

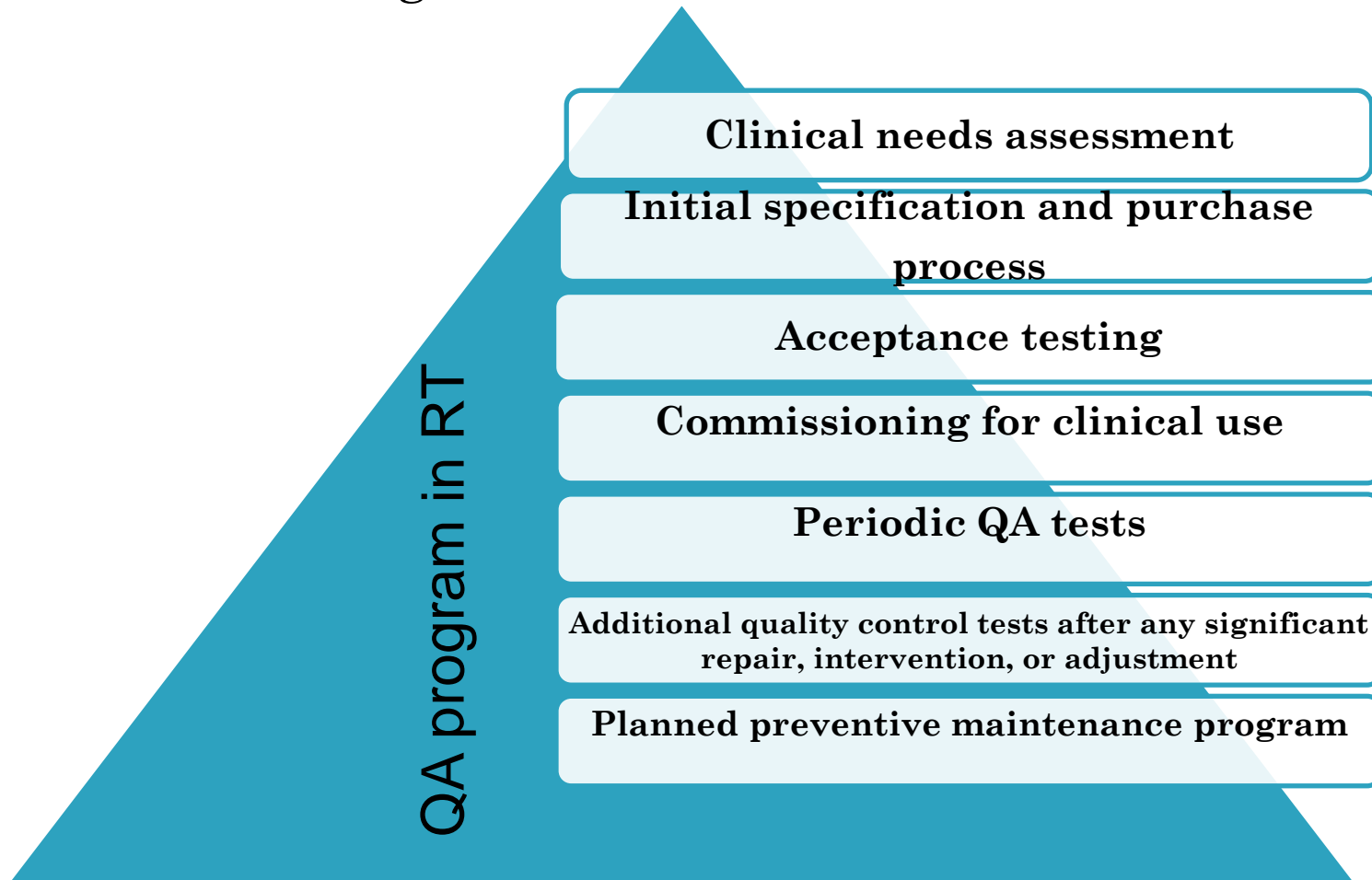


ACCEPTANCE TEST CRITERIA OF RADIOTHERAPY EQUIPMENT

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QUALITY ASSURANCE PROGRAMME OF RADIOTHERAPY EQUIPMENT

QA program for a radiotherapy unit consists of actions as shown following



QUALITY ASSURANCE PROGRAMME CONTD..

- Quality assurance, Acceptance tests and commissioning in radiotherapy are subset of QA program where acceptance tests and commissioning constitute a major part in this QA program for radiotherapy.
 - Common terms with respect to QA program used in radiotherapy
 - Quality Assurance
 - Acceptance testing
 - Type approval/type test
- } Quality/safety standard




QUALITY ASSURANCE IN RADIOTHERAPY

- 'Quality assurance in radiotherapy' is all procedures that ensure consistency of the medical prescription, and safe fulfilment of that prescription, as regards the dose to the target volume, together with minimal dose to normal tissue, minimal exposure of personnel and adequate patient monitoring aimed at determining the end result of the treatment.



ACCEPTANCE TESTS OF RADIOTHERAPY EQUIPMENT

- Acceptance of equipment is the process in which the supplier demonstrates the baseline performance of the equipment to the customer.
 - Equipment compliance with manufacturers specifications
 - Acceptance tests assure that
 - Specifications contained in the purchase order are fulfilled.
 - Leakage radiation from the equipment is within prescribed tolerance
 - Radiotherapy equipment is free of electrical hazards to staff and patients.
 - Performance of the equipment is complying with regulatory requirement
- 

TYPE TEST/DESIGN APPROVAL/TYPE APPROVAL

- Type test/Design approval/Type approval-

Approval, issued by the competent authority, based on evaluation of the device to ensure that it conforms to safety standards.



