Authorization and Inspection of Linear Accelerators Used in Radiotherapy
Day 4

IAEA
International Atomic Energy Agency

Agenda

- Day 4
  - Morning session:
    - Inspection Process
    - Review of Site Visit LINAC Facility:
      - Facility Layout,
      - Operation,
      - Safety Features,
  - Afternoon session - Visit to existing LINAC facility

Inspection Program Development

Inspection Program Development

- Learning Objectives
  - *After this section, the students should understand the components of an inspection program*
  - This section should take 60 minutes

Inspection Program Development

- The achievement and maintenance of a high level of safety in the use of radiation sources depends on there being a sound legal and governmental infrastructure, including a national regulatory body with well-defined responsibilities and functions

- These responsibilities and functions include establishing and implementing a system for carrying out regulatory inspections and taking necessary enforcement actions

Inspection Program Development

- The principal component of monitoring safety is on-site inspection and is normally where a major proportion of the regulatory body's resources should be allocated. Inspections are also the principal means by which direct personal contact between operators and regulatory body's personnel is achieved

Inspection Program Development

- Primary example of a quality control on inspection content is an Inspection Checklist
  - Helps Organize
  - Comprehensive
  - Easy Record Keeping
  - Citation Reference
  - Reference for Exit Interview and Report

Inspection Program Development

- Inspection reports for a given facility should include:
  - What was inspected
  - Personnel present, interviewed, and/or authorized
  - Any deficiencies or violations found
  - Corrective or enforcement actions that should be taken
  - Recommendations for future actions made by the inspector

Inspection Program Development

- Inspection reports must be detailed as their intent is to:
  - Provide a basis for future regulatory action
  - Document the regulatory history of a facility
  - Provide a basis for identifying major or generic issues that necessitate special inspections

Inspection Program Development

- Types of inspections
- Inspections generally comprise:
  - (a) initial or pre-operational inspections carried out prior to a practice commencing work with radiation, sometimes required as part of the process of authorization;
  - (b) planned inspections of existing authorizations usually at specified frequencies;

Inspection Program Development

- Types of Inspections (continued)
  - (c) inspections with the purpose of making investigations when the regulatory body so deems necessary; and
  - (d) inspections carried out following cessation of the radiation practice or if an authorization is otherwise cancelled, to provide an independent check for matters such as confirmation of the removal of radiation sources and radiation warning signs, decontamination of the facilities, etc.

Inspection Program Development

- An unannounced inspection provides the regulatory body with the opportunity to see a facility operating under its usual, normal working conditions. For this reason, performance of unannounced inspections should be the one preferred by the regulatory body.

- Announced inspections provide the inspectors with the opportunity to discuss and make prior arrangements with key personnel for interviews and to ensure that relevant specific documentation, which may be needed by the regulatory body to be seen during the inspection, will be available.

Inspection Program Development

- The Enforcement Process:

- Enforcement actions are the means by which the regulatory body can respond to non-compliance with the law or with specified conditions of the authorization certificate and should be commensurate with the possible consequences of non-compliance

Inspection Program Development

- Actions may range from written directions requiring corrective action within a specified time-frame to confiscation of a radiation source or, in situations where the violation implies a breach of the common law, even to prosecution by taking the responsible person to Court

- The enforcement policy should provide a response, which is commensurate with the alleged offence. In no case a sanction can be applied ‘on the spot’ for an inspector, for the principle that nobody may be sanctioned before giving him/her the possibility of depositions should be followed.

Inspection Program Development

- All breaches will require consideration by the senior regulatory body personnel (i.e. the organizational position of which should be clearly determined in the authority's internal procedures) as to whether they may deserve an administrative sanction or if the alleged breaches should be referred for prosecution.

Quiz-Questions

1. How is an inspection checklist developed?
2. What are two purposes of the inspection report?
3. Can an inspection checklist be the inspection report?

Quiz-Answers

1. How is an inspection checklist developed?

   Inspection checklist should contain all the requirements from the local regulation relevant to the modality being inspected

2. What are two purposes of the inspection report?

   Provide a basis for future regulatory action, document the regulatory history of a facility, and provide a basis for identifying major or generic issues that necessitate special inspections

3. Can an inspection checklist be the inspection report?

   Yes, provided it contains: What was inspected, personnel present, interviewed, and/or authorized, any deficiencies or violations found, corrective or enforcement actions that should be taken, recommendations for future actions made by the inspector

Criteria for All Phases of Facility

Criteria for All Phases of Facility

- Learning Objectives
  - *After this section, the students should understand what is reviewed during each step of the step-wise inspection approach and recognize certain equipment that will be available at the facility.*
- This section should take 60 minutes

Criteria for All Phases of Facility

- Commissioning and Shielding Verification
  - Prior to an accelerator being released to treat humans
    - an onsite inspection must be performed to ensure the vault was build in accordance with the submitted Shielding Evaluation
    - Commissioning of the Accelerator should be complete
  - A licensee will notify the Regulatory Body when the Linear Accelerator has been installed, and when the required testing has been completed

