Authorization and Inspection of Linear Accelerators Used in Radiotherapy
Day 2

IAEA
International Atomic Energy Agency

Agenda

- Review of Previous Day
- Day 2
  - Treatment Planning
  - Regulation Development
  - Sample Regulation Review
  - Authorization/Licensing process

Treatment Planning

Treatment Planning

- Learning Objectives
  - After this section, the students should understand how gantry angles and beam modifiers affect the absorbed radiation deposited in the patient's body and how deposition can be optimized for patient treatment.

- This section should take 90 minutes, a 10 minute break may be provided

Treatment Planning

- Creating personalized treatment
- Team: Radiation Oncologist, Dosimetrist, Physicist
- Account for diagnosis, stage of disease, anatomy, etc.
- Selection of LINAC Parameters
  - Isocenter coordinates in patient
  - Gantry, collimator, treatment couch angles
  - Jaw positions and MLC shapes
  - Monitor unit settings

The Manual Method

- 2D x-rays to determine beam shape
- Depth would be determined based on patient anatomy
- Beam dose would be calculated by hand and later by computers based on measured beam characteristics

Modern Treatment Planning

- Advanced computerized treatment planning systems (TPS)
- Use computerized tomography (CT) to map anatomy in 3D
- Can place and visualize the beams
- Can design all beam modifications

Typical Workflow

- Referral to Radiation Oncology
- Consult with the Radiation Oncologist
- CT simulation
- Treatment Planning
- Safety Checks
- Treatment: split into ~10-40 days
- Routine safety checks throughout
- Follow-up

Linear Accelerators

- The beam is shaped as it exits the machine to match the shape of the patient's tumor

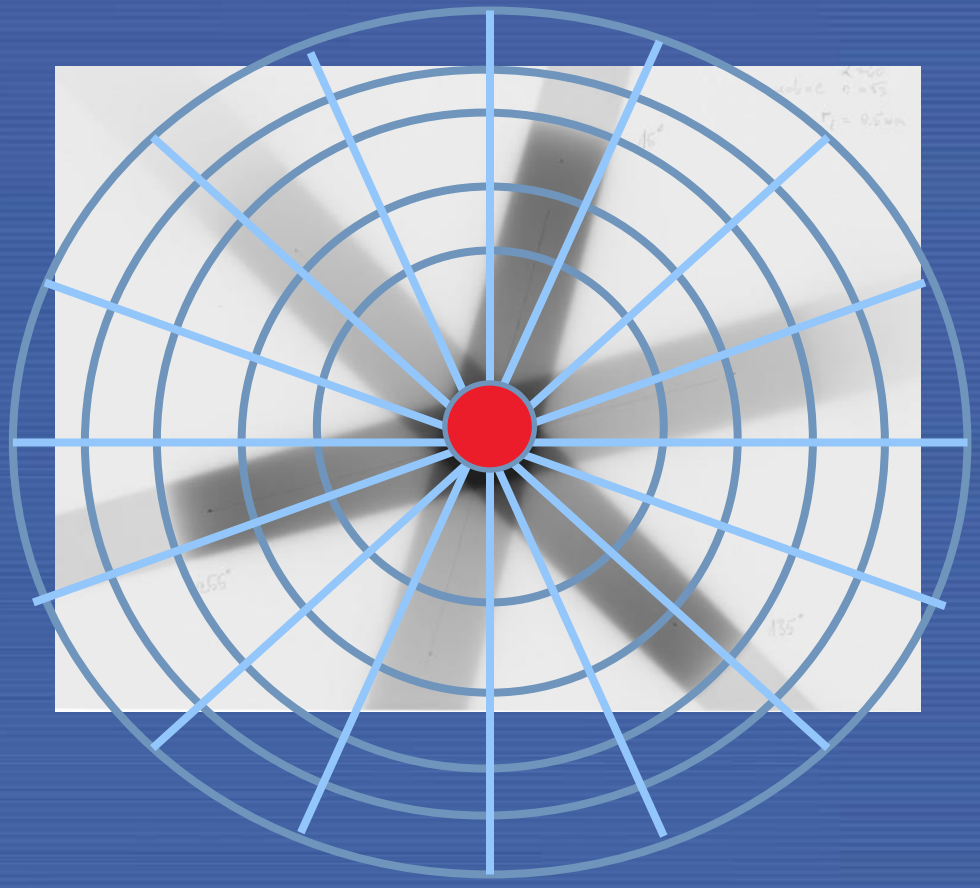
- The modified beam is directed to the patient's tumor

Linear Accelerator Machine

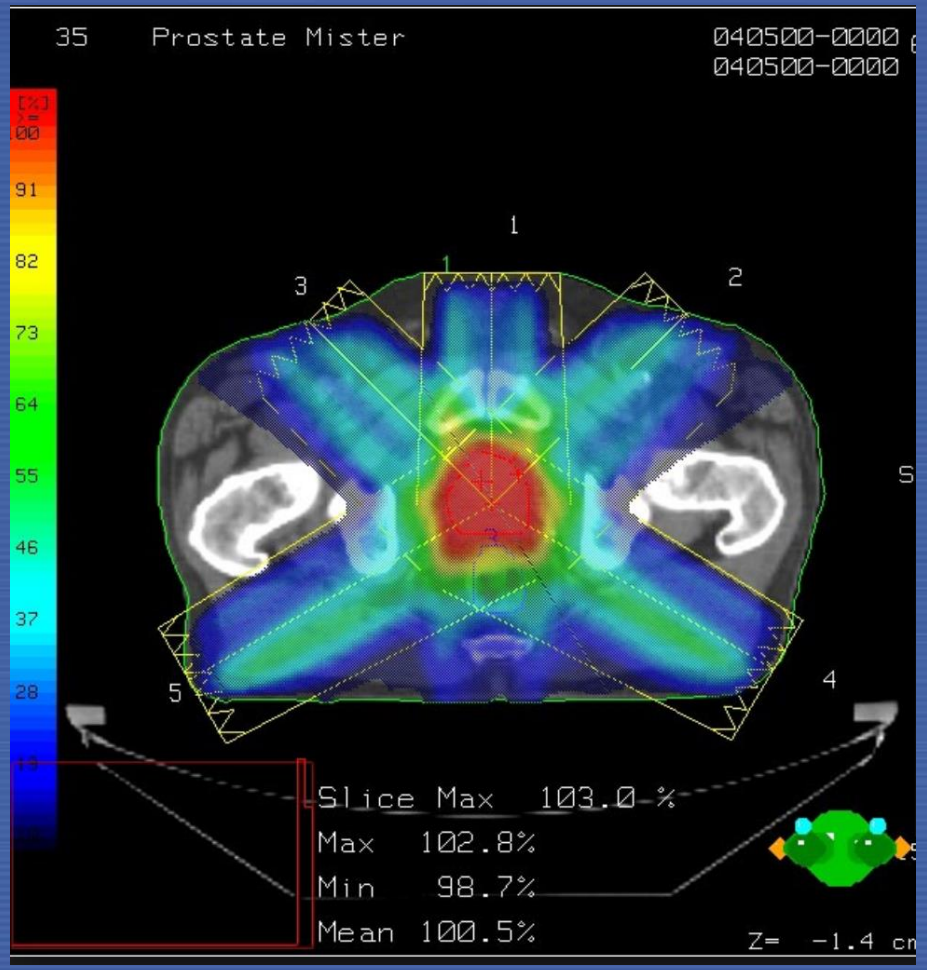


Isocenter

- A point in space where the central axis of the beam converges
- 100cm away from the source
- The disease should be positioned in the isocenter for effective treatment



Isocenter


35 Prostate Mister
040500-0000
040500-0000
[%]
100
91
82
73
64
55
46
37
28
1
2
3
4
5
Slice Max 103.0 %
Max 102.8%
Min 98.7%
Mean 100.5%
Z= -1.4 cm

Common Treatment Modalities

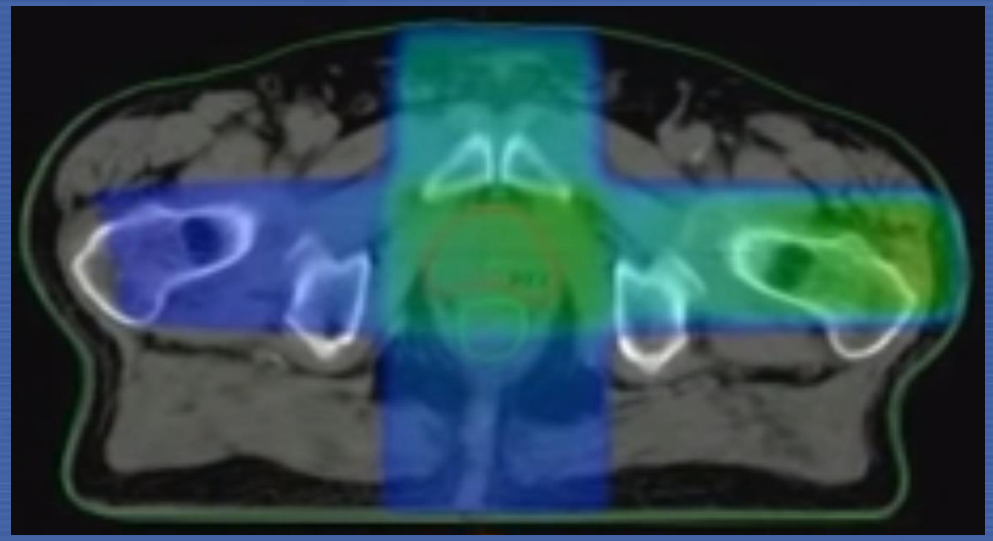
- 3D Conformal Radiation Therapy (3DCRT)
- Intensity Modulated Radiation Therapy (IMRT)
  - Step-and-Shoot
  - Sliding Window
  - Volume Modulated Arc Therapy (VMAT)
- Stereotactic Body Radiotherapy (SBRT)
- Stereotactic Radiosurgery (SRS)
- Electron Therapy

3D Conformal Radiation Therapy

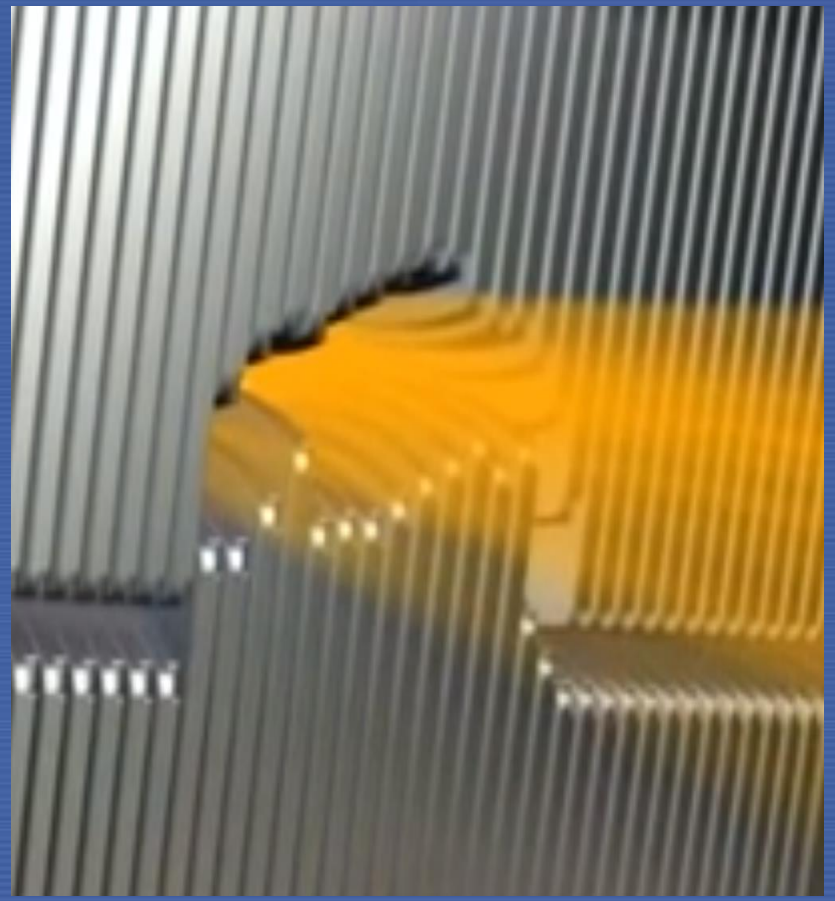
- The beam is collimated to conform to the tumor shape by the jaws and Multileaf Collimator (MLC)
- Wedges can further shape the beam
- Multiple beam angles can be used
- “Forward Planning”

