



INSPECTION PROTOCOL FOR MEDICAL LINEAR ACCELERATORS

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Prepared by
**CRCPD's H-40 Task Force on the Inspection Protocol
For Radiation Machine Based Therapy Treatments**

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FOREWORD

The Conference of Radiation Control Program Directors, Inc. (CRCPD) is an organization made up of the radiation control programs in each of the 50 states, the District of Columbia, and Puerto Rico, and of individuals, regardless of employer affiliation, with an interest in radiation protection. The primary purpose and goal of CRCPD is to assist its members in their efforts to protect the public, radiation worker, and patient from unnecessary radiation exposure. CRCPD also provides a forum for centralized communication on radiation protection matters between the states and the federal government, and between the individual states.

One method of providing assistance to the states, as well as to other interested parties, is through technical and administrative publications. Most technical publications of CRCPD are written by various committees, task forces or special working groups. Most administrative publications are written by staff of the Office of Executive Director (OED).

CRCPD's mission is "to promote consistency in addressing and resolving radiation protection issues, to encourage high standards of quality in radiation protection programs, and to provide leadership in radiation safety and education."

This particular publication, *Inspection Protocol for Medical Linear Accelerators*, contains inspection protocols developed by CRCPD's H-40 Task Force on the Inspection Protocol for Radiation Machine Based Therapy Treatments. This document is intended to provide guidance for state inspectors who conduct inspections of medical facilities that utilize one or more megavoltage therapeutic radiation machines which are subject to Part X of the *Suggested State Regulations for the Control of Radiation* (SSRCR). However, the varied complexity, configurations and functionality of these megavoltage therapeutic radiation machines makes it very difficult to develop a "one size fits all" inspection guidance document. Consequently, this document will focus primarily on common inspection elements and will not fully address some of the unique issues associated with specialized equipment such as CyberKnife and Tomotherapy units. However, Appendix A does include reference material which may be used by states that need to develop their own inspection protocols for these categories of therapeutic radiation machines.

CRCPD's H-40 Task Force is also aware that the prior training and experience of state inspectors conducting these inspections varies from state to state. Therefore, in addition to serving as a field manual for actually conducting inspections, this guidance document is also intended to be used as a training document for new inspectors who have a minimum familiarity with therapeutic radiation machines.


Bill Dundulis, Chairperson
Conference of Radiation Control
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Section 1.0 INSPECTION OBJECTIVES

- 1.1 The inspector should independently verify that the registrant has established a safety culture. This should be accomplished through direct observations of registrant² activities, discussions with cognizant registrant representatives, and if necessary, a review of selected records that the registrant's activities are being conducted in a manner that will protect the health and safety of workers, the general public and patients.
- 1.2 The inspector should conduct the inspection in a manner that will allow him/her to develop conclusions about the registrant's performance relative to the following objectives:
 - (a) The registrant has controlled access to therapeutic radiation machines so as to limit radiation exposure to workers and members of the public to values below Agency regulatory limits.
 - (b) The registrant has maintained shielding of therapeutic radiation machines, including any updates and modifications, in a manner consistent with operating procedures and design and performance criteria for devices and equipment, as submitted to state agency for review.
 - (c) The registrant's safety culture is patient-centered and includes implementation of comprehensive safety and quality control measures to ensure that only the prescribed radiation dose for a patient is delivered appropriately to that patient.
 - (d) The registrant has implemented a radiation dosimetry program to accurately measure and record radiation doses received by workers or members of the public as a result of the registrant's use of therapeutic radiation machines.
 - (e) The registrant has appropriate radiation instrumentation to perform both surveys and calibration of their therapeutic radiation machines.
 - (f) The registrant has implemented a training program to ensure that workers are knowledgeable of radiation uses and safety practices; skilled in radiation safety practices under routine and non-routine conditions; and empowered to implement the radiation safety program.
 - (g) The registrant has established a safety culture which is appropriate for the scope of use; mandates that As Low As Reasonably Achievable (ALARA) practices are implemented; requires assessments of past performance, present conditions and future needs; and ensures that appropriate action is taken when needed.
 - (h) If applicable, the registrant has implemented a program for review of all therapeutic radiation machine-related activities performed by contracted personnel.
 - (i) The registrant has implemented a QA program for checks and tolerances of all modalities for the therapeutic radiation machine with daily, monthly, and annual records.

² The term "registrant" will be used throughout this document. This term should be changed to "licensee" in states that license therapeutic radiation machines.

