RADIATION SAFETY CULTURE FOR DEVELOPING COUNTRY: BASIS FOR A MINIMUM OPERATIONAL RADIATION PROTECTION PROGRAMME

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ABSTRACT

The purpose of this document is to present a methodology for an integrated strategy aiming at establishing an adequate Radiation Safety infrastructure for developing countries, non major power reactor programme. Its implementation will allow these countries, about 50% of the IAEA's Member States, to improve marginal radiation safety, specially to those recipients of technical assistance and do not meet the Minimum Radiation Safety Requirements of the IAEA's Basic Safety Standards for Radiation Protection [1,2].

Progress in the implementation of safety regulations depends on the priority of the government and its understanding and conviction about the basic requirements for protection against the risks associated with exposure to ionizing radiation. There is no doubt to conclude that the reasons for the deficiency of sources control and dose limitation are
related to the lack of an appropriate legal and regulatory framework, specially considering the
establishment of:

- An adequate legislation;
- A minimum legal infrastructure;
- A minimum operational radiation safety programme;
- Alternatives for a **Point of Optimum Contact,** to avoid overlap and conflict, that is: A "**Memorandum of Understanding**" among Regulatory Authorities in the Country, dealing with similar type of licensing and inspection

I -- INTRODUCTION

More than 50% of the IAEA's Member States although have minimum infrastructure of radiation safety, its levels do not meet minimal qualifying factors. In many of them there are two or three Regulatory Authorities, and in each insufficient staff and skill in relation to basic safety and radiation protection knowledge, operational experience, and understanding the meaning of the license process to grant a license. The deficiency of such level of infrastructure, difficult the license process as well as the control of sources and inspection of practices and facilities. Without such control, how Regulatory Authority can guarantee the effectiveness of dose limitation, to protect workers, public and particularly the patients?

High number of such Regulatory Authorities is under the Ministry of Health. The Ministry of Health is extensively involved in many complex countries' problems, like pauperism, sanitary conditions and other assistance and public health concern and this make difficulty the establishment of mechanism to implement a reasonable system to control radiation sources and dose limitation. On the other hand, the lack of a Safety Culture

Understanding on Radiation Safety, delays more than the necessary the introduction of laws, or in the increasing of minimal resources to operate a regulatory programme. The improvement depends on the possibility and capacity that the Regulatory Authority has to dialogue with the member of the government where he is subordinated and in obtaining the minimum necessary resources. Mischance to develop has the Regulatory Authority if it discharges its activities only as Section, Service or Division in the Governmental Organization, due its weak capacity of going ahead in obtaining better resources. Considering this scenario, the role of an IAEA expert in the country assumes fundamental importance to help in the promotion of a national radiation protection infrastructure, toward the basic requirements of the Standards. When the IAEA infrastructure provides an expert to such country, its ability should demonstrate, besides the technical information, the capacity to persuade the government about the necessity to approve legislation and the minimum condition of resources to implement a basic programme for radiation safety in the country. These objectives will be much understandable to be succeed if the expert apprehends the characteristics, filling and culture of the country and can express his argumentation in the country's language. One of the main expert's task in the country is to learn whos'who in the country to select people to dialogue toward the Safety Culture Implementation.

If Safety Culture means attitudes and behavior for ensuring adequacy in safety and radiation protection, this must be also part of the expert's knowledge on about the country really can do. The expert is the greatest opportunity to help the Regulatory Authority these countries to obtain the minimum resources from the government to provide a regulatory structure and to implement oriented regulation for the most practices in use. The expert also shall have the attitude, to help in identifying what is possible to improve with the resources already available. If he is not succeeded or is not able, the radiation safety instead to improve will decline, and the main problems will continue in the future.

II -- SOURCES IN THE COUNTRY AND WHAT SHOULD BE DONE?