Set of accepted criteria against which the quality of the equipment can be assessed. e.g. IEC for radiotherapy equipment



DIFFERENCE BETWEEN TYPE TESTING AND ACCEPTANCE TESTING

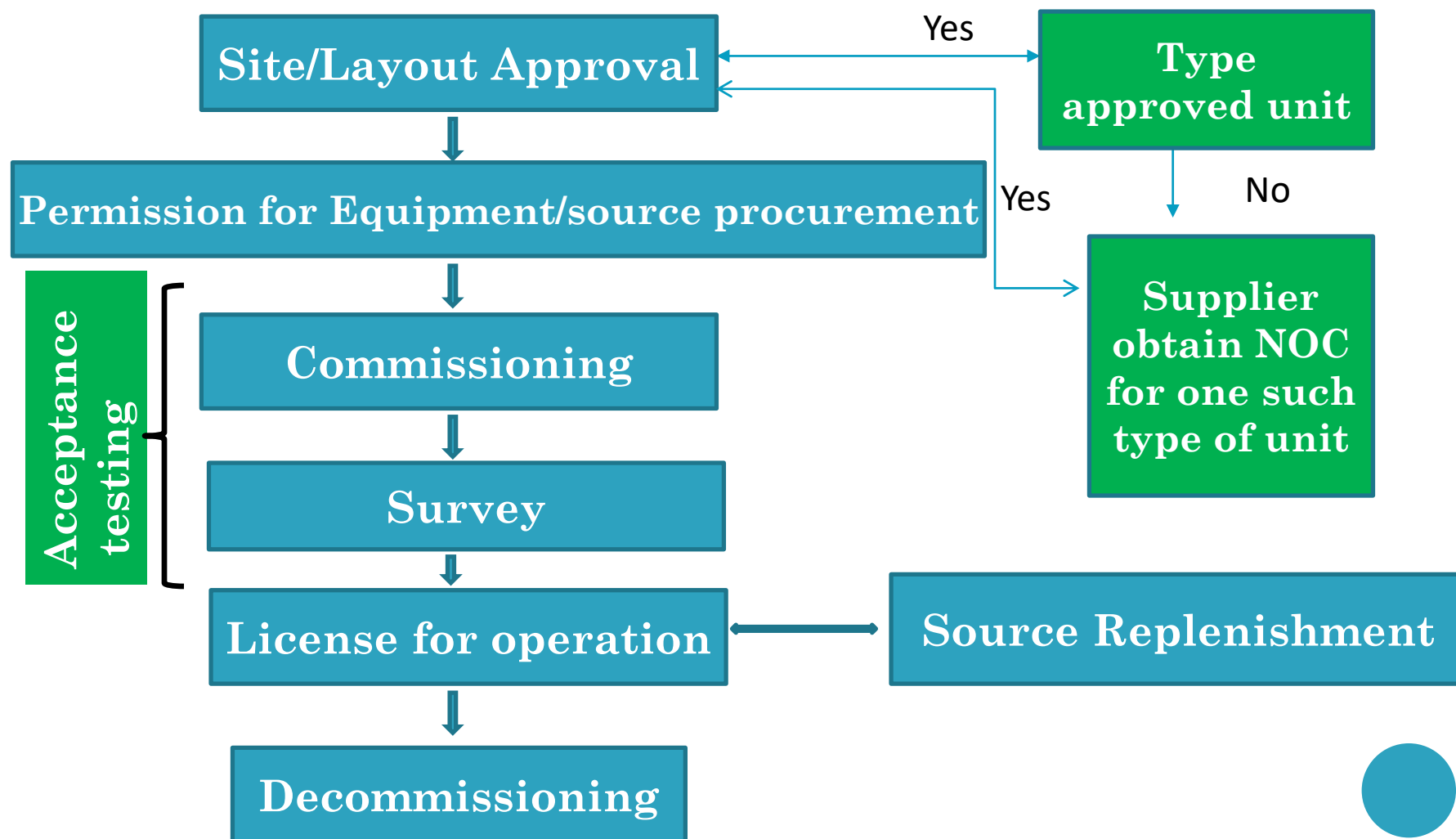
Type Testing

- Responsibility of manufacturer to demonstrate compliance to regulatory body with relevant standard e.g. IEC
- Only first unit of each type

Acceptance testing

- Responsibility of Manufacturer's to demonstrate compliance as per their acceptance test protocol to user institute
- Each unit installed in the hospital

CONSENTING PROCESS IN RADIOTHERAPY



RADIATION SAFETY IN RADIOTHERAPY

Radiation Safety is achieved by two ways:

Built-in Safety

&

Operational Safety

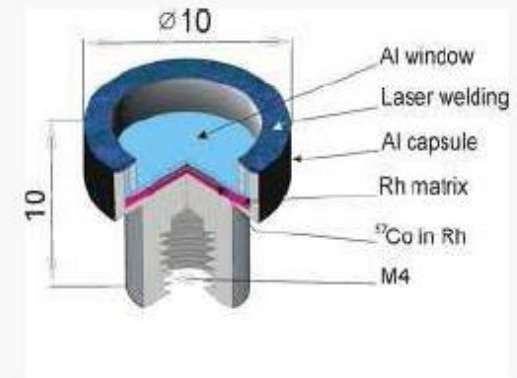


Built-in Radiation Safety



- **Sealed Source** – **Classification**

(safety of worker and public)



- **Equipment** – **Type-approval**

Electrical, Mechanical,
Radiological

(safety of rad. worker and patient)



Built-in Radiation Safety



- **Installation – Plan Approval**

Thick concrete walls, maze

(safety of rad. worker, public and patients' relatives)



- **Transport Package – Package approval**

(safety of worker, public)



BUILT IN SAFETY IN A RADIOTHERAPY EQUIPMENT

- Source Type
- Source Housing / Head Shielding
- Safety feature and Interlocks



SOURCE TYPE

Sealed Source: They are special form of radioactive sources

- Tested and certified as per the relevant standards – **Source Certificate** (*AERB safety standard titled 'Testing and Classification of Sealed Radioactive Sources' [AERB/SS/3(Rev.1), 2001]*)

Few conditions are as follows:

- Encapsulation will not leak radioactive material under normal and maximum credible accident conditions
- Non toxic and non reactive to body fluids (brachytherapy)
- No gaseous daughter products



SOURCE HOUSING / HEAD SHIELDING

- Source Housing Shielding Adequacy in OFF position
 - Telecobalt
 - Remote afterloading Brachytherapy unit
- Source Housing Shielding Adequacy in ON position
 - Telecobalt
 - Accelerator



SOURCE HOUSING SHIELDING ADEQUACY IN OFF POSITION-TELECOBALT

The source housing shall provide adequate shielding so that the leakage/stray radiation levels do not exceed the **prescribed limits**

- Beam OFF (with maximum loading capacity of the Head) the absorbed dose rate due to stray radiation measured
 - At **1m** from the source, the leakage shall not exceed **20 μ Gy/hr** (2mR/hr)
 - At any readily accessible position **5cm** from the surface of the housing radiation level shall not exceed **200 μ Gy/hr** (20 mR/hr)