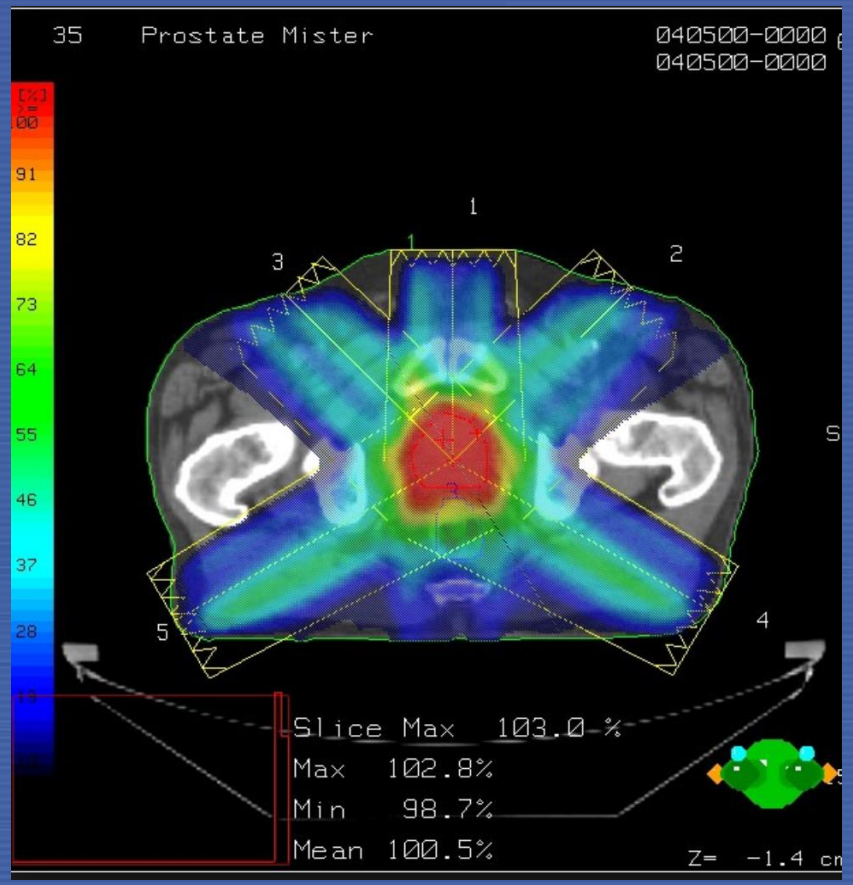
Introduction To Linear Accelerators

- 3-D Conformal Radiation Therapy



Multileaf Collimator Use With Gantry





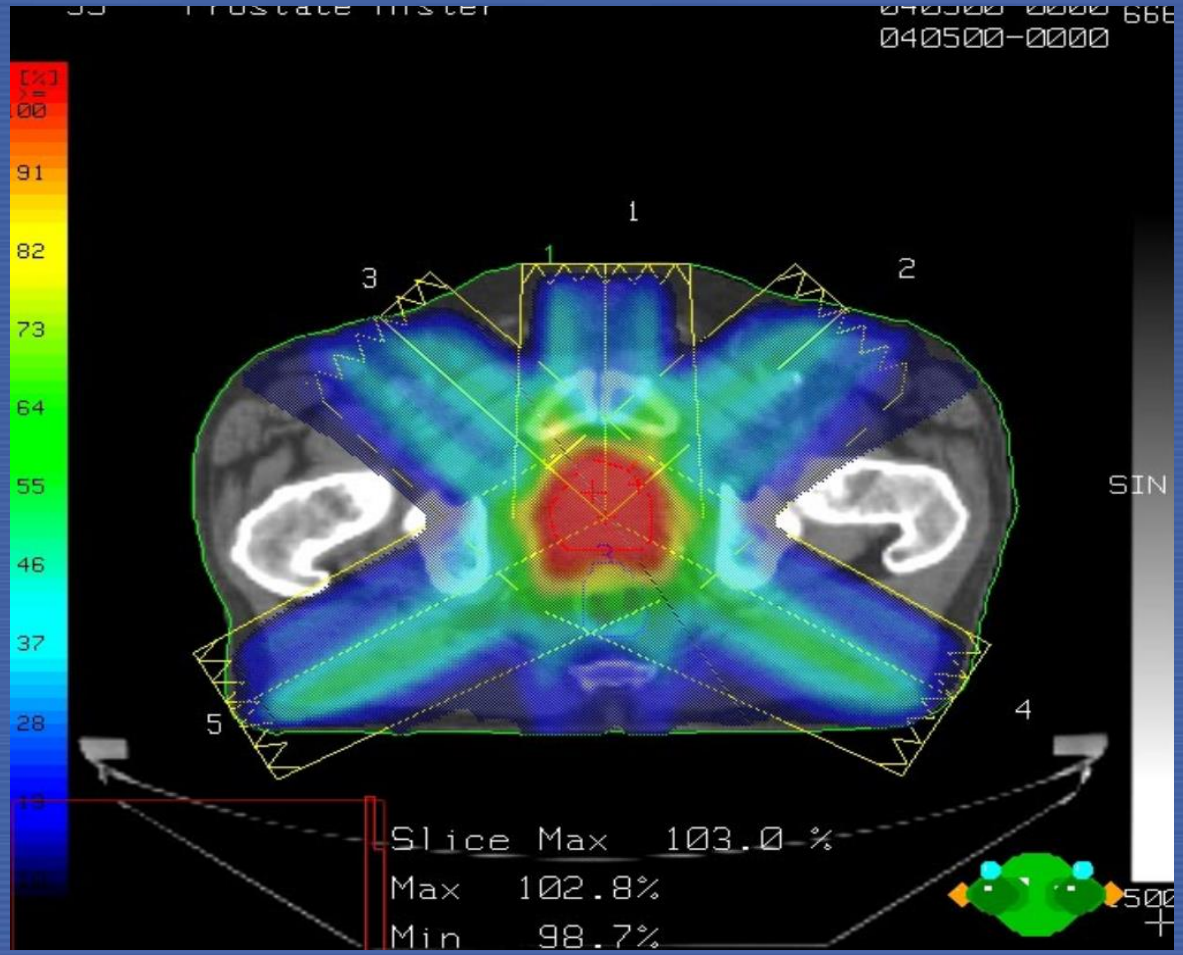
Intensity Modulated Radiation Therapy

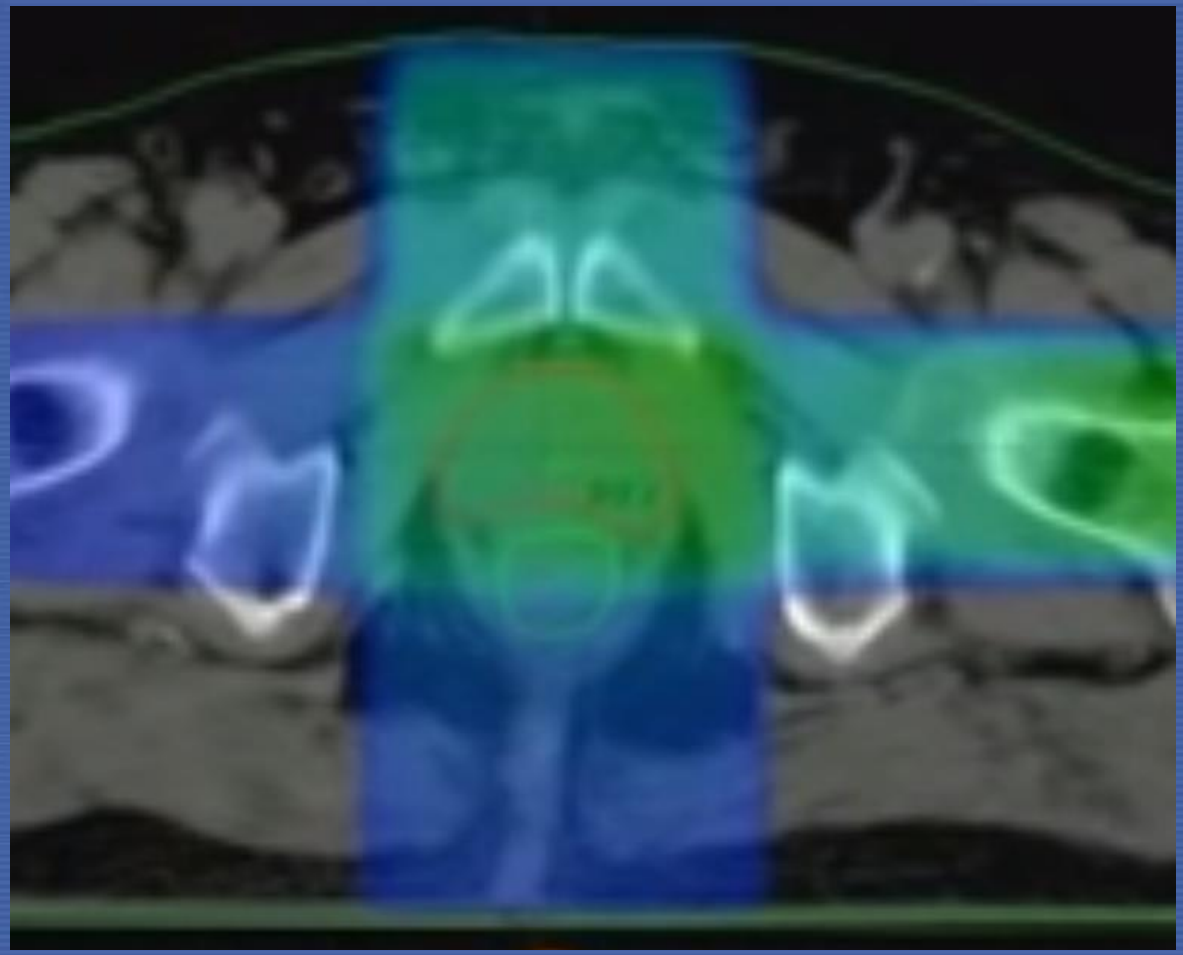
- Not conformal
- Complex shapes determined by the TPS
- “Inverse Planning” - describe desired outcome, TPS tries to achieve it

