



# **Regulatory Framework and Radiation Protection as Basis for Evaluation**

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# Regulatory Framework for Nuclear Safety and Radiation Protection

- **International Instruments**
  - Conventions
  - Safety Fundamentals
  - Codes of Conduct
  - Safety Requirements and Guides
- **National Instruments**
  - Legislation
  - Regulations
  - Guidance Documents



# International Instruments 1

- Conventions

- The Convention on Early Notification of a Nuclear Accident – 1986
- The Convention on Assistance in the Case of Nuclear Accident or Radiological Emergency – 1987
- The Convention of Physical Protection of Nuclear Material – 1987, scope extended in 2005
- The Convention on Nuclear Safety – 1994
- The Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management – 2001
- Vienna Convention on Civil Liability for Nuclear Damage – 1997



# International Instruments 2

- **Safety Fundamentals**
  - Fundamentals Safety Principles (SF-1)
- **Codes of Conduct**
  - Code of Conduct on the Safety and Security of Radioactive Sources – 2004
  - Code of Conduct on the Safety of Research Reactors – 2004



# International Instruments 3

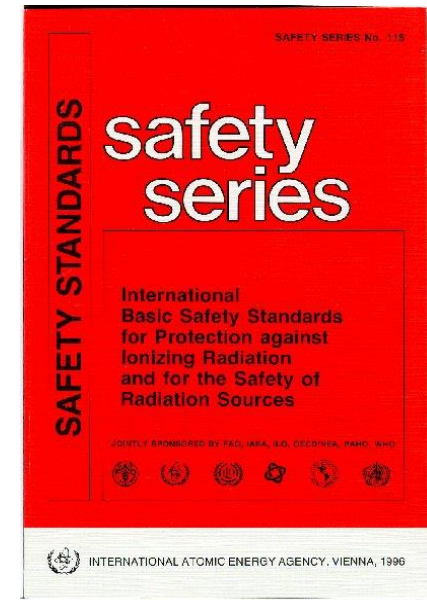
- **Safety Requirements and Guides**

- International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources (SS115)
- Preparedness and Response for a Nuclear or Radiological Emergency Safety Requirements (GS-R-2)
- **Management Systems Requirements for Facilities and Activities (GS-R-3)**
- All safety requirements of the series NS-R-xx, WS-R-xx, TS-R-xx
- Safety Guides GS-G-1.1 to 1.5 and RS-G-1.9
- Guidance on the Import and Export of Radioactive Sources
- **Handbook on Nuclear Law**



# RADIATION SAFETY INFRASTRUCTURE

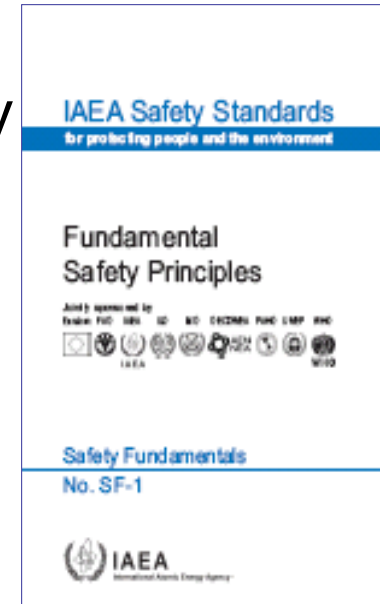
- RADIATION SAFETY
  - 1994-2004 Model Project on the  
“Establishment of Radiation Protection  
Infrastructure”
  - The BSS 1996





# NUCLEAR SAFETY INFRASTRUCTURE

- Basic Safety Fundamentals SF-1, 2006
  - Shows that basic safety principles for
    - nuclear safety,
    - radiation protection,
    - Waste management and transport safety are similar





# THE IAEA FUNDAMENTAL SAFETY PRINCIPLES

- **Principle 1: Responsibility for Safety**

The prime responsibility for safety must rest with the person or organization responsible for facilities and activities that give rise to radiation risks

- **Principle 2: Role of Government**

An effective legal and governmental framework for safety, including an independent regulatory body, must be established and sustained

- **Principle 3: Leadership and management for safety**

Effective leadership and management for safety must be established and sustained in organizations concerned with, and facilities and activities that give rise to, radiation risks.