SOURCE HOUSING OFF POSITION – BRACHYTHERAPY

Leakage Radiation Dose Rate ($\mu\text{Gy.h}^{-1}$) when loaded with maximum Capacity:

- **HDR Unit**

- **100 $\mu\text{Gy/hr}$ (10 mR/hr) at 5 cm from the surface & 10 $\mu\text{Gy/hr}$ (1 mR/hr) at 1m from the source**

- **Manual after-loading system/emergency storage container/ in-house transport container**

- Portable 500 $\mu\text{Gy/hr}$ (5cm) 20 $\mu\text{Gy/hr}$ (1m)
- Mobile 1000 $\mu\text{Gy/hr}$ (5 cm) 50 $\mu\text{Gy/hr}$ (1m)



SOURCE HOUSING ON POSITION LEAKAGE- TELECOBALT

○ Collimator Transmission

- Absorbed dose anywhere in the area protected by the beam limiting device should not exceed 2% of maximum absorbed dose for a 10cm x10 cm radiation field measured on the radiation beam axis at the same distance of the useful beam

○ Patient Plane:

Circle of 2m radius, centered on and perpendicular to the beam axis but excluding the area defined by the collimators

Absorbed dose at **1m** from the source

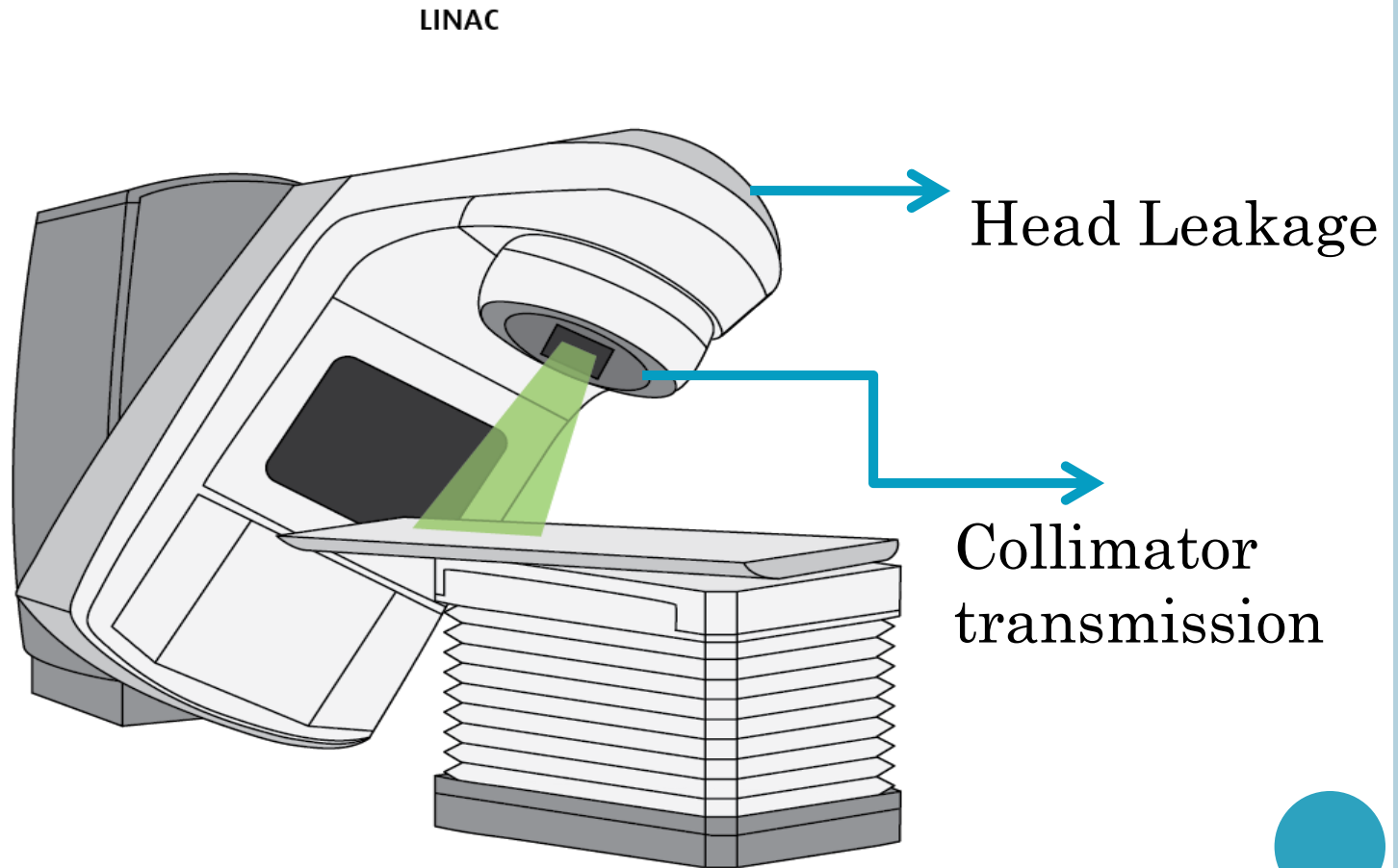
- Maximum – shall not exceed 0.2% of absorbed dose for 10X10 cm² field
- Average-shall not exceed 0.1% of absorbed dose for 10X10 cm² field

○ Other than patient plane

- Absorbed dose rate due to leakage radiation at 1m from the source should not exceed 0.5% of that of 10X10 cm² field



