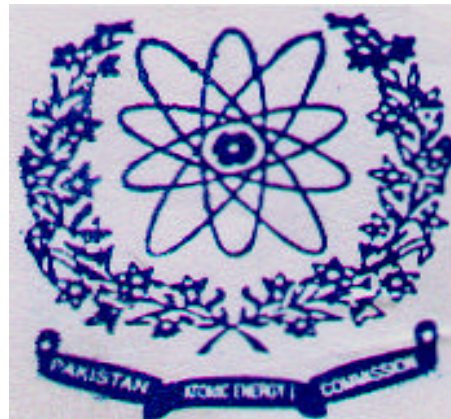


# Regulatory Requirements For Medical Teletherapy Facilities



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# Preface

This regulatory guide describes regulatory requirements for medical teletherapy facilities. It includes requirements for medical exposure, particularly general and design requirements for superficial, deep X-ray therapy, megavolt and electron beam therapy and sealed sources therapy facilities. The appendix to the guide may be of interest for those who are concerned with the installations and design of new radiation facilities. This guide is intended mainly for use by medical physicists, radiotherapists and operators of teletherapy facilities who are directly responsible with radiation protection requirements. The requirements in the guide would ensure effective radiation control and measures during operations of such facilities.

## **Introduction**

The development of super voltage machines and isotope teletherapy units has produced a dramatic change in the practice of radiotherapy. The leading radiotherapists throughout the world have pointed out that several types of cancer can be better controlled and treated today using high energy radiations than was possible earlier.

The development of sophisticated teletherapy machines e.g. betatrons, linacs etc. has brought with it an awareness and concern of the potential hazards of ionizing radiation to users, patients and other exposed persons. These machines are important tools in modern medical practice and it is unthinkable to discontinue their use, as long as the associated risks can be controlled within reasonable limits. Although the operation of teletherapy facilities is usually being carried out within the prescribed dose limits, however, the International Commission on Radiological Protection (ICRP) has recommended that all exposure should be kept as low as reasonably achievable (ALARA), economic and social factors being taken into account. Adherence to established rules reduces radiation risks to extremely low levels.

## **2. Scope**

This regulatory guide is applicable to all radiation sources including X-rays employed in the practice of Radiotherapy. It is concerned with protection against radiation emitted by radiation sources and medical X-ray equipments including linacs. The requirements in this report use the terms "shall" and "should". "Shall" indicates a recommendation that is necessary or essential to meet the currently applicable requirements of protection. "Should" means an advisory recommendation that is to be applied when practicable. The words and expressions used in this guide shall have the meanings assigned to them in the Pakistan Nuclear Safety and Radiation Protection (PNSRP) Ordinance-1984 and PNSRP Regulations-1990.

## **3. Regulatory Requirements for Medical Exposure**

The important requirements for medical exposures have been briefly described in the following sections.

### **3.1 Responsibilities**

The licensee shall ensure that for therapeutic uses of radiation, calibration, dosimetry and quality assurance requirements prescribed in the report are conducted by or under the supervision of a qualified expert in medical physics.

### **3.2 Justification Of Medical Exposure**

Medical exposures should be justified by weighing therapeutic benefits they produce against the radiation detriment they might cause, taking into

account the benefits and risks of available alternative techniques that do not involve medical exposures.

### 3.3 **Optimization Of Medical Exposures**

#### A. **Design Considerations**

The licensee shall:-

- a. Taking into account information provided by suppliers, identify possible equipment failures and human error that could result in unplanned medical exposures;
- b. Take all reasonable measures to prevent failures and errors, including the selection of suitably qualified personnel, the establishment of adequate procedures for the calibration, quality assurance and operation of diagnostic and therapeutic equipment, and the provision to personnel of appropriate training and periodic retraining in the procedures, including protection and safety aspects;
- c. Take all reasonable measures to minimize the consequences of failures and errors that may occur; and
- d. Develop appropriate contingency plans for responding to events that may occur, display such plans prominently, and periodically conduct practice drills.