# THE IAEA FUNDAMENTAL SAFETY PRINCIPLES

- **Principle 4: Justification of facilities and activities**  
Facilities and activities that give rise to radiation risks must yield an overall benefit.
- **Principle 5: Optimization of protection**  
Protection must be optimized to provide the highest level of safety that can reasonably be achieved.
- **Principle 6: Limitation of risks to individuals**  
Measures for controlling radiation risks must ensure that no individual bears an unacceptable risk of harm.



# THE IAEA FUNDAMENTAL SAFETY PRINCIPLES

- **Principle 7: Protection of present and future generations** People and the environment, present and future, must be protected against radiation risks.
- **Principle 8: Prevention of accidents**  
All practical efforts must be made to prevent and mitigate nuclear or radiation accidents.
- **Principle 9: Emergency preparedness and response**  
Arrangements must be made for emergency preparedness and response for nuclear or radiation incidents.



# THE IAEA FUNDAMENTAL SAFETY PRINCIPLES

- Principle 10: Protective actions to reduce existing or unregulated radiation risks

Protective actions to reduce existing or unregulated radiation risks must be justified and optimized.

- These 10 principles have been applied by INSAG to the five fundamental phases of an NPP
  - Pre-decision phase
  - Decision phase
  - Implementation phase
  - Operational phase
  - End of life phase



# Legal Framework for Nuclear Development & Regulation

**National Constitution**

**National Legislation**

**International Treaties & Obligations**

**Development &  
Infrastructure**

- National Policies on Peaceful Uses
- National Support Structure
- Integration with other national programs
- Emergency Response
  - Liability Regime
- Decommissioning & Disposal

**Regulatory Regime**

- Statutory Authority
- Implementing Regulations
  - License
- Industry Codes
- Guidance Documents
- Operator's Procedures and Plans



# Safety and Security

- The **Safety Principle** is primarily: the prevention of harm and protection of health, safety and the environment.
- The **Security Principle** recognizes the importance of preventing diversion or malicious acts.
- The **Sustainable Development Principle** recognizes a duty to prevent undue burden and degradation of the environment on future generations



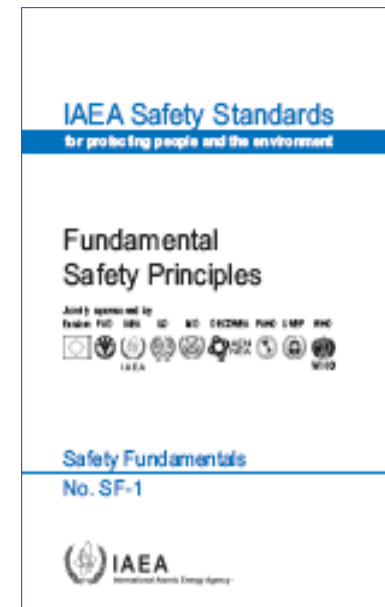
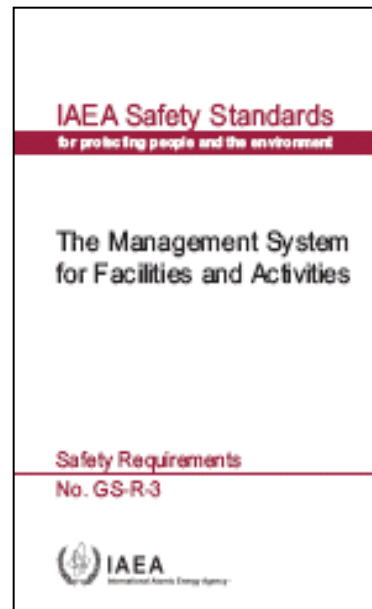
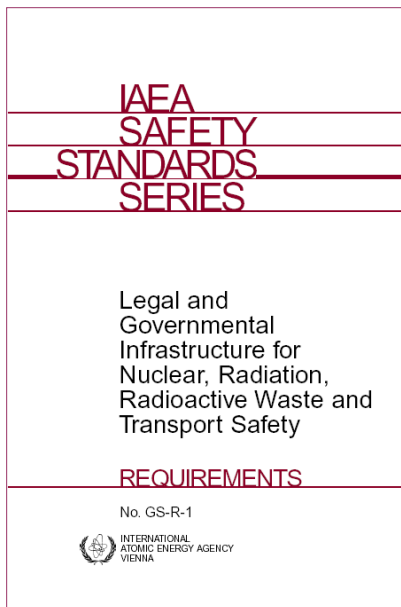
# Governmental and Regulatory Framework for Safety