PICTORIAL REPRESENTATION OF LEAKAGE/ TRANSMISSION



PATIENT PLANE AND OTHER THAN PATIENT PLANE

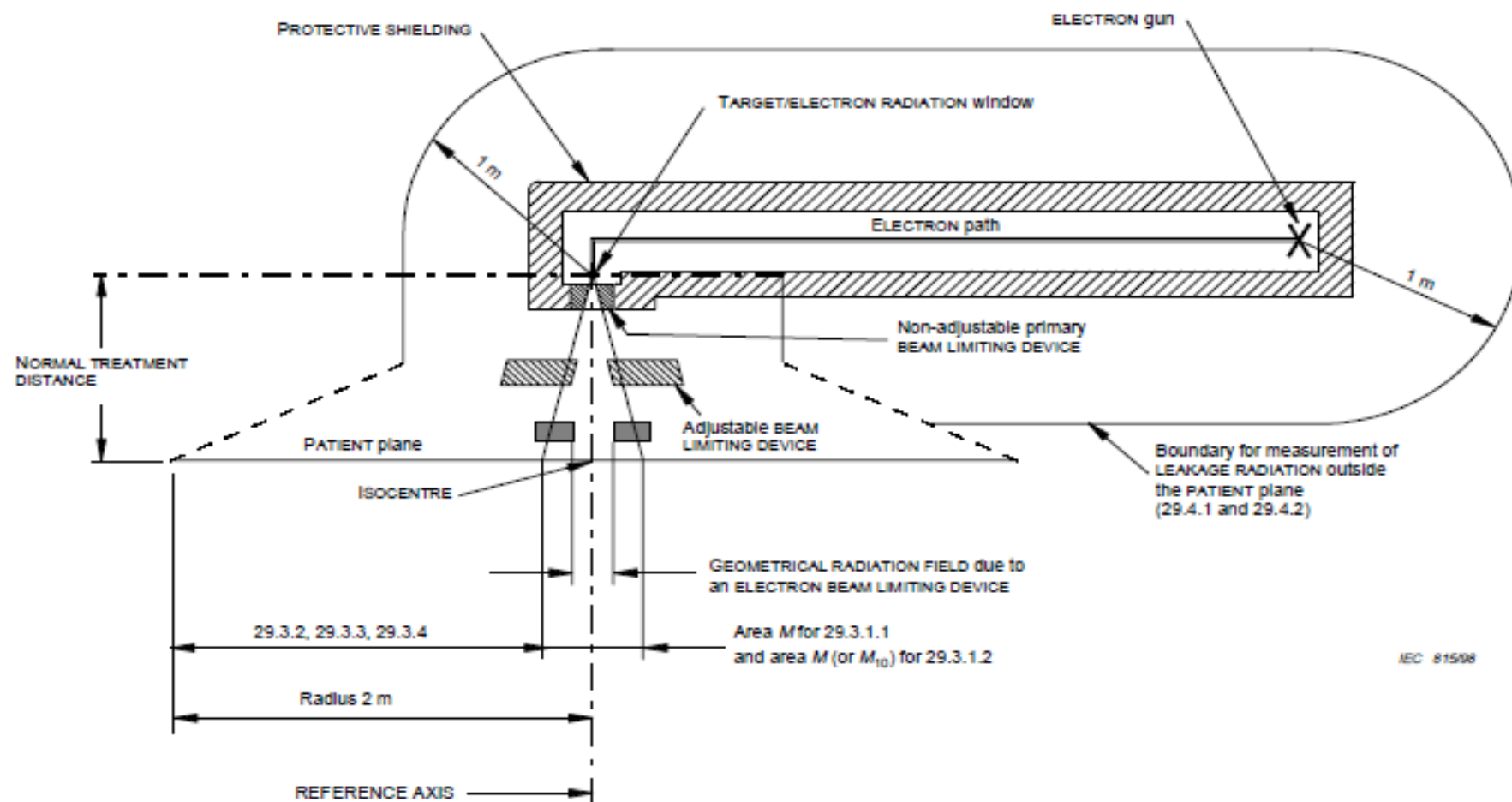
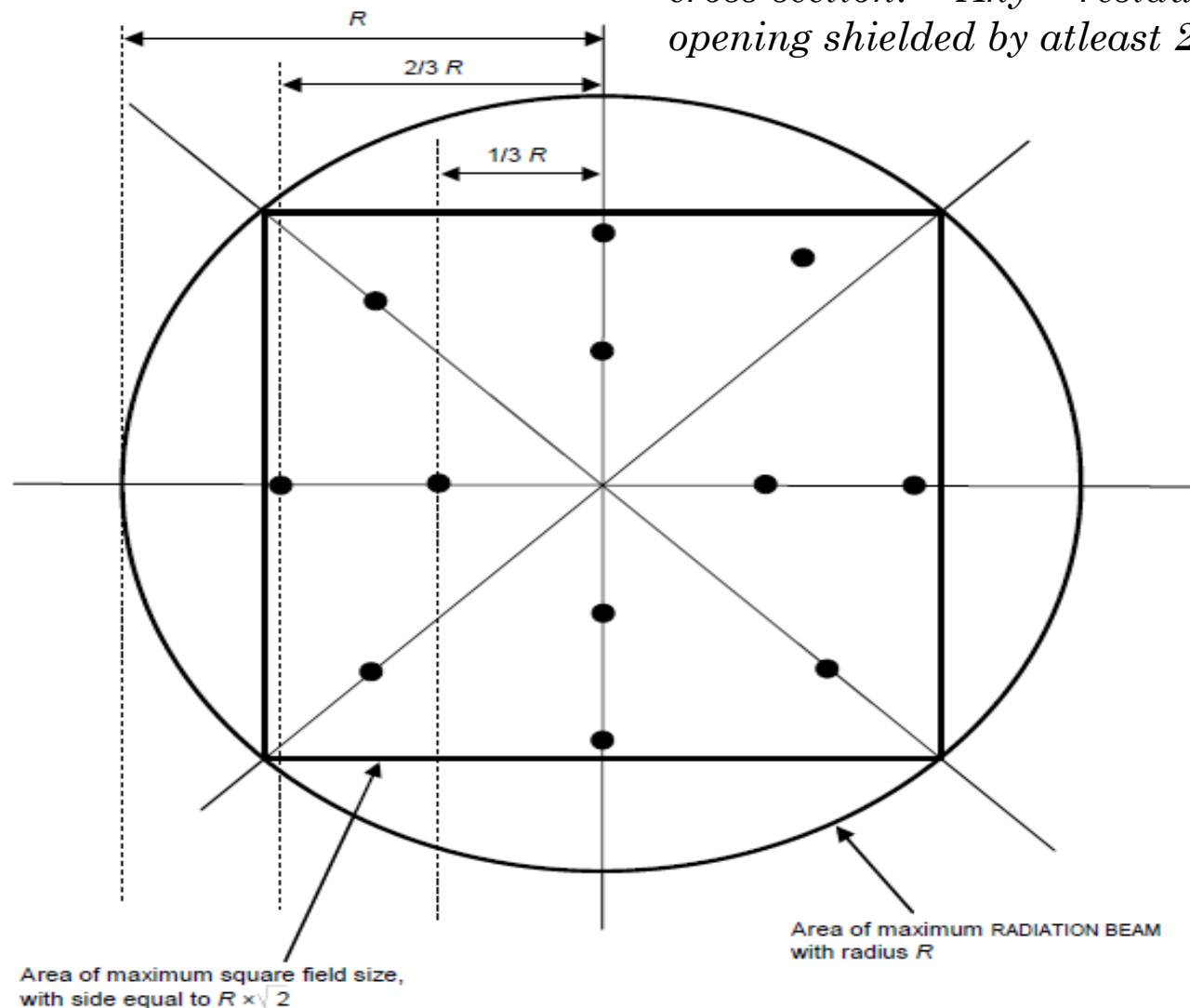


