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Technical White Paper: Guidance for State Programs that Regulate the New Therapy Modality Electronic Brachytherapy

Developed by CRCPD's
H-36 Task Force on Electronic Brachytherapy

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EXECUTIVE SUMMARY

Electronic brachytherapy is a relatively new cancer treatment modality that is used to treat breast, skin, gynecological, and other cancers. By definition, it is the delivery of brachytherapy (radiation directly on or into the target) with electronic systems (rather than a radionuclide). Because electronic brachytherapy systems generate lower energy beams than the commonly used radionuclide brachytherapy sources, it requires much less radiation shielding. Therefore, it can be used in controlled settings, without a specially shielded vault, such as in the office of an authorized user or in an operating room.

There are currently two approved electronic brachytherapy systems, the Zeiss Intrabeam® and the Xoft Axxent®. The Zeiss Intrabeam® system was first approved to treat intracranial lesions in 1999 using the treatment technique Intra-operative Radiation Therapy (IORT). In 2005 the system was approved to treat disease of the whole body, including skin lesions and gynecological applications. Currently, its use in superficial non-cancerous diseases is under investigation. Xoft's Axxent® electronic brachytherapy system has been approved by the FDA for the full range of brachytherapy indications including IORT at various disease sites. Electronic brachytherapy-IORT is a promising method that permits radiation oncologists to deliver radiation to internal sites that have been exposed during surgery with minimal harm to normal adjacent tissues.

Although it is of great interest in the field of radiation oncology, electronic brachytherapy is not widely available. This white paper describes the technical features and radiation safety procedures associated with Xoft Axxent® and Zeiss Intrabeam® Electronic Brachytherapy (the only systems of their type in use today). Regulatory measures associated with registration, operation, and inspection of these therapy systems will be described.

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INTRODUCTION

The main considerations for using the Xoft Axxent® and Zeiss Intrabeam® electronic brachytherapy systems are the low radiation dose to normal tissues near the radiation therapy treatment site and the shielding required for protecting personnel in and around the treatment room. Because of the low-energy x-ray source associated with these systems, their use location is not limited to the shielded therapy suites necessary for linear accelerators and Iridium-192 high-dose rate (HDR) after-loading brachytherapy.

The Xoft system is similar to HDR after-loading brachytherapy, in principle, because the radiation delivery system is high-dose rate and it delivers the source stepwise into one of several types of previously inserted applicators. It is different, however, because the source in its current configuration is larger and less flexible. A major advantage of electronic brachytherapy is that the energy emitted from the source (50 kVp) is relatively low compared to Iridium 192 based HDR brachytherapy, and therefore the radiation shielding requirements for electronic brachytherapy are much less than for HDR sealed source brachytherapy. Disadvantages associated with electronic brachytherapy (not found in HDR sealed source brachytherapy) are heat and electrical injury risks.

It is important to note that although the distribution of radiation within the tissues is affected, the total radiation dose delivered to the tissue is not directly related to the beam energy (or shielding requirements). The dose of radiation to the tumor and normal tissues, and the associated risks and benefits, can be considerable. While this new form of low energy brachytherapy may reduce the radiation shielding requirements associated with the higher energy radiation used in HDR brachytherapy, electronic brachytherapy requires the same level of care and understanding of the principles of radiation therapy as other forms of brachytherapy. The regulator's concerns include: operator and physicist training, physician user qualifications, quality assurance source calibration, source positioning accuracy, treatment planning, shielding requirements, and operating and emergency procedures.

The H-36 Task Force is assigned to develop standards that will ensure safe use of this new modality. The manufacturers Xoft and Zeiss, as well as the American Society for Radiation Oncology (ASTRO), the American College of Radiation Oncology (ACRO), and the American Brachytherapy Society (ABS) have offered guidance regarding the many areas of concern. The American Association of Physicists in Medicine (AAPM) has developed numerous reports covering operational use of similar modalities. These reports can be used to establish a basis for new standards for electronic brachytherapy.

