LECTURE NOTES

Authorization and Inspection of Linear Accelerators

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1.0 REGULATION DEVELOPMENT

1.0 Regulation Development

The Role of Government

The essential role of government in the development and establishment of regulations is to provide the legal authority to administer and enforce the regulations. The objectives that the government wishes to achieve with the regulations should be defined as high level policy, with a focus on preserving the health and safety of workers, members of the public, and property.

Though each government is responsible for the safety of operation in their own nation, since risks can potentially expand beyond the nation's borders communication and cooperation with the international community and respect and observance for international safety standards is important for preserving the health and safety of the global population and environment.

The government is responsible for establishing the laws or statues that provide the framework for regulation, as well as authorizing the tools for enforcing regulations such as a regulatory body. The framework should clearly state the:

a) Safety principles for protecting people, property, and the environment from radiation risks
    1) Principles should Include stipulation of the necessary level of competence for responsible persons
    2) Provision for arrangements to build and maintain expertise for the regulatory body to discharge its duties
    3) Provision for arrangements for increasing, maintaining, and verifying the technical competence of persons working for authorized parties
b) The facilities and activities that will be subject to regulation
c) The types and rational behind the authorizations to be granted, and the decision-making process behind granting approval
d) Identification of interested parties and the process for allowing their input
e) Provision for assigning legal responsibility of maintaining safety to authorized persons or organizations
f) Establishment of a regulatory body
g) Authority to review, assess, and inspect authorized facilities, and enforce regulations, including specification of offences and corresponding penalties
h) Authority to promulgate regulations
i) Process for appealing decisions of the regulatory body
j) Financial responsibilities for decommissioning and termination of responsibilities and criteria for release from regulatory control.
k) Provision for emergency response and security

If several authorities are involved, the division of authority within the regulatory framework shall be explicitly defined.

Approval of Regulations

Each government's structure for enacting laws is different. The drafting and approval of regulations must be carried out in accordance with their legislative process. One of the

fundamental requirements for establishing requirements of protection and safety is that the prime responsibility rests on the organization responsible for the facilities and activities that give rise to the risks.

Establishment of a Regulatory Body

The government must legally establish the regulatory body, providing it with the authority and resources necessary to perform its statutory duties. These duties may include the development and promulgation of regulations, the drafting of guidance for implementation of regulations, review and approval of applications for authorizations or amendments to existing authorizations, inspection of authorized facilities and activities, enforcement of regulations including levying sanctions, and releasing facilities from regulatory control when appropriate criteria are met.

Staffing of the Regulatory Body

A human resources plan shall be developed that states the number of staff necessary and the essential knowledge, skills, and abilities required for them to competently perform all necessary regulatory functions. It should cover recruitment, development and maintenance of competency, and turnover.

The management system should be organized to contribute to the achievement of the regulatory body's safety goals. It should function openly and transparently and be continuously assessed and improved. Its functions are to ensure the responsibilities of the regulatory body are being met, to optimize the performance of the body by means of planning, control, and supervision of its activities, and through leadership foster a safety culture in the regulatory body. Management should ensure that regulatory control is stable, consistent, and objective through the establishment of specified policies and procedures.

Independence of the Regulatory Body

Though stakeholder influence of the regulatory body is appropriate when establishing its scope and statutory obligations, in its operation it must be free from undue influence from other entities. In order to ensure its independence, it must ensure the regulatory body has;

a) Sufficient authority, resources, and competent staff
b) The ability to make independent regulatory judgements and decisions
c) Freedom from political, economic, or outside pressures from other governmental bodies, authorized parties, or other organizations
d) The ability to advise and report to other governmental bodies on the safety of authorized facilities and activities
e) Authority to cooperate with other state or international regulatory bodies and organizations to cooperate and share expertise and experience.
f) Freedom from conflicts of interest
g) Authority to require all necessary safety information and access to any premises be granted for the purposes of reviewing and inspecting an authorized party or applicant.

h) Authority and capability to communicate with governmental authorities at a high level when necessary for effectively performing its functions

Cooperation with Other Regulatory Bodies

Assistance from other states and international organizations should be sought from the government where its experience and resources are insufficient to meet international safety standards

a) Where training programs within the state are insufficient, arrangements for training shall be made with other states or international organizations
b) Support may come from outside organizations on a temporary or permanent basis, and a dedicated support organization may be established, so long as conflicts of interest are managed, formal contracts are observed, and it is made clear that the receipt of advice does not relieve the regulatory body of its assigned responsibilities.

Operating and regulatory experience and lessons learned should be arranged to be disseminated and received between states and to authorized parties, international reporting and knowledge networks, and other relevant authorities. This sharing of knowledge helps enhance the safety and security of all authorized facilities and activities.

Establishment of Technical Services

The government shall make arrangements as necessary to ensure there is access to technical services such as personnel dosimetry and calibration services. This can be a governmental, commercial, or other non-governmental provider. Calibration services traceable to a national or international standard shall be available for the therapy class equipment with which absorbed dose determination is performed. Organizations that provide these services should obtain accreditation or other official recognition that they meet the standards to calibrate equipment used for absorbed dose determination.

Maintenance of Safety Related Records

The following records should be maintained by or their maintenance facilitated by the regulatory body.

a) Copies of the most recent authorization for facilities and activities along with their applications and supporting documents
b) Copies of all amendment applications
c) Copies of inspection reports, enforcement histories, and corrective actions for each authorized party
d) Records of doses from occupational exposure
e) Records relating to the safety of facilities and activities
f) Decommissioning records
g) Records of events, incidents, or allegations involving authorized parties and documentation of the resolution

The Role of the Regulatory Body

The regulatory body must act within and be dependent on the legal framework established by the government. The primary objective of the regulatory body is the verification and assessment of safety in compliance with regulatory requirements. It should emphasize the continuous enhancement of safety as a general objective. The regulatory functions shall continue with each authorized party from the time of authorization until release from regulatory control.

Scope of Authority

Objectives

The regulatory functions of the body shall provide confidence that:

a) Safety is optimized
b) Safety assessments verify that a high level of safety is achieved
c) Site evaluation confirms that the site operations and conditions are in accordance with authorization
d) Facilities are designed and constructed to meet the relevant regulatory requirements
e) Facilities are operated and activities are conducted in accordance with the authorization
f) Authorized parties have the human, organizational, financial, and technical capabilities to operate facilities and conduct activities safely
g) The shutdown of facilities and cessation of activities comply with regulatory requirements

Responsibilities

a) The government is responsible for providing sufficient resources to the regulatory body to fulfill its statutory obligations.
b) The regulatory body is responsible for structuring its organization and managing its resources. Resources shall be allocated based on associated risk in accordance with a graded approach.

Functions

a) Establish formal and informal liaison between the regulatory body and authorized parties on all safety related issues to achieve their common objectives. The objectives, principles, and criteria for safety on which its requirements, judgements and decisions are based should be shared freely with all applicants.

The Development of Regulations and Guidance Documents

Regulations

Regulations give specific requirements on how the law is to be applied in practice. They should be generally applicable to activities and facilities, with more detail being tied to a specific facility's authorization.

They codify the legal requirements and help maintain uniform application of the law. They tend to be more technical than the law.

Regulations should be:

a) Consistent with and closely linked to the corresponding law
b) Clear, understandable, unambiguous, and precise
c) Comprehensive
d) Not in conflict with other regulations or laws
e) Realistic and able to be followed
f) Abide by any relevant international standards and conventions

Due to the ever-changing landscape of technology, politics, and economics, there should be a process for reviewing and amending regulations as needed. However, due to risks in modifying well established practices, any regulatory changes shall be carefully scrutinized.

A balance should be struck between flexible regulations able to adapt to changing needs and detailed requirements for which it's easy to determine if they're being met. The former can be satisfied by performance regulations, which generally specify an objective that must be met, whereas the latter can be satisfied by prescriptive regulations which describe what must be done.

Guidance Documents

Guidance documents are developed by the regulatory body as an aid to authorized parties and those applying for authorization. Guidance documents should be made publicly available to all authorized parties. They provide detailed technical and operational guidelines to ensure that regulatory and legislative requirements are met. They should not impose requirements themselves but rather provide interpretation of performance-based regulations or describe what the regulatory body considers good practice.

They shall demonstrate the framework for the regulatory requirements and conditions to be incorporated into individual authorizations. From reading and following the guidance documents authorized parties should understand how to comply with regulatory requirements. Guidance documents shall also establish the criteria to be used for assessing compliance.

They should also include guidance regarding the overall regulatory process, including the process for applying for authorization, guidance on filling out an application, fees for authorization and any recurring fees to maintain authorization. They should list the different types of authorization and criteria to assist in determining which category their activities would fall under.

They should be comprehensive such that applicants for authorization referencing the appropriate guidance document should be able to reasonably complete an application with all required supplemental documentation, understand the regulatory requirements that would accompany authorization including inspection frequencies and criteria, renewal schedules, and requirements for filing an amendment. Any forms and worksheets, example annual safety program review checklists, required postings can

also be included or made available to authorized parties. Contact information and information on how to make payments should also be included. Supporting references, identification of any official technical support organizations that may assist them, and example policies and procedures may be included for further assistance.

They must be reviewed and revised periodically to ensure the most current state of the regulatory framework is reflected. This should be incorporated into the process for amending regulations. Consideration should be taken of relevant international safety and technical standards. Relevant experience gained should be incorporated.

Regulatory Development Process

Collaboration with Stakeholders

Applicable IAEA Guidance

Extensive guidance is freely available for states developing new regulatory programs

The guidance compiles significant experience and knowledge gathered from many countries over many years

Following guidance competently will help the state establish a program in line with others in the international community.

International Community

The international community has a stake in the development of regulations as it pertains to the perception of the regulated activities, how it impacts international relations, and its impact on commerce.

Medical Facilities and Personnel

The regulated activities and parties are most impacted by the regulations.

Input from these parties should be solicited and respected and care should be taken to mitigate conflicts of interest.

A collaborative relationship toward safety will produce better results than a contentious relationship. Showing respect and appreciation for the impacts of the regulations on authorized parties is important for building this collaborative relationship.

Impacted Industry

Industries impacted by these regulations beyond the directly regulated parties and activities should be included in the input process.

Examples are medical device manufacturers such as linear accelerators and CT scanners, treatment planning software developers, standards laboratories, consulting companies, etc.

Conflict of interest must be managed.

Committees of Experts

Solicitation of comments from recognized experts in the field can be useful in drafting and effective regulatory rulebook, especially in helping with the prioritization and allocation of limited resources.

Members of the Public

As the members of the public will be served by the authorized parties and their safety is directly at stake, the ability for them to provide comment is essential for fostering goodwill and demonstrating transparency to the public.

