

**BASIC ELEMENTS  
OF A  
REGULATORY PROGRAMME  
FOR  
RADIATION SAFETY**

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# IAEA TECDOC 1067: Organization and implementation of a national regulatory infrastructure governing protection against ionizing radiation and the safety of sources

- Legal framework
- Regulatory programme
- Role of Regulatory Authority in emergency situations
- Assessment of the effectiveness of the regulatory programme
- Cost effectiveness of the regulatory framework
- Priority actions

IAEA-TECDOC-1067

*Organization and  
implementation of a  
national regulatory infrastructure  
governing protection against  
ionizing radiation  
and the safety of radiation sources  
Interim report for comment*

*Jointly sponsored by FAO, IAEA, OECD/NEA, PAHO, WHO*



**IAEA**

February 1999



# **Objectives of TECDOC 1067**

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- **To assist Member States to establish or improve radiation safety infrastructure in order to implement the requirements of International Standards**
- **Member States receiving assistance in the area of radiation/nuclear technology from FAO, IAEA, ILO, PAHO or WHO are conditionally expected to implement the Standards**



# **Basic Elements of a Regulatory Programme for Radiation Safety**

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- **1. REGULATIONS**
- **2. NOTIFICATION**
- **3. AUTHORIZATION ( REGISTRATION OR LICENSING )**
- **4. INSPECTION**
- **5. ENFORCEMENT**
- **6. EMERGENCY RESPONSE**
- **7. ACCIDENT INVESTIGATION AND FOLLOW-UP**
- **8. AVAILABILITY OF TECHNICAL SERVICES**
- **9. INTERAGENCY CO-ORDINATION AND CO-OPERATION**
- **10. STAFFING AND TRAINING**
- **11. FUNDING**
- **12. INFORMATION DISSEMINATION**



# **Elements of a Regulatory Programme:**

## **REGULATORY PROGRAMME CHARACTERIZATION**

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**ORGANIZATIONAL PHASE**

**IMPLEMENTATION PHASE**

**FULLY OPERATIONAL PHASE**



# **Elements of a Regulatory Programme:**

## **ORGANIZATIONAL PHASE OF A REGULATORY PROGRAMME**

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- **AUTHORIZATION, INSPECTION AND ENFORCEMENT PROGRAMMES ARE IN THE EARLY STAGE OF DEVELOPMENT**
- **ARRANGEMENTS FOR EMERGENCY RESPONSE AND ACCIDENT INVESTIGATION ARE BEING PLANNED**
- **ESSENTIAL TECHNICAL SERVICES ARE IN THE PROCESS OF BEING ESTABLISHED AND OTHERS ARE UNDER EVALUATION**
- **THE NEED FOR INTERAGENCY CO-ORDINATION AND CO-OPERATION ARE IN THE PROCESS OF BEING IDENTIFIED**



# **Elements of a Regulatory Programme:**

## **IMPLEMENTATION PHASE OF A REGULATORY PROGRAMME**

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- **LEGISLATION AND MAIN PERFORMANCE REGULATIONS ARE IN PLACE**
- **NOTIFICATION OF THE POSSESSION AND USE OF RADIATION SOURCES IS VIRTUALLY COMPLETE, AND AUTHORIZATIONS ARE BEING ISSUED, PARTICULARLY FOR THE MORE HAZARDOUS SOURCES**
- **INSPECTION AND ENFORCEMENT PROGRAMMES ARE IN PLACE AND PROBABLY AT THE LATER STAGES OF IMPLEMENTATION**
- **EMERGENCY RESPONSE AND ACCIDENT INVESTIGATION PROGRAMMES ARE AT THE LATE PLANNING STAGE, IF NOT AT THE EARLY STAGES OF IMPLEMENTATION**



# **Elements of a Regulatory Programme:**

## **IMPLEMENTATION PHASE OF A REGULATORY PROGRAMME**

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- **MOST ESSENTIAL TECHNICAL SERVICES ARE AVAILABLE AND OTHERS ARE SCHEDULED TO BECOME AVAILABLE**
- **CO-ORDINATION AND CO-OPERATION ARRANGEMENTS WITH KEY AGENCIES ( e.g. Customs ) HAVE BEEN ESTABLISHED**
- **THE ORGANIZATIONAL STRUCTURE AT THE REGULATORY AUTHORITY IS ESTABLISHED AND THE CORE OF THE STAFF IS APPOINTED AND TRAINED**