Commissioning of Linear Accelerator Facility

- Commissioning of a Linear Accelerator
  - Fully characterize all energy settings
  - Input for Treatment Planning System
  - Set machine limits
  - Set tolerances for Quality Assurance tests (monthly, daily)

Commissioning of Linear Accelerator Facility

- Information required to characterize
  - Output definition
  - Beam intensity profiles
  - Depth dose at varying field sizes
  - Measurements off central axis
  - Measurements of MLC
  - Beam modifiers

Commissioning of Linear Accelerator Facility

- Shielding Survey Verification
  - Measurements can be independently verified by inspector onsite
  - Typical Set Up criteria
    - For Primary Barrier measurements, no phantom should be used
    - For Secondary Barrier measurements, a phantom should be used
    - Set machine to highest dose rate and maximum field size
    - Set the machine to the desired energy
    - Set the machine at the selected gantry angle (e.g. 0^{o}, 90^{o}, 180^{o}, 270^{o}, any oblique angles as needed)
    - Repeat as needed

Commissioning of Linear Accelerator Facility

- Once commissioning is determined to be satisfactory, the licensee should be allowed to treat patients.
- For this reason, during the commissioning inspection, a review of the programs submitted during licensing should also be performed:
  - Radiation Protection Program
  - Equipment and Instrumentation
    - Adequate to perform Quality Control
  - Prescription control procedures

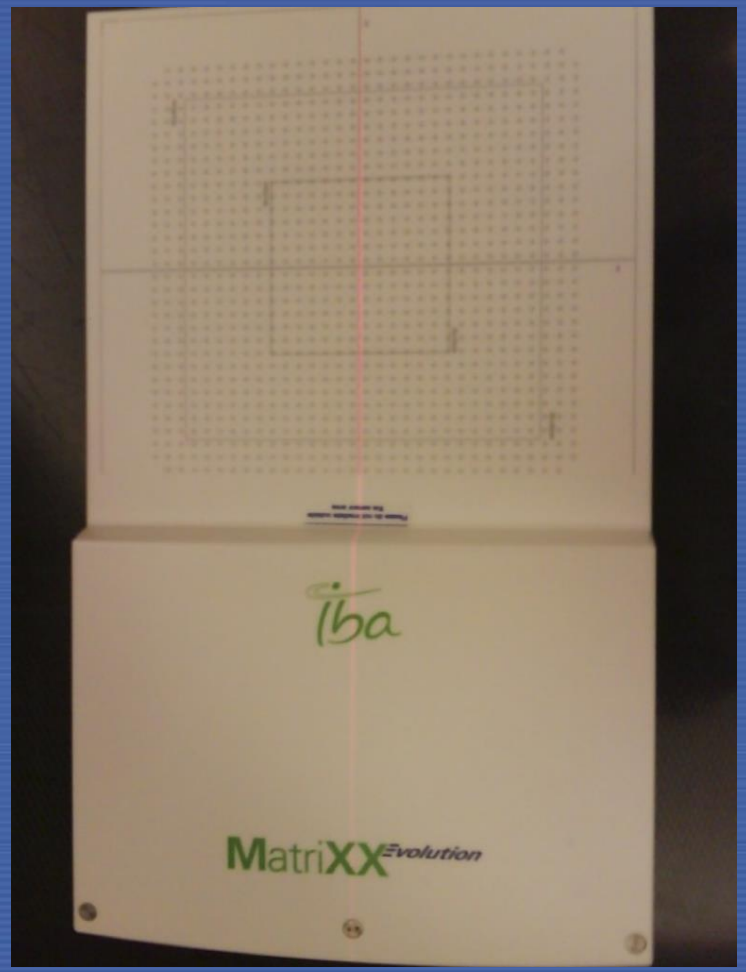
Facility Criteria Review

- Radiation Detection Devices Possessed should be identified in the license application
  - Make
  - Model
  - Maximum Energy
  - Uses
  - Calibration

Facility Criteria Review

- Equipment needed to measure outputs (QA)
  - Array
  - Ion Chambers
  - Water Tanks
  - Solid Water