Section 2.0 PRE-INSPECTION ACTIVITIES

- 2.1 **File Review-Routine Inspection.** Prior to a routine inspection, the inspector should review the registrant's file. The effort expended on inspection preparation should be based upon the complexity and scope of the registrant's activities and on the experience level of the individual inspector. As a minimum, an inspector shall review:
- (a) The certificate(s)³ of registration to determine if any unusual conditions or restrictions have been imposed by the Agency.
 - (b) All reports or documents submitted by the registrant since the last inspection to include:
 - (1) All shielding evaluation(s) conducted by Agency staff for therapeutic radiation machine(s) installed (or scheduled to be installed) since the last inspection, as well as any related documentation submitted by the registrant.
 - (2) The registrant's recent inspection and enforcement history (e.g., results of the last inspection and any unresolved/open items).
 - (3) All complaints and/or allegations pertaining to the registrant's facility submitted since the last inspection, including any resolution of these complaints and/or allegations.
 - (4) All reports of misadministration(s)⁴ or other event(s) submitted by the registrant since the last inspection.
 - (5) If the registrant has a Radiation Safety Committee (RSC), copies of all RSC minutes.
 - (6) Any commitments made by the registrant or restrictions imposed by the Agency as a result of a Confirmatory Action Letter or other enforcement action issued since the last inspection.
 - (c) Consultation with the Radiation Control Program Supervisor to determine if there are any special issues to be reviewed during the inspection.
- 2.2 **File Review-Reactive Inspection.** A reactive inspection is usually performed in response to an incident, allegation or information obtained by the Agency (e.g., misadministration report). A reactive inspection will usually focus on one or several issues, and may or may not examine the rest of a registrant's program. Therefore, a file review should be limited to those items that will be examined during the inspection.
- 2.3 **Schedule Inspection.** Routine inspections may be scheduled with the appropriate facility representative no more than two (2) weeks⁵ prior to the actual inspection date. This should ensure that the necessary medical physics staff, equipment and documents will be available. The time required to conduct an inspection at a therapeutic radiation machine facility will vary with both the complexity of the facility and the experience of the inspector. However, a minimum of four (4) hours should be anticipated. Reactive inspections may be scheduled or unannounced, depending on

³ The mechanism for registration of a therapeutic radiation machine may vary from state to state. Some states may issue a single registration to cover all units at a given facility (including simulators and "on-board" localizers) and provide a total tube count. Other states may require a separate registration for each therapeutic radiation machine at a facility. The file review should include all therapeutic radiation machines that will be inspected during the site visit.

⁴ The term "misadministration" will be used throughout this document. This term should be changed to "medical event" in states which have adopted the NRC terminology for these events.

⁵ The actual advance notice (or lack of notice) given before an inspection will vary depending on the specific state's policy.

the issue(s) that triggered the inspection. Consult with the Radiation Control Program Supervisor before contacting the registrant about a pending reactive inspection.

2.4 **Notice of Inspection.** A Notice of Inspection, if allowed by state policy, should be issued to confirm the date, time and materials that will be reviewed during the routine inspection. As a minimum, a Notice of Inspection should request the registrant to have the following individuals and records available for the inspection:

(a) **Individuals:**

- An individual qualified to operate each therapeutic radiation machine.
- A Qualified Medical Physicist (QMP)
- The Radiation Safety Officer (RSO).

(b) **Records (since last inspection):**

- A master list of registrant staff involved in prescribing, planning, reviewing or administering radiation therapy doses, including the assigned responsibilities of each individual.
- Records of service repair or upgrade performed on all therapeutic radiation machines.⁶
- QMP's full calibration report(s), including commissioning and acceptance testing of new or upgraded therapeutic radiation machine(s).
- U.S. National Institute for Standards and Technology/American Association of Physicists in Medicine (AAPM) Accredited Dosimetry Calibration Laboratory (NIST/ADCL) calibration report(s) for all chamber(s), electrometer(s), etc. used for full calibration and acceptance testing.
- Copies of all correspondence to/from the Agency regarding registrant's operations, including any required reports (e.g., an overexposure or misadministration).
- Reports of independent verification used to corroborate calibration, including any registrant response(s) to noted items of concern.
- Appropriate radiation shielding evaluations, radiation protection survey reports and Agency approval letters pertaining to the registrant's facility.
- Reports of periodic quality assurance checks and corresponding written procedures for conducting periodic quality assurance checks.
- All other documents/reports prepared as part of the registrant's overall quality control program.
- Personal dosimetry monitoring reports available for review.
- Documentation of required initial and annual refresher training.
- Any other items the registrant may wish to review with the inspector.