Basically the use of radioactive materials in these countries, non major power reactor programme, can be considered in one of the following possibilities:

Single use	☞ medical application
Multiple use	☞ medical and some industrial application
Extensive use, without radioisotope production	☞ medical, general industrial application and some research
Extensive uses, with radioisotope production	☞ medical, general industrial application, research and some radioisotope distribution

Up to the present, many of these countries, still use old sources manufactured to standards lower than would be acceptable today, as well as obsolete equipment's. Many of these sources, mainly Ra-226 and Cs-137, probably were imported before national legislation. Without proper control of sources and practices and in this including waste management system, there is likely to be high the percentage of overexposure, specially in industrial radiography workers and in hospital patients. ***Lamentable in patients high overexposure is discovered only in tragic circumstances, like in the Accidents in Zaragosa (Spain) and Costa Rica.***

2.1) Essential need for countries without or little infrastructure:

Legislation;
Minimum legal infrastructure;
Minimum operational radiation safety programme;
Minimum staffing training in the Basic Regulatory Requirements.
Minimum users training in safety and radiation protection

2.2 Essential need for countries with some or reasonable infrastructure

Minimum operational radiation safety programme;
"**Memorandum of Understanding**" among Regulatory Authorities in the Country, dealing with similar type of licensing and inspection
Staffing training in the Basic Regulatory Requirements.
Users training in safety and radiation protection

2.3 - How to start?

To start the Regulatory Authority should to consider the legislation already in the country, and then to adequate it, according the Minimum Requirement considering the statement on "Strengthening National Capabilities" [8,9]. In parallel should establish an administration system considering the hazards' categories of the sources, in these including the old sources and equipment, already in use or considered as spent sources or obsolete equipment.

Excluding fuel cycle, out of the scope of this document, the tables I, II, III and IV can be adopted as suggestion for the main practices already in use. [3,4,5,6,7]

TABLE I - CATEGORIES OF HAZARD

CATEGORY	CHARACTERISTICS
0	Very low routine dose; no risk of significant contamination; negligible accident scenarios [1]
1	Low routine dose; low risk of significant contamination; low health risk from worst accidents, normally with no consequences for public exposure.
2	Low routine dose; some risk of minor contamination; some health effects possible with worst case emergencies, but negligible risk for public exposure.
3	Low to high routine dose; risk of significant contamination; potential for prompt health effects from worst case emergencies, with potential for public exposure.

[1] Practices and radiation sources for which exemption may be permitted and no infrastructure is needed beyond the basic laws

TABLE II -- INDUSTRIAL SOURCES AND HAZARD CATEGORY

MAIN ACTIVITIES	HAZARD CATEGORY		
	1	2	3
Industrial Radiography Off-Site			③
Industrial Radiography in fixed installation with radioactive sources exceeding 1 TBq, and X ray generators exceeding 400 kV		②	
β and γ Gauges and neutron thermalization. Sources should be limited to not more than equivalent 40 GBq (1 Ci) of Cesium-137 and 40 GBq (1 Ci) Americium-241 or 0.1 μg of Californium-252		②	
γ Gauges and neutron thermalization using sources exceeding equivalent 40 GBq (1 Ci) of Cesium-137 and 40 GBq (1Ci) Am-241 or 0.1 μg of Californium-252			③
X-ray fluorescence gauges, diffraction and spectrometry		②	
Electron capture devices	①		
Static eliminators	①		
Industrial and research irradiation facilities using sources not exceeding 4 TBq (100 Ci)		②	
Industrial and research irradiation facilities using sources exceeding 4 TBq (100 Ci)			③
Uses of unsealed radioactive in industry and engineering		②	③

TABLE III -- MEDICAL SOURCES AND HAZARD CATEGORY

MAIN ACTIVITIES	HAZARD CATEGORY		
	1	2	3
Beam Therapy			③
Accelerators and neutron generators			③
Brachyterapy			③
Therapeutic Treatment			③
Diagnostic Treatment		②	
"In vitro" Laboratory	①	②	
others' like bone density, ophthalmologist	①		