Detector Arrays



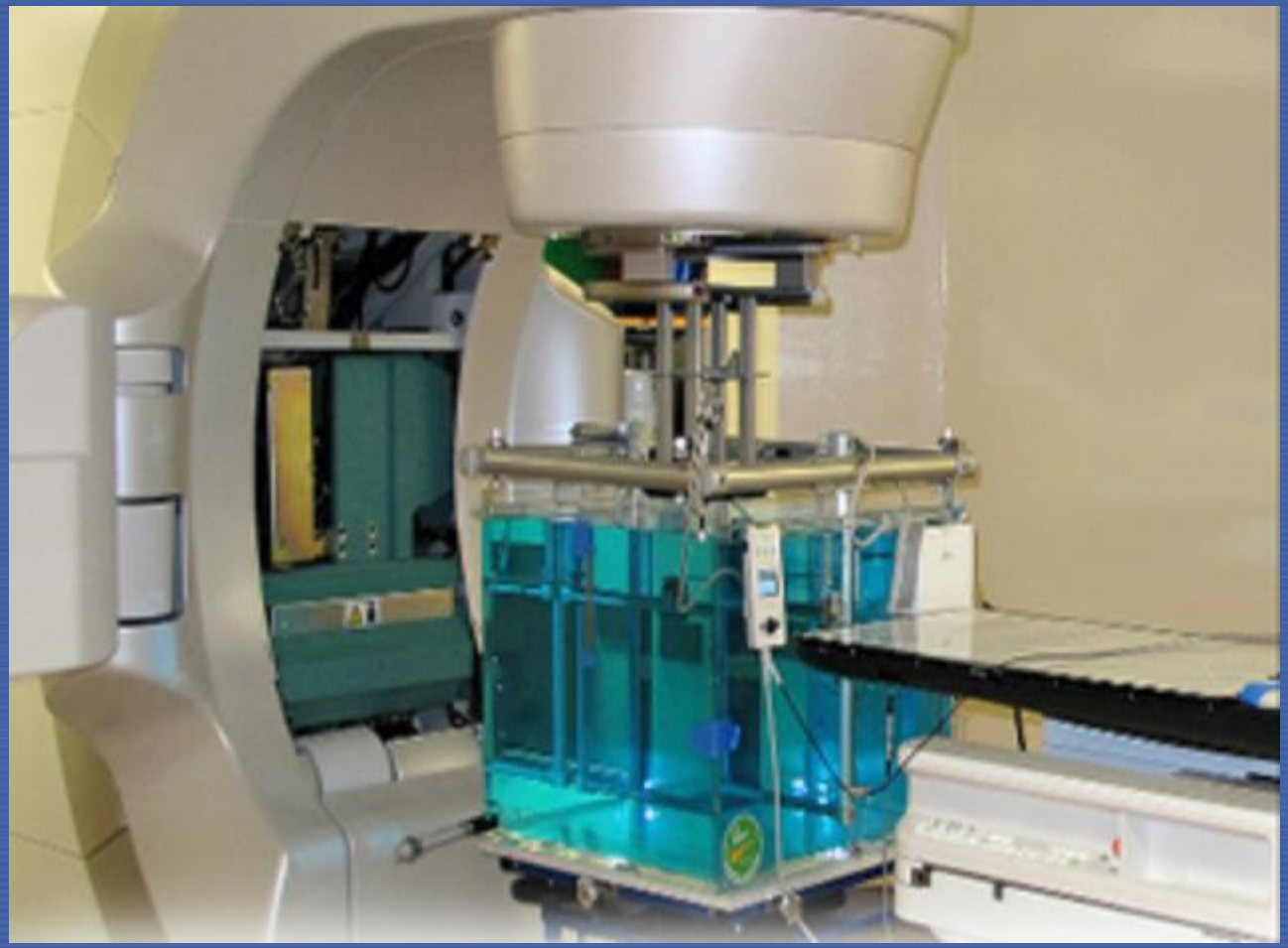
Ion Chamber



Electrometer



Water Tank



Facility Criteria Review

- Equipment needed for workplace monitoring
  - Ion Chamber
  - Neutron Meter
  - Area Monitors

Equipment – Portable Ion Chamber Survey Meter



Portable Ion Chamber



FLUKE Biomedical

Specifications

Radiation detected	Beta	> 1 MeV
	Gamma and x-rays	> 25 keV
Operating ranges, response time	0 to 5 µSv/h (5 sec) 0 to 50 µSv/h (2 sec) 0 to 500 µSv/h (1.8 sec) 0 to 5 mSv/h (1.8 sec) 0 to 50 mSv/h (1.8 sec)	
Accuracy	Within 10 % of readings between 10 % and 100 % of full scale indication on any range, exclusive of energy response (calibration source is ^{137}Cs)	

Portable Neutron Detector



Facility Criteria Review



- Occupational Dose Program
  - ALARA Levels
    - RSO Review

Facility Criteria Review

- Reporting Procedures
  - How to identify a deviation from the prescription
  - When to notify RSO
    - Accident or Incident
    - Equipment Failure
  - Training in procedure

Facility Review Criteria

- On-going inspections
  - Should be completed at a frequency determined by the Regulatory Body
  - Ensure the safety of the clinical site for the patient, staff, and members of the public through observation and reviewing documentation.

Quiz-Questions

1. What is Commissioning of a Linear Accelerator and when is it done?
2. What is the role of the regulator during commissioning of a Linear Accelerator?
3. Are Neutron Detectors necessary for every inspection and all licensees?
4. What equipment is the ideal survey instrument for the inspector?

Quiz-Answers

1.What is Commissioning of a Linear Accelerator and when is it done?

Fully characterizing the beam for baselines and treatment planning. To be done after installation and acceptance and prior to patient treatment.

2.What is the role of the regulator during commissioning of a Linear Accelerator?

