostate volume recorded.

An attending physician **should** evaluate the patient for possible pubic arch interference.

The physician **shall** relay to dosimetry or physics the target volume dose, isotope, source strength, and any other special problems and consideration. The written prescription **should** be prepared before the treatment planning process begins.

b. Treatment Plan

Correct patient name and ID number **shall** be verified when importing volume study images into the treatment-planning computer. Brachytherapy physicist prior to ordering implant sources **shall** review all treatment plans. The treatment plan review **shall** include verification of: patient name and ID number, prescription dose, source type, source model, source strength, template alignment, image plane spacing, target volume compared to ultrasound machine calculation, target coverage (by reviewing both the dose volume histogram and individual isodose lines throughout the target volume), simplicity and technical practicality of the plan, BASE plane position, and location of individual sources and needles. The physicist **shall** verify that the treatment plan is in agreement with the written directive. All deviations from the written directive, possible problems, and concerns **shall** be discussed with the radiation oncologist (Authorized User).

Prior to the implant procedure (preferably prior to ordering sources) the physician **shall** review the plan for clinical adequacy, accuracy, and technical practicality.

c. Source Ordering and Calibration

To order interstitial sources, an Isotope Request Form (Appendix IV) **shall** be completed by the attending physician or physicist, the sources ordered by the physicist, and the form faxed to the Radiation Safety Office so they are prepared to receive the radioactive source shipment.

A physicist **shall** check in all isotope shipments. Vendor documentation **must** agree as to isotope, form, and strength of the isotope with the order form. Source **must** have been leak tested with last 6 months. Package **must** have been surveyed by Radiation Safety and the outer container wipe tested.

Verification of vendor calibration against NIST standards of at least 10% of the shipment **shall** be performed. The number of sources or ribbons **must** be counted. The Source Receipt Form, an integral part of the ROC inventory system, **should** be used.

Paperwork documenting vendor calibration, receipt, leak tests, and number of sources **should** be appended to Source Receipt Form.

In the event of procedure cancellation, the manufacturer **shall** be contacted by a physicist, as soon as possible, and arrangements for order cancellation **shall** be made.

d. Needle/Applicator Preparation

- *Seed/Needle Loading Patterns* – Prior to implant the brachytherapy staff shall verify via autoradiograph the needle loading patterns are in accordance with the treatment plan loading patterns.
- *Needle Box Loading Patterns*- Prior to implant the brachytherapist shall verify that the needles are loaded into the box as per the treatment plan.
- *Mick Cartridges*- Prior to implant the brachytherapy staff shall verify

  All Mick Applicator Components are available in the O.R.

  Appropriate # of mick cartridges are placed into the transport/handling pig in the O.R. (under sterile conditions)

  Appropriate # of "Mick" Sterile needles are available in the O.R.

2. Implant

Twenty four (24) hours within time of implant, a physicist **shall** perform ultrasound machine quality assurance as outlined above. Prior to the procedure all patients shall be identified in accordance with the ROC QMP program. During the implant, there **shall** be a redundant method for verification of needle placements. All modifications to the written directive **shall** be documented prior to completion of the procedure and signed by the attending physician (Authorized User).

Following the implant, the patient, operating room, and supplies (including trash) **shall** be surveyed as described above. The final source count **shall** be performed at this time. The prostate implant inventory and disposal form shall be used for source accountability. All sources (implanted in the patient, extra sources implanted, sources removed through

cystoscopy, and sources not used) **shall** be counted and documented in the prostate implant inventory and disposal form

3. Post-Implant Plan

   All post-implant plans **shall** be reviewed by a physicist. The review shall include verification of: patient name and ID number, prescription dose, source type, source model, source strength, image plane spacing, target volume compared to pre-implant plan volume, target coverage (by reviewing both the dose volume histogram and individual isodose lines throughout the target volume), accuracy of source identification on CT images, and number of identified sources. The physicist **shall** verify that the treatment plan is in agreement with the written directive. All deviations from the written directive, possible problems, and concerns **shall** be discussed with the radiation oncologist (Authorized User). The radiation oncologist **shall** review the plan for clinical adequacy, accuracy.

E. Training and Experience

   a. Radiation Workers (physicists / physics residents / brachytherapists) shall complete appropriate sections of their respective credentialing forms before independently participating in each of the different types of Brachytherapy procedures.
   b. Credentialing of Radiation Oncology Physicians and Physician Residents shall be performed via the Radiation Safety Program review and approval for Authorized User status under 10 CFR 35 uses.
   c. Credentialing of Radiation Oncology Medical Physicists shall be performed via the Radiation Safety Program review and approval for Authorized Medical Physicist status under 10 CFR 35 uses requiring an authorized medical physicist.

Barnes Jewish Hospital
Department of Radiation Oncology
Medical Physics Division

Prostate Brachytherapy Logistics

Scheduling: Nursing shall use IMPAC and the brachy board to schedule the patient for specific procedures (pre implant US vol study, pre implant MR, implant date, post implant CT and MR studies).