GENERAL OPERATION PRINCIPLES

At the writing of this paper, there are currently two FDA-approved electronic brachytherapy systems marketed in the United States. They both deliver x-ray energies up to 50 kVp. One system is the Axxent® system produced by Xoft Inc. of Fremont, California. It delivers a low energy x-ray at a high-dose rate using a disposable multi-use miniaturized x-ray tube. The system consists of a control unit, an embedded electrometer, a well chamber, and a miniature x-ray tube housed inside a casing (the source). This source can be positioned in close proximity to the tumor, using one of several applicators.

The other system is the Intrabeam® mobile radiosurgery system produced by Carl Zeiss Surgical Gmbh of Oberkochen, Germany. It delivers a low energy photon beam to the tumor bed from a radiation source generator located in one of the several sized spherical applicators, an electronic magnet controlled support stand, and a control console. The Intrabeam® radiation source is certified for extended (but limited total) use and the applicators are reusable, biocompatible, and radiation resistant.

THE XOFT AXXENT® SYSTEM

The Xoft system is one of two commercially available brachytherapy systems capable of delivering brachytherapy from an electronic source. The Zeiss system will be described subsequently. It is expected that similar low energy electronic brachytherapy technology may be developed by others.

The disposable Xoft source consists of a miniature x-ray tube (2.2 mm diameter) that is housed inside a semi-flexible water cooled probe. The probe is 250 mm in length and 5.4 mm in diameter. Should there be a high voltage failure or break in the cooling system, the treatment program terminates automatically, and the completed treatment data is saved in memory. The manufacturer recommends that no fraction of the treatment plan exceed 10 minutes. A display on the controller shows elapsed time, total planned time, the time remaining at the current dwell position, and a schematic of the source's current position.

A positioning drive called the "controller pull back arm" moves the probe inside one of several available applicators according to a programmed treatment plan. The plan is transferred to the controller using a patient-specific USB flash drive. Once calibration is completed, the flash drive is inserted and the calibration information is saved and the treatment plan updates accordingly. As measured in water at 3 cm, the 15 watt source has a maximum energy of 50 kVp, which is similar in energy to the radionuclide I-125 that is used in therapeutic seed implants (28 kV functional and 35 kV maximum).

The radiation source is calibrated in accordance with a protocol developed at the University of Wisconsin-Madison Medical Radiation Research Center. It compares the

response generated by the active Xoft source to that of an I-125 seed standard. The calculations developed yield air kerma rates that were verified using an Attix free-air ionization chamber to the well chamber response from the same source. Each source is calibrated prior to patient use, resulting in at least one calibration per day for each patient that is treated.

This new technology was originally developed for breast brachytherapy with a balloon type applicator. The indications have since been expanded, through approval by Food and Drug Administration, for use in other sites and for other indications. For example, there are conical applicators for skin or external surface lesions (including head, neck, and extremities), cylindrical applicators for vaginal or rectal treatments, and multi-channel applicators for treating larger or more complex sites.

Correct positioning of the applicator is verified and dose calculations are performed according to standard practices in brachytherapy (imaging and computer treatment planning as needed). The radiation source dwell time and positioning are programmed so that the source moves back along the applicator in millimeter steps after coming in contact with the furthest point inside the applicator. For proper operation, the source assembly should be maintained as straight as possible, and should not be expected to negotiate curves that exceed 15 degrees.

THE ZEISS INTRABEAM® SYSTEM

The Zeiss electronic brachytherapy system is similar to the Xoft in that it uses a low energy x-ray system. It has been used most often in the application of radiation directly to the tumor bed exposed surgically in the operating room (intra-operative radiation therapy [IORT]).

The system is described by the manufacturer as a mobile Photon Radio Surgery System (PRS), not to be confused with a stereotactic radio surgery system that uses a highly precise beam of photon or proton radiation to treat a tumor or abnormality of the brain, and most recently, other parts of the body like the lung or the liver. The radiation source in a stereotactic radio surgery system is typically a gamma-knife, linear accelerator (linac), or cyclotron. Whereas, the PRS system produces an electron beam in the main housing unit that is accelerated before entering a drift tube where the beam is directed to the x-ray target located at the end (tip) of the drift tube. A point source of low energy x-rays of 50 kVp is created around the tip of the 3.2 mm diameter drift tube. The system has a variety of spherical applicators of varying size that are cleaned and sterilized for reuse. The remainder of the system is wrapped in a sterile clear plastic cover during treatments. Attenuation scatter and depth of application are taken into account by the Applicator Transfer Function (ATF). There is an optical interlock system that detects the applicator being used and indicates proper positioning. After insertion, the applicator and tumor bed target are made to conform and they are stabilized with sutures. The positioning of the applicator may be verified using ultrasound. The distance between the applicator surface and skin should be monitored as the skin dose can be significant at distances of less than 1 centimeter.