TABLE IV -- OTHERS' SOURCES AND HAZARD CATEGORY

MAIN ACTIVITIES	HAZARD CATEGORY		
	1	2	3
Manufacturing process involving unsealed radiochemical			③
Uses of thorium manufacturing			③
Lightening warning manufacturing		②	
Smoke detector manufacturing		②	
Storage of Large quantity of radiopharmaceuticals			③
Transport and distribution			③
Research involving animals and vials		②	

2.4 - Second Stage

In this stage alternatives should be instituted in the country to enable the Regulatory Authority, ***still using the conditions and the technical skills already available***, to implement

the minimal radiation protection, according with the above tables. A Seminar on "Implementing Principles on Radiation Protection and the Safety of Radiation Sources" [1] should be made (Annex I) and the following directives should be taken into account:

- WHO IS WHO IN THE SAFE USE OF RADIOACTIVE MATERIAL?
- WHO IS RESPONSIBLE FOR WHAT IN IONIZING RADIATION?

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- MINISTRY OF ENVIRONMENT
- MINISTRY OF LABOR
- MINISTRY OF HEALTH
- NUCLEAR ENERGY COMMISSION

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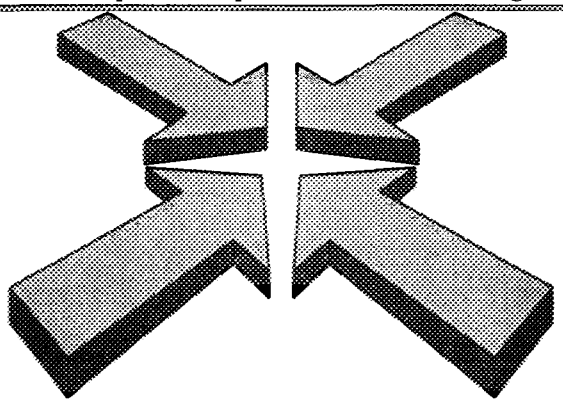
What is the point of optimum contact among them?



Two important indicators need to be analyzed to achieve proper legislation, that's mean objectives and planning and minimum requirement's approach, in terms of strategy, resources and actions.

A - Initial Actions: Toward to the Initial Minimum Cost and High Social Benefit

B - Identification of Individuals, Institutions and Skill

A -- INITIAL ACTIONS MINIMUM COST AND HIGH SOCIAL BENEFIT ☞ LOOK INTO	**FUNDAMENTAL**
Mechanisms to recruit the necessary expertise already in the country	National organization for technical co-operation and Assistance
Establishment of a Regulatory Advisory Committee (Point of Optimum Contact)	Liaison with public authorities
Participation of all users	Liaison with organizations
Questionnaire to collect information on radiation safety status to establish the exact profile in the country	Liaison with public authorities and organizations -- database available
Combination of financial resources, to support the increasing of national budget, fees and fine paid by the users	Specific legislation.
Increasing know-how through expertise combination, including law, regulation, training, education and IAEA Technical Co-operation projects	National, regional and sub-regional level of interaction for Technical Co-operation Assistance

B -- IDENTIFYING INDIVIDUALS, INSTITUTION AND SKILL	DATA
Whos' who in the country to help in the objectives for enabling the fundamental legislation for safety and radiation protection, according the size and scope of practices subject to regulate?	Names, institution, conditions of agreement between governmental Institutions. Approach for co-operation and co-ordination
Skill in basic safety and radiation protection, and operational experience -- (who that had attended Regional or International Training Courses supported by the IAEA) -- to joint in the planning of an organized programme for radiation protection?	Names, institution, conditions for agreement between governmental Institutions. Condition for new designation. Approach for co-operation and co-ordination (point of optimum contact)
Institution in the country that can provide a systematic radiation safety training programme for RPO and workers.	Conditions, possibility of agreement, governmental arrangements.
Institution in the country to participate in Emergency Planning	Organization, governmental arrangements, schedule for implementation
Institution with technical support to provide service in dosimetry and radiation monitoring capabilities for both on-site and off-site monitoring, as appropriate?	Organization, conditions, possibility of agreement between Governmental Institutions
Projection of areas for improvement	Specific needs in terms of consultants. human and material resources required

In this stage a minimum government infrastructure should also be established, considering the following tables, V and VI.