Drafting Regulations

The authority to enact regulations comes from the State and can be delegated to the regulatory body. Certain situations might prompt an agency to begin rulemaking, including

1. New technologies
2. Improved understanding of technologies through new data, experiences, and accidents
3. Concerns with the efficacy of the current regulations
4. Recommendations from other agencies or advisory committees within the government
5. Petitions from interest groups, corporations, and the public
6. Lawsuits filed by interest groups, industry, or the public
7. Recommendations from within the regulatory agency itself

The process of drafting regulations differs from country to country, and likely a process is already established that must be followed. The process might include issuing a public notice that rulemaking will commence, followed by the development and review of a proposed rule, then publication of the proposed rule for public comment. Then the review of public comments which will help inform the development of a final rule.

In developing regulations for an activity or activities, first grade the relative risk of the activities carried out by authorized parties.

For the lowest associated risk determine if regulation is necessary based on available resources or if the activity should be exempt from regulation.

For the highest associated risk, specific detailed attention may be warranted from the regulatory body.

When there is a risk that the regulatory body wishes to mitigate through regulation, it must be determined if the regulation should be a prescriptive or performance regulation. If the regulation is prescriptive, an understanding of the facility, staff, and equipment is necessary to determine what resources are available and how they can be put to use in the least burdensome way to mitigate the risk. If a regulation is a performance regulation, then the objective to mitigate the risk simply needs to be stated, and achieving that objective would be up to the authorized party. However, guidance on how it might be achieved could be provided in a guidance document.

For example, the risk of unintentional exposure of the LINAC beam to staff, patients, or other members of the public is mitigated by the prescriptive requirement that the beam be interlocked with the door so it will not deliver unless the door is closed, and that visual monitoring of the room be available at the LINAC console to ensure the room is clear and the patient is still in position when the beam is turned on.

For ensuring LINAC beam output stability, simply saying it should be verified to be within 3% on a daily basis and 2% on a monthly basis allows flexibility in how it is achieved.

Public Comments

It shall hold meetings or otherwise solicit feedback from the public and interest parties regarding proposed regulations.

Interested parties including the public shall have the opportunity to be consulted in the process of making significant regulatory decisions, subject to national legislation and international obligations.

It's possible that the public comments necessitate the issuance of another proposed rule and public comment period, or an extended comment period.

Final Enactment

The final enactment process may look different from country to country. The process might be that after public comments are received and the public comment period has ended, they are reviewed and where appropriate may be incorporated into the final rule. The final rule is drafted by the regulatory body, then sent to committee for review. Once the review is complete and the rule has been deemed satisfactory, it will be published along with the date on which it goes into effect. This allows authorized parties impacted by the rule change time to make arrangements or changes to meet the new requirements.

Considerations in Development of Regulation

Safety

The primary goal in the development of a regulatory program is to create an enforceable framework for compelling authorized parties and activities to adopt workflows, policies, and procedures that best protect the health and safety of workers, patients, members of the public, the environment, and property. The primary focus should be on rules that most effectively meet the above goal. The allocation of state resources and the resources of authorized parties should be designed to most efficiently and effectively achieve the goal of safety, especially when resources are limited. Priority should be given to the activities which pose the greatest safety risks, and the most cost-effective solutions.

Needs of the Public

The regulatory body is in service to the public. Their needs should be carefully considered when developing regulations. Their safety, public perception, financial impacts, and resource allocation must be considered. How regulations might impact the availability of treatment for the public should be taken into account. Other

considerations might arise from the public feedback, all of which should be seriously examined.

Needs of Industry

The needs of the regulated industry must be taken into account. Care must be taken in understanding the resources available to authorized parties. Regulations should be developed using a graded approach, that is to say the level of analysis, documentation and actions necessary to comply with the regulation is commensurate with the magnitude of any hazard involved and the particular characteristics of the facilities. This approach will help identify the areas with the highest risk, help direct effort and resources to those specific areas, and prevent the regulations from becoming burdensome.

Regulations must be sufficient that if followed it can be assured with a high level of confidence that the safety of the activity, personnel involved, any patients, and the public is sustained. They must also be reasonably achievable by authorized parties.

The regulatory body could also consider what support or resources might be made available to the regulated industry to ease the burden of regulation and build goodwill between the regulatory body and authorized parties.

Technical Aspects

Certain technical aspects should be controlled in regulation to ensure patient and worker safety

Patient Treatment Procedures and Quality Management

Written directives are the physician's orders for treating the patient with radiation therapy. There is essential information that must be included:

a) Patient name
b) Dose per fraction
c) Number of fractions
d) Total dose
e) Type (electron vs photon) and energy of beam
f) Authorized user signature and date

Once the written directive and treatment plan is approved and has passed all safety checks satisfactorily it is ready for patient treatment. The patient will be scheduled for fractionated treatment in accordance with the written directive. Additional quality checks will be performed at regular intervals for continued plan and treatment quality assurance.

a) **Immediately preceding the first treatment**, with the treatment parameters loaded into the treatment console, they shall be checked against the parameters from the treatment plan to ensure congruence.
b) **On the first day of patient treatment**, the therapists shall verify the patient's identity using at least two form of identification. They shall confirm the

correct treatment plan is being used and the correct site is being treated. The dose and fractionation shall be confirmed against the prescription.

c) **On subsequent days of treatment**, the therapists shall confirm the patient's identity by two forms of identification, that the correct plan is being treated, and that the correct fraction is being treated. The prescription is reviewed for changes and any patient notes are reviewed.

d) **After treatment**, the therapists shall confirm that treatment delivery was according to plan and that treatment parameters were properly recorded.

On a weekly basis the patient's treatment progress shall be reviewed. There are several mechanisms through which this should be done.

An evaluation of treatment progress between the patient and physician where side effects can be evaluation, the physician can discuss progress and provide support including answering the patient's questions and concerns. A physical exam may be performed as appropriate. The nurse takes vitals and patient weight to evaluate their overall health.

a) Radiation therapists review patient documentation to ensure all required documents are present and the appropriate approvals are in place. The prescription, orders, and patient notes are reviewed for information. After treatment the source-to-surface distance (SSD) is measured and compared against the planned SSD to check for trends in patient positioning, with large deviations being reported to the Physicist.

b) The physicist performs a chart review checking that the treatment parameters for each treatment were properly recorded and match the planned parameters. Imaging is checked, daily patient shifts based on imaging are reviewed and the SSD measurements are reviewed to identify any trends in patient positioning that may need to be accounted for. The prescription, physician's orders, and patient notes are reviewed to check that any changes to the patient's treatment plan were made and if so whether the changes have been implemented. A review of the chart to ensure all required documents are present and signed shall be performed as well.

c) An interdisciplinary chart rounds shall occur where the patient's overall progress is reviewed including the above items. Communication among team members and any concerns are shared.

Record and Verify Systems

a) The recording and verification of treatment parameters was done by reviewing the parameters entered into the treatment console against a printout or manual recording of the planned parameters. Then after treatment the delivered parameters would be recorded into a paper treatment log which would be reviewed by the physicist on a regular basis.

b) Computerized record and verify systems (R&V) are designed to automate or facilitate the recording of treatment parameters and the comparison of delivered treatments against planned treatments. Communication between

the treatment console and the R&V allow for automated recording of the treatment parameters.

c) Modern record and verify systems have also become a radiation oncology electronic medical records system, into which patient documents, prescriptions, treatment plan parameters, schedules, progress notes, etc. Can be loaded. They are often designed to communicate with treatment planning systems using DICOM-RT, which is a standardized treatment plan data format so that treatment plans and planning images can be easily transmitted to the R&V, and then to the treatment console.

d) Routine QA of these systems to ensure proper transfer of data should be performed. Whenever these systems are upgraded comprehensive testing of functionality and data fidelity should be performed to ensure no loss of treatment information or corruption of treatment plans has taken place.

Calibration, Quality Control, and Quality Assurance

The applicant shall either submit details of or commit to creating and maintaining a QA program, including proper procedures for calibration, quality control, and quality assurance. These procedures should describe the structure, responsible individuals, and duties of the QA program. They should detail the procedure for equipment acceptance, calibration, and maintenance. They should detail the quality control tests that are to be performed on all devices and equipment, as well as the tolerances and frequencies of these tests. The results of these tests shall be maintained. The actions to be taken when tolerances are exceeded should also be described. Finally, regular preventative maintenance should be performed on the machine, with records of this maintenance kept. The frequency of each of these tests, parts replacements, adjustments, or repairs and their associated testing limits should be described in the procedure.

Equipment

Sufficient calibrated and well-maintained equipment must be available to perform the QA tests described in the QA program. Certain devices such as the ion chamber and electrometer shall have a calibration that's traceable to national or international standards.

i. Ion Chamber

Ion chambers are used to independently measure the beam output. This should be a therapy class ion chamber, which requires calibration every two years. The calibration shall include a charge-to-dose calibration coefficient.

ii. Electrometer

Electrometers are used with ion chambers to provide the bias voltage that allows charge collection. The charge is collected and read by the electrometer. Electrometers require calibration every two years.

iii. Water tank

A water tank of greater than 30x30x30cm3 is a useful tool for performing the annual absorbed dose determination. Larger tanks that are able to scan an ion chamber in three dimensions are essential for the initial commissioning of the LINAC, and can be useful for annual dose profile verification. Translation along the vertical axis allows for annual depth dose verification.

iv. Detector arrays

Two-dimensional ion chamber or diode arrays can take simultaneous measurement of many points across the radiation field. This is useful for taking dose profiles monthly and annually for flatness and symmetry verification, for daily output QA, or for patient-specific treatment plan QA.

v. Other QA tools

To perform comprehensive QA of the machine other tools are useful to complete the QA as described in the protocols. Examples may be:

a) Graph paper or a stable, accurate ruler for field size measurements, couch translation verification
b) A level for gantry and collimator indicator verification
c) Calibrated source-to-surface distance indicators to verify the optical distance indicator

Testing

Acceptance Testing

After the LINAC is installed, acceptance testing is performed in the presence of the installer to confirm that the LINAC is operating within specifications. The tests to be performed are agreed upon between the vendor and the facility, unless minimum acceptance testing standards could be mandated by the government. This is typically represented by the signing of a legal document transferring operation control over to the facility.

Commissioning

Commissioning is the collection of all the data necessary to fully characterize the LINAC as input into the treatment planning system. The required measurements for input into the treatment planning system differ depending on the system, but would include some combination of depth dose curves at various field sizes, beam profiles at various depths and field sizes, field size output factors, jaw and MLC parameters.

The collection and input of this data is of the utmost importance as it will impact the quality and accuracy of every patient treatment. The accuracy of commissioning should be validated through the measurement of treatment plan deliveries to ensure that what is planned is actually what is delivered by the machine.

Commissioning measurements should also be used as baseline comparisons for QA testing, as the goal of future QA is to maintain the LINAC performance within an acceptable range of what was characterized in the treatment planning system.

