

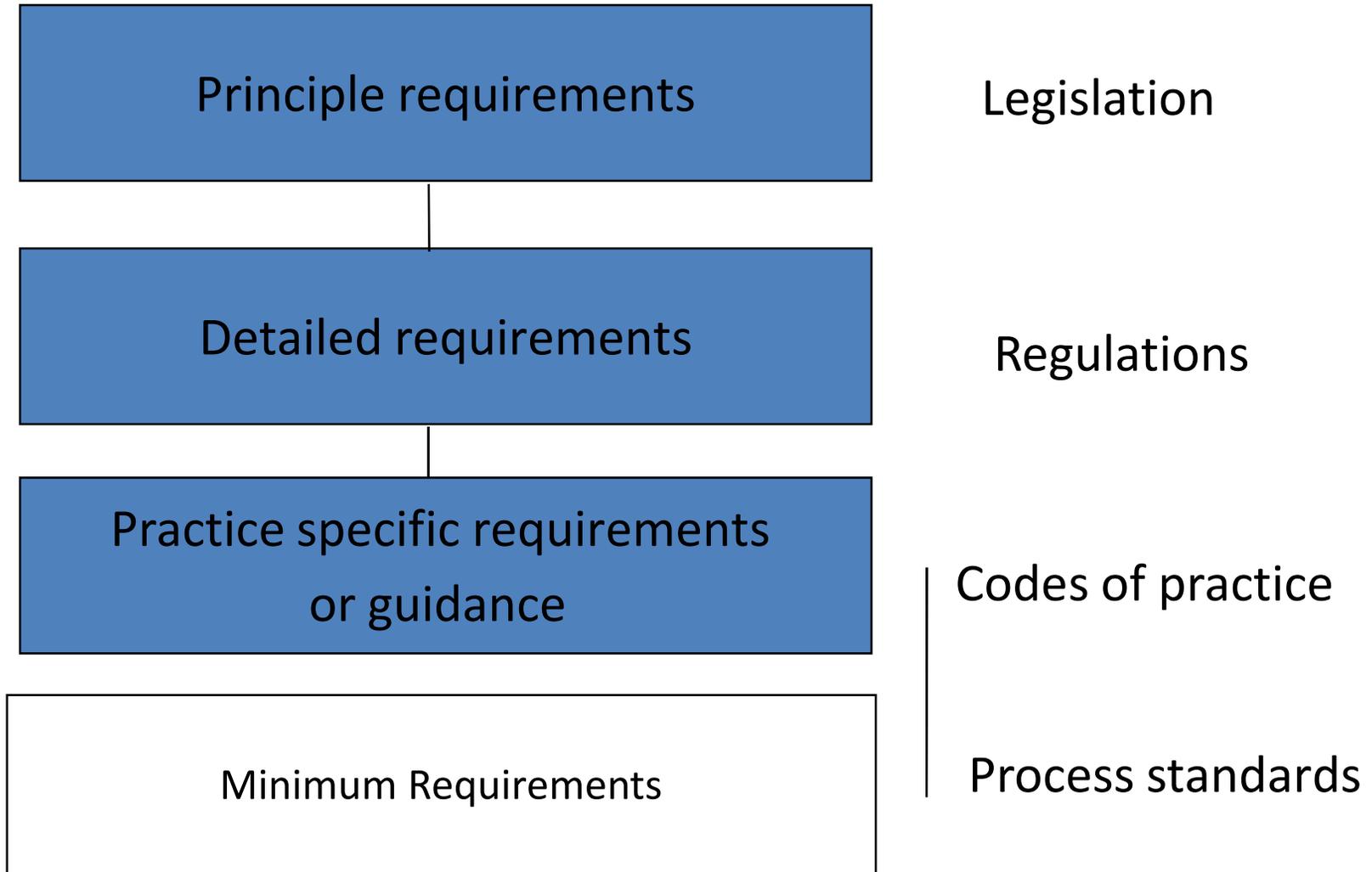
# The Concepts of Minimum Requirements in Regulatory Work