Section 3.0 INSPECTOR RESPONSIBILITIES DURING INSPECTIONS

3.1 A determination regarding safety culture and compliance with Agency requirements should be based on direct observation of work activities; interviews with workers, demonstrations by appropriate workers performing tasks regulated by the Agency, and, where appropriate, a review of selected records.

⁶ If simulators or other equipment are to be included in the inspection, the registrant should also be requested to have maintenance records, calibration records and written logs available for each simulator.

- 3.2 The Agency inspector shall not under any circumstances knowingly allow an unsafe work practice or a violation which could lead to an unsafe situation to continue in his/her presence in order to provide a basis for enforcement action. Unless an inspector needs to intervene to prevent an unsafe situation, direct observation of work activities must be conducted such that the inspector's presence does not interfere with patient care.
- 3.3 Discussion of the inspector's observations and interviews with the workers should not occur during the preparation or delivery of medical treatment.
- 3.4 The inspector should keep the registrant informed of all significant inspection findings throughout the course of the onsite inspection and not wait until the exit meeting to inform the registrant's senior management of these findings.
- 3.5 During the conduct of the inspection, if the inspector identifies equipment or instrumentation that has failed to perform as designed, the inspector should ensure that registrant operations are stopped immediately and that such equipment or instrumentation be appropriately repaired and tested prior to the next treatment.

Section 4.0 SPECIFIC INSPECTION GUIDANCE⁷

- 4.1 **Entrance Meeting**. The inspector must inform the registrant's representative that an inspection is being conducted as soon as possible after arriving on site and indicate the tentative schedule for discussing or reviewing selected inspection items with various registrant personnel.
 - (a) Registrant personnel who will need to be interviewed during the inspection should be identified during this meeting. This should give the registrant the opportunity to have the most knowledgeable individuals present to respond in the areas being inspected.
 - (b) Ask the registrant representative to identify any recent problems related to the program, such as equipment failures and unusual radiological problems (e.g., excessive personnel exposures, quality assurance problems). The representative's responses may help in assessing management's awareness of the radiation protection program.
- 4.2 **Observation of Actual Registrant Facilities and Activities**. The inspector should perform a walk-through of the registrant's facility to make general observations of the condition of the facility and the activities being performed. The walk-through may be performed at any time during the inspection. However, it must not interfere with patient care. The inspector may need to return to some portions of the facility at a later time to observe specific activities.
- 4.3 **Clinical Staff Qualifications**. Determine that all of the registrant's clinical staff involved in prescribing, planning, reviewing, or administering radiation therapy doses has the appropriate training and experience.
 - (a) Each physician meets the requirements for authorized user (AU) established in X.3c.
 - (b) Each QMP meets the requirements of X.3d.⁸

⁷ All regulatory references are to *Suggested State Regulations for the Control of Radiation – Part X: Therapeutic Radiation Machines*, revised March 2009. A state should change each Part X reference to their equivalent regulation.

⁸ Agency staff shall also check CRCPD National QMP registry to determine if individual physicist is listed. State requirements for licensure of medical physicists supersedes X.3d.