The licensee in co-operation with suppliers shall ensure the following with regard to equipment consisting of radiation generators and those containing sealed sources used for medical exposures:

- a. Whether imported into or manufactured in the country where it is used, the equipment conform to applicable standards of the International Electro-technical Commission (IEC) and the International Organization for Standardization (ISO) or to equivalent national standards;
- b. Performance specifications and operating and maintenance instructions, including protection and safety instructions, be provided in English language understandable to the users and in compliance with the relevant IEC or ISO standards with regard to "accompanying documents" and that this information be translated into local language where ever appropriate;
- c. Where practicable, the operating terminology (or its abbreviations) and operating values be displayed on operating consoles in English/Urdu language acceptable to the user;
- d. Radiation beam control mechanisms be provided, including devices that indicate clearly and in a fail-safe manner whether the beam is " on " or " off " ;

- e. As nearly as practicable, the exposure be limited to the area being examined or treated by using collimating devices aligned with the radiation beam;
- f. The radiation field within the treatment area without any radiation beam modifiers (such as wedges) be as uniform as practicable and the non-uniformity be stated by the supplier; and exposure rates outside treatment area due to radiation leakage or scattering be kept as low as reasonably achievable.
- g. Irradiation installations using radioactive sources be fail-safe in the sense that the source will be automatically shielded in the event of an interruption of power and will remain shielded until the beam control mechanism is reactivated from the control panel;
- h. High energy radiotherapy equipment shall;
  - i. *Have at least two independent “ fail safe ” systems for terminating the irradiation; and*
  - ii. *Be provided with safety interlocks or other means designed to prevent the clinical use of the machine in conditions other than those selected at the control panel;*
- i. The design of safety interlocks be such that operation of the installation during maintenance, if interlocks are bypassed, could be performed only under direct control of the maintenance personnel using appropriate devices, codes or keys.
- j. Radioactive sources for teletherapy be so constructed that they conform to the definition of a sealed source.
- k. When appropriate, monitoring equipment be installed or be available to give warning of an unusual situation in the use of radiation generators and radionuclide therapy equipment.

**B. *Operational Considerations***

The licensee shall ensure that:-

- a. Exposure of normal tissue during radiotherapy be kept as low as reasonably achievable consistent with delivering the required dose to the planning target volume, and organ shielding be used when feasible and appropriate;
- b. Radio-therapeutic procedures causing exposure of the abdomen or pelvis of women who are pregnant or likely to be pregnant be avoided unless there are strong clinical indications;
- c. Any therapeutic procedure for pregnant women be planned to deliver the minimum dose to any embryo or fetus; and
- d. The patient be informed of possible risks.

**C. Calibration**

The licensee shall ensure that:-

- a. Radiotherapy equipment be calibrated in terms of radiation quality or energy and either absorbed dose or absorbed dose rate at a predefined distance under specified conditions.
- b. The calibration be carried out at the time of commissioning a unit, after any maintenance procedure that may have an effect on the dosimetry and at intervals approved by Directorate of Nuclear and Radiation Protection (DNSRP).

**D. Clinical Dosimetry**

The licensee shall ensure that the following items be determined:-

- a. For each patient treated with external beam radiotherapy equipment, the maximum and minimum absorbed doses to the planning target volume together with the absorbed dose to a relevant point such as the centre of the planning target volume, plus the dose to other relevant points selected by the medical practitioner prescribing the treatment; and
- b. In all radio-therapeutic treatments, the absorbed doses to relevant organs.
- c. The prescribed absorbed dose at the prescribed beam quality be delivered to the planning target volume; and
- d. Doses to other tissues and organs be minimized.

**E. Quality Assurance ( QA ) For Medical Exposure**

There shall be a written QA programme of the facility which shall include among other things the following:-

- a. Measurement of the physical parameters of the radiation generators and irradiation installations at the time of commissioning and periodically thereafter;
- b. Verification of the appropriate physical and clinical factors used in patient treatment;
- c. Written records of the relevant procedures and results;
- d. Verification of the appropriate calibration and conditions of operation of dosimetry and monitoring equipments; and
- e. Regular and independent quality audit reviews of the quality assurance programme for radiotherapy procedures.

## 4. Requirements for Teletherapy Facilities

The following sections provide detailed requirements on the equipments and procedures applicable to radiotherapy.