Intensity Modulated Radiation Therapy

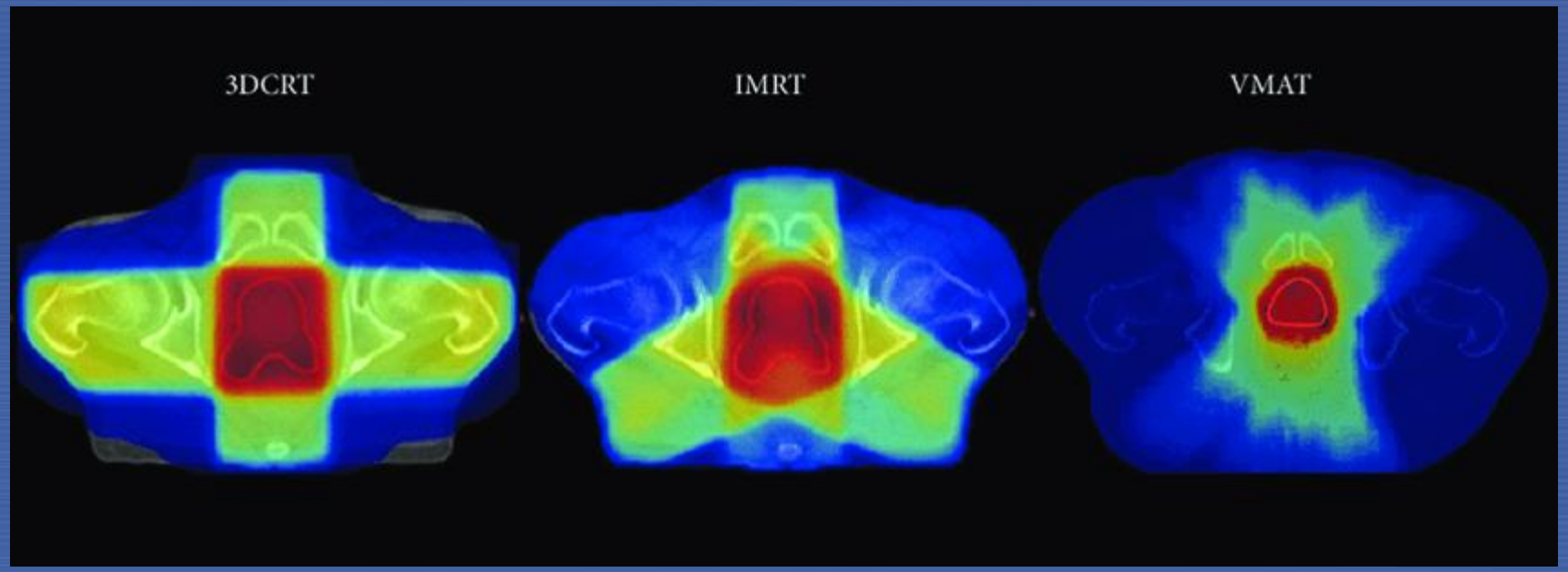
- Step-and-Shoot
  - Beam turns off when MLC moves
- Sliding Window
  - Beam runs continuously while MLC move but stops when gantry moves
- Volume Modulated Arc Therapy (VMAT)
  - Beam runs continuously while MLC and gantry move

IMRT vs 3DCRT





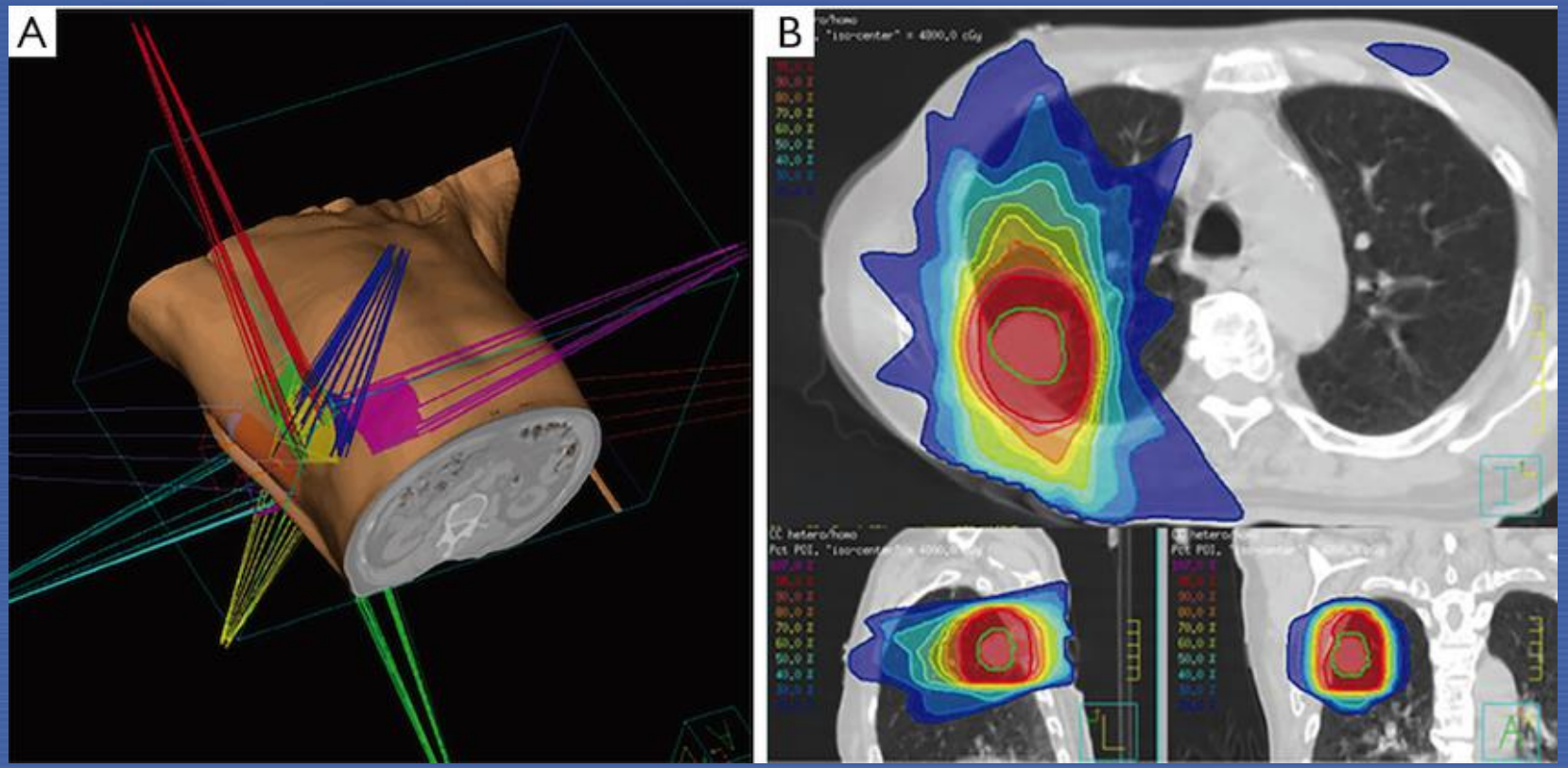
IMRT vs 3DCRT



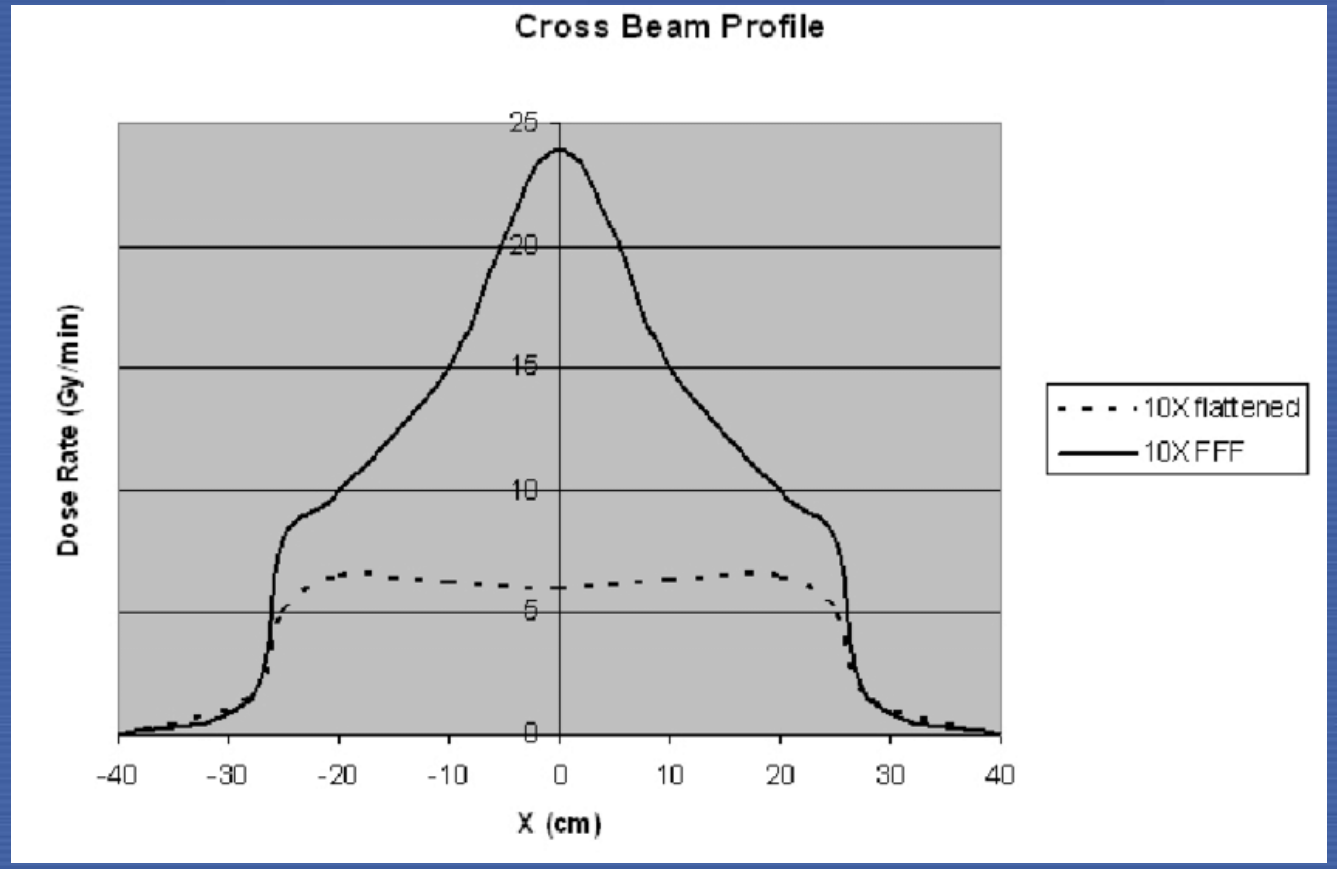
Stereotactic Body Radiotherapy

- Used to deliver 5X typical fraction dose
- Non-coplanar
- VMAT and advanced optimization