The regulator reviews the surveys and commissioning results completed by the qualified medical physicist during an onsite inspection.

3. Are Neutron Detectors necessary for every inspection and all licensees?

Neutron detectors should be used to verify shielding for Linear Accelerators > 10 MV.

4.What equipment is the ideal survey instrument for the inspector?

Hand held Ionization Chamber and occupational monitoring dosimeter

Inspection Approaches

Inspection Approaches

- Learning Objectives
  - *After this section, the students should understand how inspections verify the safety of the clinical site for the patient, staff, and members of the public through observation and reviewing documentation.*
- This section should take 60 minutes

Inspection Approaches

- Stepwise inspection
  - Confirmatory after construction
    - Prior to patient treatment
  - Initial inspection
    - After first patient treatment
- Inspection Frequency (established by individual country)
  - 1 year for Registered Facilitates
  - 5 years for Licensed Facilities

Inspection Approaches

- Inspection Frequency at Registered Facilities
  - Annually (1 year)
  - a registered facility does not need to provide their policies and procedures to the regulatory authority; however, registered facilities are inspected more frequently for this reason.
  - Inspection frequencies – registered versus licensed facilities have different risk profiles therefore inspection frequencies are based on those profiles.

Inspection Approaches

- Inspection Frequency at Licensed Facilities
  - 5 years
  - Procedures relevant to radiation safety and patient care have been submitted to the state, as well as responsible individuals, and procedures and responsible designated individual's names and credentials are maintained by the regulatory authority.
  - Licensed facilities must request approval from the regulatory body in the form of a license amendment before implementing changes to any approved procedures.
  - Since the procedures are deemed adequate for safe control the inspection frequency is less than a registered facility.

Inspection Approaches

- Other types of inspections
  - Reactive
  - Selective
  - Performance Based

Inspection Preparation

- Inspection Preparation
  - Review the last inspection
    - What did we review the last time? (or last 2 times?)
    - What are the specifics of this licensee that I need to consider? (this is a reason to use narrative reports)
      - High turn over
      - Patient loads
      - Compliance issues
      - Modalities used

Inspection Preparation

- What was observed previously?
- Which key staff were interviewed?
- What compliance issues or concerns were identified (if any)?
- What communication did the licensee receive?
- What were the corrective actions identified?
- Were corrective actions implemented?

Inspection Preparation

- Review Relevant Regulations
- Review Local Inspection Procedures and Checklists
- Review License Commitments
- Select Proper Instrumentation
  - Ion Chamber
  - Dosimeter
- Safety considerations
  - Exposure

Inspection Questions

- Prepare questions for the licensee
  - Questions to help answer the items on the checklist:
    - Can I observe while you …
    - How do you do ….
    - What does ____ mean?
    - How is ____ used?
    - Explain how you …
    - Walk me through this procedure

Conducting Inspection

- What to review
  - IAEA TECDOC (11/14/19) Section 5. Inspection Process, Conduct of Inspection - Section 5.6
  - Previous Violations and Corrective Actions
  - Higher Risk Programs
    - Therapy
    - New modalities added

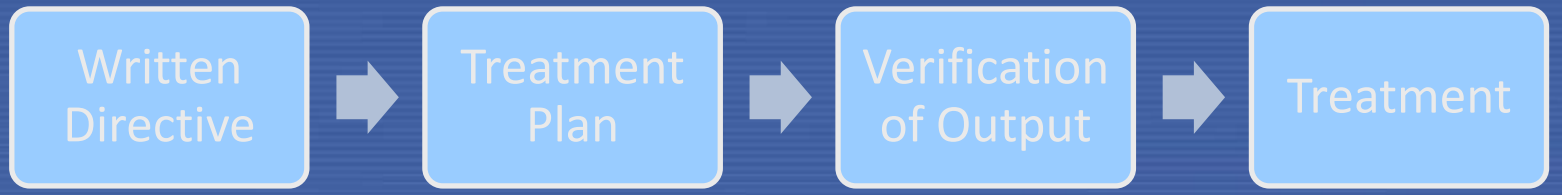
Conducting Inspection

- What to review:
  - Previous Violations
    - Confirm corrective actions
  - Annual Audit
    - Identified violations, incidents
    - ALARA review
    - New practices and procedures
  - Radiation Safety Committee Meeting Minutes/Record

Conducting Inspection

- Entrance meeting with upper management
  - Length of inspection
  - Scope
  - Previous Violations
  - Exit meeting
- Exit meeting with upper management
  - Brief RSO first
  - Apparent Violations