Figure 103 – Elevation view – Application of LEAKAGE RADIATION requirements (29.3 and 29.4)

MEASUREMENT SET UP

Collimator transmission measure in air, at NTD with maximum buildup, detector 1 cm^2 maximum cross-section. Any residual field opening shielded by at least 2 TVLs



Leakage Radiation
measurement in
'Patient Plane'-16
point measurement-
Residual field closed
by at least 3 TVLs

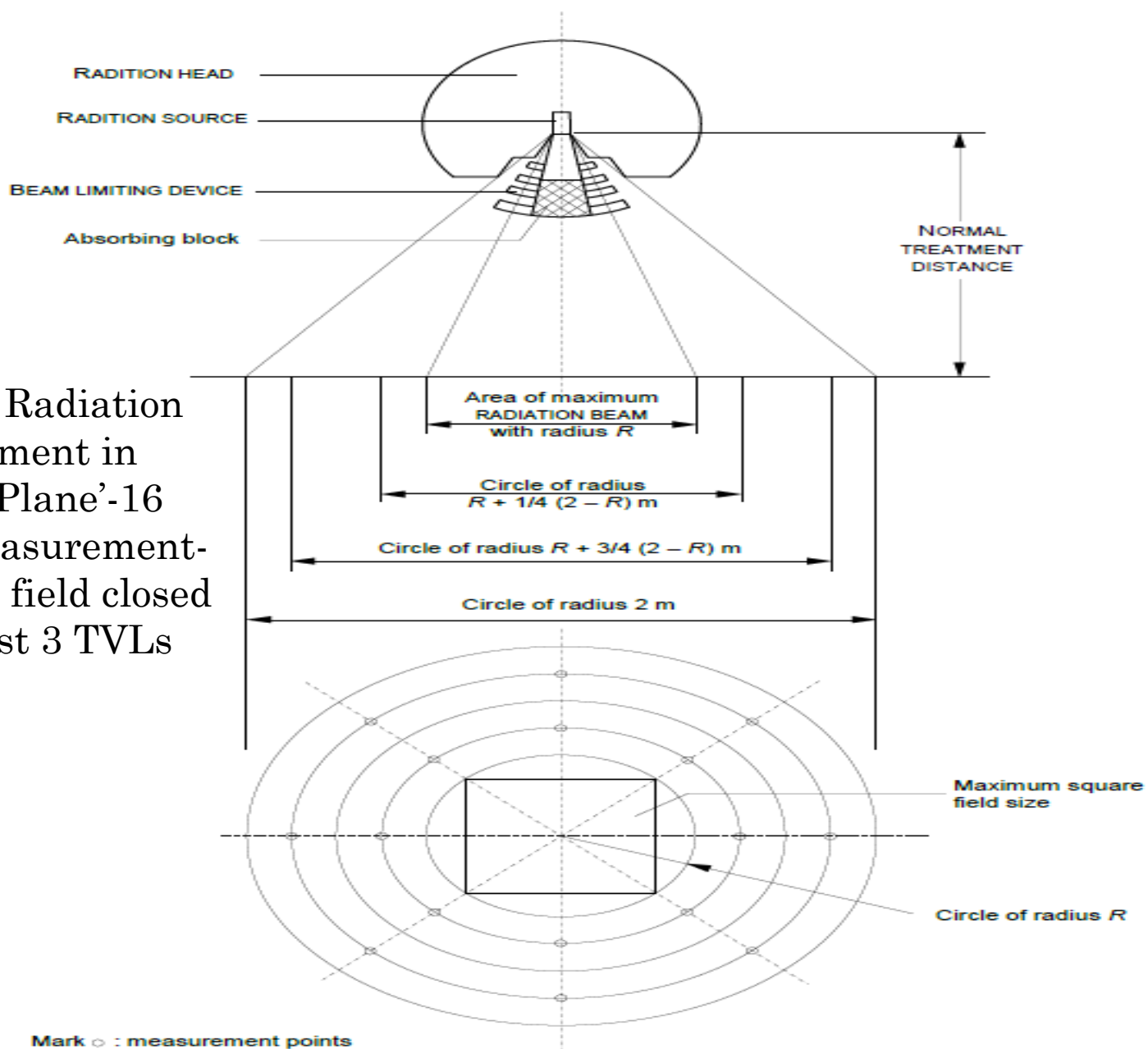


Figure 201.102 b) – The 16 measurement points of the average LEAKAGE RADIATION, as mentioned in 201.10.2.4.2 a)

SOURCE HOUSING ON POSITION LEAKAGE- ACCELERATOR

- Collimator transmission
 - Maximum not greater than 2% of absorbed dose rate due to 10x10 field at NTD
 - Average not greater than 0.75% of 10x10 output
 - In case of tertiary collimators : not greater than 5%
- Patient Plane
 - Photon leakage 0.2 % maximum and 0.1% average (of 10x10 field) in an area of radius 2m centered on the beam axis, but excluding the area covered by BLD
 - Neutron leakage in patient plane less than 0.05% max and 0.02% average of the maximum absorbed dose of 10x10 Field
- Other than patient plane
 - Photon leakage-not greater than 0.5% of maximum dose for 10x10 field
 - Neutron leakage: Not greater than 0.5% of the maximum absorbed dose due to x-ray or electron radiation.