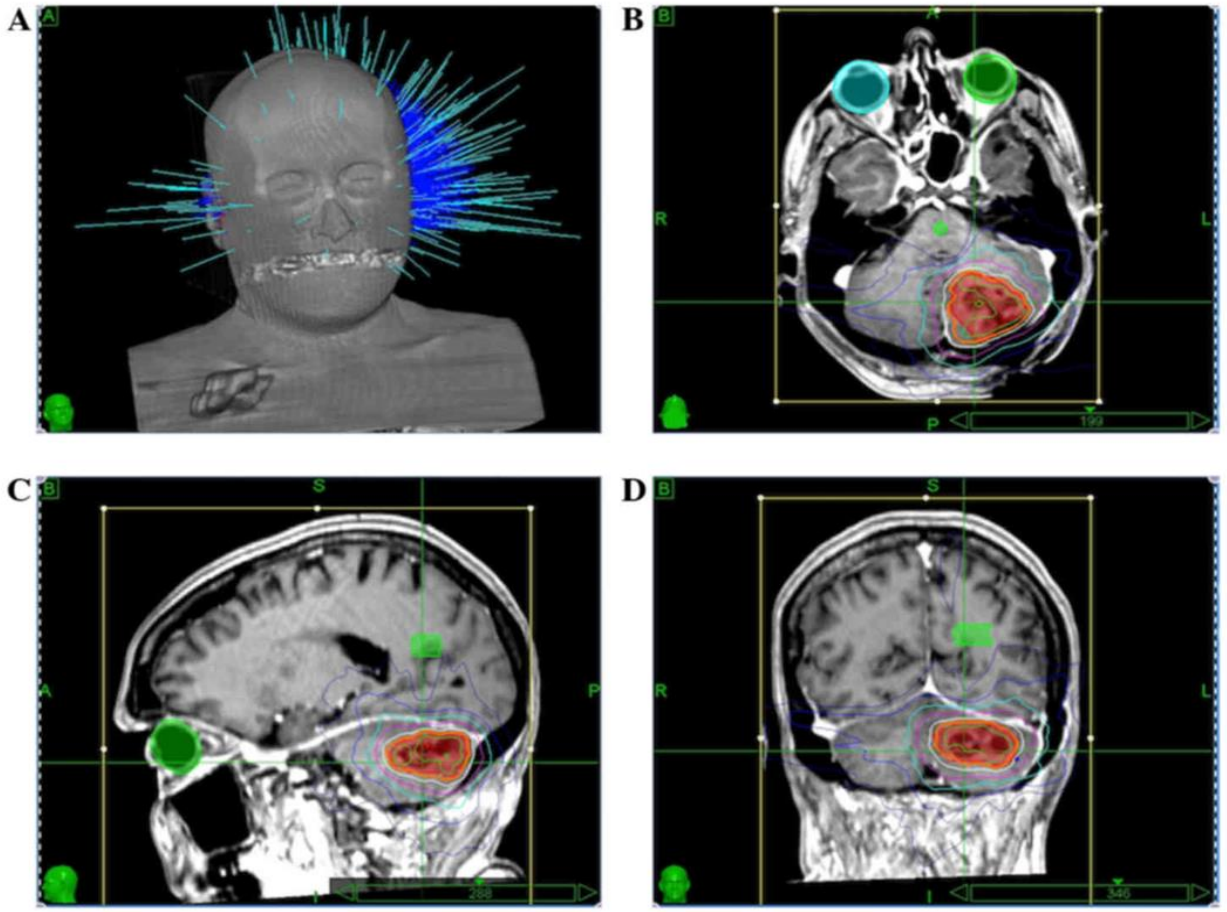
Stereotactic Body Radiotherapy



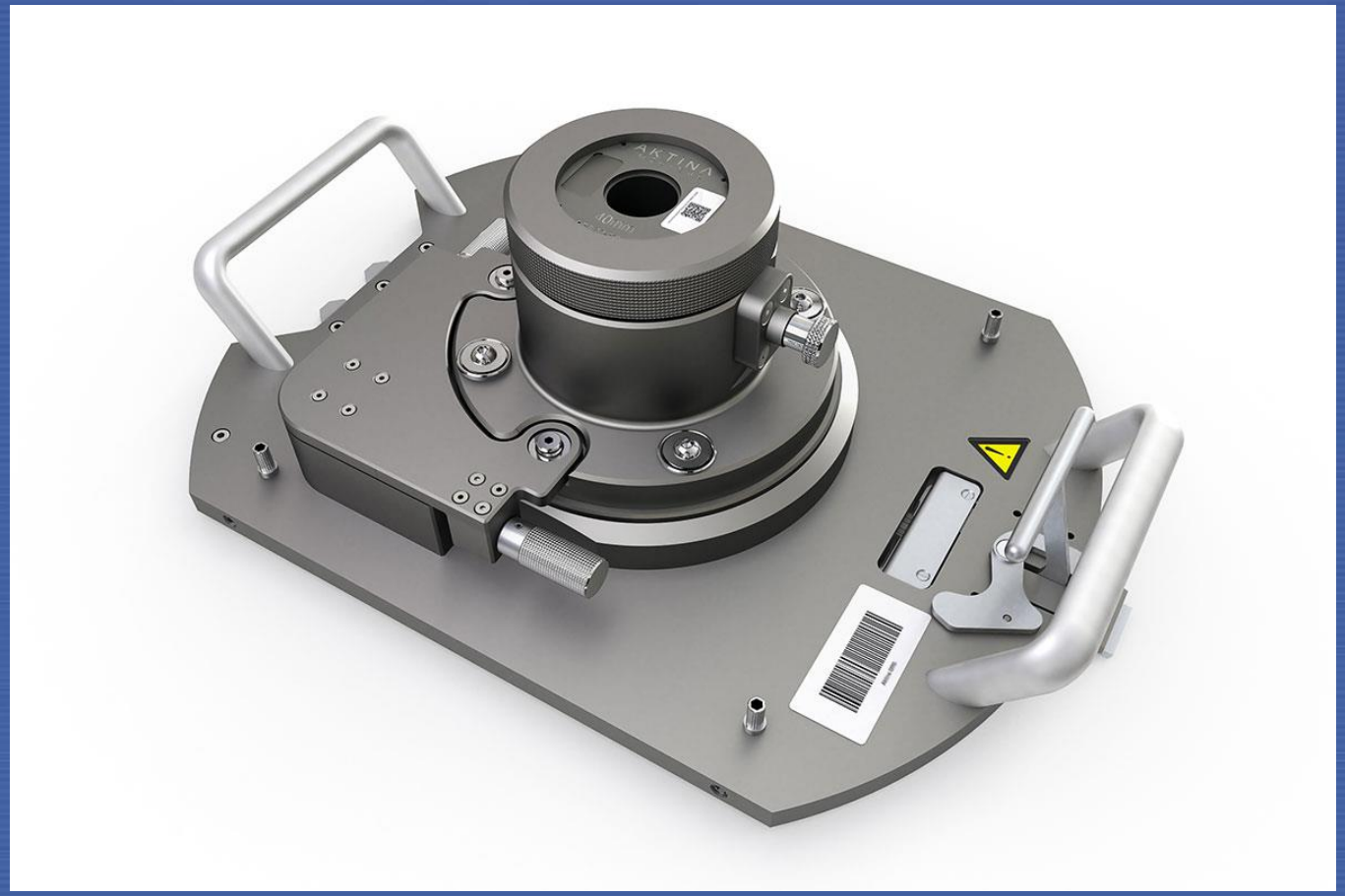
Stereotactic Body Radiotherapy



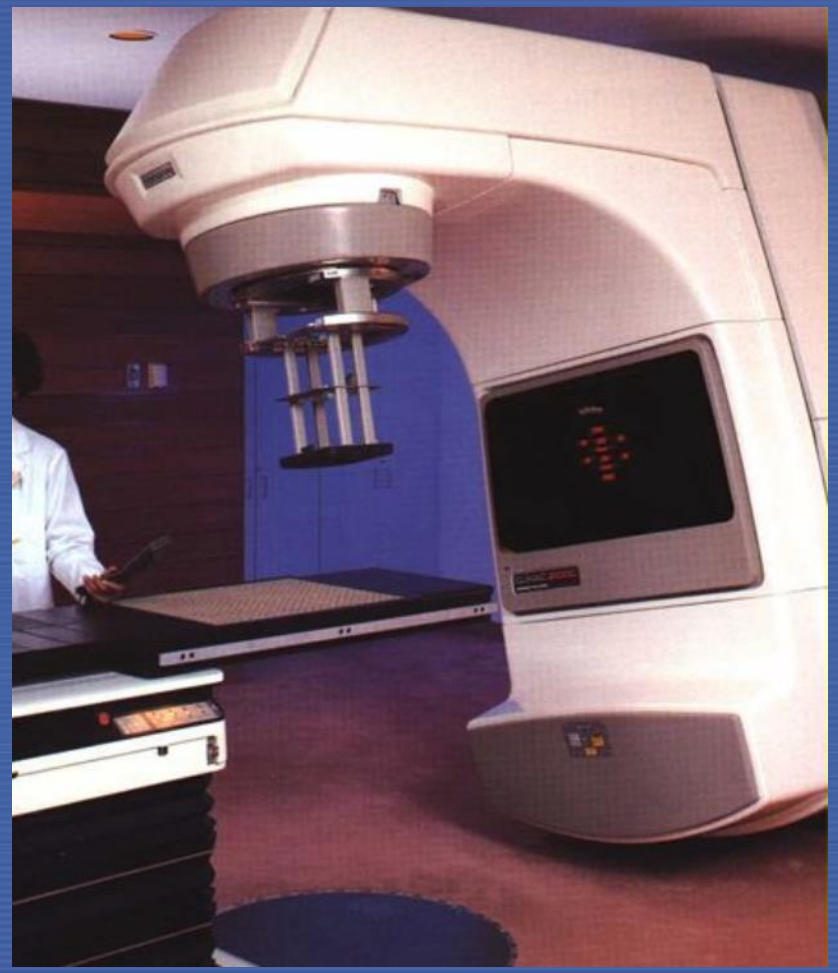
Stereotactic Radiosurgery



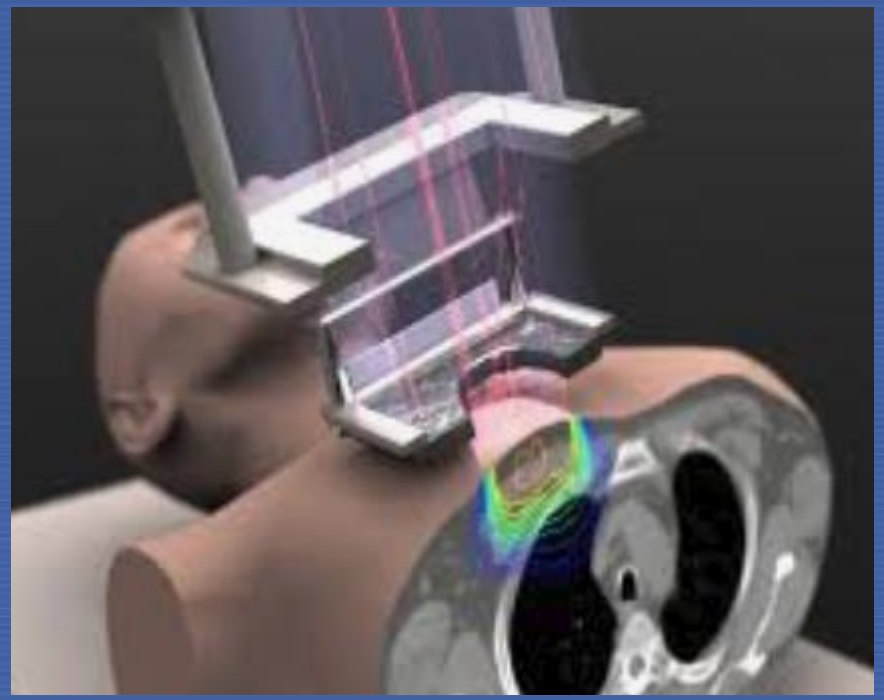
Stereotactic Radiosurgery



Electron Therapy



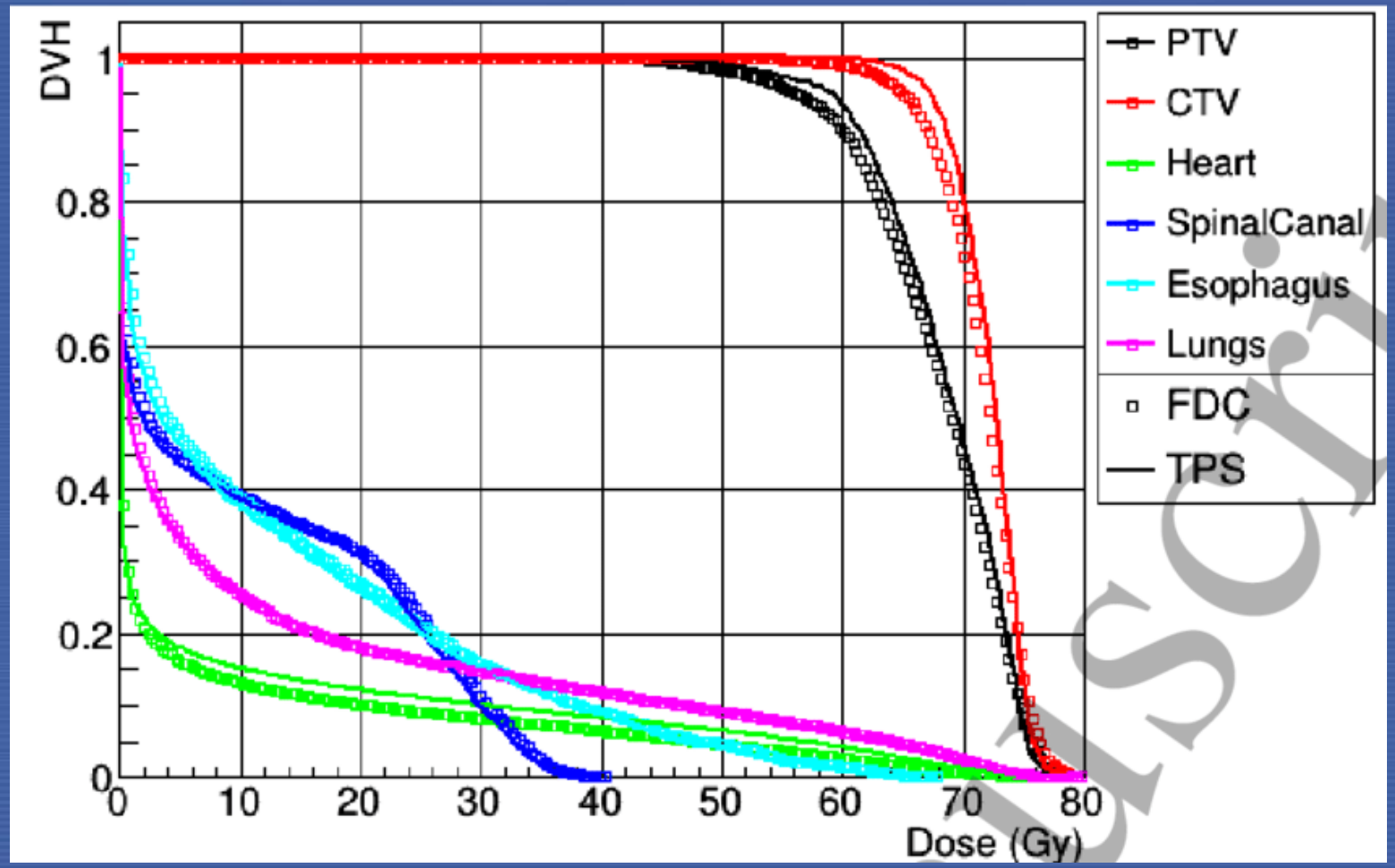
Electron Therapy



Structure Terminology Overview

- GTV = Gross Tumor Volume
- CTV = Clinical Target Volume
- PTV = Planning Target Volume
- ITV = Internal Target Volume
- OAR = Organs at Risk
- PRV = Planning Risk Volume

The Dose Volume Histogram



Manuscript

Depth Dose

PDD of Photon beam

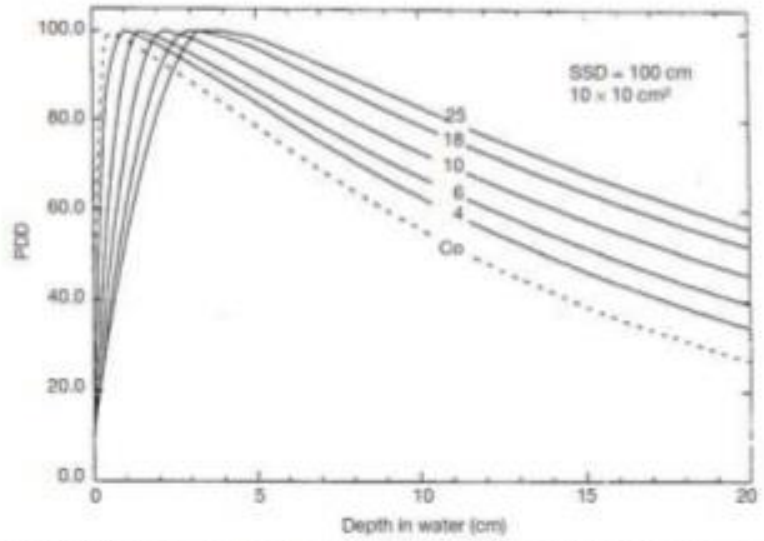


FIG. 6.10. PDD curves in water for a 10 × 10 cm² field at an SSD of 100 cm for various megavoltage photon beams ranging from ^{60}Co γ rays to 25 MV X rays.

PDD of Electron beam

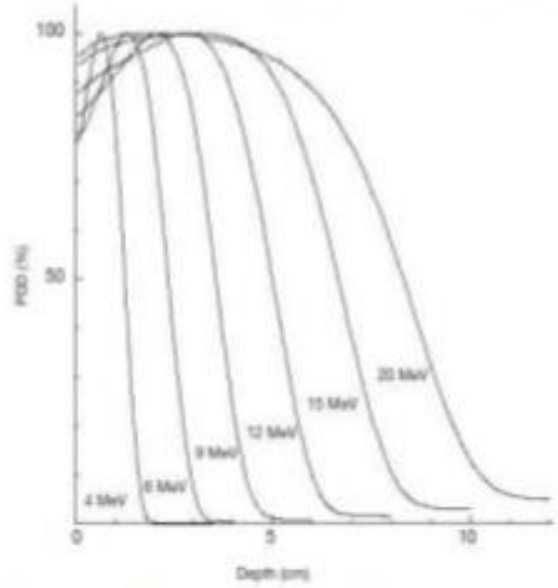
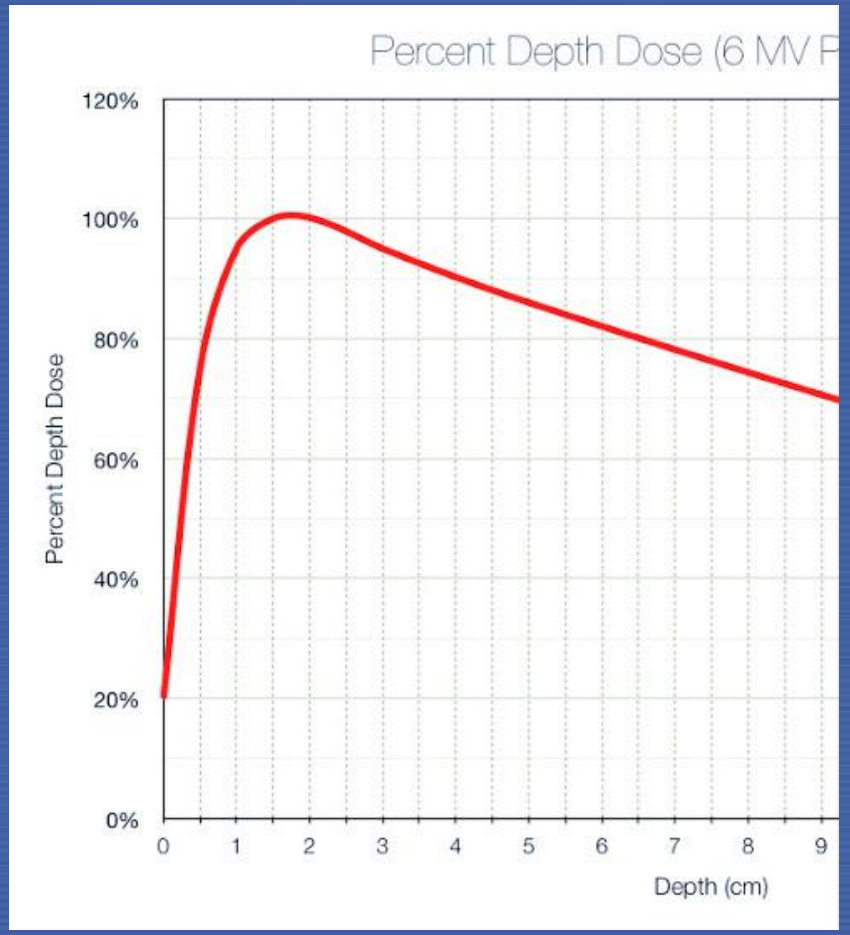