Daily Linac QA

Limited testing with less precise setup and equipment is done daily to ensure all key parameters are still functional, and nothing has gone wrong with the machine to make it unsafe to treat patients. Below is a list of tests recommended by the AAPM TG142 for daily QA.

Day of Treatment Checks (Day 1, slide 83)

a) Written directive is signed
b) Treatment isocenter is verified
c) Computer calculations are verified
    1. Input
    2. Output
    3. Data Transfer
    4. MU independent check
d) Acceptance testing is performed by a qualified individual
e) QC testing is performed and reviewed by a qualified individual
f) Treatment parameters entered into treatment console match treatment plan

TABLE I. Daily.

	Machine-type tolerance		
Procedure	Non-IMRT	IMRT	SRS/SBRT
Dosimetry			
X-ray output constancy (all energies) Electron output constancy (weekly, except for machines with unique e-monitoring requiring daily)		3%	
Mechanical			
Laser localization	2 mm	1.5 mm	1 mm
Distance indicator (ODI) @ iso	2 mm	2 mm	2 mm
Collimator size indicator	2 mm	2 mm	1 mm
Safety			
Door interlock (beam off)		Functional	
Door closing safety		Functional	
Audiovisual monitor(s)		Functional	
Stereotactic interlocks (lockout)	NA	NA	Functional
Radiation area monitor (if used)		Functional	
Beam on indicator		Functional	

Monthly Linac QA

Monthly testing with more precise setups and equipment is done to check key parameters for drift and check that all tolerances are met. Trends from monthly and daily QA can inform decisions on whether adjustment, replacement, or repair is necessary. Below is a list of tests recommended by the AAPM TG142 for monthly QA.

TABLE II. Monthly.

Procedure	Machine-type tolerance		
	Non-IMRT	IMRT	SRS/SBRT
Dosimetry			
X-ray output constancy Electron output constancy Backup monitor chamber constancy		2%	
Typical dose rate[a] output constancy	NA	2% (@ IMRT dose rate)	2% (@ stereo dose rate, MU)
Photon beam profile constancy		1%	
Electron beam profile constancy		1%	
Electron beam energy constancy		2%/2 mm	
Mechanical			
Light/radiation field coincidence[b]		2 mm or 1% on a side	
Light/radiation field coincidence[b] (asymmetric)		1 mm or 1% on a side	
Distance check device for lasers compared with front pointer		1mm	
Gantry/collimator angle indicators (@ cardinal angles) (digital only)		1.0°	
Accessory trays (i.e., port film graticle tray)		2 mm	
Jaw position indicators (symmetric)[c]		2 mm	
Jaw position indicators (asymmetric)[d]		1 mm	
Cross-hair centering (walkout)		1 mm	
Treatment couch position indicators[e]	2 mm/1°	2 mm/1°	1 mm/0.5°
Wedge placement accuracy		2 mm	
Compensator placement accuracy[f]		1 mm	
Latching of wedges, blocking tray[g]		Functional	
Localizing lasers	±2 mm	±1 mm	< ± 1 mm
Safety			
Laser guard-interlock test		Functional	

Annual LINAC QA

Annual LINAC QA includes a check the LINAC dose output with the most precise measurement. The IAEA TRS 398 describes an international code of practice for absorbed dose determination in external beam radiotherapy.

In general, annual LINAC QA, with its more precise setups and lower tolerances, is an opportunity to identify and adjust beam parameters to closer agree with baseline measurements.

TABLE III. Annual.

Procedure	Machine-type tolerance		
	Non-IMRT	IMRT	SRS/SBRT
Dosimetry			
X-ray flatness change from baseline		1%	
X-ray symmetry change from baseline		±1%	
Electron flatness change from baseline		1%	
Electron symmetry change from baseline		±1%	
SRS arc rotation mode (range: 0.5–10 MU/deg)	NA	NA	Monitor units set vs delivered: 1.0 MU or 2% (whichever is greater) Gantry arc set vs delivered: 1.0° or 2% (whichever is greater)
X-ray/electron output calibration (TG-51)		±1% (absolute)	
Spot check of field size dependent output factors for x ray (two or more FSs)		2% for field size $<4\times4$ cm^2, 1% $\geq4\times4$ cm^2	
Output factors for electron applicators (spot check of one applicator/energy)		±2% from baseline	
X-ray beam quality (PDD_{10} or TMR_{10}^{20})		±1% from baseline	
Electron beam quality (R_{50})		±1 mm	
Physical wedge transmission factor constancy		±2%	
X-ray monitor unit linearity (output constancy)	±2% ≥5 MU	±5% (2–4 MU), ±2% ≥5 MU	±5% (2–4 MU), ±2% ≥5 MU
Electron monitor unit linearity (output constancy)		±2% ≥5 MU	
X-ray output constancy vs dose rate		±2% from baseline	
X-ray output constancy vs gantry angle		±1% from baseline	
Electron output constancy vs gantry angle		±1% from baseline	
Electron and x-ray off-axis factor constancy vs gantry angle		±1% from baseline	
Arc mode (expected MU, degrees)		±1% from baseline	
TBI/TSET mode		Functional	
PDD or TMR and OAF constancy		1% (TBI) or 1 mm PDD shift (TSET) from baseline	
TBI/TSET output calibration		2% from baseline	
TBI/TSET accessories		2% from baseline	
Mechanical			
Collimator rotation isocenter		±1 mm from baseline	
Gantry rotation isocenter		±1 mm from baseline	
Couch rotation isocenter		±1 mm from baseline	
Electron applicator interlocks		Functional	
Coincidence of radiation and mechanical isocenter	±2 mm from baseline	±2 mm from baseline	±1 mm from baseline
Table top sag		2 mm from baseline	
Table angle		1°	
Table travel maximum range movement in all directions		±2 mm	
Stereotactic accessories, lockouts, etc.	NA	NA	Functional
Safety			
Follow manufacturer's test procedures		Functional	

Patient-Specific QA

For each treatment plan generated, the calculated MU should be double checked independently by either another verified calculation program or through the use of the machine data to calculate the MU by hand. Reasonable agreement between the two methods gives confidence that the treatment planning system is operating correctly.

For intensity modulated plans where the MLC undergo complex movements to generate an optimized dose distribution, direct measurements of the plan delivered dose compared with the dose calculated by the treatment planning system

Linear Accelerator Staffing

Policy should be developed describing the requirements for maintaining the competence of the appropriate staff

Radiation Oncologist

a) Medical Doctorate
b) Radiation Oncology Residency
c) Device specific training
d) Explicitly listed on authorization document as the authorized user

Dosimetrist

a) Basic radiation physics
b) Training in the facility's treatment planning system
c) Instruction in the capabilities and limitations of the treatment machine.
d) Training in specific procedures

Medical Physicist

a) May be listed on authorization document
b) May require board certification to practice independently
c) Master's degree or higher in Medical Physics, Physics, Engineering, or other physical science.
d) 2 years professional training
e) Training with the specific equipment, devices, and procedures

Radiation Therapist

a) Basic radiation physics and radiation safety training
b) Classroom and hands-on clinical training in the treatment of patients including patient setup, machine operation
c) Training in the facility's specific policies and procedures, including on any QA responsibilities of the therapist
d) Training in operation of the facility's machines

Radiation Safety Officer

a) Can serve multiple roles, e.g. Medical Physicist
b) Master's degree or higher in Medical Physics, Physics, Engineering, or other physical science.
c) 1 year professional training
d) 200 hours classroom training
e) Training in all authorized activities/devices

Practical Aspects

The resources and equipment available to the regulatory body and authorized parties may differ from country to country. It is important that the resources allocated to the regulatory body be sufficient to exercise all its duties and fulfill its responsibilities. And

sensitivity must be given towards the resources available such that the authorized parties can reasonably meet regulatory expectations. These practical considerations must be taken into account in order to develop a program that is functional given the state of the government, society, and industry. That's why pursuing the development of regulations and inspection and enforcement programs with a focus on safety using a graded approach is so important. Investment of limited resources to where they will give the best returns towards safety is paramount.

Public Perception

Regulatory guides and regulations shall be made available to the general public, along with promotion of the principles and criteria for safety established in the regulations.

The regulatory body shall establish provision for communication with the public and interested parties on regulatory judgements and decisions.

The regulatory body shall create a provision for informing the public and news media about the radiation risks associated with facilities and activities, their requirements for protection of people and the environment, and the regulatory body processes.

References

Regulatory Development

1. Day 2, Slides 48-80
2. Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses, Final Report (NUREG-1556, Volume 9, Revision 3)
3. 10 CFR Part 35 – Medical Use of Byproduct Material
4. IAEA GSR1: Government, Legal, and framework for safety

Calibration, Quality Control, and Quality Assurance

1. Day 1, slides 79-95 & Day 2, slides 40-42
2. AAPM Task Group 142: Quality assurance of medical accelerators
3. AAPM Task Group 40: Comprehensive QA for Radiation Oncology
4. IAEA TRS398: Absorbed dose determination in external beam radiotherapy
5. IAEA Tecdoc989: Quality Assurance in Radiotherapy
6. IAEA publication (ISBN 92-0-107304-6) Review of Radiation Oncology Physics: (A Handbook for Teachers and Students).

Linear Accelerator Staffing

1. Day 3 Slides 3-21
2. Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses, Final Report (NUREG-1556, Volume 9, Revision 3)
3. 10 CFR Part 35 – Medical Use of Byproduct Material

2.0 AUTHORIZATION PROCESS

2.0 Authorization Process

Authorization

Authorization by the regulatory body shall be a prerequisite for all facilities and activities that fall under the regulatory body's authority.

The applicant shall be required to submit an adequate demonstration of safety in support of their application.

Initial Submission

Step-wise authorization shall be given for different stages in the lifetime of the facility: Construction, commissioning, treatment of humans, and decommissioning. The activities authorized shall correspond to the stage.

The application shall include:

a) The facility's address
b) The facility diagram, including areas surrounding the linear accelerator vault
c) An accompanying shielding calculation with all proper dimensions and assumptions stated, and any facility specific information that impacts the calculation
d) Staff training and qualifications
e) Devices, capabilities, and their intended use
f) Other regulated activities
g) Additional equipment for maintenance and quality assurance of the devices
h) Policies and procedures established to ensure safety of staff, patients, and the public
i) A safety assessment in which the regulatory body can assess the risks and determine the degree of regulatory control required for the facility and activities

Application Review

Upon receipt of the application the regulatory body shall review the proposed activities, devices, and all supporting documents.

Through the supplied information the regulatory body should be able to acquire an understanding of the design of the facility or equipment, the concepts on which the safety of the design is based, and the operating principles proposed by the applicant.