### 4.1 **X-ray Therapy Apparatus Operating At Tube Voltage Below 150 Kv**

1. The housing of tubes designed for superficial X-ray therapy shall be such that, at every specified rating of the tube in that housing, the dose rate from the leakage radiation does not exceed 10 mGy/hr (1000 mrad/hr) at any position 5 cm from the tube housing or its accessory equipment. For the area over which these measurements shall be made should be 10 cm<sup>2</sup> at a distance 5cm from the tube or source housing.
2. Superficial X-ray therapy equipment shall be so designed as to prevent unintentional combinations of tube voltage and filtration. Means (control settings or meters) at the control panel shall be provided to indicate tube voltage and current when these can be varied, and for easy recognition of the filtration being used.
3. The tube shall not be held by hand and it shall be fixed in correct position through mechanical devices.
4. Due to the low inherent filtration and short focus-window distance, the dose rate close to the window of a low voltage tube used for superficial therapy is very high, and even brief exposure to the radiation beam may cause serious injury. For this reason, special care is necessary to avoid accidental exposure. An audible signal or warning light prominently mounted on the housing shall be provided for any such tube, in order to indicate when the tube is energized.

### 4.2 **X-ray Therapy Apparatus Operating At Tube Voltage Between 150-500 Kv**

1. Each X-ray tube shall be enclosed in a housing such that at every specified rating of that tube in that housing, the dose rate from the leakage radiation measured at a distance of 1m from the focus does not exceed 10 mGy/hr (1R/hr) to the patient at a distance of 5 cm from the surface of the housing or its accessory equipment.
2. At the control panel, means (control settings or meters) shall be provided to indicate the voltage and current when these can be varied, and for easy recognition of the filtration being used.
3. Permanent diaphragms or cones, in combination with the tube housing shall comply with the exposure requirements for leakage radiation as given in section 4.2 para (1).
4. Additional cones or adjustable diaphragms should be employed to reduce the integral dose to the patient as much as practicable.

5. The equipment shall be provided with an automatic timer which will terminate the exposure after the preset time has elapsed.
6. X-ray therapy equipment capable of operating above 150 KVp shall not be operated routinely until the radiation safety of the installation has been established by a protection survey. All the therapy equipment shall be operated in conformance with recommendations of the protection survey.

#### 4.3 **Mega Volt X-ray And Electron Beam Therapy**

1. The dose rate due to leakage radiation (excluding neutrons) at any point outside the maximum useful beam, but inside a plane circular area of radius 2m centred around, and perpendicular to, the central axis of the beam at the normal distance of treatment, shall not exceed 0.20% of the exposure rate on the axis at the same distance.
2. The dose rate of leakage radiation (excluding neutrons) at 1m from the path of the electrons between their origin and the target or the electron window shall not exceed 0.5% of the exposure rate on the central axis of the beam at the normal treatment distance.
3. The beam-limiting devices (adjustable diaphragms, cones etc.) shall be so adjusted that the leakage radiation imparts less energy to the patient than is imparted by a treatment field of 10 cm<sup>2</sup>. Similarly if the maximum field size is 35 x 40 cm<sup>2</sup>, the transmission of radiation through the diaphragms shall not exceed 0.8%.
4. For the safety of patient the accelerator shall be provided with two independent dose monitoring systems. The separation shall be such that any failure or malfunction in one system does not influence function of the other system. The detectors of the two systems shall be provided inside the radiation head.
5. The indicator showing the pre-selected number of monitor units and the indicator showing the accumulating number of monitor units shall both be displayed at the control panel.
6. Due to the complexity of accelerator and the possibility of changing the parameters, all efforts should be made by systems of interlocks to prevent mistakes being made in the selection of types and energy of radiation wedge filters, scattering foils, etc.
7. Parameters essential for the correct performance of a radiation treatment shall be displayed at the control panel.

#### 4.4 **Sealed Sources GAMMA Beam Therapy (General/Design Requirements)**

1. Every sealed source used for beam therapy shall be enclosed in a housing such that, with the beam control mechanism in the

OFF position, the dose rate from the leakage radiation measured at a distance of one meter (1m) from the source does not exceed to 10  $\mu$  Gy/hr (1m rad/hr). At any readily accessible position 5 cm from the surface of the housing, the dose rate from the leakage radiation shall not exceed 100  $\mu$  Gy/hr (10m rad/hr).