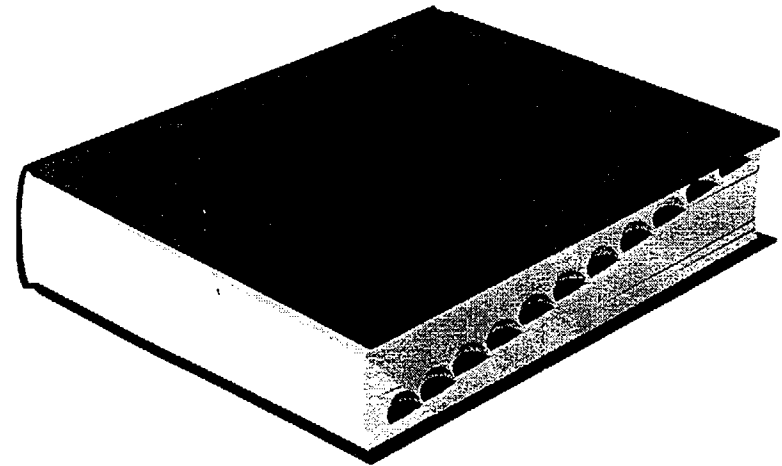


# Elements of a Regulatory Programme: Regulations

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## Purpose:

- codify radiation safety requirements
- define administrative procedures
- ensure protection and safety of public, workers and patients



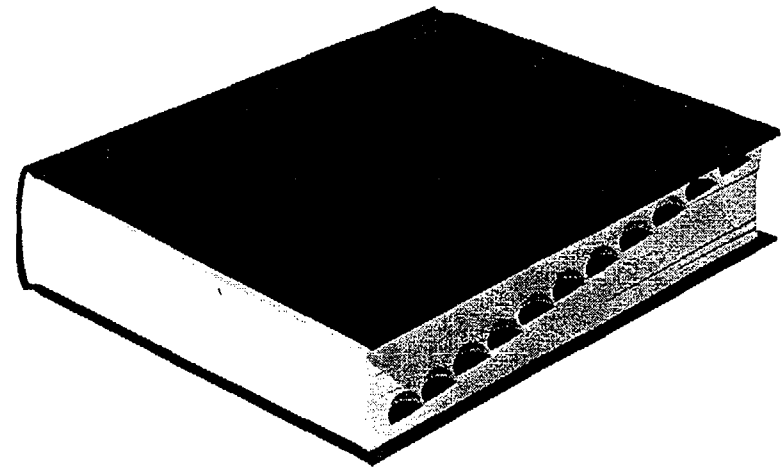


# Elements of a Regulatory Programme: Regulations

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Regulations should be:

- clearly written
- unambiguous
- precise
- enforceable
- revised





# Elements of a Regulatory Programme: Regulations

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## Performance Regulations

- Easy to prepare
- Applicable to a range of practices
- General requirements-  
focus on overall radiation  
safety objectives

(eg: carry out 'adequate'  
monitoring using 'appropriate'  
equipment)

## Prescriptive Regulations

- Difficult to prepare
- Practice specific
- Clearly defined  
requirements  
  
(eg: where and how to conduct  
workplace monitoring)



# Elements of a Regulatory Programme: Regulations

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## Performance Regulations

- Require professional judgment for application
- Should not need changing frequently
- May need interpretation for application to specific practices