- (c) Each individual who will be operating a therapeutic radiation machine for medical use meets the requirements of X.3e.⁹
 - (d) Other clinical staff (e.g., dosimetrists) has received appropriate training for their duties and responsibilities.
 - (e) If applicable, all visiting authorized users have met the requirements of X.3h. and required records have been maintained.
 - (f) The registrant's operating procedures must specifically address how the QMP is to be contacted for problems or emergencies, as well as the specific actions, if any, to be taken until the QMP can be contacted [X.7r.].
- 4.4 **Facility Workload.** Evaluate the registrant's average weekly workload, by therapeutic radiation machine, energy and modality (e.g., IMRT, Arc, SRT, etc.) to determine if it is within the design workload specified in the submitted shielding plan for each therapeutic radiation machine.
- 4.5 **Maintenance Records [X.3j.].** Review all records of service, repair or upgrade performed on the therapeutic radiation machine(s) at the registrant's facility since the last inspection. This review should include maintenance records for all therapeutic radiation machines that are no longer in clinical use, but which were in clinical use at any point since the last inspection.
- (a) Verify that a maintenance log is being maintained for each therapeutic radiation machine. If maintenance logs are maintained electronically and/or at some location not under the department's direct control (e.g., biomedical engineering department), determine that each individual maintenance record is retrievable on a real-time basis.
 - (b) Verify that preventive maintenance is performed in accordance with the registrant's written procedures.
 - (c) Note the date and time of completion for any service, repair or upgrade that could change radiation output for the therapeutic radiation machine. Cross-check with registrant calibration records to ensure that appropriate calibration/quality control check was performed prior to returning the therapeutic radiation machine to clinical use.
 - (d) Verify that each maintenance record has the signature of the person authorizing the return of the therapeutic radiation machine to clinical use after service, repair or upgrade.
- 4.6 **Full Calibrations and Acceptance Testing [X.7t.].** Review all records of acceptance testing (if applicable) and full calibrations performed on the therapeutic radiation machine(s) at the registrant's facility since the last inspection.
- (a) If applicable, verify that acceptance testing and commissioning have been conducted before the first medical use following installation or reinstallation of the therapeutic radiation machine.
 - (b) Verify that a QMP has performed a full calibration of each therapeutic machine, including all applicable parameters for all energies, at intervals not exceeding twelve (12) calendar months.
 - (c) Verify that a QMP has performed all elements of a full calibration necessary to determine that all parameters are within acceptable limits:
 - (1) Whenever a quality assurance check indicates that the radiation output differs by more than five percent (5%) from the value obtained at the last full calibration and the difference cannot be reconciled.

⁹ State requirements for licensure of individuals who will be operating a therapeutic radiation machine for medical use supersedes X.3e.

- (2) Following any component replacement, major repair, or modification of components that could significantly affect the characteristics of the radiation beam.
 - (d) Verify that the full calibration record for each therapeutic radiation machine includes:
 - (1) The manufacturer's name;
 - (2) The machine's model number and serial number;
 - (3) The model and serial number of each instrument used to calibrate the machine;
 - (4) The date of the calibration; and
 - (5) The signature of the QMP responsible for performing the calibration.
- 4.7 **Dosimetry Equipment [X.4c.]**. Verify that the registrant has a calibrated dosimetry system available for use which has been calibrated by NIST/ADCL.
- (a) Verify that the NIST/ADCL calibration of any dosimetry equipment used for a full calibration was performed within the previous twenty-four (24) months and after any servicing that may have affected system calibration.
 - (b) If the registrant utilizes another dosimetry system for a quality assurance check, this dosimetry system shall have been inter-compared with a dosimetry system with NIST/ADCL calibration. If applicable, verify that this dosimetry system has been inter-compared with the NIST/ADCL calibrated dosimetry system within the previous twelve (12) months and after each servicing that may have affected system calibration.
 - (c) Verify that the registrant maintains a record of each dosimetry system calibration and inter-comparison which includes: the date; the model and serial numbers of the instruments that were calibrated, inter-compared; the correction factors that were determined; the names of the individuals who performed the calibration, inter-comparison; and evidence that the inter-comparison was performed by, or under the direct supervision and in the physical presence of, a QMP.
- 4.8 **Misadministration(s) and Other Reportable Events [X.5b.]**. If applicable, review the records of any misadministration(s) or other reportable events that have occurred since the last inspection.
- (a) Review documentation of all misadministrations and other reportable events to ensure that appropriate notifications have been submitted, within the required timeframe, to the Agency, the referring physician and the individual who was the subject of the misadministration.
 - (b) If there are any additional reportable events that have not been submitted to the Agency, verify that there is documentation and, if applicable, determine the reason the report had not been submitted.
 - (c) Verify if any corrective action proposed by the registrant has been implemented and review any relevant documentation.
- 4.9 **Quality Management Program [X.5a.]**. Review the registrant's quality management program to ensure that radiation is being administered as directed by the authorized user(s).
- (a) If applicable, review all independent verification reports and verify actions taken by the registrant for all results outside the range 0.95-1.05 of actual value.
 - (b) Verify that the registrant's procedure for a written directive includes a requirement that it be dated and signed by an authorized user prior to the administration of radiation to the patient. In a

“paperless” facility, verify the security protocols in-place to ensure that an electronic signature (to indicate review/approval) can only be generated by the indicated individual.