Inspection


Written Directive
Treatment Plan
Verification of Output
Treatment

Inspection

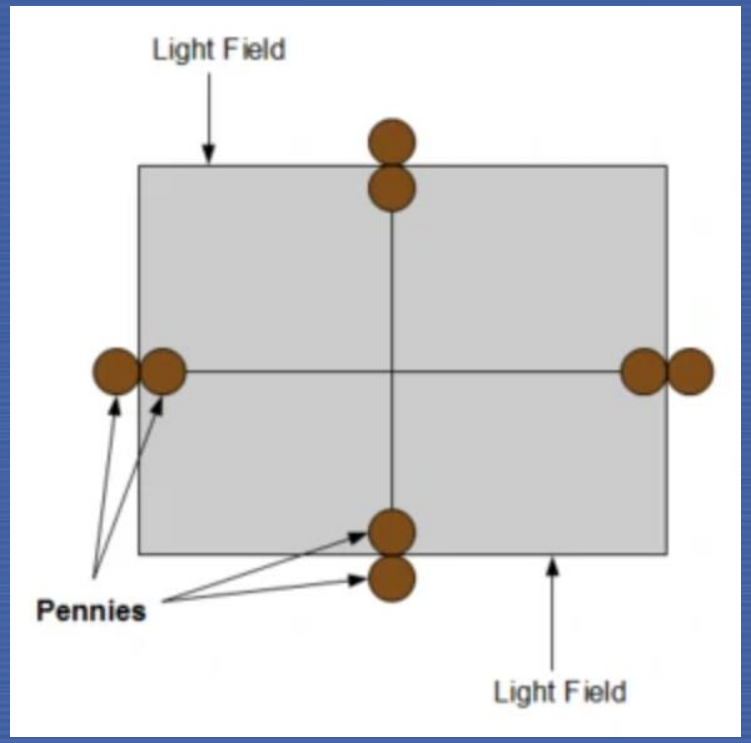
What are the safety features for ensuring security and safety?