- Introduction of Nuclear Power Programmes requires significant enhancement of the existing infrastructure, including:
  - National policy, strategies and legal, regulatory and organizational framework
  - Establishment of an independent, competent, regulatory body, adequately staffed
  - Assignment of responsibility for safety
  - Adequate mechanisms for communications



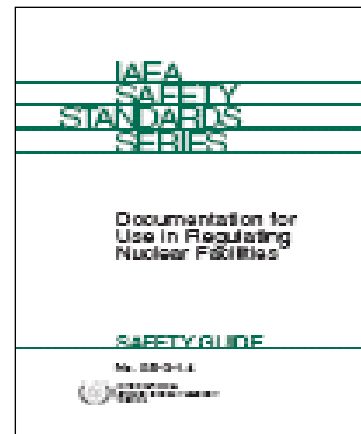
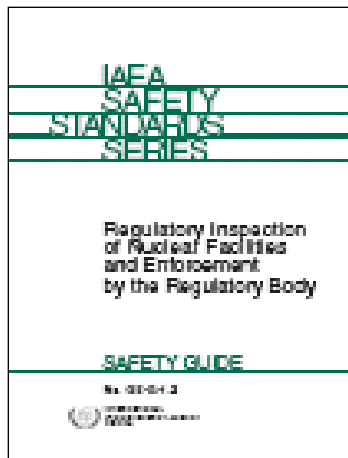
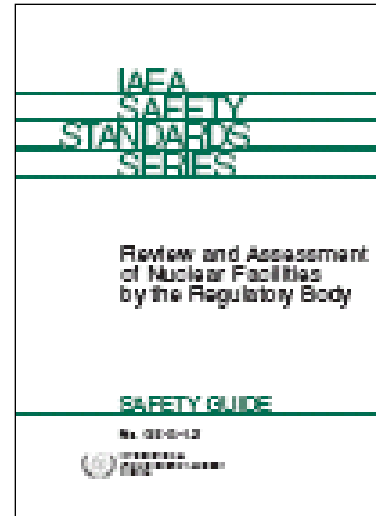
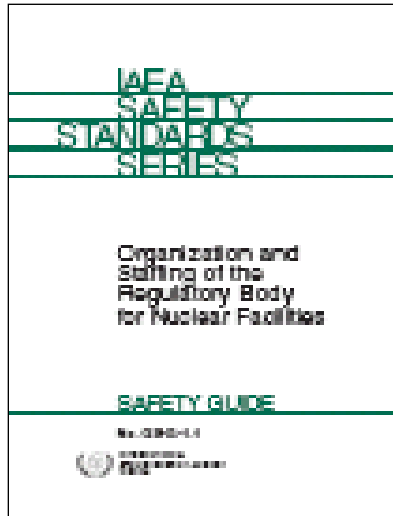
# IAEA Safety Standards Legal and Regulatory Framework

- Fundamental Safety principles SF-1
- Requirements :
  - GS-R-1
  - GS-R-3





# IAEA Regulatory Guidance Legal and Regulatory Framework



IAEA Africa Regional Workshop in Establishing Self-Assessment  
Mechanisms and Capabilities, Mombasa, Kenya, 23-27 August 2010





# Governmental Responsibility for Safety

- National Policy and Strategy
- Establishment of a national framework for safety:
  - Clearly allocated responsibilities
  - Provides for effective coordination
- Establishment of independent regulatory body
- Responsibility for safety