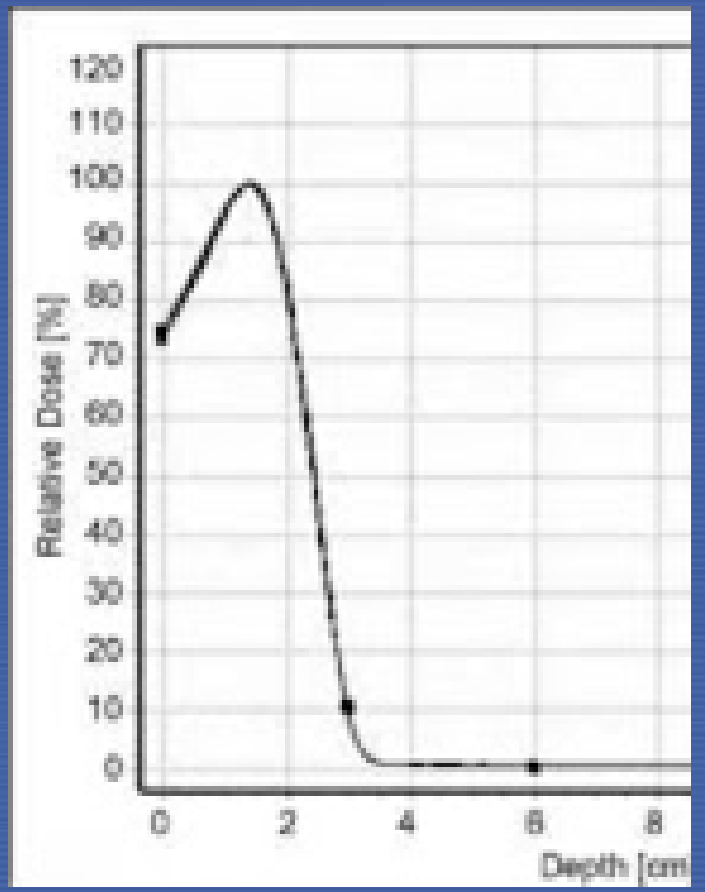
FIG. 8.3. Central axis PDD curves for a family of electron beams from a high energy linac. All curves are normalized to 100% at z_{max}.

Bolus



Bolus


Percent Depth Dose (6 MV F
120%
100%
80%
60%
40%
20%
0%
Percent Depth Dose
0
1
2
3
4
5
6
7
8
9
Depth (cm)


120
110
100
90
80
70
60
50
40
30
20
10
0
Relative Dose [%]
0
2
4
6
8
Depth [cm

Immobilization Devices



Immobilization Devices



Neutron Dose to Patient

- Neutrons are not accounted for in treatment planning software
- Depends on
  - The Linear Accelerator Model
  - Beam shaping used
  - Beam energy
- Low dose, won't contribute to treatment, carries low risk for patient

Prescriptions/Written Directive Procedure Requirements

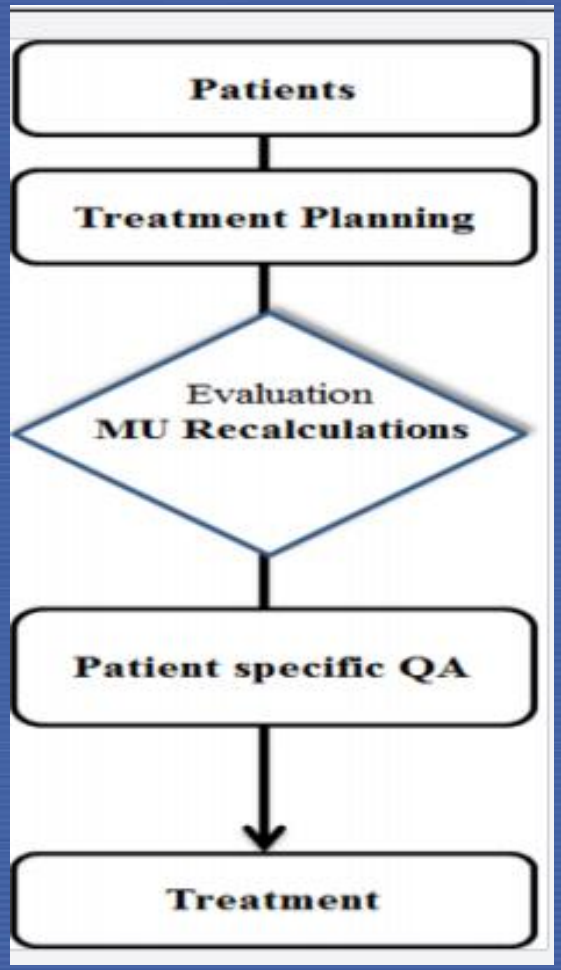
- Name
- dose per fraction
- number of fractions
- total dose
- authorized user signature and date
- Isotope (or) type and energy of beam