Typically the radiation oncologist and physicist simultaneously supervise patient care. All personnel in the room with the patient during the treatment are occupationally exposed to radiation and are provided personal dosimetry. Radiation shielding should be used as needed, depending on exposure levels and optimum application of radiation safety principles.

Pre-treatment calibration verification is performed 24 hours before patient treatment. Multiple patients may be treated on the same day following verification. Dose rate is affected by the diameter of the applicator used, the beam energy, and current level. Minimum calibration standards are addressed in the registration section of this paper. Other concerns include sterilization of applicators, the balancing of the stand, and factors that directly affect the system's calibration, the x-ray source, the two ion chambers, and the x-ray alignment tool.

COMPARE AND CONTRAST THE TWO TECHNOLOGIES

XOFT

- X-ray source inside of body
- Tungsten target, resulting in a different spectrum and depth dose curve compared to the gold target used by Zeiss
- High voltage and water together inside of body
- Calibration required before each treatment
- CT images may be required for treatment planning, depending upon the site and type of implant
- Dose fall-off is greater than photon radionuclides, but less than beta emitters
- Power to source is 15 watts, average spectrum energy 24.5 - 26.7 at 50 kV operation and a maximum current of 300 μA

ZEISS

- X-ray source outside of body
- Dose is monitored online with the Internal Radiation Monitor (IRM)
- High voltage is outside of body
- As with the Xoft, calibration required before each treatment; however the same calibration can be used if two deliveries are scheduled for the same day

- Single dose delivery and single source position
- Planning does not require imaging, but imaging may be useful for certain applications
- Dose fall-off is greater than photon radionuclides, but less than beta emitters
- Fixed dose rate, either quasi-spherical dose distribution or isotropic dose distribution that is dependent on the diameter of the applicator
- Stand positioning and balance are essential
- Gold target, 50 kV peak, maximum current is 40 μA

SHIELDING AND DESIGN CRITERIA

Even though the Xoft and Zeiss systems are in many ways like high-dose rate (HDR) brachytherapy, the low energy of these electronically generated sources have some logistic advantages. Most notably they do not require a special shielded vault. Xoft provides the Axxent Flexi-shield, a small flexible 0.4 mm lead equivalent shielding drape to place over the treatment area. ASTRO lists a typical 15 mR/hr reading at the controller where the operator is positioned. The controller is the mobile housing that delivers power to the electronic brachytherapy source and controls the source movement. It is usually positioned a short distance from the patient during treatment. The value provided by the manufacturer is somewhat higher, 10-50 mR/hr in the operator's position at the controller. A lone operator in the room can be adequately protected with a six foot tall portable shield. Additionally, as with HDR brachytherapy, the operator of an electronic brachytherapy system is able to interrupt the treatment any time the patient needs immediate care.

Facility design criteria provided by Xoft lists the output from a bare source at 6000 mR/hr at one meter. The typical source inside a balloon applicator, inserted in a patient, and shielded with the manufacturer-provided Axxent Flexishield, will generate an exposure rate of approximately 70 mR/hr at one meter. The maximum recommended treatment time per fraction is 10 minutes.

Linear attenuation (μ):	(50kVp source)	gypsum (wall board)	μ = 1.64/cm
		Lead	μ = 14.5/cm
Tenth Value Layer (TVL)	Same	wall board	TVL = 1.40 cm
		Lead	TVL = 1.59 mm

A small mobile shield may be used between the patient and the operator to assist in reducing radiation exposure in keeping with ALARA (keeping dose as low as reasonably achievable). If possible, all other personnel should be stationed outside the room.