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# Structure of Legal framework



# Elements and concepts of legislation

## “ Enabling legislation

- . Basic legal document enacted by the national legislative body
- . Simple as feasible
  - need for subsequent amendments should be minimised
- . Consistent with national situation
  - realistic expectations and effective use of resources more important than “an ideal system”

## **Legislation (Law, Act, Statue**

- . Establishment of regulatory authority
- . Allocation of responsibilities
- . Establishment of fundamental protection principles and structures
- . Interagency co-ordination and co-operation
- . Mechanism for appealing
- . (Establishment of services and facilities needed, but not otherwise available)

# Regulations

- “ More specific than the law on protection and safety requirements
- “ Apply to practices and sources within practices
- “ Developed by the Regulatory Authority
- “ Issued by the legislative body, Ministry or Regulatory Authority (varies depending on the national legal system)

# Codes of practice, Guides

- . Usually developed and issued by the Regulatory Authority
- . Practice specific advice on how to achieve protection and safety requirements defined in legislation or regulations
- . May or may not be legally binding - other procedures might be followed to achieve the same protection and safety goals

# Minimum Requirement

- “ States in a simplified way the **standards** of safety to be met before a specific authorization is issued
- “ Much more specific and more detailed
- “ Incorporates the advises to be given by Safety Advisers
- “ Useful for determining stages for the purpose of issuing permits
- “ Can be changed more frequently than law or regulations

# Question?

” Who issues ‘Standards’ ?

## Performance versus prescriptive regulatory instruments

The development of radiation safety regulation involves a balance between two opposing instruments:

- “ the need for flexibility to permit easy adaptation of the regulations to evolving circumstances and technology (called ‘performance regulatory instruments’)
- “ the need to include detailed requirements for ease in determining when the requirements are being met ( called ‘prescriptive regulatory instruments’).

“ **A performance orientated regulatory system is more general, and simply specifies the overall radiation safety requirement and basic operational parameters.**

- . a performance orientated regulatory system would require the licensee to plan and organize operations so that exposures are maintained as low as reasonably achievable and demonstrate this by using ‘adequate’ workplace monitoring and ‘appropriate’ instruments.
- . It might also require the maintenance of adequate records to demonstrate compliance

“ **A prescriptive orientated regulatory system is more specific and states how to achieve radiation safety in practice.**

- . a prescriptive regulatory system would be practice specific and it would define exactly how to achieve adequate restriction of exposure
- . It might indicate when and where to conduct workplace monitoring, what type of instrument should be used and how and what records should be maintained

“ **most regulations contain both performance and prescriptive requirements, but can often be characterized as being either predominantly performance orientated or prescriptive orientated.**

“ Performance orientated regulatory instruments have some advantages

- . they can be relatively easy to develop,
- . are focused on objectives on what is to be achieved in terms of protection and safety.
- . they can be made applicable to a range of practices involving ionizing radiation
- . if carefully drafted, do not need to be changed frequently to keep up to date with changing technology.

“ However, a major disadvantage is that they need to be interpreted in relation to different practices. This places a significant burden on the time and skills of both the regulatory staff and the license holders

## **Advantages of Prescriptive regulatory instruments are**

- “ they are largely practice-specific and so have the advantage of providing, both, the regulatory staff and the user with clearly defined requirements for a particular practice.
- “ They prescribe what to do to comply with the requirements and how to do it in order to achieve an adequate level of protection and safety.
- “ they reduce the time and skills necessary to perform a licensing review or conduct an inspection.
- “ they enable the authorization and inspection process to focus on simple verification of compliance.

## **A highly prescriptive approach can have some undesirable side effects**

- “ they can drive a ‘compliance culture’ rather than a ‘safety culture’ if positive steps are not taken to prevent it.
- “ they are more difficult to prepare, requiring more detailed and expert knowledge of the specific practice in question and considerable experience in operational radiation safety.
- “ they are narrowly applicable to a specific practice and may need to be regularly amended to keep pace with technology changes.