PRE-IMPLANT

Physician
- Performs Pre-Implant Ultrasound Volume Study
- Prints images
- Fills the prescription

Brachytherapy RTT
- Places prescription and images within patients chart and places it on the Brachytherapy cart (located in the physician's workroom near the treatment rooms 6 and 7)

Dosimetry
- Transfers the US Volume study to Variseed laptop
- Registers the template
- Verifies prescription is written
- Selects the source to be used for planning
- Completes appropriate sections of the brachy board.

Physician
- Contours and plans the case
- The final plan shall be labeled "Final_Preplan_Initials_date"
- Completes the appropriate sections of the brachy board.
- Informs Dosimetry of preplan completion (for billing)

Dosimetry
- Prints the brachy board page (contains the information on the date the plan was generated and approved)
- Informs physics that patient's pre-plans are ready for "on screen" evaluation

Physics
- Performs "Onscreen" evaluation
- Prints the pre plan
- Attaches the printed brachy board page the back of the plan
- Orders the sources
- Informs Brachy RTT staff of ordered sources
- Completes respective sections on the brachy board (Phys Approval and Seeds Ordered)

Dosimetry
- Ensures all paperwork is completed and in the chart
- Reviews that all items in the brachy board are completed with the exception of "Docu Done"
- Completes the "Docu Done" on the brachy board.
- Sends Chart to Brachy RTT staff

POST-IMPLANT

Patients shall have post-implant CT and MR. They must be performed on the same day and under similar patient setup conditions.

Post-implant brachy charts shall be placed on the prostate brachy cart in the physician's workroom near the treatment rooms 6 and 7.

Simulator Staff

Transfers all images to the Variseed laptop.

Dosimetry/Imaging Staff

-Imports CT and MR images. Names them Post Op CT and Post Op MR1 and Post Op MR 2.
Selects isotope and identifies seeds on CT

Ensure correct selection when identifying seeds, selecting isotope, number of seeds, and activity per seed. Look at prescription for the final numbers.

Contours the OAR on CT
Completes the appropriate section on the brachy board: "OAR Cntr" and "Seed Ident"
Notifies physician that the plan is ready for contouring.

Physician

Contours the Prostate volumes on CT and MR
Verifies OAR contours on CT
Updates brachy board to indicate that target contours are done. Set the "MD Cntr" to yes.

Dosimetry/Imaging Staff

Fuses the post implant CT and MR- **using the CT and MR prostate contours as guide**
Updates the board: "Fusions" to yes

Physician

Reviews the fusion and contours
Approves the plan by naming it "Final_PostPlan_Initial_Date"
Completes the appropriate section on the brachy board. Set "MD Plan Apprv" to yes.
Informs dosimetry plan is ready for printing.

Dosimetry

Prints the plan
Prints the brachy board page containing the date and time of post plan implant approval and attaches it to the post implant plan
Completes the "Docu Done" on the brachy board.
Notifies physics that plan is ready for final review.

Physics

Reviews the post plan on screen and signs the post plan
Completes the appropriate section on the brachy board- "physics sign"
If there are any issues with the printed post plan, physics will

Modify the brachy board so that "MD Plan Apv" and "Docu Done" are returned to "No" status.
Have dosimetry perform necessary corrections

Dosimetry must re-print plan with corrections and alert physician of necessity to re-review plan and update the board

BACKUPS

There is a specific drive in each of the Variseed computers (laptop and desktop) that points to a network backup drive. Patients must be backed up on these drives for their respective year. Do not delete any files.

Mick Applicator and Cartridge Use Procedure in the Operating Room

NOTE: Each Mick cartridge will have 15 seeds

1) RTT will place all Mick needles in the needle box according to the treatment plan.
2) Under sterile conditions, RTT place all sterile Mick cartridges in the sterile Mick cartridge holders (screw them in). Place this holder next to the needle box.
3) Physician shall pick the cartridges from the cartridge holder and place them on the Mick applicator.
4) Physician and RTT shall keep a count of seeds being deposited in the patient for each used cartridge.
5) Upon completion of use of a cartridge, physician will place the cartridge back on the sterile cartridge holder, screw it in, and pick another cartridge if required.
6) Upon completion of the implant,
    a. All cartridges must be screwed in the cartridge holders by the physician.
    b. RTT will account for all cartridges.
    c. RTT will unscrew each cartridge and visually count the number of remaining sources.
        i. Be carefully when unscrewing the cartridge from the holder based. DO NOT SEPARATE THE METALIC PART FROM THE SEED HOLDER PART
7) RTT will document the number of sources **not implanted** and complete the source accountability form. Make sure that the total number of seeds brought to the O.R. minus the number of sources not implanted agrees with the number of implanted sources.
8) RTT will inspect the Mick applicator to make sure it is empty and survey it.
9) RTT will perform survey of needles, needle box, urine bag, and, without the patient in the room, of other areas. RTT will document results in appropriate survey forms.

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