The regulatory body should be satisfied that the safety of the facility or proposed activity and the optimization of protection is demonstrated, that the submission is accurate and sufficient to allow confirmation of compliance with regulatory requirements, and any operation and technical provisions have been proven to be reliable or safe through experience and/or testing.

Policy should dictate the timeframe under which the review will take place, for example 30 days from receipt to review and response.

Any missing information in the application shall be identified. Any additional information needed to ensure that safety standards are being met shall be noted.

A request for the missing or additional information shall be drafted and submitted to the party seeking authorization within the allotted time. This request shall include the timeframe for response.

Applicant Responses

Upon receipt of the request for information, the party seeking authorization shall review the items requested, draft a response addressing each item and include all supplemental documentation, then deliver the response within the allotted time.

This may be an iterative process, with additional requests for information and responses required to reach an acceptable application.

Policy should dictate at which point an application is rejected, whether due to expiration of the timeframe, or a failure to submit all required information within a certain number of exchanges.

If an application is rejected the party seeking authorization may need to begin the application process with a new submission.

Issuing Authorizations

Based on the activities and devices for which authorization was requested, the submitted documents, policies, procedures, shielding calculation, and the safety assessment the authorization will be granted with the regulatory body imposing whatever limits, conditions, and controls deemed necessary to ensure safety of operation.

The regulatory body shall establish a process that allows the party seeking authorization to appeal against regulatory decisions relating to an authorization for a facility or activity or a condition placed on authorization.

Separate authorizations or amendment to authorizations may be required for the different stages in the lifetime of a facility, as activities change. A process for handling these changes should be implemented to ensure consistency and fairness in their handling.

The regulatory body shall document the basis for its decision in granting authorization, as it shall for renewal, suspension or revocation, and shall inform the applicant of its decision along with justifications in a timely manner as dictated by policy.

Amendment

Any proposed modification that might significantly affect the safety or a facility or activity, or runs contrary to any of the conditions on the authorization, or introduces a new activity or device, must be subject to a review and assessment by the regulatory body through an authorization amendment process.

Authorization Renewal

Due to changes in technology, regulations, activities, equipment, and facilities licenses will change over time through amendments.

To both prevent over complication of amendments and changes to an authorization over time, and allow a routine thorough revision and review of an authorized party's program, routine renewal of authorization should be required.

The frequency of renewal should be a matter of policy set by the regulatory body. To ensure timely submission of renewal a reminder may be sent to authorized parties some time prior to the submission due date.

The renewal process should begin with the authorized party submitting a new application with the most current information, activities, documents, and policies and procedures.

The review continues as if it were a new application. When the renewal is accepted the previously submitted documents can be archived so their active authorization contains only the most current information.

Application Contents

Facility Information

There are many safety features that should either be described in the application documentation or the applicant should commit to incorporating into their facility design. These items shall also be verified on inspection.

a) There must be an interlock on all doors, gates, and motion detectors that terminates the beam and prevents irradiation when they are opened, preventing accidental exposure.
b) Shielding design goals must be met for instantaneous and weekly dose rate. The amount of shielding required is dependent on the use of the areas adjacent to the vault, so careful consideration should be made for the layout of the facility to optimize safety.
c) Whether the design incorporates a thicker door or a maze to reduce the radiation dose at the entrance is an important design decision as well.
d) Proper signage must be posted/displayed, including caution radiation area signs and an indicator near the door that the x-ray beam is on.
e) Audio and visual monitoring is important for patient safety to help ensure they have not moved and so they can communicate if they are in distress.
f) Proper security should be maintained on the operation of the LINAC, including a physical key and log-in security for the treatment console.

Construction

The location of the linear accelerator vault and CT simulator should be chosen to limit the required shielding

Building these vaults at the lowest level and on the periphery of the building or adjacent to low occupancy areas will provide a significant reduction in the shielding costs.

Access conduits through the shielded vault walls are required for passing dosimetry equipment cables. In addition, ventilation ducts, water pipes, and electric cabling all need to be passed through. The holes in the shielding should be through secondary barriers, and should not be a direct path through the shielding but an 's' shape, so radiation does not have a direct path through the shielding.

Concrete is often used as an effective shielding material that is structurally sound and relatively inexpensive. Concrete vaults, however, take up a lot of space, so other materials such as steel may be used if space is a concern.

For LINACs that produce energies of 10 MV or greater neutron shielding must be considered. Due to its high effectiveness against neutrons, if concrete is used for the primary and secondary barriers and is sufficient for shielding x-rays it will be sufficient for shielding neutrons. The neutron dose is significantly lower than that of x-rays, and as the tenth-value layer (TVL) for x-rays is double that of neutrons their contribution outside these barriers is negligible. However, neutron dose at the exit of a maze or on the other side of a direct-shielded door must be controlled, as concrete cannot be used in door shielding.

Shielding calculations

(Day 3, Slides 47-73, Exercises 5 and 5.A)

The purpose of shielding calculations is to determine for a particular facility layout, vault design, and LINAC photon energies, the thickness of the shielding required to sufficiently reduce the radiation outside to meet the radiation protection limit, also known as the shielding design goal.

Shielding design goals vary depending on whether it's a controlled area (accessible only to radiation workers) or an unrestricted area (open to members of the public) as the radiation protection limits for members of the public are less. An area can be considered controlled if there are barriers to entry for non-authorized personnel or it is monitored and those authorized are specifically trained in the use of ionizing radiation.

Instantaneous dose rates, time-averaged dose rates, or a combination of the two may be used as shielding design goals. The instantaneous dose rate is the maximum reading of the dosimeter in dose per hour during beam-on, averaged over one minute. The time-averaged dose rate is the dose rate averaged over a much longer time period. Often a week is chosen. As only a small fraction of the treatment time is actual radiation beam-on time, and the main concern is cumulative dose to individuals, time-averaged dose rate can be a useful way to express shielding design goals. This is typically expressed in mSv/week, with examples in the table below.

[mSv/week]	Controlled	Uncontrolled
United States	0.10	0.02

International	0.12	0.004

To determine the barrier thickness required to shield radiation to meet the shielding design goals, the workload (W) of the linear accelerator must be calculated. The workload is the number of patients treated per day, the average dose per patient, and the number of treatment days per week, e.g.
40 patients/day* 3Gy/patient*5 days/week= 600Gy/week. Detailed equations provided in IAEA report 47 walk through the other factors required to calculate the shielding required for any LINAC vault design. Ultimately the result of the calculation is to find the attenuation factor (B) the shielding needs to supply in order to meet the shielding design goal. Once the attenuation is determined, the number of tenth-value layers can be calculated by taking the negative log of the inverse of the attenuation factor, e.g.
#TVLs = -log(B)

The shielding required can be provided by just one material or multiple different materials. The TVLs are additive, so if the result is that 6 TVLs are needed, and steel, lead, and concrete are being used in proportional amounts, then, simply 2 TVLs each of steel, lead, and concrete need to be incorporated. Data on TVLs for different LINAC energies are provided in the referenced reports.

There are multiple sources of radiation when the LINAC is energized. The primary beam which delivers the patient treatment will enter and pass through the patient, striking the wall behind them. This is the largest source of radiation and is calculated separately, each barrier it strikes is considered a primary barrier. The radiation that enters the patient and then is scattered throughout the room is another source, and it strikes all barriers, which are called secondary barriers. The radiation outside the useful radiation beam that leaks through the shielding in the LINAC head is the third source, also striking all barriers.

The primary barrier shielding required is calculated using the following equation if using weekly time-average dose rate

5.1.1. Weekly dose rate

The required attenuation of the barrier B may be determined according to a desired dose constraint (design limit) that is derived from an occupational or public dose limit. Reference [2] uses the following expression to determine the attenuation required by the barrier:

$$B = \frac{P(d+\mathrm{SAD})^2}{WUT} \tag{5}$$

where

P is the allowed dose per week (Sv·week^{-1}) outside the barrier;
d is the distance from the isocentre to the outside of the barrier, in m;
SAD is the source–axis (isocentre) distance, in m;
W is the workload, in Gy·week^{-1} at 1 m;
U is the use factor or fraction of time that the beam is likely to be incident on the barrier;
T is the occupancy factor or the fraction of time that the area outside the barrier is likely to be occupied (see Table 3).

The thickness of the primary barrier will always be much greater than that needed to shield from scatter and leakage, so they can be ignored for the primary barrier thickness determination.

The secondary barrier shielding required is calculated by first individually calculating the scatter and the leakage thicknesses. Then, if the thickness required to protect against one differs from the other by less than one TVL, the greater of the two thicknesses plus one HVL is used. This works because the greater thickness is sufficient for shielding against the more intense source, and adding another HVL to cut it in half again will more than compensate for adding the less intense source. If the thickness required differs by more than one TVL, then the less intense source can be ignored and just the greater thickness can be used as the greater thickness will be able to shield against the less intense source by more than tenfold. NCRP 151 calls this method the “Two Source Rule”.

The barrier required to shield against leakage is determined by

$$B_L = \frac{1000 P d_s^{\,2}}{WT} \tag{8}$$

where

P is the design dose limit;
d_s is the distance from the isocentre to the point of interest in m;
W is the workload;
T is the occupancy factor.

And for scattered radiation

$$B_p = \frac{P d_{\text{sca}}^2 d_{\text{sec}}^2}{aWT(F/400)} \tag{9}$$

where

P, W and T have the same meaning as in Eq. (8).
d_{sca} is the distance from the radiation source to the patient, in m.
d_{sec} is the distance from the patient to the point of interest, in m.
a is the scatter fraction defined at d_{sca}. The scatter primary ratio (a) is dependent on the energy of the X ray beam and the scattering angle. These data are tabulated per 400 cm^2 of irradiated field area for ^{60}Co, 6, 10, 18 and 24 MV X ray beams in Table 5 [2, 20].
F is the field area incident on the patient, in cm^2.

These figures are all from IAEA Report 47.

The most complicated shielding calculation is at the entrance. There are to main types of entrance. One is a direct-shielded door which is designed to independently meet the design limit when closed and is much thicker, requiring a combination of lead for photon shielding, steel for strength, and borated polyethylene (BPE) for neutron absorption if high energies are used. The other is a maze, or long shielded corridor which will prevent most of the scattered radiation from reaching the entrance thus reducing or even eliminating the door shielding requirement. The treatments of these aspects of the calculation are much more complicated and are described in the references.

For energies greater than 10 MV where neutrons are a concern, neutron dose must be accounted for. Concrete is an effective neutron shielding material as it has a high hydrogen content and neutrons can transfer great energy to hydrogen due to their similar mass. Since the concrete TVL for neutrons is about half that of concrete then so long as at least one photon TVL is used for shielding, if shielding is sufficient for photons then it will be sufficient for neutrons. This is because as with the Two Source Rule for scattered and leakage radiation, if the above conditions are met the calculated thickness would differ by more than one TVL and taking the greater (photon) thickness would be sufficient. However, if a material other than concrete is used neutron dose calculation

must be performed, which may require expert consultation to complete as IAEA Report 47 suggests. Capture gamma and neutron doses at the door or maze entrances must also be calculated as described in the references.