**They are best suited to widespread practices where the equipment and procedures do not vary significantly among different users**

## **As a practical advise,**

- “ regulatory authorities need a basic foundation of performance orientated regulatory instruments governing the general principles of radiation protection and the safety of sources.
- “ they also need prescriptive regulatory instruments based on standards that are directed at most widespread practices that have the potential for higher exposure of workers

## **This would be a useful supplement to the performance regulations. The aim should be to enable the Regulatory Authority**

- “ to use its more scarce, highly skilled personnel for the preparation of regulations and conducting inspection of those practices for which only performance regulations are available,

**Less professional judgment and discretion are required in using more precise prescriptive regulatory instruments in more or less routine situations.**

- ” Minimum requirements for authorizing x-ray premises
- ” Shielding requirements for x-ray machines
- ” Minimum requirements for acceptance test for diagnostic x-ray facilities
- ” Minimum requirements for registration x-ray machines
- ” Minimum requirements for maintenance of x-ray machines
- ” Minimum requirements for quality control tests for x-ray machines
- ” Requirements for monitoring when wearing lead aprons,
- ” Minimum requirements for x-ray grids

**NIGERIAN NUCLEAR REGULATORY AUTHORITY**  
**MINIMUM REQUIREMENTS FOR AUTHORIZATION OF DIAGNOSTIC  
RADIOGRAPHY PREMISES**

*(This document is for guidance purposes and may be reviewed by NNRA  
without prior notification)*

**1. General/Fluoroscopy Rooms**

**1.1 Size**

“ General radiographic rooms should be larger than 16 m<sup>2</sup>x5m. There should be sufficient space for a permanently built protective cubicle. Fluoroscopic rooms should be approximately 25 m<sup>2</sup>. Special procedure rooms should be considered individually.

**1.2 Doors and Walls**

“ Access doors should be of the sliding type giving better radiation protection. A clearing of 1.5 m is recommended. The overlap should be 100 mm each side. The doors should be lined with lead sheet of 2 mm thickness. The walls should be 230 mm kiln baked solid clay brick or 2 mm lead sheet sandwiched between partitioning or 115 mm brick with 6 mm barium plaster. Walls should be protected up to a height of 2.2 m.

Material	Thickness of Material (mm)	Lead Equivalence (mm) at designated Tube voltage	
		100kV	150 kV
Brick	115	1	0.9
	230	2.4	2.0
Barium Plaster	6	1	0.55
	11		

### **1.3 Ceiling and Floors**

“ X-ray rooms should preferably be sited on the ground floor of a building. If the x-ray room is above ground level the solid concrete slab of density  $2.35 \text{ g/cm}^3$  must be of 150 mm thickness. Thickness of ceiling slabs, if space above is occupied, should not be less than 100 mm. Single storey buildings do not require a ceiling slab.

### **1.4 Windows and Airconditioning Units**

“ Windows and air conditioning units should be sited at least 2 m above the floor. Alternatively access near the window must be prevented effectively. Windows of upper floor x-ray rooms can be of normal height.

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## 1.6 Protective Cubicle

“ A protective cubicle allowing space for the control as well as movement of the operator should be constructed in the x-ray room. The cubicle should be located such that unattenuated direct scatter radiation originating on the examination table or the erect bucky does not reach the operator in the cubicle. The control console should be fixed within the cubicle and should be at least 1.02 m from any open edge of the cubicle wall which is nearest to the examination table. The cubicle should have at least one viewing window which will be so placed that the operator can view the patient during any exposure. The size of the window should be at least 30 cm x 30 cm. The minimum height of the cubicle should be 2.2 meter. The lead equivalence of the wall or panel as well as the protective glass should be at 2 mm, i.e., 230 mm brick or 115 mm brick barium plastered (6 mm) or 2 mm lead sheet. The lead glass and protective material must overlap each other by at least 25 mm.

## 1.7 Change Cubicles

“ Should the change cubicles lead into the x-ray room, the doors must be lined with at least 1.5 mm lead sheet. Access doors into the x-ray room must be lockable from the x-ray room side to prevent access during exposures.