- (c) Review the registrant’s procedures for ensuring that each administration of radiation to a patient is in accordance with the written directive. Verify that this procedure includes a requirement for both an independent check of the calculations and proper transfer of this information to the patient’s treatment record.
- (d) Verify that the registrant has conducted patient-specific validation of all treatment plans which utilize (IMRT).
- (e) Verify that the registrant’s procedures include a requirement for validating the operation of any therapeutic radiation machine or treatment planning system following any software modification.

4.10 **Radiation Protection Surveys and Facility Modifications [X.4a. & X.4b.].** Review all required radiation protection surveys conducted since the last inspection.

- (a) Verify that copies of all radiation protection surveys have been submitted to the Agency.
- (b) If a radiation protection survey indicated the need for shielding modification, verify what steps the registrant has taken to address the situation.
- (c) Check if any facility or equipment modifications have been completed since the last inspection.
- (d) If applicable, verify that the registrant has taken appropriate corrective action when a radiation protection survey indicated that radiation levels:
 - (1) In a restricted area are likely to cause personnel exposures in excess of the limits specified in Suggested State Regulations for the Control of Radiation (SSRCR) D.1201a.; or
 - (2) In an unrestricted area exceed the limits specified in SSRCR D.1301a. or D.1301b.

4.11 **Periodic Quality Assurance Checks [X.7u.].** Verify that the registrant’s procedures, as established by the QMP, for conducting periodic quality assurance checks on each therapeutic radiation machine are, as a minimum, in accordance with Agency regulations.

- (a) Verify that all periodic quality assurance checks were performed with a dosimetry system that had been intercompared within the previous twelve (12) months with the dosimetry system used to perform primary calibrations. [Ref. X.4c.]
- (b) Review a representative sample of quality assurance checks for each therapeutic radiation machine.
 - (1) Verify that the checks include determination of central axis radiation output and a representative sampling of periodic quality assurance checks as defined in the registrant’s procedures.
 - (2) Verify if appropriate corrective action was taken for any periodic quality assurance check where it was determined that a parameter was not within its acceptable tolerance,
 - (3) Verify that all quality assurance checks where the parameters appeared to be within their acceptable range were reviewed and signed by either the AU or QMP within three (3) treatment days.
 - (4) Verify that all quality assurance checks were reviewed and signed by a QMP within thirty (30) days.

- (5) Verify that all applicable safety quality assurance checks listed in Agency regulations have been performed at intervals not to exceed one (1) week. Verify that each safety quality assurance check, at a minimum, ensured proper operation of:
 - (i) Electrical interlocks at each external beam radiation therapy room entrance;
 - (ii) The "BEAM-ON", interrupt and termination switches;
 - (iii) "BEAM-ON" indicator lights on the access doors, control console, and in the radiation therapy room;
 - (iv) Viewing systems;
 - (v) Electrically operated treatment room door(s) from inside and outside the treatment room; and
 - (vi) At least one (1) emergency power cutoff switch.¹⁰
- (6) Verify that each record includes: the date of the quality assurance check; the manufacturer's name, model, and serial number of the therapeutic radiation machine; the manufacturer's name, model and serial number for the instrument(s) used to measure the radiation output of the therapeutic radiation machine; and the signature of the individual who performed the periodic quality assurance check.

4.12 **Quality Assurance Checks for IMRT [X.7v.]** Review the registrant's procedures for conducting IMRT quality assurance checks on each therapeutic radiation machine capable of utilizing IMRT modality.

- (a) Verify that routine quality assurance of the delivery system and commissioning and testing (if applicable) of the treatment planning and delivery systems are being performed in accordance with Agency regulations, registrant's procedures, and the manufacturer's contractual specifications.
- (b) Verify that patient-specific validation is being conducted for each treatment plan utilizing IMRT.

4.13 **Occupational Radiation Exposure**. Verify that the registrant has an appropriate program for monitoring occupational radiation exposures. This should include assurance that:

- (a) Appropriate personal dosimetry devices are worn;
- (b) Personal dosimetry devices are processed by a National Voluntary Laboratory Accreditation Program (NVLAP) approved and accredited processor;
- (c) Each worker (for whom monitoring is required) has been advised of their accumulated dose on at least an annual basis;
- (d) All personal dosimetry reports are being reviewed by a QMP or the RSO, and that appropriate follow-up action is taken when any monitored individual appears to have exceeded applicable regulatory limits; and
- (e) Appropriate declared pregnant worker procedures were implemented.