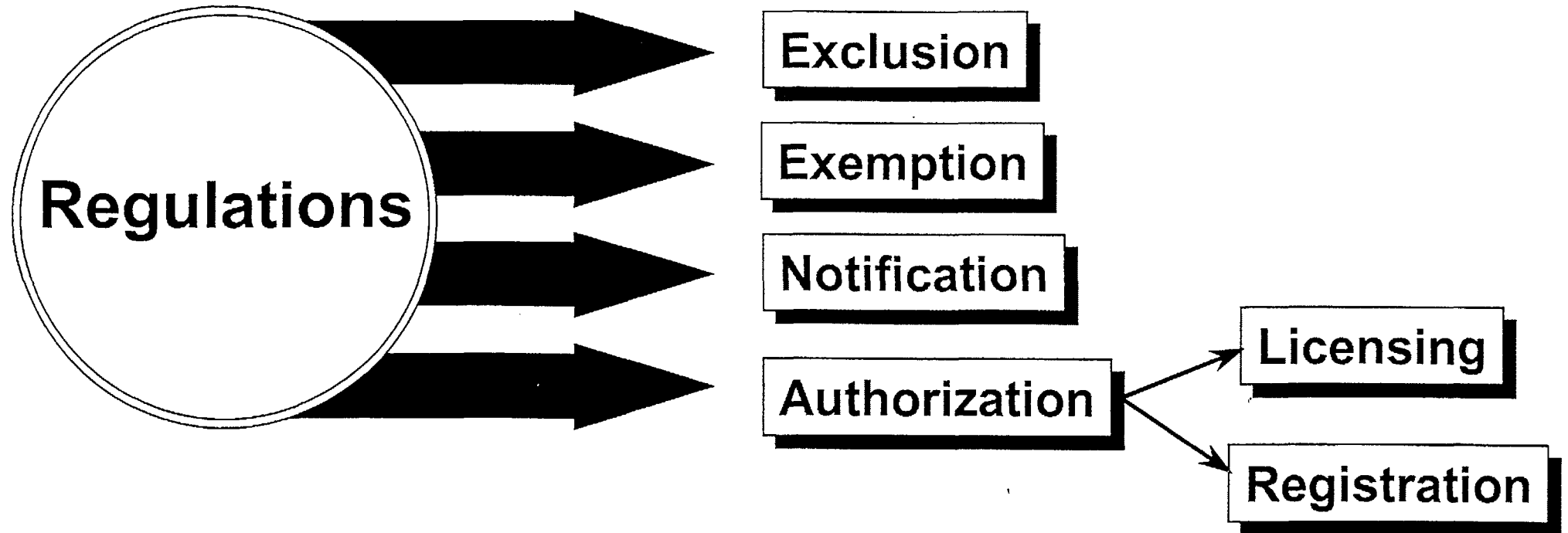
## Prescriptive Regulations

- Easy to follow
- Best suited to widespread practices using standard equipment and procedures
- Revise to keep up with improving technology
- May generate compliance culture



# Elements of a Regulatory Programme: Regulations

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# Elements of a Regulatory Programme: Exclusion & Exemption

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## Regulations need to allow for:

- Exclusion

- sources not amenable to control  
eg: potassium-40 in the body

- Exemption

- some sources may be exempt from regulatory control as they present a trivial risk  
eg: small quantities of radioactive material or low kilovoltage cathode ray tubes



# Elements of a Regulatory Programme: Notification

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- A formal notification to the Regulatory Authority from a legal person concerning possession of a source or intention to carry out a practice
  - Low risk source - may only require notification (eg: small sealed sources used in schools)
  - Other sources - application for License or Registration may act as notification



# **Elements of a Regulatory Programme: Sample Questionnaire for Notification**

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- 1. NAME AND ADDRESS OF THE LEGAL PERSON:**
- 2. NAME AND ADDRESS OF THE ORGANIZATION:**
- 3. NATURE OF THE PRACTICE IN WHICH THE SOURCE IS USED:**
- 4. IDENTIFICATION OF EACH SOURCE:**
  - (a) RADIONUCLIDE:**
    - ACTIVITY ( Bq ):**
    - CHEMICAL FORM:**
    - SEALED SOURCE: YES / NO      if YES = MANUFACTURER: / MODEL:**
  - (b) RADIATION GENERATING EQUIPMENT:**
    - MANUFACTURER:**
    - MODEL:**
    - OPERATING POTENTIAL:**
    - NATURE OF THE EQUIPMENT IN WHICH THE SOURCE IS INSTALLED:**
    - MODEL ( if appropriate ):**
- 5. DATE:**
- 6. SIGNATURE FOR LEGAL PERSON:**





# Elements of a Regulatory Programme: Authorization by Registration

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## Registration

- Used for simple practices with standard operations
    - safety ensured by design of facilities and equipment
    - procedures simple to follow
    - minimal safety training needed
    - good safety record
    - large number of users
- eg: low activity industrial gauges



# **Elements of a Regulatory Programme:**

**INFORMATION TO BE SUBMITTED BY AN APPLICANT**

**FOR REGISTRATION**

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- **CLEAR IDENTIFICATION OF THE SOURCE AND ASSOCIATED FACILITIES AND EQUIPMENT TO BE UTILIZED IN THE PRACTICE**
- **THE LOCATION OF USE**
- **IDENTIFICATION OF THE INDIVIDUAL RESPONSIBLE FOR SOURCE SAFETY**
- **AGREEMENT TO FOLLOW ALL APPLICABLE OPERATING, MAINTENANCE AND DISPOSAL REQUIREMENTS**



# Elements of a Regulatory Programme: Authorization by Licensing

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## Licensing

- Used for more complex, higher risk practices
  - Protection depends on human performance
  - Specified conditions of use  
eg: industrial radiography
- Applicant should provide:
  - detailed information of the sources and intended uses
  - a prior safety assessment
- Processing the application can be demanding on the Regulatory Authority



# Elements of a Regulatory Programme: Authorization by Licensing

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## Examples of practices requiring Licensing:

- Industrial irradiators
- Industrial radiography
- High activity industrial gauges
- Radiotherapy
- Diagnostic x-ray
- Nuclear medicine
- Unsealed sources.....