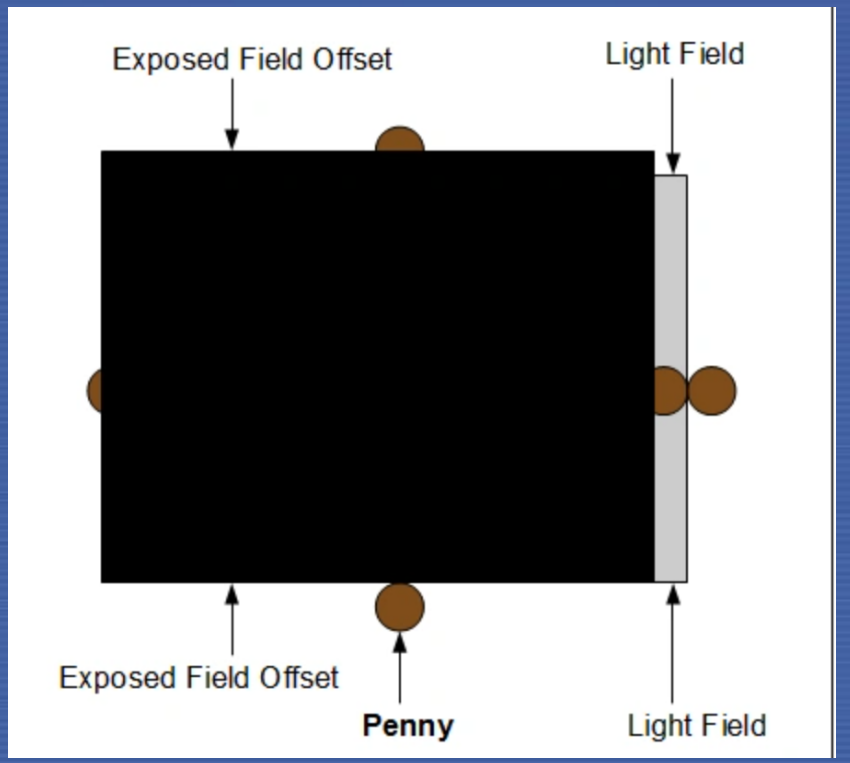




Inspection

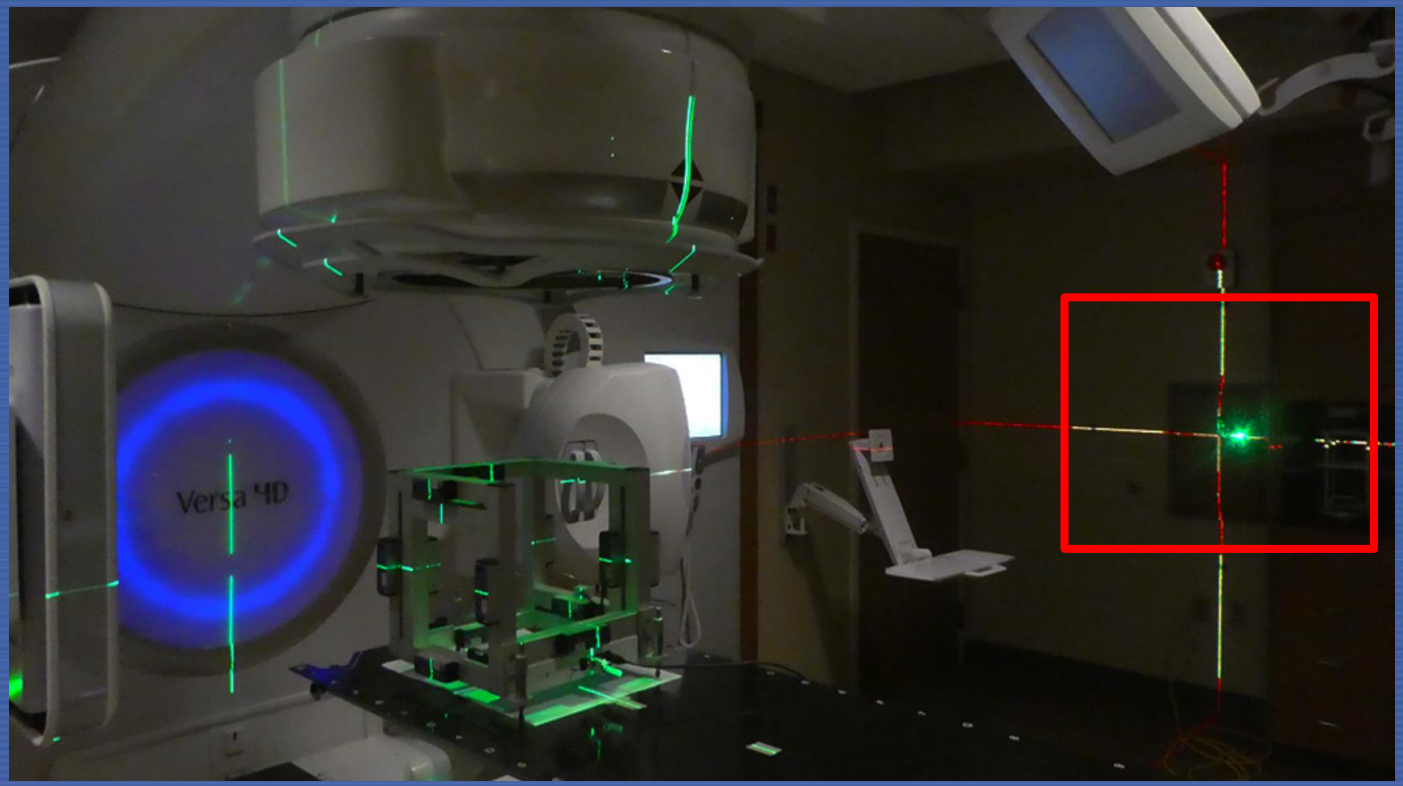
How to verify light & radiation field coincidence?