The Zeiss applicator is typically inserted into the patient in the operating room and does not require any additional room shielding. However, the use of portable shields should be a part of the radiation safety program to maintain dose to personnel ALARA when attending to the patient in the operating room during treatments. ASTRO reports the typical exposure reading two meters from the patient treatment site at 12-15 mR/hour. Use of mobile shield panels or leaded aprons will keep the occupational doses ALARA. Should personnel in the operating room need to move around or assist the patient, the therapy system can be paused or turned off, providing added radiation protection when use of shields is not feasible.

RADIATION SOURCE REGISTRATION

This section will address electronic brachyrtherapy registration concerns; it is followed by sections focusing on inspection and regulatory guidance. Electronic brachytherapy systems are x-ray machines and must be registered by a state regulatory agency because the federal government does not have a regulatory department that has the responsibility to oversee their use. Florida (Florida electronic brachytherapy rules) and Wisconsin have a registration and inspection program with associated regulations to ensure proper use of this new technology. New Jersey as well as several other states issue exemptions with conditions regarding the use of this modality.

The low energy of the x-rays eliminates the need for extensive shielding and could lead the casual observer to wrongly assume that regulatory oversight should be minimized. This modality is therapeutic in nature and has the potential benefit but also carries risk for both patient and operator injury. Despite the low energy, the doses are actually quite high compared to diagnostic x-rays with similar energies. Administration must be monitored to ensure proper application to the patient receiving the radiation treatment, and to ensure personnel working with the system and patient are not needlessly or inappropriately exposed to radiation.

Registration is initiated in the same manner as other x-ray producing systems, with the exception that the serial number of the system housing (controller) and each tube or radiation source must be registered as they are implemented. Simply stated, the registrant registers the serial number on the system housing (controller) and maintains a record of each tube serial number used for patient treatment. Administratively, there should be a radiation safety officer (RSO) to oversee the radiation safety program; a qualified medical physicist (QMP) to ensure proper calibration, machine maintenance, and treatment planning; and a radiation safety committee (RSC) if the program is to conduct procedures involving human research subjects. States that utilize the authorized user (AU) concept should expand their scope to include education and training for electronic brachytherapy.

Additionally, information should be gathered from the applicant, in the same way a particle accelerator is registered or HDR sealed source brachytherapy is licensed. The reviewer must ensure qualification and training of the AU, QMP, dosimetrist, and

operator meet established minimum standards and the location of use meets established minimum standards for protecting the patient and public from unnecessary radiation exposure. Because of similar application and potential hazards, the AU should have training and experience equivalent (and transferable) to those required for HDR radionuclide brachytherapy by the Nuclear Regulatory Commission in 10CFR 35.690, and the QMP should have training and experience equivalent to Part X of the CRCPD Suggested State Regulations for Control of Radiation. The candidate should initially be trained by the manufacturer in the operational characteristics of the electronic brachytherapy system. The QMP should have additional training regarding the system's maintenance and calibration.

The reviewer should ensure the operator is a certified therapeutic radiologic technologist that has specific training by an electronic brachytherapy system manufacturer representative. During inspection it should be obvious that the operator is familiar with the applicant's operating and emergency procedures and is aware of the location of the emergency procedures during patient treatments. Not every state requires certification of dosimetrists. It is recommended the dosimetrist be certified by a nationally recognized certifying body.

Quality assurance must be described in detail, either in the state regulations or in the applicant's registration commitments, just as it is for HDR afterloading systems. A quality assurance program should include: radiation source calibration, output checks, source positioning, inspection of all cables and treatment components, timer accuracy and linearity. The applicant's QMP should describe the frequency of the quality assurance checks and the expected operational criteria. The applicant should be required to keep records of all quality assurance testing performed to verify proper function. Also, a quality assurance check should be considered for the treatment planning system that is employed in preparation for delivery of the prescribed radiation therapy doses to the patient.

As stated earlier, this review of an electronic brachytherapy registration application will require a more in-depth review than is typically required of a diagnostic x-ray application. Most registrations will require individual conditions of use based on the applicant's facilities, equipment, and personnel.