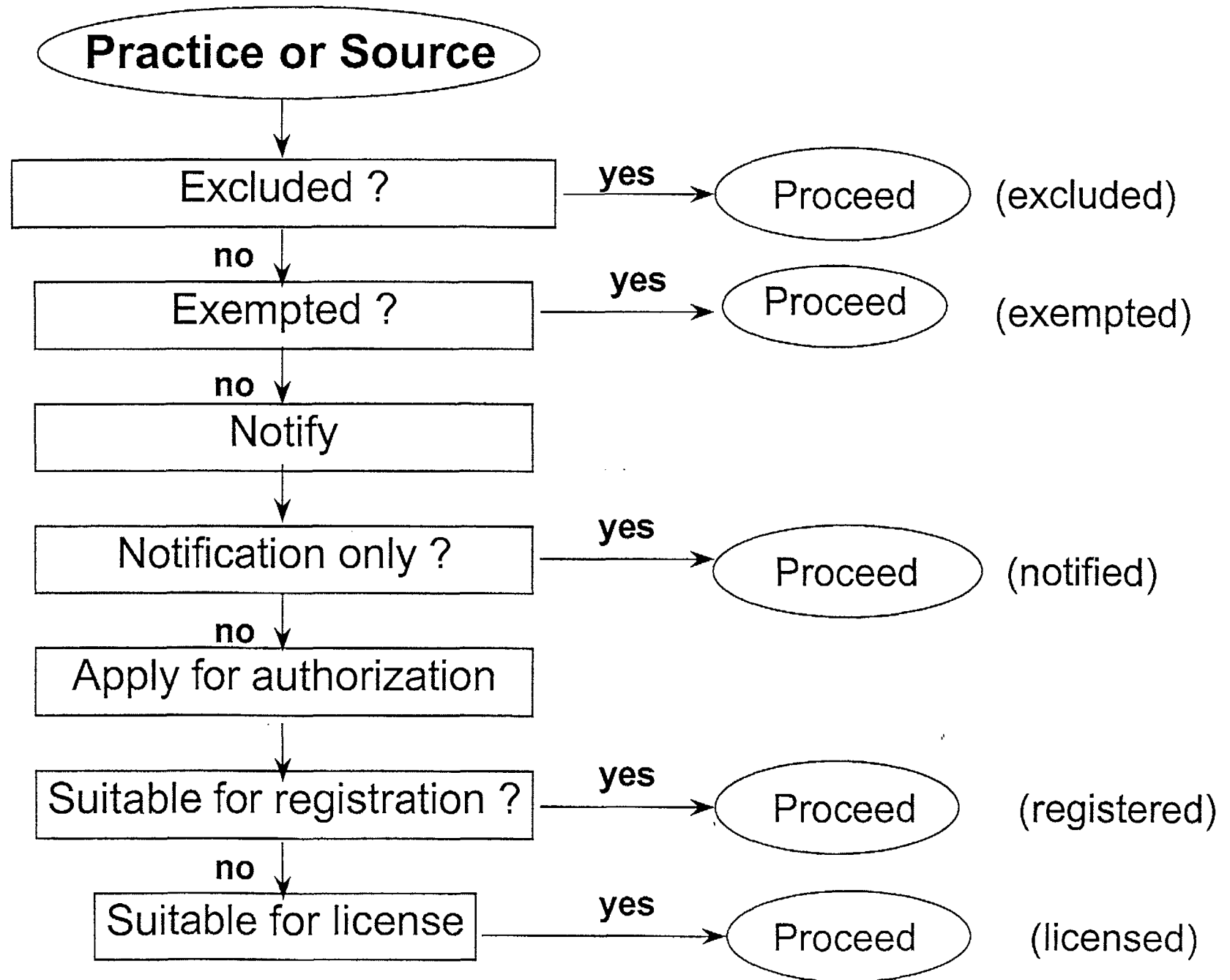
# **Elements of a Regulatory Programme:**