MAJOR SAFETY FEATURE AND INTERLOCKS

Major safety feature and interlock for the following equipment:

- Telecobalt
- Accelerator
- Remote afterloading Brachytherapy unit



SAFETY FEATURE AND INTERLOCKS-TELECOBALT

- Movement of telecobalt source : Pneumatic system or rotating drum
- Source returns to OFF position when:
 - Power failure, interruption/termination of treatment
 - Pressing the Emergency stop switches, which operate the source drawer through independent mechanism (motor)
 - Beam ON after termination not possible unless reset
 - Source retraction to safe position in case it does not achieve full ON position within 3 sec
 - Interlocked to the door
 - One of the Primary and Secondary timers, which work independently, to control irradiation is not functioning



SOME INTERLOCKS- CONTROLLING SOURCE MOVEMENT IN TELECOBALT UNIT

- Interlock to prevent further irradiation provided in case of :
 - Failure of power supply to either of the timers
 - One of the timers in a redundant timer combination is inoperative
 - Source carrier does not attain BEAM ON/OFF condition within 3 sec of initiation /termination of irradiation
 - Gantry moves during stationary beam radiotherapy
 - Movement of the Gantry does not start/stop during Moving Beam radiotherapy
 - Any selection in treatment room is different from the selection at control panel



SAFETY FEATURE AND INTERLOCKS- ACCELERATOR

- Independent monitor systems (primary and secondary) control irradiation
 - Secondary dose monitoring system terminates irradiation in case the primary MU system fails (10% or 0.25 Gy)
 - Independent timer provided in case both the MU systems fail
- Irradiation possible only with 'mode' selection
- Irradiation in photon mode is not possible, if accessories of electron mode are in use
- Accessory interlock
- Door interlock
- Emergency switches at various locations in the treatment room



SAFETY FEATURE AND INTERLOCKS- RAL SYSTEMS

- Interlock for coupling of guide tube and Treatment unit, guide tube and applicator
- Initiation & continuation of irradiation possible from the control panel
- battery-powered back-up power supply is provided to withdraw the Source in event of power failure
- Radiation monitor inside the equipment to detect failure of source to return to the Unit
- No initiation or continuation of treatment on failure of controlling timer, positional accuracy and movement of sources



Operational Safety



OPERATIONAL SAFETY

- Periodic QA of equipment
- Availability of qualified personnel
- Availability of QA tools and safety tools
- Personnel monitoring service
- Availability of written emergency procedures with contact details (incase of failure of source to return to OFF position, loss of source)
- Service and maintenance (by certified service engineers)
- Calibrated and working measuring and monitoring equipments
- Source inventory maintenance
- Integrity check of brachytherapy sources for contamination
- Safe disposal of disused sources
- Decommissioning of disused equipment as per procedures



Operational Safety

- Qualified and certified persons

(Radiation Oncologist, Medical Physicist, Radiation Therapy Technologist)



- Personnel monitoring



Operational Safety

• Work place monitoring



(Gamma Zone Monitor)



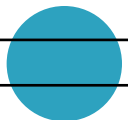
(Switches, Interlocks, Indicators)

• Preventive maintenance



TYPICAL TEST PARAMETERS OF TELECOBALT

Radiation test	Observation	Tolerance
Orthogonality of adjacent jaws		
Parallelism of opposite Jaws		
Symmetry of opposite Jaws		
Coincidence of optical beam and collimator axes		
Accuracy of isocentre		
Accuracy of table top vertical motion		
Accuracy of table top lateral motion		
Accuracy of table top longitudinal motion		
Accuracy of couch rotation scale		
Shift in optical field due to vertical motion of couch from min. to max. position		
Shift in optical field due to rotational motion of the couch from -90° to 90° position		
Accuracy of Collimator angular scale		
Accuracy of Optical Field Sizes for $\leq 10 \times 10 \text{ cm}^2$		
Accuracy of Optical Field Size for $> 10 \times 10 \text{ cm}^2$		
Positional accuracy of asymmetric jaws		
Optical Distance Indicator (ODI) range		
Accuracy of optical distance indicator		
Accuracy of Mechanical Front Pointer		
Optical field overlap $0^{\circ} / 180^{\circ}$		
Optical field overlap $90^{\circ} / 270^{\circ}$		
Optical & Radiation Field Congruence		
Coincidence between parallel opposed fields defined by MLC		



PARAMETERS OF TELECOBALT CONTD..

Radiation test	Observation	Tolerance
Timer error		
Time taken by the source drawer to reach ON position and return back to OFF position		
Penumbra width for 10x10 cm ² field at d _{max}		
Coincidence between radiation and mechanical isocentre		
Output constancy at different gantry angles		
Beam uniformity (flatness) at gantry angles 0° and 90°/270° (For 10x10 cm ²) at reference depth		
Gantry Rotation speed (.1 to 1 RPM)		
Accuracy of angular scale of gantry		
Tray position reproducibility		
Table top sag at isocenter when loaded with 135kg distributed over 2m through isocentre		
Wedge factor for various wedges		
Tray factor		
Over travel distance for MLC, if available		
Coincidence of MLC and secondary collimator axes		
Reproducibility of leaf positions		
Accuracy of Leaf positions		
Congruence between MLC fields and beam's eye view (BEV)		

TYPICAL TEST PARAMETERS OF ACCELERATOR

Dosimetry Test (Photon Beam)	Observation	Tolerance
Congruence between optical and radiation fields (Symmetric Fields)		
Congruence between optical and radiation fields (Asymmetric fields defined by over travel option of the collimator)		
Overlapping between parallel opposed radiation fields defined by jaws for 10x10 cm ²		
Overlapping between parallel opposed radiation fields defined by MLC for 10x10 cm ²		
Accuracy of radiation isocentre		
Flatness for symmetrical fields at 10 cm depth in isocentric set-up		
Symmetry for symmetrical fields at 10 cm depth in isocentric set-up		
Radiation beam penumbra for 10x10 cm ² at d _{max}		
Output (cGy/MU) for all available photon beam energies under reference condition		
Output Constancy at different times in a day		
Output constancy at cardinal positions of the gantry		
d _{max} for available photon energies		
PDD for 10x10 cm ² at 10 cm depth for available photon energies		
Percent surface dose for 30x30 cm ² [(Ds=D _{0.5mm} /D _{dmax})*100] for available photon energies 6 to 18 MV)		
Quality Index (TPR _{20/10}) for available photon energies		
Energy stability (quality index) for available photon energies at different times in a day		

PARAMETERS OF ACCELERATOR CONTD..