Medical Event Reporting Procedure

- Medical Event Reporting (example)
  - 24 hours after discovery by telephone
  - 15-30 days after discovery of the medical event a written report will be submitted
  - Expectations should be defined in the country specific regulations

Treatment Planning

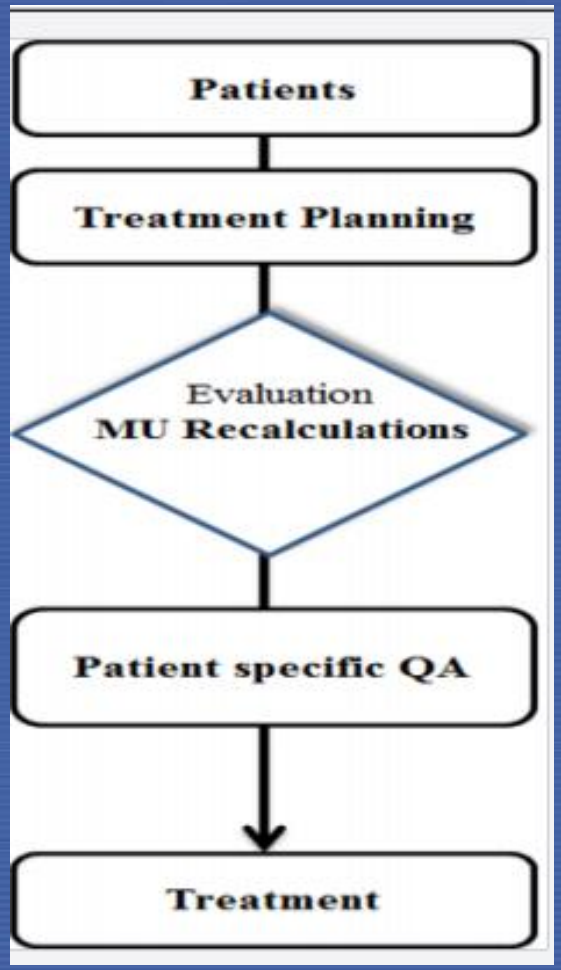
- Responsible Physician (RP) prescribes treatment by developing the Written Directive.
- Authorized Medical Physicist develops the Treatment Plan, RP approves
- Patient Treatment Simulation
- Monitor-Unit recalculations to check machine output at a single point in predetermined patient geometry. MU is determined using a water phantom at machine commissioning



Treatment Planning

- Patient identifier, Written Directive, Treatment Plan, position, etc. are reviewed by another authorized individual in accordance with written procedures

- Treatment started



Quality Management Program

- Charts reviewed
  - at least weekly,
  - before the third fraction following the start of each new treatment field or field modification
  - at the completion of treatment
- The chart review should be signed and dated by the reviewer (Oncologist, RP)

Chart Review

- Patient identification
- Treatment planning
- Simulator and setup instructions containing all relevant beam and patient parameters
- MU (minutes) calculation work sheet
- Signed and witnessed consent form
- Prescription page with signature and date
- Daily record documenting the daily and cumulative doses to all prescription, critical organ, and anatomical reference points

Chart Review

- Daily record documenting treatment aids (e.g., compensating filter, wedge) and portal and verification films
- Chronology of treatment changes and remarks
- Treatment field documentation including a graphical indication of each treatment portal and photographs of the field marking on the patient
- Descriptions of patient setup position, location of treatment field relative to external patient anatomy, special treatment devices, beam modifiers, etc., including a photograph of the patient in the setup position

Quiz-Questions

1. What is the isocenter and why is it important?
2. What is forward versus inverse planning?
3. What are GTV, CTV, and PTV?
4. Explain the effect of bolus.
5. What is the purpose of immobilization devices?
6. What minimum information should be on a written directive?
7. What are potential reporting requirements for an unintended or accidental medical exposure

Quiz-Answers

1. What is the isocenter and why is it important?

   The point of focus for radiation in which the PTV will be situated.

2. What is forward versus inverse planning?

   Manual vs Automated MLC

3. What are GTV, CTV, and PTV?

   Palpable tumor, add microscopic extension, add setup margin.

Quiz-Answers

4. Explain the effect of bolus.

Raise the surface dose.

5. What is the purpose of immobilization devices?

Setup accuracy and reproducibility.

6. What minimum information should be on a written directive?

Name, dose/fx, number of fxs, total dose, beam energy and type, physician signature.

7. What are potential reporting requirements for an unintended or accidental medical exposure

Phone call = 24 hours or on discovery, Written Report = 15-30 days

Exercise 2: Prescription Worksheet

This exercise should take 60 minutes

Regulation Development

Regulation Development

- Learning Objectives
  - *After this section the students should be able to name and identify different levels of regulatory requirements and how they are enforced.*
- This section should take 60 minutes

Regulatory Development

- Regulatory Components
  - Legislature
  - Regulations
  - Guidance Documents
  - Policies and Procedures

Regulatory Development

- Legislature
  - High level from non-technical experts
  - Delegates authority to Radiation Control Agency

  - *Regulatory Body will be established*
  - *Persons will be protected from Radiation*

Regulatory Development

- Safety Requirements GS-R-1 stipulates that: “The legislation shall establish a regulatory body with the authority:

  (a) to require any operator to conduct a safety assessment;

  (b) to require that any operator provide it with any necessary information, including information from its suppliers, even if this information is proprietary;

  (c) to issue, amend, suspend or revoke authorizations and to set conditions;

  (d) to require an operator to perform a systematic safety reassessment or a periodic safety review over the lifetime of facilities;

Regulatory Development

(e) to enter a site or facility at any time to carry out an inspection;

(f) to liaise and coordinate with other governmental or non-governmental bodies having competence in areas somewhat related with radiation safety; and

(g) to obtain such documents and opinions from private or public organizations or persons as may be necessary and appropriate

Regulatory Development



- Regulations
  - Developed by the Radiation Control Regulator
  - Has some Technical Components

  - *Radiation areas will be posted "caution radiation area" to protect persons*
  - *The posting will include a trefoil symbol*

Regulatory Development

- Regulatory or Safety Guides
  - Developed by the Regulatory Body
  - How to comply with regulatory requirements
  - Basis or background for what the language in regulation means
  - Publicly available to all Licensees

Regulatory Development

- Regulatory or Safety Guides
  - *Radiation areas should be posted at the door, with magenta and yellow trefoils and the words “caution radiation area” to protect persons*
  - *Radiation areas should be posted at the door, with an illuminating signal, to indicate when the Linear Accelerator is energized*

Regulatory Development

- Policies and Procedures
  - Developed by the Radiation Control Regulator
  - Procedures for the Regulator to follow to ensure consistency in interpretation and application

  - *Regulator will ensure licensees commit to posting areas in writing and verify posting during inspection*

Regulatory Development

Legislature	• *Persons will be protected from Radiation*
Regulation	• *Radiation areas will be posted to protect persons*
Guidance Documents	• *Radiation areas should be posted at the door, with magenta and yellow trefoils and the words "caution radiation area" to protect persons*
Policies and Procedures	• *Regulator will ensure licensees commit to posting areas in writing and verify posting during inspection*

Regulatory Development

- Regulation are developed by the Regulatory Body in Partnership with the industry stakeholders

  - IAEA
  - Committees
  - Draft Regulation
  - Public Hearings

Regulatory Development

- Regulation are developed by the Regulatory Body in Partnership with the industry stakeholders
  - IAEA
    - Safety Standards
    - TecDocs

Regulatory Development

- Regulatory requirements are developed by the Regulatory Body in Partnership with the industry stakeholders
  - Committees
    - Physicians
    - Physicists
    - Technologists
    - Lawyers

Regulatory Development

- Regulatory requirements are developed by the Regulatory Body in Partnership with the industry stakeholders
  - Draft Regulations
    - Developed with Committee and/or previous public comment input
    - Published
    - Comment Period of months for written responses

Regulatory Development

- Regulatory requirements are developed by the Regulatory Body in Partnership with the industry stakeholders
- Countries may collect information from the public in different ways
  - One example: Public Hearings
    - One or Several Days
    - Variable locations or accessible via internet to allow all affected communities to attend
    - Response from regulator not allowed or required during the meeting

Regulatory Development

- Guidance Documents
  - TecDocs are available from the IAEA that may be used as a basis to develop local guidance documents
  - Developed in partnership with committee
  - To provide basis and background for regulation and assist licensees in compliance
  - Useful tool for regulators to ensure consistency in understanding

Regulatory Development

- Policies and Procedures used during Authorization
  - Standardize what information is expected during an application
  - Standardize what is an acceptable response from the licensee
    - Less variability between reviewers even with lack of technical expertise
    - Maintaining consistency ensures enforceability across licensees and eliminates gaps in compliance coverage

Regulatory Development

- Examples of items in Policies and Procedures used during Authorization
  - May require a secondary peer review after primary completes review
  - May require Management review for all licensing actions
  - May institute a time frame for issuing a required response to application or for receiving a response from the applicant
  - Standardize communication language and time frames with licensees and applicants

Regulatory Development

- Policies and Procedures used in Inspection
  - Standardize what is an acceptable action to observe while visiting the licensee
    - Less variability between inspectors even with lack of technical expertise
    - Maintaining consistency eliminates gaps in compliance coverage by ensuring consistent review from inspectors

Regulatory Development

- Policies and Procedures used in Inspection
  - Require a secondary or peer accompaniment
  - Require Management review on inspector proficiency and/or inspection reports and/or licensee communications
  - May institute a time frame between inspection date to issuing a violation notice to the licensee, and violation notice to corrective action response from the licenesee
  - Standardize inspection communications for enforceability

Quiz-Questions

1. What is an example of an Administrative Code requirement?
2. Administrative Code is written with whose input?
3. What is an example of a Policy or Procedure?

Quiz-Answers

1. What is an example of an Administrative Code requirement?

   “A written prescription is required”

2. Administrative Code is written with whose input?

   End users, the public, regulatory body.

3. What is an example of a Policy or Procedure?

   Inspection or licensing checklists.

Sample Regulation Review

Sample Regulation Review

- Learning Objectives
  - *After this section the students should be able to understand regulatory language regarding linear accelerator use.*

- This section should take 30 minutes

Sample Regulation Review

i. Written Directives:

(1) A written directive must be dated and signed by an authorized user prior to the administration of radiation.

(2) 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.

(3) A written revision to an existing written directive may be made provided that the revision is dated and signed by an authorized user prior to the administration of the therapeutic radiation machine dose, or the next fractional dose.

Sample Regulation Review

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

Sample Regulation Review

Protection Surveys.

i. The registrant shall ensure that radiation protection surveys of all new facilities, and existing facilities not previously surveyed are performed with an operable radiation measurement survey instrument calibrated in accordance with X.8. The radiation protection survey shall be performed by, or under the direction of, a Qualified Medical Physicist or a qualified expert and shall verify that, with the therapeutic radiation machine in a "BEAM-ON" condition, with the largest clinically available treatment field and with a scattering phantom in the useful beam of radiation:

(1) Radiation levels in restricted areas are not likely to cause personnel exposures in excess of the limits specified in Part D.1201a.of these regulations.; and

(2) Radiation levels in unrestricted areas do not exceed the limits specified in Parts D.1301a. and D.1301b. of these regulations.

Sample Regulation Review

3.50. The dose limits for the public in planned exposure situations are set out in Schedule III of GSR Part 3 [2]. The dose limits for public exposure are:

"(a) An effective dose of 1 mSv in a year;
(b) In special circumstances[68], a higher value of effective dose in a single year could apply, provided that the average effective dose over five consecutive years does not exceed 1 mSv per year;
(c) An equivalent dose to the lens of the eye of 15 mSv in a year;
(d) An equivalent dose to the skin of 50 mSv in a year.