TABLE V - MINIMUM GOVERNMENT INFRASTRUCTURE

MINIMUM LEGAL REQUIREMENT	HAZARD CATEGORY		
	1	2	3
Government laws on radiation protection including the establishment of a Regulatory Authority, radiation exposure standard and conditions of uses to be authorized	①	②	③
Set reciprocity statutes	①	②	③
Set minimum design criteria for equipment and facilities	①	②	③
Authorize Inspection and Enforcement	①	②	③
Requirements to notify Regulatory Authority	①	②	③
Requirements for registration of users including disposal procedures		②	③
Requirements for licensing of users including disposal procedures			③

TABLE VI - MINIMUM GOVERNMENT INFRASTRUCTURE

MINIMUM REQUIREMENT FOR REGULATORY AUTHORITY	HAZARD CATEGORY		
	1	2	3
Technical Staff (with authority to conduct reactive inspections)	①	②	③
National registry of source inventory	-	②	③
Inspection Staff	-	②	③
Licensing Staff	-	-	③
Health Physics Support	-	-	③

2.3 - Third Stage

This stage can be understood as the implementation of a Quality Assurance Regulatory Programme, including new areas for development of skills, and improving the management of the basic elements of the Regulatory Programme: Regulations; Licensing, Registration, Notification; Compliance Monitoring and Enforcement. The progress and experience previously gained will introduce motivation, attitudes, and a new Safety Culture Mentality in government, regulatory authority, users and individuals. For such purpose the following directives, table VII to XI, could be used for guidance.

TABLE VII - GOVERNMENTAL MECHANISMS AND ACTIONS TO MAINTAIN THE MINIMUM SKILL FOR STAFF AND USERS

Working attitudes: integration and responsibilities
Regulatory Authority's Integration (Point of Optimum Contact)[2]
Licenses: Authorization Grant and Revalidation
Compliance Monitoring, Enforcement and Sanctions
Database: central collection of data
Annual Report: organization, administration, results and future projection.
Development and Growth: education, training, staff, user, facilities, equipment
Establishment of a National Radiation Protection Association and Medical Physicist Association
National and Regional Seminars

TABLE VIII - CAPACITY FOR EACH REGULATORY AUTHORITY

Appropriate Regulation
Human resources available x responsibilities
Skilled personnel according with each category of hazard
Minimum safety and technical requirements, capability of performance
Authorized uses and limits
Frequency inspection x Level of Safety and Radiation Protection and Geographical distribution of Users: On-Site and Off-Site
Enforcement x Category of non-compliance
Minimum training requirement for RPO and workers
License revalidation x Level of Safety and Radiation Protection for each user
Regulatory Authorities x Conflict of responsibility (Point of Optimum Contact)

[2]In this stage all points of internal and external interfaces, as well as overlapping should be avoided and
responsibilities should be well defined.

TABLE IX - CAPACITY OF EACH USER

Number of sources x number of workers
Number of sources x number of detectors
Number of RPO according Practice and Role and responsibilities of the RPO
Level of Dose Limitation
Investigation incident and accident
Programme of training in each user
Special authorization (e.g. radiography in urban zone)
General Procedures according with practice: record, maintenance and responsibility

TABLE X -- INTEGRATION BETWEEN REGULATORY AUTHORITIES A AND B

Review of the legislation to avoid conflicts of responsibility
Basic responsibility of each Regulatory Authority
Identification of what they really discharge
Identification of reasons they don't discharge what they should really to do
Identification for the reasons what a Regulatory Authority doesn't do thinking that other Regulatory Authority has the responsibility to do
Programme for cooperation between Regulatory Authorities
Training programme between Regulatory Authorities
Programme of inspection and enforcement
Agreement for cooperation