## **1.8 Radiation Warning Notices**

- “ Warning lights are required at the entrances to fluoroscopy and CT rooms. This light must be connected to the generator in such a way that it will illuminate during activation of the tube. A radiation warning notice must be displayed at all entrances to x-ray.

## **1.9 Radiography Rooms**

- “ The radiography room should not be clogged with unnecessary equipments, especially metallic materials such as disused or non-functional machines. This is to avoid excess scattering of radiation in the x-ray room

## **2. Special Procedures**

### **2.1 Computed Tomography**

“ All doors should be lined with 1.6mm lead sheet. The walls should be 230 mm kiln baked solid clay brick or 1.6 mm lead sheet sandwiched between partitioning or 115 mm brick with 4 mm barium plaster. Protective glass should be 0.8 mm lead glass or at least 90 mm plate glass.

### **2.2 CATH LAB**

“ Doors should be lined with 2 mm lead sheet. The walls should be 230 mm kiln baked solid clay brick or 2 mm lead sheet sandwiched between partitioning or 115 mm brick with 6 mm barium plaster. Protective glass - The lead equivalence of the viewing window must be at least 1 mm of lead.

### **2.3 Dental Unit**

“ Doors should be lined with 1 mm lead sheet and walls should also be lined with 115 mm brick or 1 mm lead sheet. If partition walls are used, lead plate with dimensions 1m x 1m and 1mm thick, should be attached to the wall. The height of the plate should be 0.5m above the floor in order to fully intercept radiation from the primary beam. This is required only in cases where the waiting room or other places of occupancy is adjacent to the dental x-ray room with patients sitting at distances less than  $\pm 3$ m from the tube head of the x-ray unit.

### **2.4 Fixed C-arm (or mobile used as a fixed unit)**

“ Doors - lined with 1 mm lead sheet Walls - 115 mm brick or 1 mm lead sheet

### **2.5 Mammographic Unit**

“ No requirements

### 3 The Darkroom

- i. To produce a radiograph of satisfactory diagnostic quality, bearing in mind minimum exposure to the patient, does not depend only on the film-screen combination and exposure techniques but also on the processing and handling of the films. This additional factor can be achieved by having a good darkroom and proper developing techniques.
- ii. The film processor could be automatic or manual, though is advised that facilities should procure automatic radiographic film processor.
- iii. The darkroom must be painted with light colours, preferably white, to help in reflecting the safelight.
- iv. The darkroom *must* be completely light-tight and well ventilated.
- v. If adjacent to a radiography (x-ray) room, the darkroom *must* be adequately shielded to ensure that exposure of personnel and film to x-ray does not occur. In this case, the door leading into the darkroom must not face the x-ray room directly or a light tight transfer cabin in the wall between the darkroom and the x-ray room can be used in passing the films to the darkroom.
- vi. The darkroom must be designed to incorporate a lockable door to ensure light tightness when undeveloped films are being handled.
- vii. A loading bench for film arrangement before developing.
- viii. There must be processing tanks for developing, rinsing, fixing, washing and drying of films.

#### **4. Electric Power Rating**

- “ The minimum acceptable power rating for a purpose-built x-ray premises should be
- (i) if a high frequency generators is envisaged, the premises should have a power rating of 12 kW at 100 kV (This is to ensure that a high-tension voltage ripple shall not be larger than 4%, if measured at 100 kV (kVp) and 100 mA).
  - (ii) if a three phase, 12-pulse or constant potential generators is envisaged, it should have 12 kW at 100 kV;
  - (iii) if a three phase, 6 pulse generators is envisaged it should have 16 kW at 100 kV; and
  - (iv) if a single phase generators is envisaged, it should have 24 kW at 100 kV.

#### **5 The Surrounding Environment**

- “ The site of a diagnostic x-ray department should be such that the occupancy of surrounding offices and other public places is as low as 1/16. A sketch of the layout of the X-ray Department specifying maximum occupancy of the areas around should be included in the application for authorization.