# Institutional Responsibilities of Government

- **The *Permission Principle*:** identify those activities that require authorization (“licensing”).
- **The *Independence Principle*:** the regulator must have the authority, capability, and resources to make safety decisions



## **Institutional Responsibilities of Government (cont.)**

- **The *Continuous Control Principle*: the regulator must have free and continued ability to monitor activities.**
- **The *Transparency Principle*: relevant information on use of nuclear energy, including incidents, is made available to the public.**



# Institutional Responsibilities of Government (cont.)

- The ***Compliance Principle***: international obligations are reflected in national law and states act so as not to do harm to others
- The ***International Co-operation Principle***: maintain relationships with counterparts in other States and international organizations.
- The ***Compensation Principle***: States must adopt means to provide adequate compensation for a nuclear accident.



# Specific Strategic Decisions of Government

- Emergency preparedness and response
- Commitment to radioactive waste and spent fuel safety
- Competence in safety (academic, learning centres, research and development, technical and professional training)
- Physical protection and security
- Provision of technical services (dosimetry, training, environmental monitoring and calibration of equipment)



# Prime Responsibility for Safety

- “The prime responsibility for safety must rest with the person or organization responsible for facilities...that give rise to radiation risks”  
(IAEA Safety Fundamentals – SF-1)
- **Prime responsibility for safety is assigned and assumed by the organization**
- Compliance with regulations and requirements imposed by the Regulatory Body shall not relieve the organisation of its prime responsibility for safety
- **Responsibility for safety can't be outsourced**



# The Responsibility of the Operator



- The *Responsibility Principle*: the operator of the facility or the person licensed to use material bears the primary burden of ensuring that its operations and activities meet safety, security, and environmental protection requirements. (CNS, Art 9)
- The *Permission Principle*: the operator or licensee may only do that which is permitted.
- The *Compensation Principle*: the operator or licensee may bear responsibility in the compensation regime for nuclear accidents.



# General Requirements for the Regulatory Body

- Organizational structure and allocation of resources
- Effective independence - safety focus
- Coordination of regulatory responsibilities
- Management system
  - Improve performance
  - Foster and support strong safety culture





# General Requirements for the Regulatory Body

- Staffing and competence
- Advisory bodies and support organizations
  - Ensure access to technical or professional expert advice
  - Advice shall not relieve regulatory body of its regulatory responsibilities



# General Requirements for the Regulatory Body

- Interaction with organisation responsible for facilities
  - Formal and informal communication
  - Professional, constructive, two way interaction (transparency and openness =inform and consult)
  - Mutual understanding and respect
- Regulatory stability and consistency

Regulatory process is a formal process, based on defined policies, safety principles, associated criteria. Regulatory procedures are defined and followed



# Regulatory Body is the Solid Foundation

## Mortar:

## Bricks:



- ✓ Law
- ✓ Regulations, safety principles
- ✓ Independence
- ✓ Organizational Structure
- ✓ Competent People
- ✓ Financial Resources
- ✓ Coordination
- ✓ Management System
- ✓ Advisory Bodies
- ✓ Interaction with licensee

✓ Safety Culture



# The Regulator



## Status

- Independent of operator or promotional agencies
- Has ability to carry out its functions
- Ability to report its findings
- Technical competence to carry out its mission
- Financial resources are provided
- Decisions may be reviewed, but not subject to arbitrary or extraneous considerations

## Powers & Duties

- Standards setting
- Licensing or Permitting
- Inspection and monitoring
- Enforcement
- Coordination with other bodies
- Dissemination of public information



# MANAGEMENT TOOLS

- **SELF ASSESSMENT**
- **NETWORKING**



# SELF ASSESSMENT

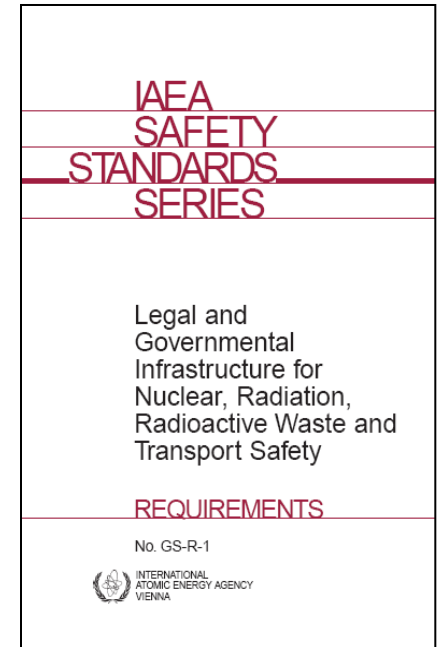
1999- IAEA-TECDOC-1090 Quality assurance within regulatory bodies