The reviewer should ensure the applicant has a radiation safety program that includes a survey meter (calibrated and designed to measure a 50 kVp x-ray beam) to monitor exposure associated with the electronic brachytherapy system operation to prevent unnecessary or unplanned radiation dose to patients and staff. A written directive prescribing the radiation dose should be prepared by the AU. Medical event criteria must be defined by the state. **If a state radiation control program has not developed a definition for a "medical event" resulting from improper use of a therapy machine, the program should develop a definition that includes, at a minimum, the suggested patient and organ dose levels listed in Section G.119(a) of the CRCPD Suggested State Regulations, with a medical event reporting requirement in the electronic brachytherapy registration.** If a medical event should occur, the applicant should have emergency procedures that include notification of the state agency responsible for the electronic brachytherapy system's registration.

The electrical hazard, unique to electronic brachytherapy, and created by the proximity of the patient to the electronic radiation source, requires regulatory attention. The applicant should develop and follow emergency procedures to manage and report medical events associated with heat or electrical injury.

The applicant should submit shielding plans, if applicable, with diagrams of the intended location(s) where the electronic brachytherapy system will be used for therapy. Construction materials and distances to uncontrolled areas should be listed along with expected workload. If the electronic brachytherapy unit is used in an existing therapy room, the applicant must make a commitment that no other function will be performed while the electronic brachytherapy unit is in operation, and that the room radiation safety systems are fully functional during electronic brachytherapy. Because the system is mobile, each location of use must be described in the applicant's registration prior to using the electronic brachytherapy system at that location. Exposure rate surveys, ensuring that public dose limits are maintained, must be performed for each location of use. The drape shield provided by the manufacturer and other portable shielding should be described, if they are used for protection of personnel located in or adjacent to the room during operation of the electronic brachytherapy system. Other multiple use location considerations are addressed in the specific points flagged below.

In conjunction with the application, the regulatory agency may want to perform a pre-registration inspection.

At a minimum, the reviewer should ensure the submitted operating and emergency procedures:

- Describe how individuals in the room during a treatment will be monitored to ensure their exposure to radiation is minimized;

- Include a commitment that the therapy system will not be used for treatments until an initial protection survey of the facility has been performed and subsequent surveys are performed following any change in the facility and system configuration;

- Include a commitment that the system will not be used if unacceptable radiation levels are noted during the protection survey;

- Include a commitment that the system will be secured from unauthorized use when not attended by the AU;

- Describe how room traffic will be controlled to prevent unnecessary radiation exposure to medical personnel;

- Include a commitment that restraints and supports will be used, if necessary, to keep personnel from having to hold patients during treatments;

- Describe procedures for the kinds of equipment failures that could occur during a treatment; the names and contact information for the QMP and RSO who will be contacted should an emergency occur; and a commitment that the operating and emergency procedures will be available in the treatment room;

- Include a commitment to notify the RSO, AU, manufacturer, and appropriate regulatory agency should a patient expire during a treatment, and notify the regulatory agency if the patient is exposed to radiation not meeting the prescribed treatment.

The applicant's described quality assurance program should include the following:

- The output calibrations will be performed by a QMP, in accordance with a nationally recognized professional association, or if not available, in accordance with manufacturer recommendations;

- The calibration procedure will include: output within a standard accepted by the industry, timer accuracy and linearity over the range of use, proper operation of the back-up exposure control system, dose distribution around the radiation source is within 5% of expected value, and source positioning within the applicator is within 1mm of expected;

- A commitment to record the above tests and to maintain the records in an auditable form, containing, at a minimum, the manufacturer's name, model number, and serial number of the electronic brachytherapy system and unique identifier for the tube that was calibrated; the model and serial number of the instrument used for the system calibration; and the name of the QMP responsible for the calibration;

- A commitment to validate output within 3% of the expected values, consistency of dose distribution within 3% of the value determined at calibration, and that the dose applied to the treatment area has a positional accuracy to within 2 mm, using imaging to determine the level of accuracy; (AAPM Task Group TG-56's report describes orthogonal films as providing the greatest accuracy);

  Note: 3% may not be achievable due to tube current drift issues. The AAPM will soon release a technical paper addressing this issue.