User Qualifications

The LINAC staff should all be properly qualified, with respective qualifications listed below

Radiation oncologist

A medical doctorate and have completed a radiation oncology residency. Device specific training for all equipment they will be responsible for using and should perform all activities under the supervision of a qualified physician until they are deemed competent to perform these activities independently. They are to be explicitly listed on the authorization document as an authorized user before acting independently, and must demonstrate sufficient training and experience to obtain that listing.

Dosimetrist

Understanding of basic radiation physics, raining in the treatment planning system, instruction in the capabilities and limitations of the treatment machine. Training in specific policies and procedures, including any QA responsibilities.

Medical physicist

Master's degree in Medical Physics, Physics, Engineering, or other physical science. Two years professional training. Training with the specific equipment, devices, and procedures. May be listed on the authorization document, may require board certification to practice independently.
Radiation therapist: Basic radiation physics and radiation safety training. Classroom and hands-on clinical training in the treatment of patients including patient setup and machine operation. Training in specific policies and procedures, including any QA responsibilities. Specific training in the operation of the facility's machines.

Radiation Safety Officer

Can server multiple roles, e.g. radiation safety officer and medical physicist. Master's degree or higher in Medical Physics, Physics, Engineering, or other physical science. 1 year professional training. 200 hours classroom training. Training in all authorized activities and devices.

Training Program

The determination of training and experience necessary in order to maintain a competent and sufficient workforce shall be a matter of national policy.

Competence should be built via didactic and technical training and research and development.

The main goal of the training is to ensure staff are capable of providing safe care for the patients and operate their equipment safely for staff, patients, and members of the public.

Delivering safe treatment and developing and executing a comprehensive quality assurance program are two important components to that safety.

Policies and Procedures

Authorized parties shall develop policies and procedures appropriate to protect the safety of staff, members of the public, and patients. These policies and procedures shall also describe workflows to ensure consistency and effectiveness of treatment.

Regulators should have the technical knowledge required to evaluate whether these policies and procedures are sufficient for meeting these objectives.

What policies and procedures are required by the regulatory body for given activities is a decision made by the regulatory body themselves, and should be a matter of policy for consistency across authorized parties. Some regulatory bodies may choose to forgo procedures and instead write certain items into the regulations or include them as conditions on authorizations. Others might instead of including a requirement as a regulation instead allow the flexibility of the authorized party committing to a procedure. A non-comprehensive list of policies and procedures that might be asked for during the licensing process, or that the authorized parties might be committed to writing and maintaining, follows:

a) Culture of safety
b) Patient identification/timeout
c) SOPs for major activities
    1) LINAC treatment
    2) CT simulation
    3) Quality assurance of devices, equipment, and patient treatment
d) Emergency procedures including disaster response
e) Training/competency requirements
f) Radiation safety training
g) Occupational monitoring program
h) Supervision of the department and staff in training
i) Equipment and device maintenance and calibration

Emergency Procedures

Emergency procedures should be available for all staff to review in a common area and shall be posted at the site of operation such as the LINAC or CT console. The emergency procedure should represent the best practices in responding to an emergency, and should provide enough step by step detail that the emergency can be resolved by following the procedure but also be succinct enough that it will not slow down the emergency response. Routine emergency drills and review of procedures can greatly enhance response readiness.

Operation

All staff shall be trained in accordance with their responsibilities on all the facility's devices and activities. Hands-on training and supervised operation shall continue until the individual has demonstrated competency with the device or activity. Competency

should be demonstrated through an objective and standardized process to best ensure the individual will operate independently in a safe manner.

For example, therapists must have training in the positioning, imaging, and treatment delivery on the specific LINACs they will be using to treat patients. This can be provided through a mix of classroom and hands-on training, whether provided through the facility itself or through a third party such as the device manufacturer. Similarly, training in designing setups for treatment with the CT simulator and performing and transferring patient scans, and assisting the physician in setting isocenter must be provided to the therapists.

Extensive training for the medical physicist shall be provided in the operation of these devices as well. They must be well versed in the physics and safety aspects of the LINAC and CT Simulator in order to safely perform QA, write appropriate procedures for use, make decisions regarding operation based on device performance, and assist in trouble shooting.

Required Equipment

Training in the use of all equipment used for patient immobilization, simulation and treatment preparation, patient safety, quality assurance should be provided and competence should be confirmed.

Machine Maintenance

The purpose of a machine maintenance program is to set out the tests, inspection items, and parts replacements that should occur on a routine basis as part of a preventative maintenance inspection as well as set out procedures for response to machine downtime in order to have a smooth process of getting on-site support to restore the machine to functionality.

Machine maintenance is typically performed by a clinical engineer, with training in the maintenance, replacement, and repair of all parts of the LINAC, the LINAC power supply, and console. Similarly, clinical engineers servicing the CT simulator should be fully trained in their service. They are also often responsible for the mechanical adjustments to the beam generating and guiding system to ensure that the beam is symmetric, centered, and flat as it was when commissioned, that the pulse size and dose rate are appropriately calibrated, and that the energy is properly tuned.

The clinical engineer can be in-house staff, a private contractor, or an employee of the LINAC manufacturer working under the terms of a service contract. After repair and maintenance either the clinical engineer will run tests on the machine and the physicist will analyze it or the physicist themselves will perform the test. What tests are required depends on the parts being replaced.

As machine downtime can be very costly to the department as well as potentially jeopardize the efficacy of patient treatment courses, it should be avoided as much as possible. That’s why a robust preventative maintenance program is so important. This is

especially true when resources don't allow for an on-site clinical engineer to quickly respond to downtime, and significant travel might be involved for one to arrive on-site.

Therapists should be trained to be vigilant in observing and reporting any issues or changes in behavior with the machine in order for serious issues to be diagnosed and corrected during off-hours before it leads to downtime if possible.

Commissioning and QA

Commissioning is a time consuming and painstaking process requiring attention to detail and mastery over the dosimetry equipment to achieve the best possible accuracy and precision in measurement. The commissioning data is considered the baseline for machine performance against which all future QA measurement is compared. It can take a well-trained and experienced physicist weeks to properly commission a LINAC. This is typically only done once per machine at installation, and with machine lifetimes lasting 5-15 years many physicists don't engage frequently enough to retain mastery in this process. In addition, the timeframe required for an individual physicist to perform this work delays the use of the LINAC for patient treatment. This is why consulting firms are often used, sending a team of physicists on-site to perform commissioning as a service, greatly accelerating the timeframe and likely improving the accuracy due to their expertise. Whether the commissioning is performed by a staff physicist or a consulting firm, oversight of commissioning should be the responsibility of a physicist with all of the training described in the user qualifications section as well as extensive experience in the commissioning process specifically.

The physicist is responsible for the development and implementation of the QA program. The QA program should be developed following the guidance of the greater physics community such as IAEA or AAPM publications, yet be tailored to best meet the needs of the program given the program's staffing, equipment, activities, and resources. The physicist shall oversee the training and verify the competency of all staff performing QA, including the tolerance and action levels. The results of the QA must be reviewed by the physicist in a timely fashion.

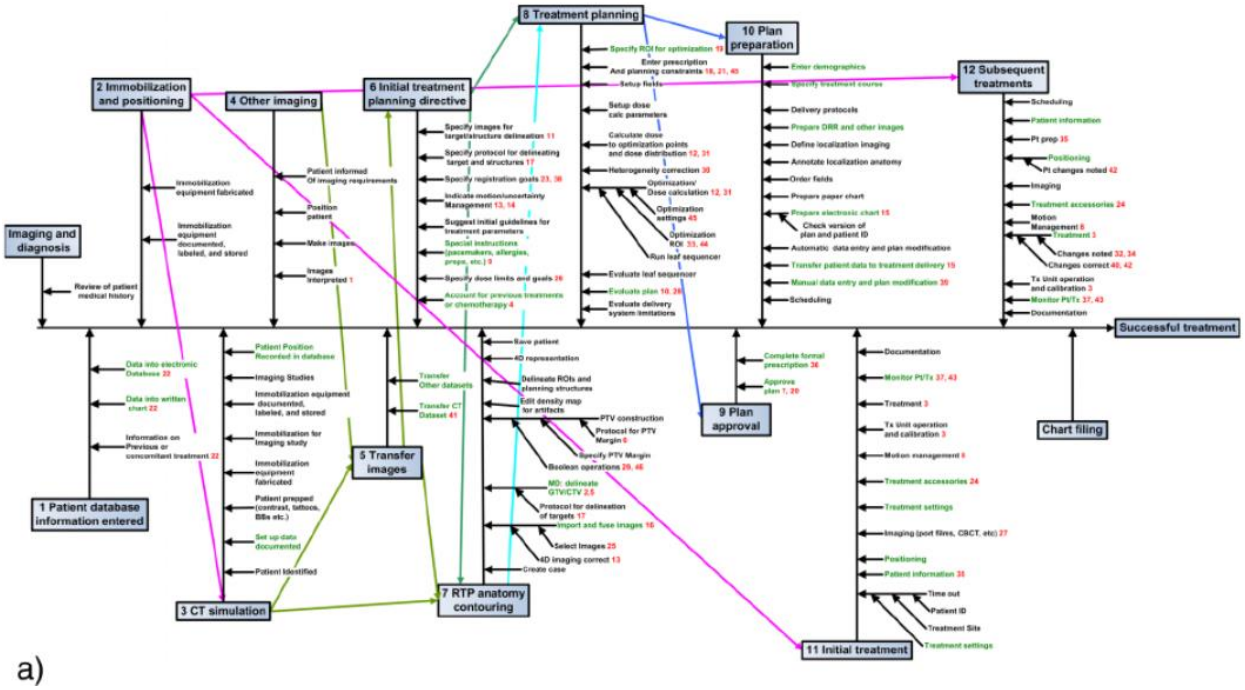
Radiation Safety Program

The radiation safety program consists of elements covered previously here, radiation protection, commissioning and QA, training, postings and notifications, patient treatment, written directives and treatment documentation, and policies and procedures.

It should be designed using a graded approach. The review and assessment of a facility or activity shall be commensurate with the associated radiation risks. Authorized parties shall agree as a condition of authorization to routinely evaluate operating experience and perform comprehensive safety reviews which shall be made available to the regulatory body. The regulatory body shall also assess the radiation risks associated with normal operation, anticipated events, and accidents prior to granting authorization and periodically throughout the lifetime of the facility. This shall be done to determine whether the radiation risks are as low as reasonably achievable.

One method of analyzing risk is the prospective approach proposed by the AAPM's Task Group 100. The proposal is that the regulatory body or authorized party review the activities for which they are authorized, or specific workflows and processes supporting those activities, and identify the possible failure modes within.