- First attempt to collect and integrate experience of MS supporting directly performance of regulatory activities
- Presents information and good practices in developing and applying QA to regulatory activities
- Identifies main/core functions of regulatory work AND support and control activities
- Promotes Management self-assessment and independent assessment of regulatory performance



# GS-R-1 Requirement for QM (2000)

- 2000 – IAEA – Safety Standards Series GS-R-1
- Requirements on the regulatory framework
- “The regulatory body shall establish and implement appropriate arrangements for a systematic approach to quality management which extend throughout the range of responsibilities and functions undertaken.”



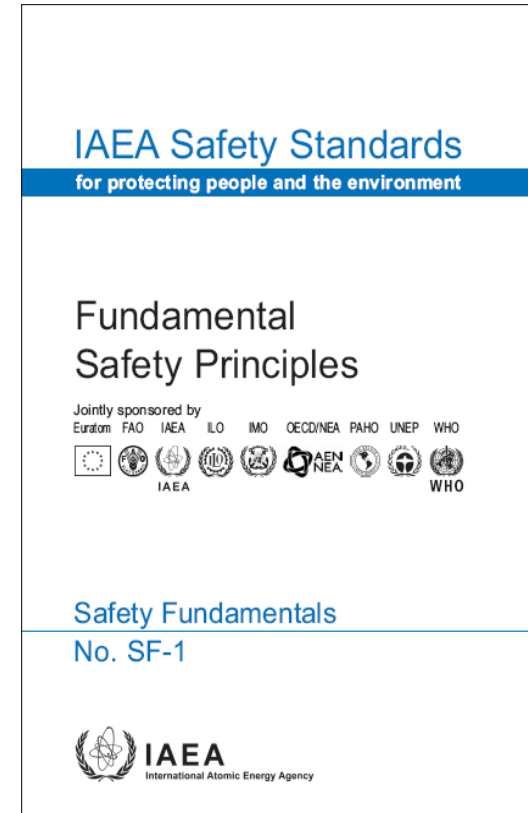


# Safety Fundamentals (2006)

## Principle 3: Leadership and management for safety

“Effective leadership and management for safety must be established and sustained in organizations concerned with, and facilities and activities that give rise to, radiation risks”.

“...The management system has to ensure...the regular assessment of safety performance...”