Dosimetry Test (Electron Beam)	Observation	Tolerance
Congruence between optical and radiation fields		
Flatness along major axes at the depth of dose maximum as separation between 90% and 50% dose points on either side of the beam profile for: 10x10 cm ² applicator and Maximum applicator size		
Symmetry along major axes at depth of dose maxima in SSD set-up (maximum ratio of absorbed doses at symmetrical points from central beam axis and more than 1 cm inside the 90% isodose contour)		
Radiation field penumbra at d _{max} for 10x10 cm ² applicator size for all available energies		
d _{max} for 10x10 cm ² applicator size for all available energies		
X-ray contamination for all available energies for 10x10 cm ² applicator size		
Most probable energy E _{p,0} at phantom surface for 20x20 cm ² applicator size for all available energies		
R ₅₀ (cm) in water for all available energies for 10x10 cm ² applicator size		
Energy stability for 10x10 cm ² applicator in terms of R ₅₀ for all available energies at different times in a day		
Output calibration (cGy/MU) for all available electron beam energies using applicator of 10x10 cm ² in SSD set-up		
Output Constancy at different times in a day		
Reproducibility for photon and electron beams		
Linearity for photon and electron beams (for ≥ 5 MU)		
Dependence of monitor response on gantry rotation		
Temporal stability of the monitor response at different times of the day		

TYPICAL TEST PARAMETERS OF REMOTE AFTERLOADING BRACHYTHERAPY UNIT

Radiation test	Observation	Tolerance
Source Position Accuracy and Reproducibility		
Source position accuracy		
Source position reproducibility		
Performance of Timer		
Timer accuracy (for set time $\geq 1\%$ of maximum pre-settable value)		
Timer Linearity		
Timer error		
Source Strength Verification		
Deviation between specified and measured source strength		
Leakage and contamination test		
Contamination from the source		
Maximum leakage radiation level at 5 cm from the surface of the HDR unit in source 'OFF' condition		
Maximum leakage radiation level at 1 m from the source of the HDR unit in source 'OFF' condition		
Treatment Planning system		
Agreement between TPS and published/manual calculation of treatment time for single and multiple source loading/ dwell position, at relevant points		
Whether checklist of data (e.g. source strength, unit of strength , distance and dose etc.) associated with TPS is in conjunction with quantity and units that will be used in clinical practice		
Agreement of source decay correction at different times of the day		
Agreement of source decay correction at different days of the week		
Correction for source strength decay before application		
Whether dose distribution is updated when dose calculation option and/or source characteristics are modified		
Quality of geometrical reconstruction (such as general shape, distance between marker and length of wires) using phantom of known geometry		

REVISED QA PROTOCOL (BACK GROUND)

- The criteria for acceptance testing of medical linear accelerator were developed by BARC in 2004
- Criteria did not cover the additional tests to be performed and tighter tolerances with respect to the advanced treatment modalities available in linear accelerators today.
- A Task Group was constituted for revision of acceptance criteria for Radiotherapy Equipment
- The documents referred to revise the QA protocols are: Old QA Protocol, Safety Code, IEC documents, IAEA documents, CAP of suppliers and QA documents of other national authorities.



FINALIZATION OF REVISED QA PROTOCOL

- QA protocol has been revised for
 - Linear accelerator
 - Telegamma units
 - Remote afterloading brachytherapy units
 - Simulators and CT simulators
- QA protocols were finalized by taking inputs from expert Medical Physicists and review by relevant committee in AERB



SALIENT FEATURE OF REVISED QA PROTOCOL

- The revised QA protocol will be useful in evaluation of performance of the equipment during commissioning/acceptance testing as well as for type approval testing.
- The revised protocol will also be useful in radiotherapy institutions to establish QA tests in accordance with AERB safety code to carry out tests during routine operation of the unit.



SALIENT FEATURE OF REVISED QA PROTOCOL (CONTD)..

- Additional tests were included to encompass
 - Advance treatment modality such as IMRT/SRS/SRT/VMAT/Un-flat beam etc.
 - Test to check emergency and failure conditions to verify the built-in safety of the unit and it is performed by creating intentional fault conditions
- Test pertaining to advance treatment modality are not comprehensive therefore additional tests needs to be carried out and submitted as per manufacturers' specifications/ customer acceptance tests.



SPECIAL ATTENTION TO REVISED QA PROTOCOL FOR ACCELERATOR

- Accelerator QA broadly covering treatment options:
 - Conventional /3D CRT
 - IMRT/IGRT
 - SRS/SRT/SBRT
 - Volumetric Modulated Arc Therapy
 - Un-flat Beam (FFF mode)
 - Any other
- QA report need to be submitted depending on the availability of treatment options




NEW TASK GROUP (TG) FORMED FOR DEVELOPING QUALITY ASSURANCE (QA)/ACCEPTANCE CRITERIA FOR SPECIALIZED RADIOTHERAPY EQUIPMENTS

- Cyberknife,
- Tomotherapy,
- Gamma Knife, and
- Intra Operative Radiation Therapy units



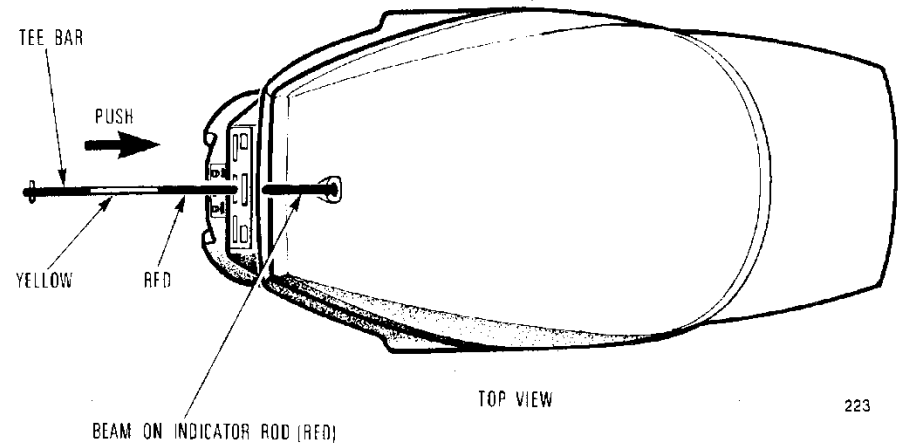
TYPICAL EMERGENCY PROCEDURES - TELECOBALT