Identifying the workflows and how they are interconnected is called process mapping. An example for an IMRT process map is shown below.



a)

Identifying the failure modes can be done by fault tree analysis, that is a logical analysis of un undesired outcome and all of the mistakes that could occur to contribute to that outcome, and how they interact.

Those failure modes by likelihood of occurrence, the severity of an occurrence, and the ease of detecting and preventing an occurrence. Then the risk prioritization number is calculated, which is the multiple of these three factors. It is represented by the equation:

RPN = O*S*D

Where the risk prioritization number (RPN) is the probability of occurrence (O) times the severity of an occurrence (S), times the likelihood of detection (D). Each of the above factors range from 1 to 10, with 1 then being the lowest possible RPN and 1000 being the highest. The process of examining these failures is failure modes and effects analysis.

TABLE II. Descriptions of the O, S, and D values used in the TG-100 FMEA.

Rank	Occurrence (O)		Severity (S)		Detectability (D)
	Qualitative	Frequency in %	Qualitative	Categorization	Estimated Probability of failure going undetected in %
1	Failure unlikely	0.01	No effect		0.01
2		0.02	Inconvenience	Inconvenience	0.2
3	Relatively few failures	0.05			0.5
4		0.1	Minor dosimetric error	Suboptimal plan or treatment	1.0
5		<0.2	Limited toxicity or tumor underdose	Wrong dose, dose distribution, location, or volume	2.0
6	Occasional failures	<0.5			5.0
7		<1	Potentially serious toxicity or tumor underdose		10
8	Repeated failures	<2			15
9		<5	Possible very serious toxicity or tumor underdose	Very wrong dose, dose distribution, location, or volume	20
10	Failures inevitable	>5	Catastrophic		>20

The overall goal of failure modes and effect analysis is to find the errors that carry the highest risk through the risk prioritization number, determine the ways that the failure could occur through fault tree analysis, and then implement safeguards to lower the probability, decrease the severity, and/or improve detectability.

References

Authorization Process

1. Day 2, Slides 82-126
2. IAEA TECDOC – Notification, Authorization, Inspection and Enforcement For the Safety and Security of Radiation Sources (Version Date: November 14, 2019)
3. Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses, Final Report (NUREG-1556, Volume 9, Revision 3)

Facility Information

1. Day 1, slides 68-77, Day 3, slides 23-45
2. IAEA Report 47 – Radiation Protection in Design of Radiotherapy Facilities
3. 10 CFR Part 35 – Medical Use of Byproduct Material
4. International Basic Safety Standards (BSS) for Protection against Ionizing Radiation and for the Safety of Radiation Sources, Safety Series No. 115, IAEA, Vienna (1996)
5. International Organization For Standardization (ISO), Basic Ionizing Radiation Symbol, ISO-1361 (ISO), Geneva (1975).
6. NCRP Report No. 151 – Structural Shielding Design and Evaluation for Megavoltage X- and Gamma-Ray Radiotherapy Facilities (2005)

Shielding Calculations

1. Day 3, Slides 47-73, Exercises 5 and 5.A
2. IAEA Report 47 – Radiation Protection in Design of Radiotherapy Facilities
    3. NCRP Report No. 151 – Structural Shielding Design and Evaluation for Megavoltage X- and Gamma-Ray Radiotherapy Facilities (2005)

Training Program

1. Day 5, Slides 43-49
2. AAPM Report TG-35 Medical accelerator safety considerations (February 26, 1993).
3. NRC Title 10 CFR 35.610 - Safety procedures and instructions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

Machine Maintenance

1. Day 5, slides 7-19
2. Comprehensive QA for Radiation Oncology: Report of AAPM Radiation Therapy Committee Task Group 40.
3. IAEA Review of Radiation Oncology Physics: A Handbook for Teachers and Students – 12.3.4. Slide 4.
4. AAPM Task Group 142 report: Quality Assurance of Medical Accelerators

Radiation Safety Program

1. Day 5, Slides 20-40
2. An analysis of radiation therapy medical events in New York State: the role of the state radiation programs in patient safety.
3. The Report of Task Group 100 of the AAPM: Application of Risk Analysis Methods to Radiation Therapy Quality Management.
4. Common error pathways seen in the RO-ILS data that demonstrate opportunities for improving treatment safety. Ezzell, Gary et al. Practical Radiation Oncology, Volume 8, Issue 2, 123 – 132
5. Hamish Porter, British Institute of Radiology (BIR) – Radiotherapy Errors and Near Misses (September 2012).
6. AAPM Report TG-35 Medical accelerator safety considerations (February 26, 1993).

3.0 INSPECTION PROGRAM

3.0 Inspection Program

The inspections shall be carried out to verify that facilities and activities are in compliance with regulatory requirements and conditions specified in the authorization.

Scope of Authority

Inspections are a verification of the control and supervision provided by the authorized party, who retain prime responsibility over their activities.

The manner, extent, and frequency of these inspections shall be a matter of policy. Unannounced inspections may be conducted within reason and consideration of the facility's available resources

Emphasis on Safety

The inspection should provide greatest focus on the areas of greatest risk. They shall cover all areas of responsibility, with the inspectors having free access to any facility or activity at any time though considering operational safety is a priority (LINAC accidents).

Inspection Checklist

An inspection checklist can be used to standardize what compliance items are reviewed by the regulatory body for each type of inspection. Associated regulatory citations should be listed next to the checklist item for ease of reference. In fact, the regulations can serve as a guide for creating the inspection checklist. A space for narrative description should be included after each item so the inspector can elaborate on findings and add detail.

As referenced in the regulatory section, items that should be considered are:

2. Structures, systems and components and materials important to safety
3. Management systems
4. Operational activities and procedures
5. Records of operational activities and results of monitoring
6. Liaison with contractors and service providers
7. Competence of staff
8. Safety culture
9. Liaison with relevant organizations for joint inspections where necessary.

Inspection Preparation

It should be remembered that the main purpose of the inspection is to verify operation safety of authorized activities and devices. In order to prepare for an inspection, the inspector should first have sufficient training and experience with the activities they will be inspecting to have confidence they will be able to perform a proper review.

In preparation for an inspection the previous inspection(s) should be reviewed. Look for what was reviewed and which roles were interviewed, and if there were any specific areas of concern identified. A close look should be taken for recommendations and violations issued as well as corrective actions and their implementation.

A review of their authorization, submitted procedures and other commitments, and relevant regulations should be performed.

An inspection plan of the areas most in need of review should be prepared. High risk areas should be reviewed every inspection, but lower priority areas may not require this. Follow up on problem areas from previous inspections is important. Specific questions should be prepared ahead of time, especially regarding particular areas of interest.

The equipment such as survey meters and dosimeters that will best serve the needs of the inspection should be identified and reserved.

On-site Inspection

On-site inspections can be unannounced, which gives the inspectors the benefit of surprise so that they can most likely observe the operations of the facility in their most natural state. Announced inspections allow for preparation, which can allow the authorized party to gather documentation and make sure key staff is present for the inspection. A follow-up scheduled inspection can sometimes be used to fill in gaps missed during an unannounced inspection, but in general all material should be available for inspectors to observe at any time during regular business hours.

There are different types of inspections. Initial inspections occur soon after authorization. These are confirmatory to ensure that all regulations and license conditions are being followed, and that the policies and procedures they committed to maintaining are in place, and that operations in general are following what was proposed in the application.

Routine inspections are often limited versions of the initial inspection, where select areas are reviewed and any identified problems can be followed up on.

Investigatory inspections are reactive, based on complaints or allegations from employees or members of the public, reported medical events, or incidents. Their scope tends to be tightly focused on the matter at hand, rather than a broad inspection of all activities.

Finally, decommissioning inspections follow the cessation of activities and removal of devices and equipment. The main goal of decommissioning is to ensure that activities have indeed ceased and radiation risks have been removed from the facility.

There is an expectation of cooperation between the regulatory body and the authorized party. The regulatory body should seek to educate and aid the authorized party in any reasonable way to improve the safety of their activities. The authorized party must comply with any request within the regulatory body’s scope of authority. Non-compliance can result in violations and enforcement action, and intentionally misleading the regulatory authority or fabricating or altering documentation is considered a violation of the highest severity. Breaching that trust can result in serious compromises in safety.

All inspections with the exception of routine inspections are one-time events. The frequency at which routine inspections occur is largely dictated by the activities authorized. The size of the institution may play a role as well, with larger and more complex programs requiring closer monitoring. It is up to the regulatory agency and their available resources as to how often inspections will take place. Frequencies may range from every 1 to 5 years. Enforcement action may lead the regulatory body to increase that frequency until they are satisfied that an offending party has sufficiently corrected the issue.

Inspection Conduct

Upon arrival, a meeting should be held with upper management to review the inspection plan and inform them of the approximate length of the inspection, the scope of the inspection, previous violations and corrective actions, and scheduling the exit meeting including the approximate timeframe and attendee list.

The inspection plan should be followed to keep the inspection on track, but should not be so rigid that the inspector cannot explore areas of concern or search deeper into potential problems. Following up on the interviews and reviews when cause for concern arises is important.

In general it is recommended to strike a conciliatory tone with the authorized party to foster openness and communication, as the goal is not to punish them for errors but to partner with them to find areas of improvement for their safety program for the benefit of their employees, patients, and the public.

The inspection checklist is an important tool for documenting the results of the inspection. The inspector must strike a careful balance of documenting as the inspection progresses so nothing is forgotten but also remaining attentive to those they are interviewing and items they are reviewing. If there are resources to send multiple inspectors it can be helpful to have a lead perform the review and interviews and an assisting inspector to document findings contemporaneously.

After the inspection is concluded, and the results are compiled, the radiation safety officer for the facility should be briefed on the findings. This is an opportunity to clear up any confusion or answer final question before presenting findings to upper management. Then the exit meeting is held, and the findings are reported including any apparent violations. They should be termed apparent as typically violations aren't made official until conferring with regulatory body management.

Inspection Report

Each inspection shall be formally documented, with the results and findings recorded and provided to the authorized party. These results can be used as feedback for the regulatory process. The inspection report is placed in the authorized party's file for reference in preparation of future inspections or for reference in ongoing enforcement if there were violations identified.

References

Inspection Program

1. Day 4, Slides 3-70, Exercise 6
2. IAEA-TECDOC-1526 Inspection of Radiation Sources and Regulatory Enforcement (Supplement to IAEA Safety Standards Series No. GS-G-1.5) April 2007.
3. IAEA TECDOC – Notification, Authorization, Inspection and Enforcement for the Safety and Security of Radiation Sources (Version Date: November 14, 2019)
4. Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses, Final Report (NUREG-1556, Volume 9)
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6. AAPM TG 35 Medical Accelerator Safety Considerations

Onsite Inspection

1. Day 2, Slide 37

4.0 VIOLATIONS AND ENFORCEMENT

4.0 Violations and Enforcement

Serving violations shall be reserved for items of non-compliance with the regulatory requirements or conditions specified in the authorization.