TABLE XI -- FEEDBACK TO THE GOVERNMENT

Analysis of the situation in the country. Identification of all difficulties and essential necessities to improve the Basic Element of a Regulatory Programme
Identification of Staff's skill from Regulatory Authorities A and B
Minimal necessity for Regulatory Authorities A and B
Technical Cooperation Programme
Toward to Safety Culture: Safety Fundamental (SS-120) and Basic Safety Standards (SS-115)

III - CONCLUSION

Legislation and Integration of Regulatory Operations are the basic key to develop Safety and Radiation Protection. Developing countries need to operate using a Point of Optimum Contact -- "**Memorandum of Understanding**" -- to better benefit of its staff, skills and facilities. Safety and Radiation Protection, fundamental part in the basic elements of a Regulatory Programme -- Licensing, Registration, Compliance Monitoring and Enforcement, can not operate in isolation or in compartment between Regulatory Authorities. Consequently developing countries should achieve a well integrated regulatory programme, with the necessary interdependence.

3.1 -- The previously statement can be summarized in the following factors:

• IAEA's expert motivation to persuade key personnel in the country
• Safety Culture motivation by Government and Competent Authority
• Elaboration of basic regulations and norms;
• Centralization of the existent resources in terms of staff and facilities;
• Integration of Authorities according with the Point of Optimum Contact;
• Establishment of a plan for training and compliance monitoring,
• Establishment of regulation for effective enforcement action,
• National and Regional Agreement and feedback
• IAEA assistance.

The effort to introduce a culture of safety and radiological protection, based on the recommendation of the [1,2] will modify the mentality of unimportance on radiological aspects and will be the determining factor in the dynamic improvement for a regulation programme.

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ANNEX -- PRINCIPLES FOR PRACTICES

PRINCIPLE 1: JUSTIFICATION OF PRACTICES -- A practice should be justified on the grounds that it produces sufficient benefit to the exposed individual(s) and to society to offset the radiation detriment that it may cause.

PRINCIPLE 2: LIMITATION OF DOSES AND RISKS -- For justified practices, other than those involving medical exposures, restrictions on the dose that an individual may incur (dose limits) shall be imposed to ensure that no person be subject to an unacceptable risk attributable to radiation exposure.

PRINCIPLE 3: OPTIMIZATION OF PROTECTION -- For exposures from any source, except for therapeutic medical exposure and the likelihood of incurring exposures shall all be kept as low as reasonably achievable.

PRINCIPLE 4: SAFETY OF SOURCES -- All reasonably practicable measures shall be taken to enhance operational safety, to prevent radiation accidents and to mitigate their consequences.

PRINCIPLE 5: JUSTIFICATION OF INTERVENTION -- Any proposed intervention shall do more good than harm.

PRINCIPLE 6: OPTIMIZATION OF INTERVENTION -- The form, scale and duration of any intervention shall be optimized so that the net benefit is maximized

PRINCIPLE 7: LOCATION OF SOURCES -- In locating a source, account shall be taken of those factors which affect the exposure, or potential exposure, of individuals and populations.

PRINCIPLE 8: DESIGN AND CONSTRUCTION OF SOURCES -- The design and construction shall be such that a source is suited for reliable, stable and easily manageable operation that ensures protection and safety with a high level of confidence. For this purpose, consideration shall be given to defense in depth, human factors, system testing and feedback of operational experience.

PRINCIPLE 9: OPERATION AND USE OF SOURCES -- The operation and use of sources shall be based upon procedures and conditions that ensure the safety and security of the sources and the optimization of radiation protection and that take into account the lessons learned from operational experience.

PRINCIPLE 10: LEGAL FRAMEWORK -- The government shall establish a legal framework for the regulation of practices and interventions, with a clear allocation of responsibilities, including those of a Regulatory Authority.

PRINCIPLE 11: RESPONSIBILITIES WITHIN THE LEGAL FRAMEWORK -- Parties responsible within the legal framework shall, as appropriate, provide for protection and safety, verify its effectiveness and prepare adequate emergency plans.