- A commitment that the dosimetry system used in the quality assurance testing will be inter-compared within 12 months with another system that has been calibrated using accepted methods;

- A commitment to notifying the QMP and AU if any parameter in the quality assurance testing is not met, and that the QMP reviews and signs each result within 30 days;

- A commitment to check the operation of the radiation exposure indicator lights; viewing and intercom systems, if applicable; operation of radiation monitors; integrity of cables, catheters, or parts that may carry high voltage; and defects

of connecting guide tubes, transfer tubes, transfer applicator interfaces, and treatment spacers;

- A commitment to turn the system off if the results of the safety device quality assurance checks indicate a malfunction of any part of the electronic brachytherapy system;

- A commitment to maintain records of quality assurance testing, calibration, and output testing in an auditable form for inspection by regulatory personnel;

- A commitment to perform and record acceptance testing of the treatment planning system. Varian and Nucletron treatment planning systems have been validated for the Xoft system (see note below). The planning system of choice must be AAPM Task Group TG-43 compliant (a description of AAPM Task Groups is on page 10). In addition to acceptance testing, the treatment plans should be checked for correct indicator positioning, as compared to applicator positioning, and the parameters of the treatment plan should be checked by a physicist using an independent means prior to each treatment regimen. The records should be in an auditable form and available for regulatory review;

- A description of where the system will be used should be provided. Because the system is portable, a memorandum of understanding addressing radiation safety may be necessary if the system is used at sites that are not under the control of the applicant. Additionally, the applicant should be required to address any concerns for the system's operation that may be compromised by damage caused during transport. The manufacturer may have a minimum quality assurance standard that will apply to systems that are routinely transported.

It must be understood that the items listed above may not be applicable to the Zeiss electronic brachytherapy system.

The following listed items apply only to the Zeiss system. As with the Xoft system, calibration procedures are addressed in the operator's manual. The applicant's calibration procedures should contain a commitment to using the operator's manual procedures and address, at a minimum, the following items (a similar list for the Xoft system was not available in the materials researched for this paper):

1. XRS probe straightening, verification and correction of the needle alignment.

2. Measurements with the Internal Radiation Monitor (IRM) of the count rate.

3. Comparison of the facility ion chamber current (corrected for pressure and temperature) to the factory ion chamber measurement. The comparison provides the ion chamber ratio.

4. Measurement of the dose rate with a secondary dose monitor.

5. Determination of the system output in standby mode and then turned off.

6. Procedures that stress the importance of not bumping or jarring the equipment. In the event that the system is jarred, needle alignment may be altered and the above tests should be repeated.

7. For dose planning purposes, the patient dose plan should include internal radiation monitor count rate, ion chamber current, and secondary ion chamber dose rate.

8. A commitment to verify and document the performance of each x-ray source before each treatment. The time required for this verification should be recorded with the test results.

A commitment to follow the AAPM recommendations in Appendix 1 of *Intraoperative radiation therapy using mobile electron linear accelerators: Report of the AAPM Radiation Therapy Committee Task Group 72*.

Note: Both Varian's BrachyVision and Nucletron's Plato treatment planning systems have been validated for the Xoft electronic brachytherapy system. The new Plato systems are no longer available because one of the parts venders can no longer provide parts. With that said, the company will continue to support the existing customers until further notice. The Oncentra Treatment Planning System that will soon be released by Nucletron will not be compatible with the Xoft system. The release of the new Oncentra treatment planning system coincides with the release of Nucletron's own electronic brachytherapy system.

INSPECTION PROCEDURES

The inspection process associated with an x-ray tube is normally conducted in accordance with regulatory standards in effect in the jurisdiction where the inspection is conducted. Due to the complex preparation associated with therapy systems and the potential for significantly large radiation exposure to patients and personnel, the inspection should address the commitments in the application in addition to the regulations. The application gives the regulatory agency an indicator of the applicant's readiness, capabilities, and knowledge. It provides details of all the commitments made during the registration process and, as stated earlier, should contain a diagram and description of all locations of use for the electronic brachytherapy system.

The inspection process associated with an electronic brachytherapy system is composed of two different activities. The first activity is the inspection of the facility and interview of the personnel responsible for its safe use. The inspector should perform radiation surveys in and around the suite while the system is in use, and compare survey results to the survey findings submitted by the applicant with the application for registration. Ideally, these surveys are performed with the tube fully energized and using a phantom, or performed during a patient treatment. **As part of the inspection, the inspector should check to see that the safety system procedures for protection against radiation and electrical hazards are checked by**

qualified personnel and that the procedures are consistent with application commitments. The interviews are used to gain a better understanding of day-to-day activities and which of those activities impact radiation safety and regulatory requirements.