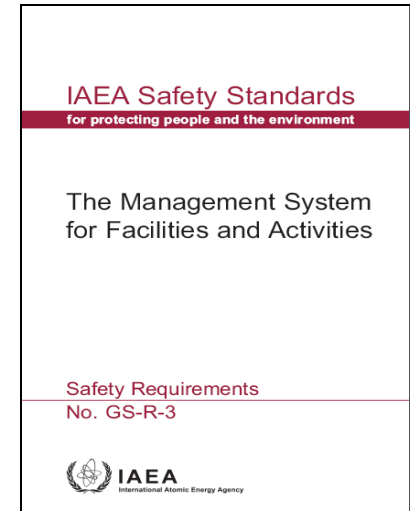






# The Management System for Facilities and Activities

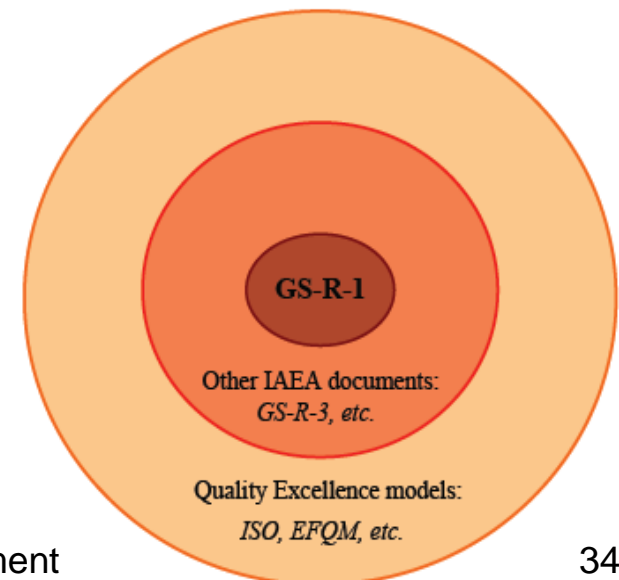
- GS-R-3 establishes requirements for a safety focused, integrated Management System
- Self-assessment requirement, applicable to regulatory bodies:
  - “senior management...shall carry out self-assessment to evaluate the performance of work and the improvement of safety culture.”
- **Management System for Regulatory Bodies**





# IAEA Self-Assessment Model for a Regulatory Body

- The IAEA self-assessment model for a Regulatory Body is based on a three tier approach
- This model is modular and can be used and adopted for implementation by any regulator at any stage of maturity
  - “Start up”, “On the way”, “Mature”
  - Small, medium size, big
- Modular assessment scope





# IAEA self-assessment Methodology for a Regulatory Body

- Self-assessment process should be repeated at regular intervals (typically every 1 to 3 years).
- If done previously, the main input for a self-assessment is the result (action plan) of the previous self-assessment.
- The optimum time for performing self-assessment is linked to the
  - (i) Regulator's annual and/or strategic planning cycle, since implementation of self assessment action plan can be resource intensive both in terms of time and manpower, and
  - (ii) to the preparatory phase of the IAEA's IRRS and other review and audit services; self-assessment should be carried out prior to and in connection with these services.



# IAEA Self-Assessment Tool-SAT

- The SAT can be used in preparation for IRRS or any other peer-review or international appraisal, but it can also be used as a 'stand-alone' tool for regular internal self-assessment.
- The SAT is not self-assessment per se, it is a tool to support the wider process, particularly the answering and analysis phases.
- All questions are based on the Requirements
- Modular structure for covering the thematic areas
- Training course on Self Assessment for Africa in June (Abuja, Nigeria) and July (Rabat, Morocco) 2009



# NETWORKING

## Importance of networking

**Regulating Safety remains a national responsibility,**

**However,**

- **Concepts, principles, challenges, difficulties and risks are global**
- **Operators are international actors, or in connection with others**
- **Workers, Patients and the Public are also inter connected**



# Importance of Networking

## Safety Fundamentals, para.1.2:

The IAEA is required by its Statute to promote international cooperation. Regulating safety is a national responsibility. However, radiation risks may transcend national borders, and **international cooperation serves to promote and enhance safety globally by exchanging experience and by improving capabilities to control hazards, to prevent accidents, to respond to emergencies and to mitigate any harmful consequences**



# Importance of Networking

**GS-R-1 para 2.6.**

**The regulatory body shall have the authority:**

**to liaise with regulatory bodies of other countries and with international organizations to promote co-operation and the exchange of regulatory information**



# Importance of Networking

**GS-R-1 para 4.11.**

**The safety of facilities and activities is of international concern. Several international conventions relating to various aspects of safety are in force. National authorities, with the assistance of the regulatory body, as appropriate, shall establish arrangements for the exchange of safety related information, bilaterally or regionally, with neighbouring States and other interested States, and with relevant intergovernmental organizations, both to fulfil safety obligations and to promote co-operation**





# Importance of Networking

**GOV/2004/52-GC(48)/1**

**“Networking is becoming recognized by Member States as a very effective instrument for enhancing the sharing of knowledge and experience essential to the prevention of accidents and to the implementation of radiation safety and security measures. Networking is also becoming recognized as an important tool for facilitating the transition from dependence to self-sufficiency and sustainability. The IAEA intends to support the development of focused networks as an effective means of improving cooperation, fostering an integrated safety approach and promoting continuous improvement”.**