2. With the beam control mechanism in the **ON** position, the dose rate from the leakage radiation measured at a distance of 1m from the source shall not exceed either 10 mGy/hr (1 rad/hr) or 0.1% of the useful beam dose rate at 1m from the source, whichever is the greater.
3. For source housing, the leakage radiation measurements should be averaged over an area not larger than 100 cm<sup>2</sup> at a source distance of 5 cm from the source housing.
4. Permanent diaphragms and cones shall afford the same degree of protection as the source housing.
5. Adjustable or interchangeable beam-limiting devices should be so constructed that the leakage radiation imparts less energy to the patient than is imparted by a treatment field of 10 cm<sup>2</sup>. Under no circumstance shall leakage radiation through these devices exceed 2% of the useful beam.
6. The beam control mechanism shall meet the following specifications:-
  - a. In the **ON** position, the source and the beam collimating device should be accurately aligned.
  - b. The mechanism should be capable of acting in any orientation of the housing.
  - c. There should be on the housing and on the control panel a warning device that plainly indicates whether the beam is **ON** or **OFF**.
  - d. The control panel should be provided with a timer that automatically terminates the exposure after a preset time.
  - e. The beam-control mechanism should be so designed as to return automatically to the **OFF** position in the event of any breakdown or interruption of the activating force and should stay in the **OFF** position until reactivated from the control panel.
  - f. When the door to the treatment room is opened, the beam control mechanism should automatically and rapidly return to the **OFF** position where it should remain until the door is again closed and the machine is manually reactivated from the control panel.
  - g. It should not be possible to switch the beam-control mechanism to the **ON** position from inside the treatment room.

7. It shall be possible to unload or repair the treatment head without exceeding the dose limits for occupational exposure recommended by the ICRP.
8. Source housings should, so far as practicable, be fire resistant. Consideration should be given to means whereby the integrity of the source housing is preserved in the event of fire.
9. The surface of the housing of the source capsule, particularly the beam aperture, together with any other locations likely to be contaminated in the event of a leakage, shall be tested for leakage of radioactive material at least every year. Should the presence of free activity of more than 200 Bq be indicated, the source shall be considered as leaking, the equipment withdrawn from use and arrangements made immediate for source repair and decontamination of equipment.
10. The equipment should be provided with a locking device to prevent unauthorized use.
11. The gamma-beam apparatus should be tested for possible leakage of radioactive material from the source after installation and at intervals not exceeding six months. An acceptable method of testing for source leakage is to wipe (with moistened cotton swabs or filter paper) accessible surface of the housing part and collimator with beam in the OFF position and to assay these wipes for transferred contamination.
12. To check alignment of source and beam collimating device, the symmetry of the radiation field about the central axis of the useful beam should be measured.

## 5. Requirements for Safety in the Shielding Design of Teletherapy Facilities

There are many factors, both safety and operational, to be considered when designing teletherapy facility. The facility shall provide for proper treatments, patient handling and comfort, and protect against unwanted radiation exposures. The important features from radiation safety point of view are:-

- i. Size of the treatment room with radiation shielding.
- ii. Access for stretchers and, for source container in case of sealed sources.
- iii. Viewing systems, indicators and interlocks.
- iv. Radiation monitors and communication system.

Teletherapy facilities can be of almost any size and shape as long as they meet the criteria for use and safety. The principle objective of radiation protection is to ensure that the dose received by any individual is as low as

reasonably achievable (ALARA) and, in any case (except for medically required doses to patients), does not exceed annual dose limits prescribed by ICRP and notified by DNSRP. A secondary objective is to prevent damage or impairment of function of radiosensitive instruments. These objectives may be achieved by any one, or a combination, of the following methods:-

- a. Sufficient distance should be provided between the individual or objects and the source or sources of radiation.
- b. The time of exposure should be limited, and
- c. A protective (attenuating) barrier between the individual or object and the source or sources of radiation should be imposed.

There is considerable variation in the shielding requirements for therapy installations due to wide range of energies and different types of equipments used. Careful planning may result in appreciable savings, particularly in the mega voltage range where the shielding is very costly. Provision for future requirements may prevent subsequent serious inconvenience and expensive alterations. This consideration is important because of the trend toward higher energies and greater workload.

It may be noted that there is no standard thickness or design which must be followed. The amount of thickness, type of material and location of shielding depends on many factors, some of which can be varied, should the user so wish. Treatment room shielding design alongwith detailed calculations shall be got approved by DNSRP. After installation of teletherapy unit inside the treatment room, the radiation doses measured in all accessible direction must comply with the radiation levels specified by DNSRP.

Typical layout for rooms of teletherapy units (Co-60 and linac) are shown in fig 1 and 2. Typical shielding calculations for treatment rooms have been computed in the Appendix.