"[68] For example, in authorized, justified and planned operational conditions that lead to transitory increases in exposures."

Sample Regulation Review

ii. In addition to the requirements of X.4a.i., a radiation protection survey shall also be performed prior to any subsequent medical use and:

(1) After making any change in the treatment room shielding;

(2) After making any change in the location of the therapeutic radiation machine within the treatment room;

(3) After relocating the therapeutic radiation machine; or

(4) Before using the therapeutic radiation machine in a manner that could result in increased radiation levels in areas outside the external beam radiation therapy treatment room.

Sample Regulation Review

iii. The survey record shall indicate all instances where the facility, in the opinion of the Qualified Medical Physicist or a qualified expert, is in violation of applicable regulations. The survey record shall also include: the date of the measurements; the reason the survey is required; the manufacturer's name; model number and serial number of the therapeutic radiation machine; the instrument(s) used to measure radiation levels; a plan of the areas surrounding the treatment room that were surveyed; the measured dose rate at several points in each area expressed in microsieverts per hour; the calculated maximum level of radiation over a period of one (1) week for each restricted and unrestricted area; and the signature of the individual responsible for conducting the survey;

Sample Regulation Review

iv. If the results of the surveys required by X.4a.i. or X.4a.ii. indicate any radiation levels in excess of the respective limit specified in X.4a.i., the registrant shall lock the control in the "OFF" position and not use the unit:

(1) Except as may be necessary to repair, replace, or test the therapeutic radiation machine, the therapeutic radiation machine shielding, or the treatment room shielding; or

(2) Until the registrant has received a specific exemption from the Agency.

Quiz-Questions

1. What parameters are regulated in a prescription?

2. What kind of survey meter is required for public dose assessment surveys?

Quiz-Answers

1. What parameters are regulated in a prescription?

   The directive should contain patients name, prescribed dose, and the signature of an authorized responsible physician that determined that dose.

2. What kind of survey meter is required for public dose assessment surveys?

   Make, model and TYPE of survey meter is not specified. Regulations stipulate that surveys be completed, survey meters must be capable of detecting the radiation being measured and users should provide calibration and information to ensure any selected meter is appropriate.

Lunch

Authorization Process

Authorization Process

- Learning Objectives
  - *After this section the students should be able to understand the key aspects reviewed during each stage of licensing a linear accelerator.*
- This section should take 90 minutes, a 10 minute break may be provided

Authorization Process

Regulators should know:

1. Where and When Linear Accelerators are installed
2. What training users have
3. What Linear Accelerators are used for
4. How Linear Accelerators are maintained for quality control and assurance of energy output and associated parameters
5. How quality is managed to ensure patient treatments are in accordance with the written directives and treatment plans

In order to protect the public from unnecessary radiation risk

Authorization Process

- Each location must be authorized to possess and/or use a linear accelerator
- Policy and procedure should dictate the minimum information required to approve an application

Authorization Process

- An “authorization” is defined in the GS-R-1 [1] as “the granting by the regulatory or other governmental body of written permission for an operator to perform specified activities.”
  - Authorization can take the form of a registration or a license

Authorization Process

- Basic Safety Standards stipulate
  - Registration is best suited to those practices for which operations do not vary significantly
  - Practices that meet the following criteria may be considered for registration:

    (a) safety can largely be ensured by the design of the facilities and equipment;

    (b) the operating procedures are simple to follow;

    (c) the safety training requirements are minimal; and

    (d) there is a history of few problems with the safety in operation.

Authorization Process

- There are two types of authorizations: personal or individual authorizations and institutional authorizations.
- Individual authorization — is granted to persons proving to the satisfaction of the regulatory body their knowledge, training and practical experience on the subject for which they have applied for the authorization. This type of authorization is not linked to any physical installation, and during their period of validity, allows the authorization holder to work at any authorized practice according to their area of expertise.

Authorization Process

- There are two types of authorizations: personal or individual authorizations and institutional authorizations.
- Institutional authorization — is granted to the facility who has applied for an authorization for the performance of a given practice, after the regulatory body is convinced that such a practice can be carried out safely, and provided that the operator has in its permanent staff at least one person holding a personal or individual authorization for performing the same practice.

Authorization Process

- Institutional Authorization Applications
  - Blank documents are publicly available
  - Summarize items necessary to *begin* a regulatory review
- Additional information may be requested at anytime in order to document compliance with a regulatory requirement

Authorization Process

1	Facility Name:	
2	Facility Address:	
3	Correspondence Address/Phone Number:	
4	Authorized Personnel that may correspond on behalf of this license (attach management delegation):	
5	Proposed Radiation Safety Officer and Credentials:	
6	Proposed Medical Physicist and Credentials:	
7	Proposed Responsible Physician and Credentials:	
8	Accelerator Description: Make: Model: Serial Number: Manufacture Year: Remanufactured Year: On Board Imaging CT: Yes ☐ No ☐	9. Maximum Accelerator Energy Data: Electrons MeV Photons MV FFF Photons MV Other Particles Other Particle Energy MeV
10	Describe use of the medical accelerator and applicable radiation safety procedures. ☐ Shielding Evaluation and Acceptance Testing only ☐ IORT ☐ IMRT ☐ Arc Therapy	

Authorization Process

- Institutional Authorization Applications are multi page submissions

- Institutional authorization applications contain specific information about a site:
  - Address
  - Users and Qualifications
  - Devices
  - Capabilities
  - Intended use *

Authorization Process

11	**Facility Diagram:** Attach a site layout drawing depicting location of each accelerator vault, room number, and operating consoles. At a minimum indicate the following on the diagram: • Function and type of occupancy of all areas above, below and adjacent to the accelerator vault. • Accelerator location and gantry positions • Location of: Scram buttons, independent radiation monitors, viewing and communication system components **Describe:** the independent radiation monitor (make, model and any maintenance testing); beam stop system, identify Recorder/Verifier (Make model and functions involved); any door interlocks (location and if "failsafe"/can be opened from inside), viewing and communication system to the patient
12	**Shielding Evaluation:** Using IAEA TecDoc 47 Provide shielding evaluation of each bunker demonstrating protection of public and workers. If the accelerator is capable of energies of >10 MeV neutron shielding must be addressed.
13	**Shielding Verification:** Submit actual survey result that validate adequacy of the shielding. Include survey meter make model and calibration certificate and name of individual completing the survey. If the accelerator is capable of energies of >10 MeV survey measurements must include neutron fluence.

Authorization Process

- Shielding
  - Neutron Activation
  - Public Areas
  - Primary and Secondary Barriers
  - Types of Use (on times and energies)

Authorization Process

- Safety Interlock Commitments:
  - Are Failsafe Door interlock switches present
  - Describe the entry interlock function referenced
  - Can the door be manually opened from inside the accelerator vault.
  - Describe the viewing and communications system and the provision for providing a back up
  - Identify the Recorder/Verifier
    - Give make, model name, and functions involved

Authorization Process

- Safety Interlock Commitments:
  - Describe independent radiation monitor in the room
  - Describe the Beam Stop System (if applicable)
    - Describe if it is retractable, and if there are any restrictions
  - Describe any custom collimation/beam shaping system and accessory not provided by the manufacturer

Authorization Process

14 Quality Assurance Program and Procedures:

Identify:

- Method for independent biannual check of output
- Equipment available for QA measurements of the Linear Accelerator Beam

Describe:

- Procedure for independent biannual check of output
- Annual calibration procedures
- If a daily warm up is done every morning by the therapists/physicist
- Daily and Monthly checks, including personnel responsibilities for completing the check and review of results
- Include tolerance for each check and corrective actions for failed checks

15 Radiation Safety Program: Describe the following:

- Disposal of the accelerator
- Prescription Control procedures: what type of patient log book/daily schedule will be kept, how are deviations from the prescription identified, reported and reviewed, How often patient charts are reviewed by a physicist to verify calculations of dose totals, how often the patients are seen by the responsible physician, and annual program review
- Describe occupational monitoring, including any surveys or area monitoring
- Initial and recurrent training for operators, include agenda of topics
- Emergency Procedures and commit to posting a copy of your emergency procedures near the accelerator control panel. Emergency procedures should not be covered or obscured by non-emergency related postings.

Authorization Process

- Procedures (QA, QM)
  - Machine Checks
  - What if they Fail
  - Prescription Control Procedures

- Equipment capable to perform specified QAs
  - Commitment to maintain calibration of equipment

Authorization Process

- Radiation Protection Program
  - Operator Training
- Workplace Monitoring

Authorization Process

- Additional Information is requested by issuing a deficiency notice
- A template should be considered to standardize language
- A reviewer should complete the review of the entire application before submitting a notice of deficiency
- At least one deficiency notice during each phase is typical

Authorization Process

- After additional material is submitted a second deficiency may be sent if the licensee did not submit adequate additional information
- Typically if an applicant does not satisfy the deficiency notice within 3 notices, it is at the discretion of the reviewer to reject the application in it’s entirety and ask the applicant to resubmit when they are more suitably prepared

Authorization Process

- Deadlines should be given, after which, an application will be considered abandoned
- Applicants should be able to request extensions
- Intent:
  - Prevent frivolous applications
  - Ensure timely follow up

Authorization Process

- Example referencing regulation:
  - “**Pursuant to Regulation X**, item Y is required. No information pertaining to item Y was submitted, provide information regarding item Y”

  - Pursuant to Regulation X, annual calibrations are required. No information pertaining to equipment required for the annual calibrations was submitted, provide equipment make model and calibration frequency.

Authorization Process

- Example Referencing Application :
  - “**Pursuant to Application item X**, item Y is required. No information pertaining to item Y was submitted, provide information regarding item Y”
  - Pursuant to Application item X, a quality management program must be submitted. Information pertaining to the quality management program was insufficient, provide commitments regarding prescriptions and control of patient doses”

Authorization Process

- Applications for a new site are approved in a Step-Wise manner
  1. Construction and Commissioning
  2. For treatment of cancer in humans
  3. For storage incident to disposal

Authorization Process

- Construction and Commissioning
  - Location where accelerator will be installed
  - Intended use
  - Details of construction
  - Shielding plan with public dose assessment
  - Name and credentials of Responsible Physicist

Authorization Process

- For treatment of cancer in humans
  - An amendment to release from construction and commissioning
    - Submit verification of shielding
    - Submit acceptance testing confirmation
    - Submit commissioning testing confirmation

Authorization Process

- For treatment of cancer in humans
  - All Quality Management procedure for ensuring prescribed dose is administered for all modalities should be submitted
    - Prescription
    - Chart round commitments
  - Responsible physicist
  - Responsible physician

Authorization Process

- For storage incident to disposal
  - Commitment to not use the machine
  - Controls that will be in place to ensure machine is not energized during storage
  - Once the accelerator is no longer functional it may be on site, but should still be tracked until it is disposed
  - Storage incident to disposal tracks old machines until they are removed.