A description of the different levels of severity and associated potential consequences should be described in a policy or in the regulations and distributed to authorized parties.

Scope of Authority

It is important that the authority given to the regulatory body be clear and comprehensive in order for it to execute its duties and responsibilities. Regulatory staff must be careful to act only within this scope of authority. There may be recourse that aggrieved parties can take against the regulatory body if they exceed their authority.

Emphasis on Safety

If risks are identified, including risks unforeseen in authorization, the regulatory body shall require corrective actions to be taken by authorized parties

Corrective actions that can be taken immediately on-site by the authorized party or the inspectors to prevent imminent safety significant events shall be taken.

Types of Violations

A violation or item of non-compliance is any failure to observe or meet a regulatory requirement. Violations can be against part of the regulatory code, against commitments listed on or tied to authorization, failure to follow established procedures, or as a result of a medical event. Violations can also be categorized by whether they were willful, whether they were an isolated lapse or a frequent occurrence, and whether it constitutes a repeated issue over several inspections.

Categories of Severity

The severity of a violation can be classified based on several considerations; some considerations are presented below:

1. Did it result in or risk injury to a person or the environment?
2. Was there a cost associated with damage to property or injury, and how large?
3. Was it willful or accidental?
4. Was it isolated or a pattern of behavior?
5. What is the compliance history of the authorized party?

Severity levels are defined by the regulatory agency, as are the penalties associated with each severity level. Criteria must be met to classify a violation as that severity, but it does not necessarily have to be classified as such if the severity is met. Some discretion may be allowed based on circumstances, but policy should be in place to help ensure fairness. An example of severity level classifications from level one being the most severe and five being the least severe is presented below:

Severity Level 1

If actual damage or injury to a person or environment was caused by the violation, OR if it was characterized by a willful action, or if there were multiple occurrences between inspections, or if it contributed to one or more additional violations.

Severity Level 2

If the violation resulted in significant potential for injury or damage to property, AND it was characterized by a willful action, or if there were multiple occurrences between inspections, or if it contributed to one or more additional violations.

Severity Level 3

There is some potential for injury or damage to property, OR it was characterized by a willful action, or if there were multiple occurrences between inspections, or if it contributed to one or more additional violations.

Severity Level 4

There is any threat to the environment or occupational or public health, AND it was characterized by a willful action, or if there were multiple occurrences between inspections, or if it contributed to one or more additional violations.

Severity Level 5

The violation was unlikely to cause actual costs or injury to the environment or occupation or public health.

Enforcement Process

Observed on Inspection

The item of non-compliance shall be identified at the time of inspection and reported to the authorized party during the exit meeting

Debriefing of Leadership

Upon completion of the inspection, results and findings shall be shared with regulatory body leadership. Items of non-compliance shall be reviewed by leadership and a discussion of whether enforcement actions need be taken and what those actions should be shall be held.

Types of Enforcement Action

- Recorded verbal notification
- Written notification
- Imposition of additional regulatory requirements and conditions
- Written warnings
- Penalties
- Suspension of authorization
- Revocation of authorization
- Prosecution

Notice Given

After enforcement actions are determined, notice shall be given to the authorized party describing the event of the investigation, the findings, any enforcement actions being taken, items requiring corrective action, and an explanation of the expected response from the authorized party and the timetable for response

A criterion for corrective actions shall be established including enforcing the cessation of activities or the shutting down of a facility where necessary.

Response From

The authorized party shall be held accountable for remedying non-compliances, for performing a thorough investigation within the agreed timetable, and for taking corrective actions necessary to prevent recurrence of the non-compliances.

Follow-up

After the agreed upon timeframe, the regulatory body shall confirm that the authorized party has effectively implemented all corrective actions in order to restore regulatory compliance and safety to their operations.

References

1. Day 5, Slides 50-58
2. NRC Enforcement Manual and Policy, NUREG-1600 (May 1, 2000)
3. IAEA TECDOC – Notification, Authorization, Inspection and Enforcement for the Safety and Security of Radiation Sources (Version Date: November 14, 2019)

5.0 TECHNICAL ASPECTS

5.0 Technical Aspects

Linear Accelerator Physics

Linear accelerators use photons and electrons to treat patients. It is important for staff of the regulatory body to have a basic understanding of the physics of linear accelerators as knowing how they function is an important factor in determining whether they are being used safely.

The energy of these photons and electrons are in the range of 4MeV-20MeV max energy. In this energy range, and interacting in human tissue, the primary interaction mechanism for photons is Compton scattering, with a preference to be forward scattered. Also, they only give a portion of their energy so much of the treatment beam will continue on through the patient. This is important for shielding as even with passing through the patient the majority of the radiation striking the inner walls of the treatment room will be along the central axis of the treatment field.

Another interaction of concern is photoneutron production, which occurs at energies of 10MeV and above. These are penetrating particles that are well shielded by materials with high hydrogen content, as hydrogen atoms can receive the entire kinetic energy of a neutron in one collision. This is important to consider when shielding for higher energy LINACS.

Electrons are charged particles which are constantly interacting with the atoms surrounding them. They can penetrate deeper as their energy increases, but they are not a shielding concern as they have a discrete maximum range much less than the thickness of the walls needed to shield photons. The photons generated from a treatment electron beam are a much lower yield than the photons generated from the electron beam striking the target as the current is much lower.

The linear accelerator is made up of many parts which operate together to accelerate electrons to strike a high atomic number target to generate x-rays, or the electron beam strikes a scattering foil to create an electron treatment field to superficially treat the patient. The components that the electron beam passes through will be listed and briefly described, and are the

a) Electron gun
b) Waveguide
c) Bending magnet
d) X-ray target (photons)
e) Primary collimator
f) Flattening filter (photons)/Scattering foil (electrons)
g) Ion chamber
h) Secondary collimator/multi leaf collimator (MLC)
i) Accessory or electron applicator

Radiofrequency energy supplied by a power source is supplied to a waveguide, which energizes the waveguide to accelerate the electrons. The power sources commonly used

are magnetrons, which are smaller RF generators and can achieve energies of ~6MeV and klystrons which are larger microwave amplifiers which take a low energy RF input and use electrons accelerated across a potential difference to amplify them to high-powered microwaves. In each case a transmission waveguide is used to transmit this energy to the waveguide.

The waveguide is a long copper tube kept under a vacuum through which electrons are accelerated. Electrons are created in the electron gun through the heating of the cathode, which are kept in controlled bunches with control electrodes and then at a pulse frequency controlled by the LINAC console are released and accelerated through a potential difference towards the anode, which is designed to guide the electron beam into the waveguide.

The waveguide contains the RF energy from the power source. It is tuned to resonate with the frequency of the RF energy, minimizing energy loss. It is segmented into several cavities. Across each is an alternating potential difference in phase with the injection of electrons, such that as the electrons reach each cavity energy is added. There is typically an energy switch on modern linear accelerators which controls the number of cavities energized thus the energy gained by the electrons. This process also tightens the electrons into bunches, which continue gaining energy throughout the waveguide until they enter the bending magnet.

The bending magnet takes the accelerated electron beam through 270 degrees and out through the LINAC head. Because of the different energies the electron beams become unfocused, and taking them through 270 degrees allows the beam to refocus. The radius of the path of the beam is determined by the electric field applied to the bending magnet and the energy of the electron beam, with higher energy electrons taking a path of a slightly larger radius and the lower energy electrons taking a path of a slightly shorter radius. The electric field applied is adjusted depending on the energy selected. The electrons are passed through a slit in the bending magnet which will filter out the higher and lower energies traveling at a larger or smaller radius, so that only energies within 3% of the nominal energy will enter the LINAC head.

When passing through the LINAC head, for photon modes, the beam first encounters the x-ray target, a fixture with a spinning disc of metal on which the electrons interact and create bremsstrahlung x-rays. The target spins because of the tremendous heat generated through these interactions, as only 5-20% of the electron energy is converted to x-rays, with higher energy electrons creating a higher photon yield. The target also needs to be cooled. The photons created have a spectrum of energies with a maximum energy equal to the energy of the electrons creating them and an average energy of roughly one third of the maximum. These photons are forward-directed, with the higher energy photons tending toward the central axis of the radiation beam.

Next the primary collimator attenuates any radiation that would be outside the useful field. The radiation that passes through is then incident on the flattening filter. As stated earlier the photon field is made up of a spectrum of energies, with more and higher energy photons directed toward the central axis. This results in a peaked dose profile,

with higher dose toward the center of the field. The flattening filter is designed to preferentially attenuate the photons in the center field to create a flat dose profile at 10cm depth.

The ion chamber is placed after the flattening filter, and measures the output of the treatment beam before it reaches the patient. The output is measured in monitor units (MU), which need to be related to dose, often described in cGy. The ion chamber must be calibrated through clinical reference dosimetry procedures, typically so that 1 MU = 1 cGy at the depth of maximum dose. The ion chamber has a feedback to the LINAC console. The treatment plan will have a determined setpoint in MU that will deliver the prescribed dose, and the LINAC console is programmed to terminate the radiation beam when that setpoint is reached. The ion chamber also has a radiation beam steering function. It has 4 different axes of measurement, 2 radially (toward and away from the LINAC) and 2 transversely (left and right). It compares the readings of these chambers, which should all be equal if the beam is perfectly symmetric radially and transversely. If they are not, it engages the steering coils in the bending magnet to direct the beam centrally.

Finally, the beam passes through the secondary collimator and MLC, which forms the radiation beam into the treatment shape. Most of the radiation outside the useful field is attenuated, with some of it being transmitted through or scattered off of the collimator and MLC. The collimator is typically made of two sets of perpendicular metal blocks that can translate into any rectangular shape up to a 40x40cm2 square. The MLC are made up of two banks of thin interlocking metal “leaves” that can go in and out of the field creating complex treatment shapes.

For electron treatments, the x-ray target is removed from the beam path and the flattening filter is replaced with a scattering foil, which is one or two metal plates that spread the tightly focused electron beam into a useful radiation field. An electron applicator is placed in the field, which serves to collect electrons that would fall outside the useful field. At the end of the applicator is the cutout which is made of Lipowitz’s alloy, a high-density metal with a low melting point. The low melting point allows for relatively safe melting and pouring of the liquid into trays that fit the electron applicator, hardening around a Styrofoam representation of the radiation field as it cools.

Within the LINAC head is also a light bulb and mirror assembly that will shine a visual representation of the radiation field. This is called the field light and it is used for verification and QA purposes, so that before treatment the therapists can verify that the field lays on the patient as was planned before they deliver radiation.