## **6. Regulation Of Teletherapy Facilities**

Pursuant to the Pakistan Nuclear Safety and Radiation Protection (PNSRP) Regulations 1990, all such facilities whether operated by PAEC or Non-PAEC (Government as well as private sectors) are required to obtain licence from DNSRP. The Regulatory safety inspections of all these facilities are being conducted regularly to verify that the requirements imposed by DNSRP are being met.

## References

1. International Commission on Radiological Protection (ICRP), Protection Against Ionizing Radiation From External Sources used in Medicine, ICRP Publication No. 33, 1982.
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5. The Safe Use of Radiation Sources, IAEA Training Course Series No. 6, 1995.
6. Treatment Room Shielding Calculations for Cobalt 60 Teletherapy Installations, Theratronics International Ltd., Canada, 1997.
7. IAEA Practical Radiation Safety Manual on High Energy Teletherapy, 1992.
8. Pakistan Nuclear Safety and Radiation Protection (PNSRP) Ordinance 1984 and PNSRP Regulations-1990.

**Computation of Protective Barriers for Shielding Design of  
Teletherapy Facilities**

In designing teletherapy facilities we need to protect three classes of people: the radiation worker, non-radiation worker, and the public at large. In order to reduce the dose to acceptable levels at the position occupied by such personnel, it is usual to place barriers of lead, concrete, or some other suitable material between them and the radiation source. For the calculations given below, the following equivalent dose limits keeping in view the As Low As Reasonably Achievable (ALARA) principle have been used:

- i. Radiation worker  $H_L = 2 \text{ mSv/yr}$  (one tenth of annual limits)
- ii. Non-Radiation worker  $H_L = 0.1 \text{ mSv/yr}$  (one tenth of annual limits)

The following formula can give a very good estimate for barrier thickness under different conditions:-

**I. Primary Protective Barrier**

$$H_L = W \times d^2/D^2 \times \frac{UT}{A} \quad \text{————— (1)}$$

- Where  $H_L$  = Equivalent dose per week or Equivalent dose per year to personnel at point in question.  
 $W$  = Workload at the isocenter of the machine  
 $d$  = Distance from the source to isocenter  
 $D$  = Distance from the source to point of interest  
 $U$  = The barrier use factor  
 $T$  = Occupancy factor of the area behind the barrier  
 $A$  = Attenuation factor produced by the barrier

Equation (1) may be rearranged as

$$A = \frac{W}{H_L} \times d^2/D^2 \times UT \quad \text{————— (2)}$$

In protection work, it is convenient to specify the barrier in terms of the number of Tenth Value Layer (TVL) which may be obtained by

$$\text{No. of TVLs} = \text{Log}_{10} A \quad \text{————— (3)}$$

## II. Secondary Protective Barrier (Leakage and Scattered Radiation)

For Linacs, the leakage is at the most 0.1% of the primary radiation whereas for isotopes machines it is 0.02 mSv/h average at 1m.

The following values of use factor (U) and occupancy factor (T) may be used:

### A. Use Factor (U) For Primary Barrier\*

Floor	=	1
Walls	=	1/4
Ceiling	=	< 1/4

\* The use factor for secondary protective barriers is usually less than 1/4.

### B. Occupancy Factor

Full Occupancy (T = 1)	Work areas such as offices, laboratories, shops, wards, nurse's stations; living quarters; children's play areas; and occupied space in nearby buildings.
Partial Occupancy (T = 1/4)	Corridors, rest rooms, elevators using operators, unattended parking lots.
Occasional Occupancy (T = 1/16)	Waiting rooms, toilets, stairways, unattended elevators, janitors' closets, outside areas used only for pedestrians or vehicular traffic.

## III.A. Typical Calculation Of Protective Barriers For Linac

### Example-1

Assuming our machine is a 25 MV linac with a workload of  $5.0 \times 10^4$  Sv/y using the following values of various factors:

#### i. Primary Barrier

$H_L$	=	$2 \times 10^{-3}$ Sv/y	( for radiation workers at control panel )
T	=	1	
U	=	1/4	
d	=	1 m	
D	=	5 m	

Using equation (2), the attenuation factor is

$$A = \frac{5 \times 10^4}{2 \times 10^{-3}} \times (1/5)^2 \times (1/4) \times 1 = 2.5 \times 10^4$$

Using equation (3), we have

$$\text{No. of TVLs} = \text{Log}_{10} A = 5.4$$

For 25 MV linac, TVL of concrete (2400 Kg/m<sup>3</sup>) is 0.50 m and TVL of lead is 0.051m. So the required thickness of concrete is 5.4 x 0.5 = 2.7 m and the required thickness of lead is 5.4 x 0.051 = 27.53 cm.