¹⁰ Although current Part X specifies weekly, standard practice is to conduct these tests no more frequently than monthly to minimize possible equipment damage. Registrant should be considered as meeting regulations if testing is done at least quarterly. This discrepancy will be addressed in next update to Part X.

- 4.14 **Training.** Verify that the registrant's personnel involved with utilization of therapeutic radiation machines have received required initial and annual refresher training appropriate to their assigned duties.
- 4.15 **Survey Instruments [X.7.a.].** Verify that the facility has at least one operable and appropriately calibrated portable radiation measurement survey instrument capable of measuring dose rates over the range 10 μ Sv (1 mrem) per hour to 10 mSv (1,000 mrem) per hour.
- 4.16 **Calibration of Survey Instruments [X.8].** Verify that all survey instruments used to demonstrate compliance with Part X have been calibrated in accordance with X.8.
- 4.17 **Patient Chart Review.** Review¹¹ a representative sample of patient charts¹² to verify that the registrant has a quality control program which ensures that radiation is being administered as directed by an AU.
- 4.18 **Independent Verifications.** Verify that each therapeutic radiation machine used by the registrant is adequately maintained in accordance with Agency regulatory requirements. The following parameters should be verified for each therapeutic radiation machine (if applicable):
- (a) Each wedge filter that is removable from the system is clearly marked with an identification number. [X.7d.]
 - (b) Each therapeutic radiation machine has at least two (2) integrating dose meters. [X.7f.i.]
Verify that each beam monitoring system:
 - (1) Is capable of independently monitoring, interrupting, and terminating irradiation; [X.7f.iii.(3)]
 - (2) Has a legible display at the treatment control panel; [X.7f.iii.(5)] and
 - (3) Will be able to retrieve the beam monitoring information displayed at the control panel in at least one (1) system for a twenty (20) minute period of time if there is an interruption of power. [X.7f.iii.(5)(d)]
 - (c) Wedge filter(s) in use are displayed at the treatment control panel. Alternatively, verify that a "wedge fault" is displayed when the wedge selected does not agree with the treatment plan. Verify that irradiation is not possible until wedge selected matches settings at control console [X.7d.iii.(3)&(4)]
 - (d) The DMU rate is displayed at the treatment control panel, and that this monitoring system provides readings by which air kerma rate or absorbed dose rate at a reference point can be calculated. [X.7i.]
 - (e) The beam interrupt switch allows irradiation and equipment movement to be interrupted at any time and then restarted by the operator without any reselection of operating parameters. [X.7l.]

¹¹ Many states have health care confidentiality statutes in addition to the federal requirements. Access to patient records by radiation control programs based in state public health agencies is typically authorized by statutory language regarding "public health inspections". Radiation control programs based in other than public health agencies should consult with their legal counsel regarding access to patient records. Even when access to patient records is authorized, it is limited to only those portions of the record essential to conducting the inspection.

¹² Patient charts should be selected to include all clinically available therapeutic radiation machines over the period since the last inspection. One (1) or two (2) charts should be from patients currently undergoing treatment. Total patient chart reviews should be limited to a maximum of twenty (20) unless the initial sample indicates there may be significant problems with radiation doses being administered to patients.