The second activity includes a review of the radiation safety records maintained by the registrant, including but not limited to: the calibration of the many x-ray tubes used by the registrant, output checks, source position verification, other required pretreatment checks, and annual and initial training records. Measures employed to ensure the therapy dose prescribed by the AU is administered to the patient should be reviewed. Other records reviewed as part of the administrative activities include postings, personnel monitoring, written directives, and the registrant's associated review process (annual audit). The inspector should identify the RSO's efforts to incorporate recommendations from the annual radiation safety review. The RSO should recognize discrepancies and effect refinement that will keep the radiation safety program in compliance with the regulatory agency's inspections that are completed according to each state's inspection schedule.

As stated earlier, there are a number of the hazards associated with the electronic brachytherapy system's operation that should be evaluated prior to its first patient use. The following is a list of suggested areas to review during the initial inspection process that can be abbreviated, or expanded, as necessary for the initial inspection and any subsequent inspections.

Site Inspection Activities:

- Verify manufacturer name, model, and serial number of system and x-ray tubes in use;

- Verify the presence of protective shielding for persons working in the patient room while the tube is energized;

- Verify the presence of and operation of the following control panel systems: electrification of panel and tube, the x-ray tube is energized, x-ray tube potential and current, a means to terminate the exposure at any time, and a means to prevent unauthorized access;

- Verify the presence of a timer at the control panel and that the timer: will not permit the tube to be energized if set to zero; is a cumulative device that is activated when the system is turned on, will retain its reading if the treatment is interrupted, and must be reset before irradiation can continue. Verify that, upon reaching the end of elapsed time, irradiation will discontinue, and that the timer permits exposure times down to 0.1 seconds and is accurate to 1% of the selected time or 0.1 seconds, whichever is greater;

- Determine through interview and observation the activities of the QMP during the electronic brachytherapy treatment process. Is the QMP present during the initial fraction of the treatment, and is the QMP or the AU present for the

remainder of the fractions? If the AU is not present, the AU should be available to respond to clinical emergencies;

- Verify operating and emergency procedures are available in the treatment room;
- Verify the operation of radiation exposure lights, viewing and intercom systems, radiation monitors, if these systems are being used as safeguards during treatments, the integrity of cables, catheters and other equipment that carry high voltage, and evaluate the system for defects of connecting guide tubes, transfer tubes, transfer tube applicator interfaces, and treatment spacers.

Site Record Review:

- Proof that the AU, QMP, dosimetrist, and operating technologist have received manufacturer specific training;
- The electronic brachytherapy system has passed its acceptance testing;
- Facility radiation safety survey;
- X-ray tube calibration records;
- The daily quality assurance has been performed and it demonstrates the system is safe to use;
- RSO program review files, and radiation safety committee minutes, if applicable;
- Survey instrument and dosimetry system calibration records;
- Patient files documenting the QMP's review of each treatment plan prior to initiating the initial treatment of a patient;
- Records of the safety system checks the QMP established;
- Emergency procedures specify how the QMP can be contacted if not immediately available and describes the actions to take until the QMP is contacted;
- Records of periodic checks of radiation exposure lights, viewing and intercom systems, radiation monitors, if these systems are being used as safeguards during treatments,
- Records of integrity checks of cables, catheters and other equipment that carry high voltage, and defects of connecting guide tubes, transfer tubes, transfer tube applicator interfaces, and treatment spacers;
- Records of a written directive in all patient files reviewed. Determine when and how the registrant is checking for adequate treatment directives. Look for the

registrant records documenting chart checks. How soon after initiation of the treatment plan is the patient chart reviewed?

REGULATORY GUIDANCE

Electronic brachytherapy systems are not regulated by the Nuclear Regulatory Commission, nor specifically regulated by any state public health department. The following is a list of regulatory guidance that should be considered when developing state regulations and guidance for registration and inspection of an electronic brachytherapy system.