ii. **Secondary Barrier**

In this case the dose rate at 1 m is at most 0.1% of the primary, so the workload is 50 Sv/y, using the following values of various factors:

$$\begin{aligned} H_L &= 2 \times 10^{-3} \text{ Sv/y (for radiation workers at control panel)} \\ T &= 1 \\ U &= 1 \\ d &= 1 \text{ m} \\ D &= 4 \text{ m} \end{aligned}$$

Using equation (1) the attenuation factor is

$$A = \frac{50}{2 \times 10^{-3}} \times (1/4)^2 \times 1 \times 1 = 1.56 \times 10^3$$

Using equation (2), we have

$$\text{No. of TVLs} = \text{Log}_{10} A = 3.19$$

The required thickness for concrete is 1.6 m and that of lead is 16.29 cm.

### III.B. **Typical Calculation Of Protective Barriers For <sup>60</sup>Co**

#### **Example-2**

Assuming our machine is teletherapy unit with <sup>60</sup>Co source of 444 TBq (12000 Ci) with a workload of 2.0 x 10<sup>4</sup> Sv/y, using the following values of various factors:

i. **Primary Barrier**

$$\begin{aligned} H_L &= 2 \times 10^{-3} \text{ Sv/y (for radiation workers at control panel)} \\ T &= 1 \\ U &= 1/4 \\ d &= 1 \text{ m} \\ D &= 5 \text{ m} \end{aligned}$$

Using equation (2), the attenuation factor is

$$A = \frac{2 \times 10^4}{2 \times 10^{-3}} \times (1/5)^2 \times (1/4) \times 1 = 10^5$$

Using equation (3), we have

$$\text{No. of TVLs} = \log_{10} A = 5$$

For  $^{60}\text{Co}$  TVL of concrete ( $2400 \text{ Kg/m}^3$ ) is 0.23 m and TVL of lead is 0.042m. So the required thickness of concrete is  $5 \times 0.23 = 1.15 \text{ m}$  and the required thickness of lead is  $5 \times 0.042 = 21 \text{ cm}$ .

ii. **Secondary Barrier**

In this case of  $^{60}\text{Co}$  teletherapy unit, the leakage radiation is  $20 \mu \text{ Sv/hr}$  at 1m, so the workload is  $2.88 \text{ Sv/y}$ , using the following values of various factors:

$$\begin{aligned} H_L &= 2 \times 10^{-3} \text{ Sv/y (for radiation workers at control panel)} \\ T &= 1 \\ U &= 1 \\ d &= 1 \text{ m} \\ D &= 4 \text{ m} \end{aligned}$$

Using equation (1) the attenuation factor is

$$A = \frac{2.88}{2 \times 10^{-3}} \times (1/4)^2 \times 1 \times 1 = 90$$

Using equation (2), we have

$$\text{No. of TVLs} = \log_{10} A = 1.96$$

The required thickness for concrete is 0.45 m and that of lead is 8.2 cm.



Typical Room Layout Of Linac

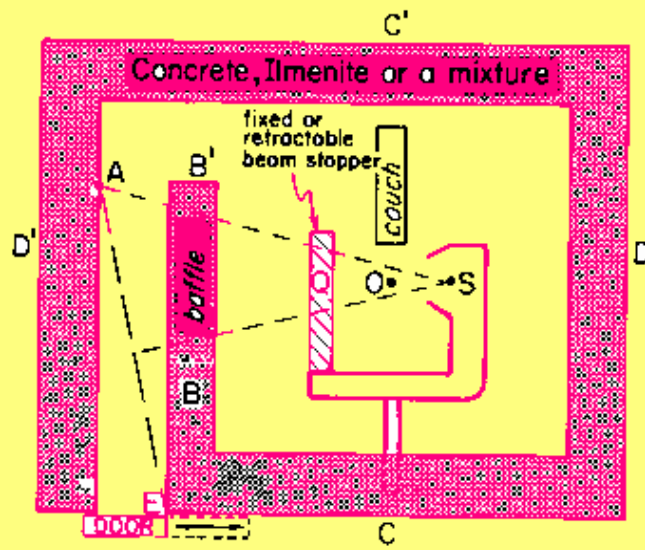


Fig-2