The design and installation of a linear accelerator is such that the gantry, collimator, and treatment table axes of rotation are around one singular point, called the isocenter. This design ensures that no matter the angle applied to any of the above, the radiation beam central axis remains focused at that single point. By positioning the disease at the isocenter, multiple gantry, collimator, and treatment table angles can be applied yet the focus of the radiation remains on the tumor, allowing for tumorcidal dose while keeping dose to organs-at-risk (OAR, organs that are in the vicinity of the PTV and may receive

dose from the treatment beams) at acceptable levels. Isocenter is usually 100cm away from the source in linear accelerators.

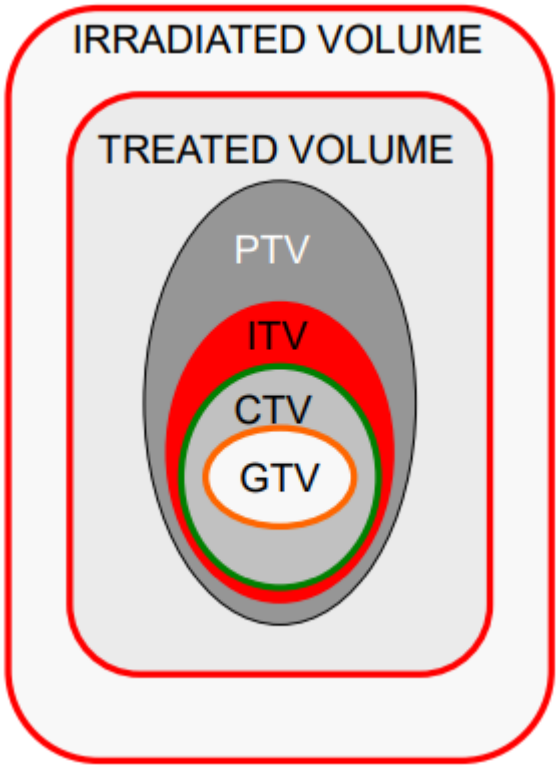
Treatment planning

The dosimetrist, radiation oncologist, and physicist work together to develop a personalized treatment plan for the patient

The radiation oncologist determines the anatomy to be treated and prescribes a dose regimen based on the patient workup: diagnosis, physical examination, disease stage, biopsy results, medical imaging results, genetic testing, etc. This includes:

a) The prescribed dose to the target
b) The allowable hotspot (max dose)
c) Other dose objectives to the target and OAR

The patient undergoes simulation which consists of a 3-dimensional CT scan, providing a graphical representation of their anatomy. Using this graphical representation, the treatment target can be delineated by the radiation oncologist. Several contours are drawn in this delineation.



a) The GTV or gross, palpable tumor mass is termed the Gross Tumor Volume
b) The CTV or Clinical Target volume is an expanded contour beyond the palpable tumor that containts subclinical microscopic extension of disease that also must be treated.
c) The ITV or Internal Target Volume is defined for tumors that undergo significant motion, such as those in the thorax or abdomen, expanding the target volume

to account for this motion is necessary. Other motion management techniques can be used to reduce or account for this movement as well.

d) Finally, the PTV or Planning Target Volume contour is a further expansion is applied to the target to account for the geometric uncertainty of positioning and treatment. The PTV expansion can be reduced as improvements in imaging and treatment precision reduce the positioning uncertainty.

The dosimetrist contours all OAR. Calculating and reporting dose to OAR is an essential component of treatment plan quality evaluation. The radiation oncologist physician prescribes the treatment planning technique, whether it be 3D conformal, IMRT, VMAT. In all cases after calculation and initial evaluation by the dosimetrist the radiation oncologist will review the plan to ensure clinical objectives are met. The physicist reviews the plan for technical issues, ensuring the contours are accurate, the prescription is met, optimization parameters are appropriate, and safety considerations are observed.

Patient-specific QA is performed. This includes a secondary calculation of plan MUs, either through manual calculation or a second, independent calculation algorithm. If the plan is modulated (IMRT or VMAT) delivery quality assurance must be performed prior to treatment, by directly measuring the dose delivered by the plan and comparing it to the plan calculation. Detector arrays are often used for this purpose.

If it is an electron treatment, custom blocks will be used and the dose is calculated, and adjustments are made to the plan as necessary to meet objectives. This may be an iterative process, especially with less experienced dosimetrists.

3D conformal

Static beams at one or more gantry angles and a static block to conform to the tumor dimensions at each gantry angle. The dose from each beam can be weighted to create a dose distribution that conforms tightly to the tumor volume, keeping healthy tissue dose low.

This type of planning is called “Forward Planning”, where the dosimetrist determines the machine parameters and then calculates the dose outcome.

Other beam modifying devices such as wedges can be placed in the field.

The dose is easily scaled by changing the MU of each beam.

IMRT – Intensity Modulated Radiation Therapy

This is a form of “Inverse Planning”. The dosimetrist provides the dose objectives and beam angles, then the treatment planning system iteratively tests complex and changing MLC shapes to find the best solution.

The best solution is determined by the objective function, a weighted function that tests how far from each dose objective the current solution is, and compares that with previous solutions to slowly improve the dose distribution. Once the solution can no longer be improved this is considered the “optimal” treatment solution.

This technique allows for treating of multiple targets or different areas within the same target to different dose levels, called “dose painting”.

The optimization process requires significant computational resources, MLCs, and modern treatment planning systems and LINAC console software.

a) Step-and-shoot IMRT: The MLC forms distinct shapes, delivers beam, then turns off while MLCs move to the next shape.
b) Sliding window IMRT: The radiation beam remains on as the MLCs move.

VMAT – Volume Modulated Radiation Therapy

Similar to IMRT, VMAT allows for gantry rotation during treatment as well.
The MLC are in constant movement as with sliding window IMRT.
In order to perform a dose calculation, the constantly moving MLC are broken into discrete shapes called control points by the treatment planning software. Each control point accounts for a certain amount of gantry movement and MLC movement.

The dosimetrist determines the optimal beam arrangement to meet the physician's plan objectives. Blocking of the treatment beam to conform to the tumor would be applied. The jaws are brought in to the edge of the PTV to cover just the target with prescription dose and attenuate the remaining beam.

MLC or custom blocks may be used to attenuate and shape the beam further
If IMRT/VMAT optimization will be monitored by the dosimetrist. Some time should be spent to push the optimization to achieve an optimal plan rather than just an acceptable plan, however dosimetry resources may be limited in allowing this.

Biology of Cancer Treatment

Approximately 50% of cancer patients receive radiation therapy as part of their treatment regimen, with chemotherapy, hormonal therapy, and surgery other common treatments in conjunction with radiation or alone. External beam therapy is the most common form of radiation therapy, with linear accelerators taking an ever-growing share over Co-60 teletherapy.

The hallmarks of cancer are sustained proliferation, evading growth suppressors, replicative immortality, resisting cell death, inducing blood vessel growth, and activating invasion (metastasis).

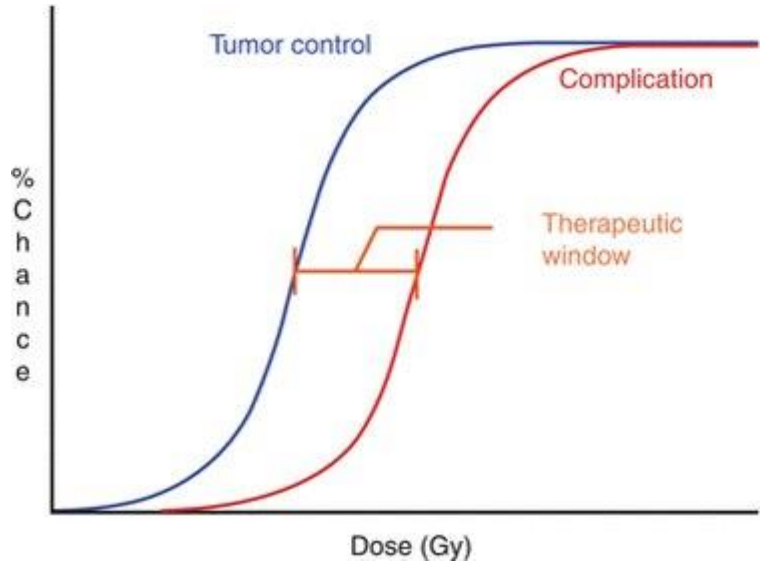
The currently accepted theory of cancer cell destruction is that radiation can interact with the DNA of the cell or create reactive molecules in the DNA's environment, causing damage which will prevent replication. Due to compromised repair mechanisms in cancer cells this can lead to the death of the cancer cell whereas healthy cells may recover at a higher rate.

Cells are most radiosensitive in the mitotic phases, right around the time of cell division. Therefore, highly proliferative cells such as many cancers are the most radiosensitive. Cancers are defined and classified by their cell type, tissue, or organ of origin. Different classifications of tumors respond differently to treatment.

Higher doses will destroy a higher percentage of the cancer cells, but will also cause more toxicity in the patient. By taking advantage of the healthy cell's

ability to repair, but balancing the cancer's ability to proliferate, treatment is usually delivered in a fractionated fashion. The optimal dose per fraction and fractionation schedule are dependent on the cancer type which also accounts for the organs typically adjacent to the cancer and their radiosensitivities.

By fractionating treatment, the goal is to increase the probability of tumor control while reducing the probability of complication. At the desired tumor control probability, the dose between that required to achieve that level of tumor control and the dose to complication is called the therapeutic window



Slowly proliferating cancers can be better treated with fewer fractions and higher dose per fraction, whereas more aggressive cancers are better suited to be treated with more fractions at a lower dose per fraction.

To properly protect organs against unnecessary toxicity it is important to understand how radiation affects their function. A serial organ such as the spinal cord will show a degradation in function if there is damage to one area. Serial organs such as nerves in the brainstem, spinal cord, nerve bundles in the arms, or the ocular nerve are impacted by high maximum doses, so this is usually controlled for in treatment planning.

A parallel organ such as the lung, kidney, or liver have functional units such that if one area receives high dose and can no longer function there are other units to make up for the loss of function. However, if too many functional units are impaired then toxicity becomes more likely. Therefore, parallel organs are usually scored to reduce the dose over large portions of the organ, or to reduce the mean dose to the organ.

Dose escalation protocols have been introduced with the advent of improved imaging and positioning to reduce uncertainty in the targeting of the tumor,

improved delivery accuracy, and improved dosimetry accuracy. As dose to the tumor can be increased while keeping the normal tissue toxicity normal, tumor control can be safely improved. It is important to understand that to use these protocols state of the art equipment is required, as without it unacceptable complications may arise in the patients.

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1. Day 2 Slides 3-45
2. ICRU Report 50: Prescribing, recording, and reporting photon beam therapy.
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