Authorization Process

- All information submitted and procedures are binding
- They can be inspected against as they are commitments from the licensee and descriptions as to how they will comply with regulation
- The license document will include reference to these items to communicate to the licensee the standards they are being held against, above and beyond the regulation
- If changes to procedures are made, they should be resubmitted for review and cannot be used until approved by the regulator

Authorization Process

- Additional Types of Licensing Actions:
  - Amendment to an existing license
  - Renewal of an existing license (typically every 5 to 10 years)
  - Termination of an existing license

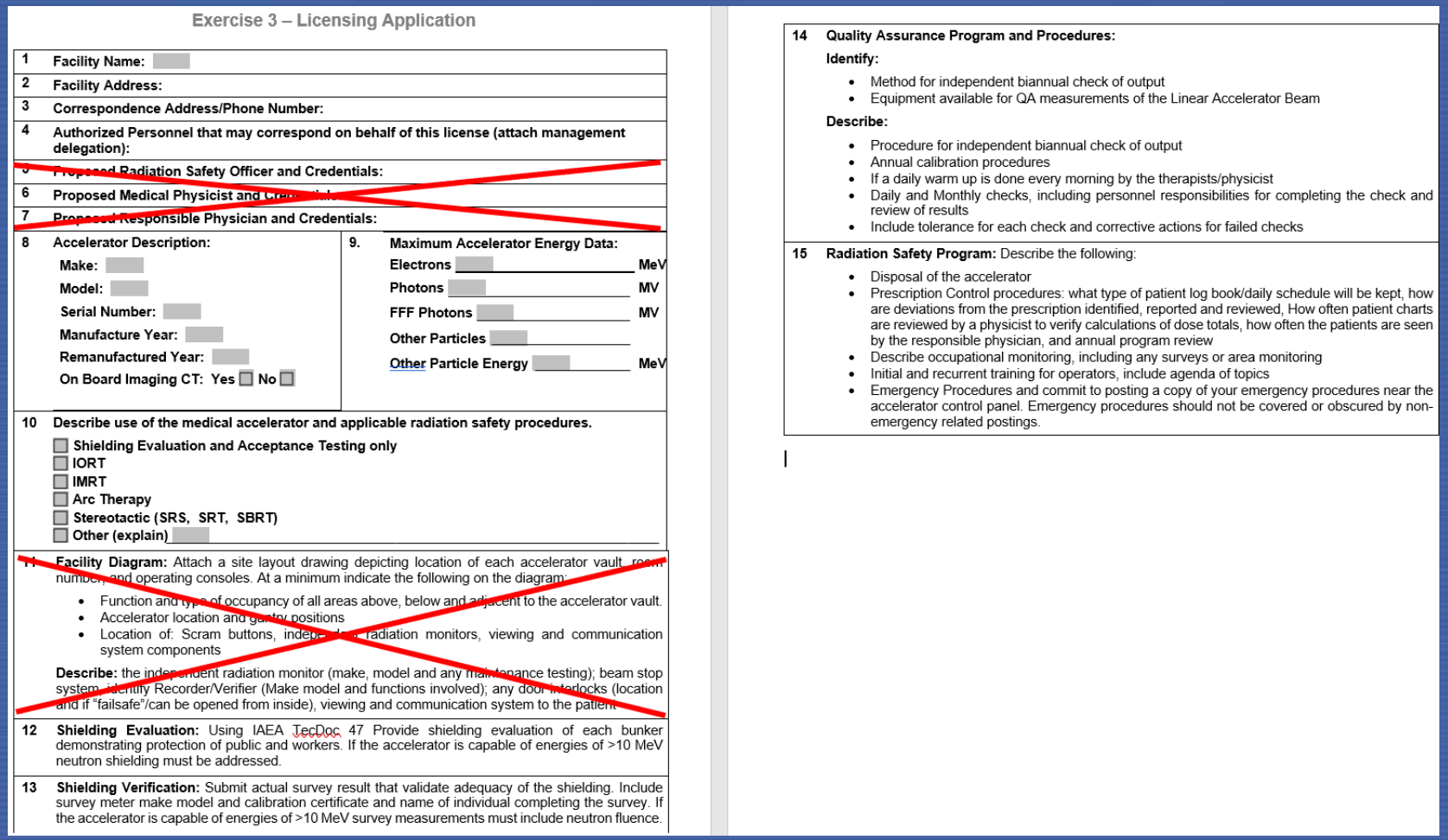
Authorization Process

- License Amendments:
- New users or remove existing users
- New Uses
  - Vendor or additional training
  - Additional equipment needed
  - Shielding evaluations needed

Authorization Process

- Documentation for Amendment:
  - A selection of items (prompts) from the application form for a new license application can be used as a guide to ensure all relevant information is submitted regarding a change
    - For example a new use:
      - item 12 shielding evaluation,
      - item 13 shielding verification,
      - item 14 QA,
      - item 15 QM procedures, emergency procedures, annual audit and training may need to be updated

Authorization Process



Exercise 3 – Licensing Application

1	**Facility Name:**
2	**Facility Address:**
3	**Correspondence Address/Phone Number:**
4	**Authorized Personnel that may correspond on behalf of this license (attach management delegation):**
5	**Proposed Radiation Safety Officer and Credentials:**
6	**Proposed Medical Physicist and Credentials:**
7	**Proposed Responsible Physician and Credentials:**

8	**Accelerator Description:** **Make:** **Model:** **Serial Number:** **Manufacture Year:** **Remanufactured Year:** **On Board Imaging CT: Yes ☐ No ☐**	9.	**Maximum Accelerator Energy Data:** **Electrons** _____ **MeV** **Photons** _____ **MV** **FFF Photons** _____ **MV** **Other Particles** _____ **Other Particle Energy** _____ **MeV**

10 Describe use of the medical accelerator and applicable radiation safety procedures.

- ☐ **Shielding Evaluation and Acceptance Testing only**
- ☐ **IORT**
- ☐ **IMRT**
- ☐ **Arc Therapy**
- ☐ **Stereotactic (SRS, SRT, SBRT)**
- ☐ **Other (explain)**

11 Facility Diagram: Attach a site layout drawing depicting location of each accelerator vault, room number, and operating consoles. At a minimum indicate the following on the diagram:

- Function and type of occupancy of all areas above, below and adjacent to the accelerator vault.
- Accelerator location and gantry positions
- Location of: Scram buttons, independent radiation monitors, viewing and communication system components

Describe: the independent radiation monitor (make, model and any maintenance testing); beam stop system; identify Recorder/Verifier (Make model and functions involved); any door interlocks (location and if "failsafe"/can be opened from inside), viewing and communication system to the patient.

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- Method for independent biannual check of output
- Equipment available for QA measurements of the Linear Accelerator Beam

Describe:

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- Annual calibration procedures
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- Initial and recurrent training for operators, include agenda of topics
- Emergency Procedures and commit to posting a copy of your emergency procedures near the accelerator control panel. Emergency procedures should not be covered or obscured by non-emergency related postings.

Authorization Process

- Documentation for Amendment:
  - A selection of items (prompts) from the application form for a new license application can be used as a guide to ensure all relevant information is submitted regarding a change
    - For example a new user:
      - item 5, 6 or 7 should be submitted

Authorization Process

Exercise 3 – Licensing Application

1	**Facility Name:**
2	**Facility Address:**
3	**Correspondence Address/Phone Number:**
4	**Authorized Personnel that may correspond on behalf of this license (attach management delegation):**
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7	**Proposed Responsible Physician and Credentials:**

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- ☐ **IMRT**
- ☐ **Arc Therapy**
- ☐ **Stereotactic (SRS, SRT, SBRT)**
- ☐ **Other (explain)**

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- Initial and recurrent training for operators, include agenda of topics
  Emergency Procedures and commit to posting a copy of your emergency procedures near the accelerator control panel. Emergency procedures should not be covered or obscured by non-emergency related postings.

Authorization Process

- Documentation for Renewal:
  - Renewals occur every 5-10 years
  - Entire application should be resubmitted for review with updated procedures and users
  - Previous license and procedures remain valid during review

Authorization Process

- Documentation for Termination:
  - Surveys of material prior to release
  - Documentation of disposal from vendor

Authorization Process

- Terminations (or modifications)
  - Residual Contamination (Activation Products) Survey
  - For radiation machines capable of generating photon and electron energies above 10 MV prior to machining, removing, or working on therapeutic radiation machine components which may have become activated due to photo-neutron production

Authorization Process

- Terminations
  - Survey information
    - Background characterization
    - Meter Selection
    - Efficiencies and Calibration
    - Locations of measurements

Authorization Process

- Information on a license document

Sample Medical Accelerator License*

1. Sample Accelerator Hospital
2. 200 Main Street
   Anytown, YourCountry 12345

3. License number
4. Expiration date
5. Docket No.
   Reference No.

6. Byproduct, source, and/or special nuclear material	7. Make/Model/Serial Number	8. Maximum Output (type and energy)
A. Varian	A. TruBeam	A. Photon: 20 MV Electron: 22 MeV
B. Elekta	B. Precise	B. Photon: 15 MV Electron: 22 MeV

9. Authorized use:
   A. For Shielding and Commissioning Testing Only.
   B. For the treatment of cancer in humans.

CONDITIONS

10. Linear Accelerators may be used or stored only at the licensee's facilities located at 200 Main Street, Anytown, YourCountry 12345.
11. The Radiation Safety Officer for this license is Sarah Smith, M.S.
12. Licensed material is only authorized for use by, or under the supervision of:
    A. The following individual is the responsible physician for the material and medical uses indicated:

	Material and Use
David Jones, M.D.	Linear Accelerators for treatment of cancer in humans.

    B. The following individual is an authorized medical physicist:

	Material and Use
Sarah Smith, M.S.	Linear Accelerators for commissioning, calibration and maintenance, and dosimetric planning in accordance to instructions from a responsible physician as listed above.

13. The licensee shall use the services of a third party qualified expert or third party TLD system to verify the accelerators radiation output every 2 years.
14. The licensee shall establish a quality management program to provide high confidence that radiation is administered as directed by the responsible physician.
15. The licensee shall establish procedures to ensure that the therapy dose is correct, and as prescribed by the responsible physician. The licensee shall establish procedures that specify; the time-frame in which the check shall occur, based on the specific therapy plan; the protocol used to make the check, and designate which staff member will perform the check.
16. Except as specifically provided by the license, the licensee shall possess and use the accelerator(s) described in this license in accordance with statements and representations contained in:
    Application dated January 1, 2222, signed by Sara Smith, M.S.

    The most recent statements, representations, and procedures shall govern if they conflict with previously submitted documents, unless otherwise specified by a license condition; and the Administrative Code shall govern the licensee's statements in applications or letters.

Authorization Process

Sample Medical Accelerator License*

1. Sample Accelerator Hospital
2. 200 Main Street
   Anytown, YourCountry 12345

3. License number
4. Expiration date
5. Docket No.
   Reference No.

6. Byproduct, source, and/or special nuclear material	7. Make/Model/Serial Number	8. Maximum Output (type and energy)
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Authorization Process

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Quiz-Questions

1. What are the three phases of licensing a linear accelerator?
2. What is required to release a linear accelerator for medical use?
3. What is a type of amendment?

Quiz-Answers

1. What are the three phases of licensing a linear accelerator?

   Commissioning and Shielding Testing only, Treatment of Cancer in Humans, and Storage Incident to Disposal.

2. What is required to release a linear accelerator for medical use?

   Survey documentation to demonstrate adequate shielding, commissioning and acceptance testing verification, responsible physician, medical physicist, prescription control procedures, radiation safety program details.

3.What is a type of amendment?

   New user, new use, new machine, termination

Exercise 3: Application Checklist

This exercise should take 60 minutes

Summary : Questions and Answers

Treatment Planning Quiz-Questions

1. What is the isocenter and why is it important?
2. What is forward versus inverse planning?
3. What are GTV, CTV, and PTV?
4. Explain the effect of bolus.
5. What is the purpose of immobilization devices?
6. What minimum information should be on a written directive?
7. What are potential reporting requirements for an unintended or accidental medical exposure

Treatment Planning Quiz-Answers

1. What is the isocenter and why is it important?

   The point of focus for radiation in which the PTV will be situated.

2. What is forward versus inverse planning?

   Manual vs Automated MLC

3. What are GTV, CTV, and PTV?

   Palpable tumor, add microscopic extension, add setup margin.

Treatment Planning Quiz-Answers

4. Explain the effect of bolus.

Raise the surface dose.

5. What is the purpose of immobilization devices?

Setup accuracy and reproducibility.

6. What minimum information should be on a written directive?

Name, dose/fx, number of fxs, total dose, beam energy and type, physician signature.

7. What are potential reporting requirements for an unintended or accidental medical exposure

Phone call = 24 hours or on discovery, Written Report = 15-30 days

Authorization Process Quiz-Questions

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Authorization Process Quiz-Answers

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