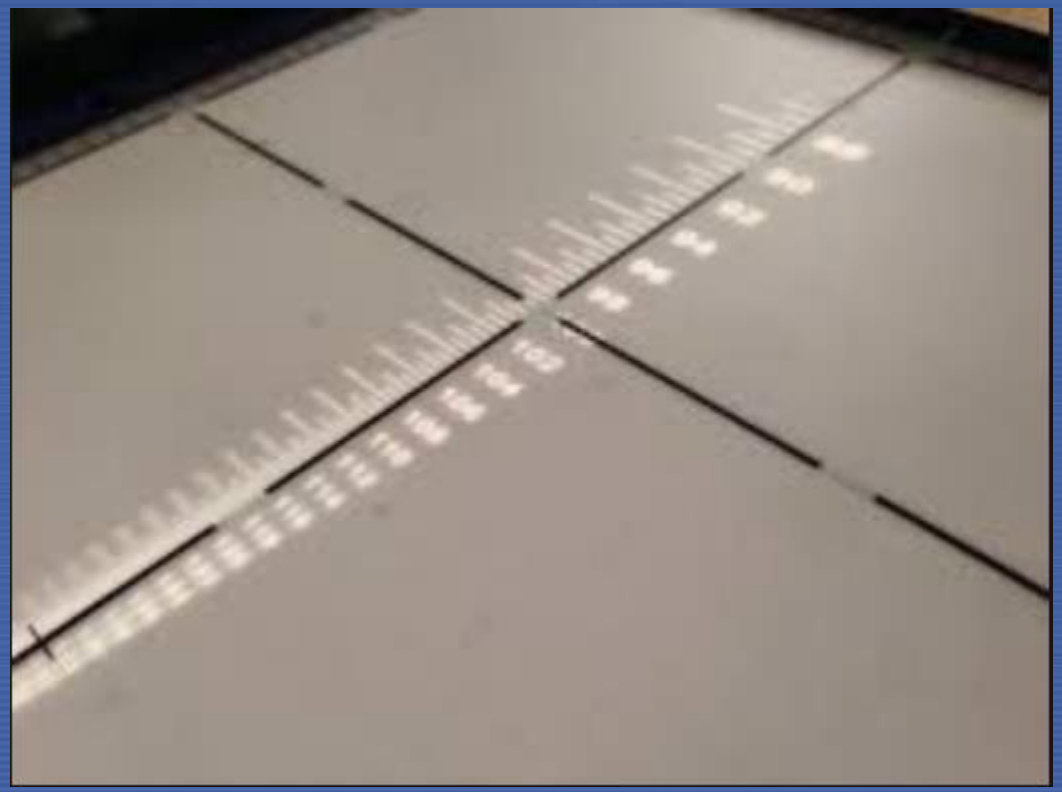
Inspection

How to verify laser cross hair positioning



Inspection

Optical Distance Indicator



Equipment – Ion Chamber Survey Meter



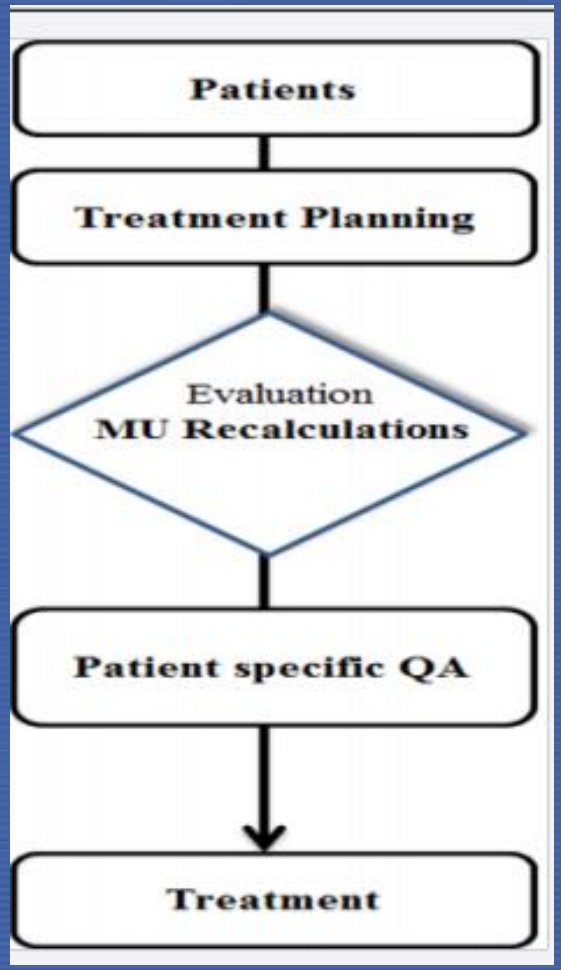
Immobilizing the Patient





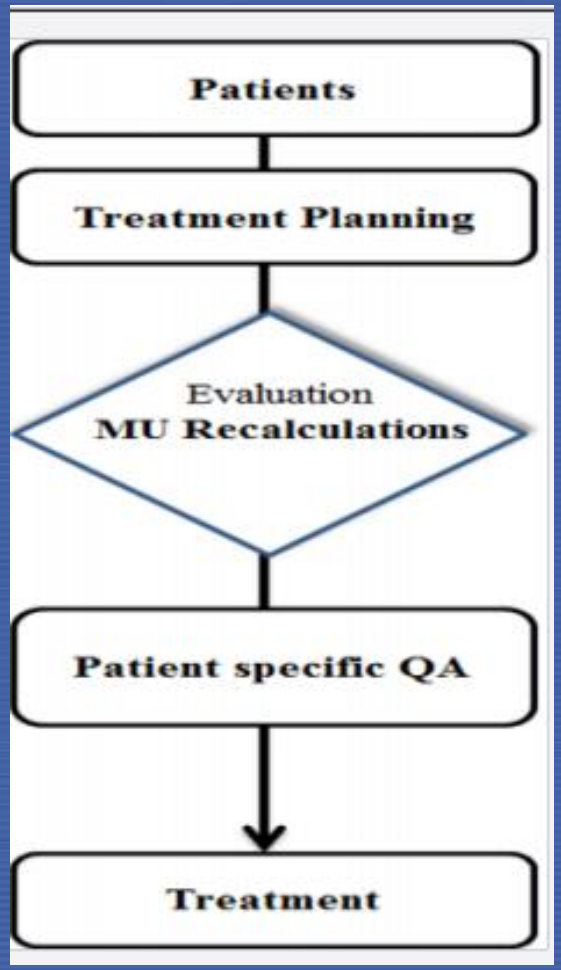
Clinical/Inspection Workflow

- Responsibly Physician prescribes treatment
- Authorized Medical Physicist develops the Treatment Plan.
- Responsible Physician approves.