In case the source does not go to OFF position in a telecobalt unit

- Press the emergency stop button
 - Turn OFF the power Key and switch ON power again. If source does not go to OFF position,
 - Remove the patient from the treatment room.
 - Inform the RSO
 - Rotate the gantry such that the primary faces away from the maze area.
 - Enter the treatment room wearing TLD, pocket dosimeter
Carry a survey meter
 - With the T-rod, push the drawer firmly such that the source goes to OFF position. For rotating wheel, turn the wheel in the direction indicated till the source goes to OFF position
 - Inform the service engineer
- 

MANUAL RETRACTION OF SOURCE TO OFF POSITION

- Emergency T-rod to be kept at maze entrance or control panel



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Fig. 2.1. Source Drawer T-Bar



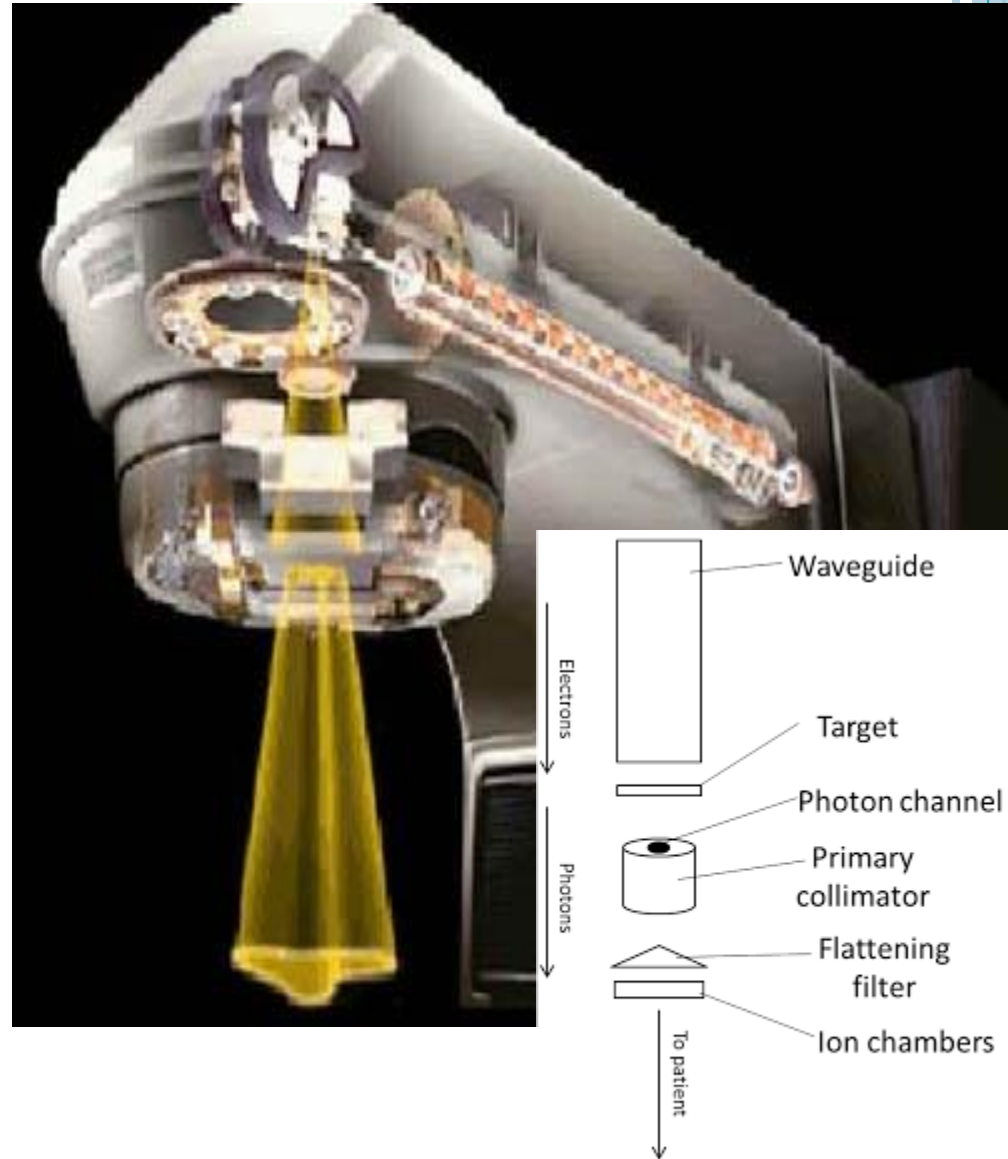
BRACHYTHERAPY-EMERGENCY PROCEDURES

- Press the interrupt button / emergency stop button at TCP/emergency stop button on the Unit Head
- In case it does not go to OFF position, Use the hand crank and manually retract the source to OFF position.
- If it fails, remove the applicator using long handled forceps and put in the emergency storage container
- If unable to remove applicator, cut the source guide tube and place in emergency container
- At every level, monitor the radiation levels in the room
- Patient monitoring prior to release



RADIATION SAFETY ISSUES WITH LINEAR ACCELERATOR

- Beam should be monitored as it could change due to electrical variations
- Positional variation in target, flattening filter, scattering foil could result in undesired beam output.
- Neutron production for high energy beams



ACCIDENT DUE TO INADEQUATE QA PROGRAM-ONE EXAMPLE

Case (wrong calibration of Accelerator after repair):

- **Case History:** In Zaragosa (Spain) Accelerator fault developed after repair. Electron beam was restored but electron energy was misadjusted. Accelerator delivered 36 MeV electrons, regardless of energy selected. Treatments resumed without notifying physicists for beam checks.
- **Cause:** Repair of Accelerator was carried out by untrained service engineer. QA was not performed after repair.
- **Consequence:** Dose rate was 3 to 7 times more than intended. A total of 27 patients were affected with massive overdoses and by distorted dose distribution due to wrong electron energy. At least 18 of these patients died from the accidental overexposure.

COMMON DISCREPANCIES THAT MAY LEAD TO AN INCIDENT/ACCIDENT

- Inadequate Quality Assurance (QA) program
- Use of treatment planning system (TPS) and other software without thorough testing and QA
- Absence of standard operating procedure for implementation of technologies
- Unit repaired by untrained service engineer
- Errors in Calibration and acceptance processes of users



Thanks for your Kind
Attention