# Importance of Networking

- **To share experience (good practices and challenges) of discharging regulatory functions**
- **To gain from lessons learnt by others when establishing/strengthening a regulatory infrastructure**
- **To foster direct contacts between people**
- **To optimize resources by setting up joint actions**
- **To develop common guidance, regulations**
- **To organize joint inspections, peer reviews**



# Importance of Networking

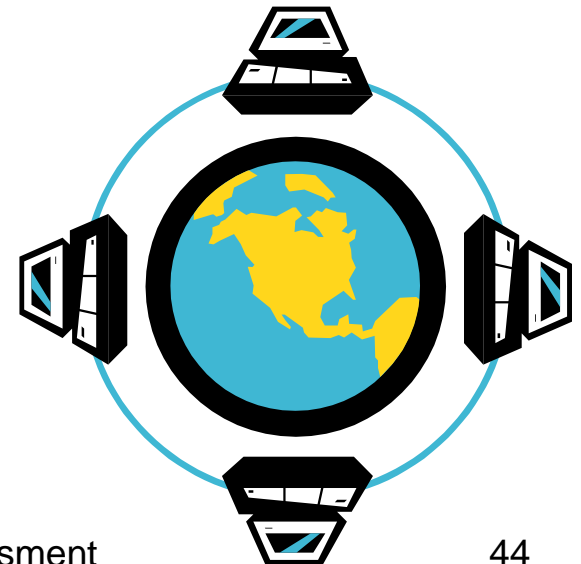
- **To improve the regulatory control of sources (import/export issues, transport, waste...)**
- **To identify and solve common issues (orphan sources, unregulated historical practices,...)**
- **To face common challenges (nuclear power, uranium mining, radiotherapy centres,...)**
- **To coordinate inputs to safety issues at the international level**
- **To raise a stronger voice in international debates**
- **To optimize technical and financial assistance from senior regulatory bodies, from IAEA**



# RaSaReN – current members

71 Countries, 171 Licensees

- Africa: 22 countries
- Asia: 17 countries
- Europe: 19 countries
- Latin America: 13 countries





# Present and future of Networking

- **RegNet** : coordination of existing and new regulators networks
- **GNSN**: Global Nuclear Safety Network
- **FNRBA NETWORK** : [www.fnrba.org](http://www.fnrba.org)

IAEA is only the facilitator



# OBSERVATIONS AND RECOMMENDATIONS

- Developing Nuclear power programme and establishing a national safety infrastructure is a complex process
- Involves the development of a governmental, legal and regulatory framework
- as well as the necessary training and expertise for **all nuclear stakeholders**: regulatory body, operator, technical support organizations, etc.



# OBSERVATIONS AND RECOMMENDATIONS

- Nuclear safety is and must remain a national responsibility which cannot be delegated.
- Newcomers' money cannot substitute ownership and commitments to safety and security



# OBSERVATIONS AND RECOMMENDATIONS

- Nuclear Power Programme is a long process for newcomers, lasting about 15 years until the first nuclear reactor becomes operational. **Such a figure appeared in different presentations and should be taken into account when preparing national strategies**





# OBSERVATIONS AND RECOMMENDATIONS

- Nuclear newcomers should sign, ratify and apply the package of Treaties and Conventions, including the Vienna Convention on Civil Liability for Nuclear Damage, to join the nuclear community
- Cooperation and interactions between regulators of vendor and buyer countries.



# $R_x$ for Governmental and Regulatory Framework for Safety

~~Magic Pill~~



**Ownership for safety + People = Safe Operation**

IAEA Africa Regional Workshop in  
Establishing Self-Assessment

# Self-confidence Meter



Healthy Uneasiness/Wariness





# Conclusions

- All elements of Governmental and Regulatory Framework for Safety have to be addressed
- Sufficient time should be allowed for establishing the regulatory framework and an independent regulatory body
- Early planning and prompt action is key for ensuring success
- Development of a nuclear safety culture and good safety practices will be neither easy nor automatic
- Regional and interregional cooperation



THANK YOU FOR  
YOUR ATTENTION