**INFORMATION TO BE SUBMITTED BY A LICENSING**

## **APPLICANT**

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- **DETAILED INFORMATION RELATED TO THE PROPOSED USE OF THE SOURCE**
- **THE RADIATION PROTECTION AND SOURCE SAFETY PROVISIONS**
- **AN ASSESSMENT OF THE NATURE, MAGNITUDE AND LIKELIHOOD OF THE EXPOSURES ATTRIBUTED TO THE SOURCE**
- **CLEAR IDENTIFICATION ( names, qualifications, training experience, etc. ) OF PERSONNEL WHO HAVE KEY RESPONSIBILITIES FOR PROTECTION / SAFETY AND THOSE WHO COULD SUBSTANTIALLY AFFECT THEM BY VIRTUE OF TASKS INVOLVING OPERATION OR MANIPULATION OF RADIATION SOURCES**





# **Elements of a Regulatory Programme: Revalidation of Licenses & Registrations**

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- **Licenses and registrations should be revalidated after a set time interval**
  - ensures details are up to date
  - forces a review by user and Regulatory Authority
  - reminds users that they must meet regulatory obligations
- **Time interval depends on:**
  - inspection policy
  - safety record
  - stability of users operations
  - any changes in regulatory requirements



# **Elements of a Regulatory Programme: Authorized Legal Person**

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The authorized legal person holding the registration or license has the prime responsibility of ensuring the protection and safety for the authorized radiation sources





# **Elements of a Regulatory Programme: Compliance Monitoring**

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## **Purpose:**

- to determine regulatory compliance
- to assess whether protection and safety standards are adequate

## **Mechanism:**

- **on-site inspection**
- radiation safety appraisals
- accident notification/investigation
- feedback from users



# Elements of a Regulatory Programme: Compliance Monitoring

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## On-site inspection:

- Main method of assessing compliance
- Performance regulations - skilled inspectors
- Prescriptive regulations - staff with basic radiation safety training
- Risk and history (previous accidents/violations) determine priority and frequency of inspections
- Database (RAIS) and performance indicators can help identify priorities



# Elements of a Regulatory Programme: Performance Indicators

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## Indicators of potential degraded safety performance

### Examples:

- Lack of senior management commitment to safety
- RPO too busy with other assignments
- Not enough trained staff
- High staff turnover
- Inadequate quality assurance
- Poor communication
- Poor housekeeping



# **Elements of a Regulatory Programme: Enforcement**

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**Enforcement by the Regulatory Authority falls into 3 broad categories:**

- (In)formal instructions
  - no immediate threat to health and safety
- Temporary suspension of operations
  - potential for immediate threat to health & safety
- Permanent suspension of operations (revocation of license or registration)
  - continual regulatory infractions compromising H & S

Regulatory Authority should be empowered to impose sanctions



# Elements of a Regulatory Programme: Accident Investigation

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Investigations by the user or Regulatory Authority to determine why accident happened and who was responsible

- determine root causes and contributing factors
- assess radiological consequences
- identify corrective actions
- derive lessons learned
- recommend preventative actions
- feedback of findings
- review regulatory programme



# **Elements of a Regulatory Programme: Dissemination of Information**

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The Regulatory system should include a mechanism for periodic dissemination of information to users, manufacturers and suppliers about protection and safety matters



# Elements of a Regulatory Programme: Emergency Intervention

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Registrant/Licensee has prime responsibility for emergency intervention

Regulatory Authority has:

- general supervisory responsibilities
- specific, direct role in off-site emergency response (national emergency plans)