1. Facility design criteria in the International Electrotechnical Commission standards for medical electrical equipment that are referenced in the AAPM regulatory guidance listed below.

2. CRCPD Suggested State Regulations, Part G. Use of Radionuclides in the Healing Arts, March 2003; and Part X, Therapeutic Radiation Machines, March 2009.

3. Electronic Brachytherapy Report prepared by the Emerging Technology Committee of the American Society for Radiation Oncology, May 23, 2009.

4. The AAPM response to the 2007 CRCPD request for recommendations for model regulations for electronic brachytherapy, January 2009.

5. Physician (AU) training standards in 10 CFR 35.690, January 2010; and physicist (QMP) training standards in Part X, referenced above.

6. Manufacturing requirements in Code of Federal Regulations, 21, Parts 500-898, April 2010.

    - 21 CFR 801 addresses labeling;
    - 21 CFR 807 addresses registration and listing;
    - 21 CFR 820 addresses good practices in quality assurance; and
    - 21 CFR 1000-1050 Sections 531-542, addresses electronic product radiation control.
    - Manufacturer submitted FDA Form 510(k).

7. Part XVI Electronic Brachytherapy, Florida Administrative Code, March 2009.

8. Expanded approval status of the Xoft electronic brachytherapy system, web announcement that the FDA approved the Xoft system on March 4, 2009, for surface brachytherapy and IORT.

9. AAPM Task Group Reports:

- *Dosimetry of interstitial brachytherapy sources: Recommendations of the AAPM Radiation Therapy Committee Task Group No. 43* addresses tests for well counter constancy, beam stability, source positional accuracy, output stability, timer linearity, dummy marker/source position coincidence, controller functionality and safety interlocks and treatment planning data verification;

- *Code of practice for brachytherapy physics: Report of the AAPM Radiation Therapy Committee Task Group No. 56* addresses brachytherapy code of practice;

- *High dose-rate brachytherapy treatment delivery: Report of the AAPM Radiation Therapy Committee Task Group No. 59* addresses high-dose rate delivery system concerns, including training, and responsibility of staff and development of written procedures;

- *AAPM protocol for 40-300 kV x-ray beam dosimetry in radiotherapy and radiobiology, a Report of the AAPM Radiation Therapy Committee Task Group No. 61* provides a protocol for kV radiation beams; and

- *Intraoperative radiation therapy using mobile electron linear accelerators: Report of the AAPM Radiation Therapy Committee Task Group No. 72* addresses installations of mobile linacs**,** Appendix 1.

10. Xoft documents:

- Proposed quality assurance checklist; and

- Xoft Axxcent Operator's Manual - Model 110.

APPENDIX. DEFINITIONS

AAPM - American Association of Physicists in Medicine.

ACRO - American College of Radiation Oncology.

ABS - American Brachytherapy Society.

ALARA - As low as reasonably achievable.

ASTRO - American Society for Radiation Oncology.

ATF - Applicator Transfer Function is defined as the ratio between the dose rate in water in the presence and in the absence of the applicator as a function of the distance from the target of interest.

AU - Authorized User (see definition below)

Authorized User - A physician who meets the training and experience requirements listed in 10 CFR 35.690, January 2009.

Electronic brachytherapy - A method of radiation therapy using an electrically generated source of ionizing radiation to deliver a radiation dose at a distance of up to a few centimeters by intracavitary, intraluminal or interstitial application, or by applications with the source in contact with the body surface or very close to the body surface.

IC Ratio - Ion Chamber ratio.

HDR - High-Dose Rate, used in conjunction with sealed source brachytherapy.

IORT - Intra-Operative Radiation Therapy.

IRM - Internal Radiation Monitor.

NRC - Nuclear Regulatory Commission.

Obturator - A disk or plate that closes an opening.

PRS - Photon Radiosurgery System.

QMP - Qualified Medical Physicist (see definition below)

Qualified Medical Physicist - An individual who meets the training and experience requirements listed in Section X.3.d. of Part X, "Medical Therapy," CRCPD Suggested State Regulations, March 2009.

RSC - Radiation Safety Committee.

RSO - Radiation Safety Officer.

XRS - X-Ray Source.