- (f) The therapeutic radiation machine has a suitable irradiation control device (timer) to terminate the irradiation after a pre-set time interval.
 - (g) Irradiation is not possible until a selection of appropriate filtration has been made at the treatment control panel, either manually or automatically. [X.7d.iii.(1)]
 - (1) Verify that irradiation is not possible if the filter selected is not in the correct position. [X.7d.iii.(2)]
 - (h) Irradiation is not possible until a new selection of a number of dose monitor units (DMU) is made at the treatment control panel, and the pre-selected number of DMU is displayed at the control panel until reset. [X.7h.]
 - (i) Irradiation is not possible until selection of radiation type is made at treatment control panel, and that radiation type selected is displayed at the treatment control panel before and during irradiation.
 - (j) Irradiation is not possible unless selection of energy is made at treatment control panel, and nominal energy value selected is displayed at treatment control panel before and during irradiation.
 - (k) Warning/fault indicators are properly displayed at the control panel, and that irradiation is not possible until all warning/fault indicators are cleared.
- 4.19 **Confirmatory Measurements.** Verify by direct observations and independent measurements that area radiation levels are within Agency regulatory limits.
- (a) Identify survey instrument(s) used to make independent measurements (i.e., manufacturer, model and serial number and date of last calibration).
 - (b) Describe type and results of measurements and determine if these measurements are consistent with measurements obtained by the registrant during their most recent facility radiation survey.
- 4.20 **Registrant Review of All Therapeutic Radiation Machine-related Activities Performed by Contracted Personnel.** If applicable, verify that:
- (a) The registrant is reviewing work completed by contracted personnel who perform therapeutic radiation machine-related activities in the same manner that all other activities conducted under the registration are reviewed; and
 - (b) All parties to contractual arrangements are aware of their respective duties and responsibilities, as well as the reporting and feedback mechanisms implemented to ensure that appropriate actions are taken to address the contractor's findings, particularly, potential regulatory violations.
- 4.21 **Special Registration Conditions.** If applicable, verify the registrant's compliance with any special registration conditions that are unique to a particular practice, procedure, or piece of equipment used by the registrant. The inspector should verify that the registrant understands the additional requirements, and maintains compliance with the special registration conditions.
- 4.22 **Exit Meeting.** At the conclusion of the inspection the inspector should discuss preliminary inspection results with the most senior registrant representative available at the facility.
- (a) The inspector should explain any cited violation of Agency requirements and the inspector's understanding of the registrant's corrective action plan for each violation.

- (b) Although deficiencies identified in some areas are not always violations, the inspector should bring such deficiencies to the attention of the registrant's management at the exit meeting.
- (c) The inspector should inform the registrant that inspection results, including the characterization of proposed enforcement actions, could change based on Agency management review.

Section 5.0 DOCUMENTING INSPECTION RESULTS

- 5.1 The inspector shall complete either an Agency-approved checklist or a narrative inspection record, as directed by Agency management, to document inspection results.
- 5.2 Documentation of inspection results shall include enough detail to make it clear what requirement was violated, how it was violated, who violated the requirement, and when it was violated. If the registrant provides immediate or long term corrective action for the violation, this information should also be included as part of the documentation.
- 5.3 The inspection results shall then be prepared for supervisory review and transmittal to the registrant in accordance with established Agency enforcement protocols.

APPENDIX A – REFERENCES

1. **GENERAL REFERENCES**

"Comprehensive QA for Radiation Oncology, AAPM Report No. 46," prepared by Committee Task Group 40 (1994)¹³. http://www.aapm.org/pubs/reports/RPT_46.PDF

"AAPM Code of Practice for Radiotherapy Accelerators: AAPM Report No. 47", prepared by Radiation Therapy Task Group 45 (1994). http://www.aapm.org/pubs/reports/RPT_47.PDF

"Guidance Document on Delivery, Treatment Planning, and Clinical Implementation of IMRT, AAPM Report No. 82" prepared by the IMRT Subcommittee of the AAPM Radiation Therapy Committee (2003). http://www.aapm.org/pubs/reports/RPT_82.pdf

"Quality Assurance for Computed Tomography Simulators and the Computed Tomography-Simulation Process, AAPM Report No. 83", prepared by the AAPM Radiation Therapy Committee Task Group No. 66 (2003). http://www.aapm.org/pubs/reports/RPT_83.pdf

"Quality Assurance of Medical Accelerators, AAPM Report 142", prepared by AAPM Task Group 142 (2009). http://www.aapm.org/pubs/reports/RPT_142.pdf

2. **CYBERKNIFE REFERENCES**

"Technical White Paper: An Educational Report on CyberKnife[®] Quality Assurance Testing", CRCPD Publication E-07-3 (April 2007). <http://www.crcpd.org/Pubs/CyberknifeWhitePaper.pdf>

"Quality Assurance for Robotic Radiosurgery, AAPM Report 135", prepared by AAPM Task Group 135 (2011). http://www.aapm.org/pubs/reports/RPT_135.pdf; Erratum: http://www.aapm.org/pubs/reports/RPT_135_Errata.pdf

3. **TOMOTHERAPY REFERENCES**

"Technical White Paper: An Educational Report On Helical IMRT", CRCPD Publication E-11-3 (April 2011). http://www.crcpd.org/Pubs/HelicalIMRT_WhitePaper.pdf

"QA for Helical Tomotherapy, AAPM Report 148", prepared by AAPM Task Group 148 (2010). http://www.aapm.org/pubs/reports/RPT_148.pdf

¹³ This report has been partially updated. Recommendations in Table II (linear accelerator QA) are superseded by AAPM Report 142.