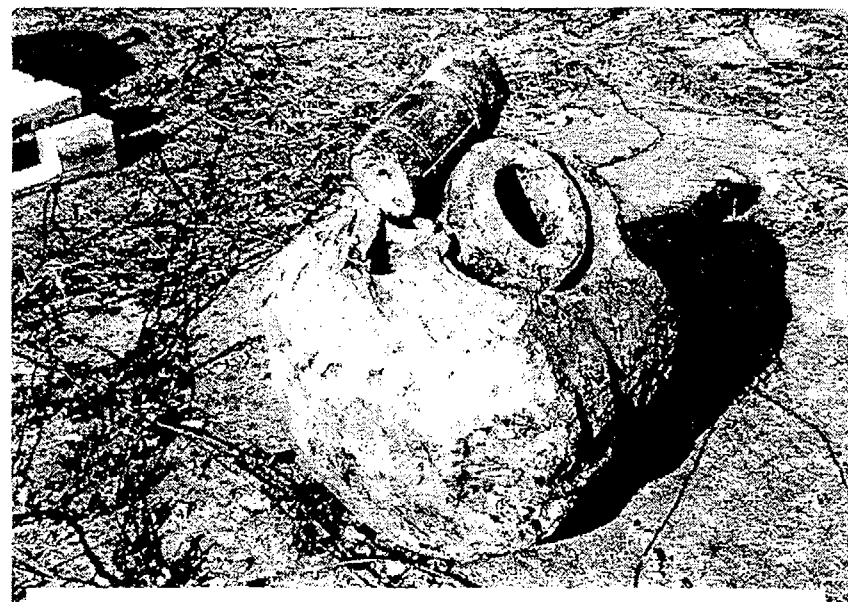


# Elements of a Regulatory Programme: Emergency Intervention

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**Government should have national emergency plans to deal with:**

- Lost, stolen or abandoned sources
- illegally imported sources
- falling satellites
- widespread contamination
- overexposed persons



Abandoned radiotherapy head  
found at scrapyard





# **Elements of a Regulatory Programme: Effectiveness of Regulatory Programme**

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**To ensure that the regulatory programme is effective, the Regulatory Authority should:**

- have procedures for quality assurance
- analyze programme data



# **Elements of a Regulatory Programme: Effectiveness of Regulatory Programme**

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**Does the Regulatory Authority have:**

- adequate resources ?
- trained and experienced staff ?
- adequate supervision of quality:
  - ◆ of authorization and inspection systems ?
  - ◆ of enforcement actions ?



# **Elements of a Regulatory Programme: Effectiveness of Regulatory Programme**

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## **Analysis of Programme Data**

Analyze type and frequency of non-compliances, review:

- existing regulations and advice
- need for additional regulatory requirements
- authorization procedures
- inspection priorities

**Note: Use of a database can facilitate the analysis**



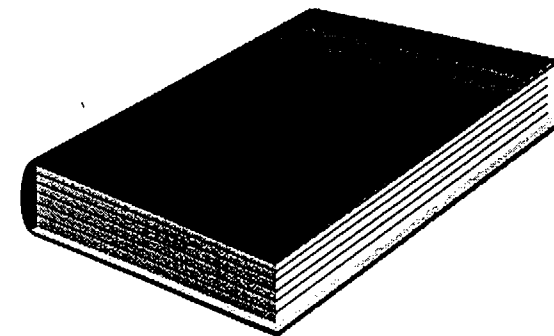
# Elements of a Regulatory Programme: Effectiveness of Regulatory Framework

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## Ensuring Effectiveness

- Provide advice for users and the Regulatory Authority
- Use of consultants & advisory committees
- Use of generic safety assessments

(Note: consider using existing published information)





# Elements of a Regulatory Programme: Effectiveness of Regulatory Framework

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## Advice for Users and Regulatory Authority

- Guides for applicants and users
  - practice specific
- Standard review plans
  - for use by Regulatory Authority during authorization assessments
- Inspection manuals
  - aid efficiency and quality control
  - enables use of less skilled staff



# **Elements of a Regulatory Programme: Effectiveness of Regulatory Framework**

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## **Use of Consultants and Advisory Committees**

- Consultants with specialized expertise, can;
  - enhance technical depth and breadth of expertise
  - be cost efficient and effective
  - supplement authorization and inspection procedures
- Caution !
  - consultants can only advise
  - ensure no conflict of interests



# **Elements of a Regulatory Programme: Effectiveness of Regulatory Framework**

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## **Use of Consultants and Advisory Committees**

### ● **Advisory Committees**

- May include other government departments, scientific organizations, industry
- help to ensure policies & regulations are clear, practical and complete

### ● **Caution !**

- need clear terms of reference, focused agendas and deadlines
- similar cautions to use of consultants



# **Elements of a Regulatory Programme: Effectiveness of Regulatory Framework**

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## **Generic Safety Assessments**

- Suited to standard devices with widespread use
- Produced by experts in conjunction with Regulatory Authority, manufactures & suppliers
- Cost effective





# Elements of a Regulatory Programme: Priority Actions

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Initial actions should include:

- enact legislation to establish national radiation protection infrastructure
- establish and empower Regulatory Authority
  - provide adequate resources
- ensure availability of technical services
- prioritize authorization and inspection of practices
- prepare performance regulations



# IAEA TECDOC 1067: Organization and implementation of a national regulatory infrastructure governing protection against ionizing radiation and the safety of sources

## TECDOC 1067 includes:

- Sample Legislation
- Sample Regulations

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