Clinical/Inspection Workflow

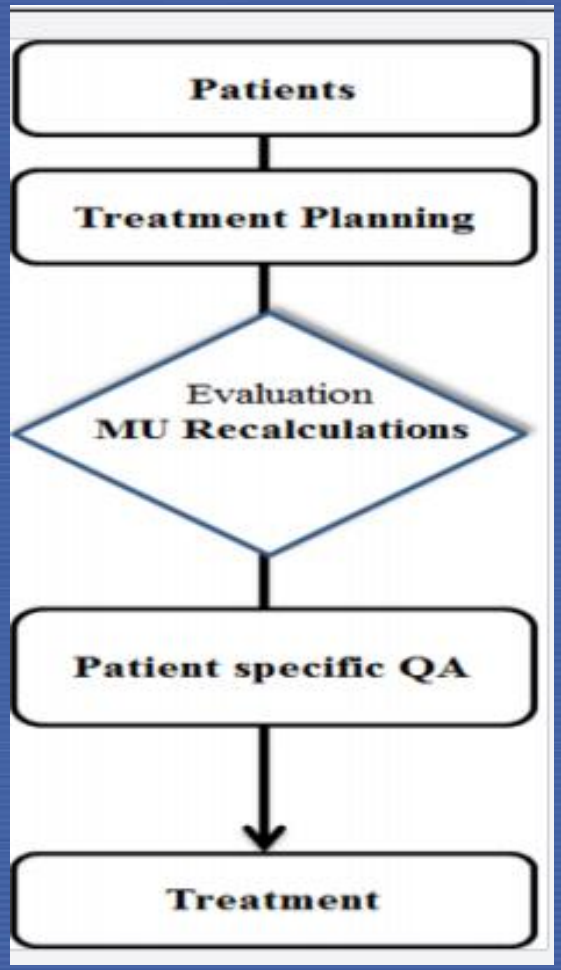
- Monitor-Unit recalculations to check machine output at a single point in predetermined patient geometry.
- MU is determined using a water phantom at machine commissioning



Clinical/Inspection Workflow

- Patient Identification, Prescription, Treatment Plan, position, etc. are reviewed by another authorized individual in accordance with written procedures.

- Treatment started.



Clinical/Inspection Workflow

- What is on the Written Directive?

The written directive must contain the patient or human research subject's name, the type and energy of the beam, the total dose, dose per fraction, treatment site, and number of fractions.

(4) For teletherapy: the total dose, dose per fraction, number of fractions, and treatment site;

(5) For high dose-rate remote afterloading brachytherapy: The radionuclide, treatment site, dose per fraction, number of fractions, and total dose;

Clinical/Inspection Workflow

- How do you verify the patient dose is in accordance with the treatment plan?

ii. Procedures for Administrations. The registrant shall develop, implement, and maintain written procedures to provide high confidence that:

(1) Prior to the administration of each course of radiation treatments, the patient's or human research subject's identity is verified by more than one method as the individual named in the written directive;

(2) Each administration is in accordance with the written directive;

(3) Therapeutic radiation machine final plans of treatment and related calculations are in accordance with the respective written directives by:

(a) Checking both manual and computer generated dose calculations to verify they are correct and in accordance with the written directive; and

(b) Verifying that any computer-generated calculations are correctly transferred into the consoles of authorized therapeutic medical units;

(4) Any unintended deviation from the written directive is identified, evaluated and appropriate action is taken; and

(5) The registrant retains a copy of the procedures for administrations for the duration of the registration.

Clinical/Inspection Workflow

- How do you verify the patient dose is in accordance with the treatment plan?

§ 35.457 Therapy-related computer systems.

The licensee shall perform acceptance testing on the treatment planning system of therapy-related computer systems in accordance with published protocols accepted by nationally recognized bodies. At a minimum, the acceptance testing must include, as applicable, verification of:

(a) The source-specific input parameters required by the dose calculation algorithm;

(b) The accuracy of dose, dwell time, and treatment time calculations at representative points;

(c) The accuracy of isodose plots and graphic displays; and

(d) The accuracy of the software used to determine sealed source positions from radiographic images.

Inspection - Treatment Delivery

- How was treatment delivered?
- Was it delivered in accordance with the Prescription?
- Was the Prescription Control Procedure followed?
- Was it delivered in accordance with the Treatment Plan?
- Were the Treatment Plan Procedures followed?

Inspection Flow

- Review Inspection Checklist
- Perform Onsite Inspection
- Review Inspection Observations with Regulatory Authority
- Draft Hypothetical Correspondence to Licensee

Inspection Documentation

- Documentation verification of interview answers
  - Who performs this check?
  - How often is this reviewed?
  - Who signs the written directive?
  - Who is present at initiation of treatment?
  - Who reviews the treatment plan?
  - Review required procedures.
  - Note: “If it isn’t documented, it didn’t happen.”

- Inspection Report: Official record of inspection findings

Quiz-Questions

1. What is the main goal of an inspection program?
2. What are the 4 types of inspections?
3. What are the benefits of unannounced vs announced inspections?
4. True of False – "On the spot" sanctions are reasonable for observed violations.

Quiz-Answers

1. What is the main goal of an inspection program?

   Verify operational safety

2. What are the 4 types of inspections?

   Initial, routine, investigatory, decommissioning

3. What are the benefits of unannounced vs announced inspections?

   Unannounced – snapshot of normal operation. Announced – get full access to personnel/resources

4. True of False – "On the spot" sanctions are reasonable for observed violations.

   False

Exercise 6: Inspection Checklist

This exercise should take 30 minutes +

Lunch

Inspection Visit to LINAC Facility

This exercise concludes the day