CHALLENGES IN THE ACTUAL APPLICATION OF INTERNATIONAL SAFETY STANDARDS AND NATIONAL REGULATIONS WHEN USING RADIATION IN MEDECINE

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Introduction -1-

- Use of ionizing radiation for medical purposes is an important source of human exposure
- New Medical Imaging, with potential of rise in radiation doses delivered to the patients
- Severe radiation accidents have occurred in radiotherapy

illustrate the need of a Radiation Protection program and the place to be reserved to Radiation Protection of Patients

Introduction -2-

- The BSS establish the basics of Radiation Protection with responsibilities, principles and different aspects that should be covered by an effective radiation protection program
- Implementation of the BSS depends on local situations, technical, financial and human resources and involvement of many individuals and bodies

➢ What are the challenges in implementation of BSS requirements in radiation protection of patients?

SUMMARY OF THE PRESENTATION

- Role of Legislation and Regulations
- Role of the Regulatory Body in Radiation Protection of Patients BSS requirements implementation:
  - How, when and what to verify in this implementation
  - Enforcement of the regulations
  - Limits of the implementation of the BSS in RP of Patients
- Examples of radiation protection implementation in some African countries

Legislation and Regulation

- Legislation and Regulations shall be promulgated by "national authorities"
- based on and in compliance with International BSS and ICRP recommendations
- shall include
  - the protection of the patient during the medical exposure weather for diagnosis or for therapeutic purpose and during the exposure in research or for medical-legal needs or another reason apart from the occupational exposure

- Effective independent Regulatory Body (RB) empowered to regulate inspect and enforce is the evident condition
- The RB shall be provided with sufficient human and material resources in order to be able to regulate, to control and inspect the practices and to enforce the regulation of the patient protection at the same level as that of the workers and the public
- Radiation protection principles : justification, optimization and limitation

Radiation Protection of Patients Requirements

Includes

- Justification
- Optimization and ALARA principle application
- Guidance levels
- Quality Management program
- Equipment design and role of suppliers
- Role of RP professionals, medical physics specialists and qualified experts
- the obligation of the training of Doctors who prescribe and realize the diagnostic or therapeutic procedures
- The obligation of respect of medical prescription

Role of Regulatory Body in radiation protection of patients

- The BSS define in the protection of the patients the responsibilities and assign the prime responsibility to the legal person or licensee and to the employer, the subsidiary responsibilities are assigned to the doctors prescribing and those realizing the examination or the treatment involving an exposure for the patients

- Other responsibilities to :
  - the manufacturers of medical equipment or devices emitting ionizing radiation,
  - the suppliers selling or importing the radioactive sources,
  - Dosimetry technicians
  - supervisors, medical physicists, radio chemists or other intervening professionals

- The Regulatory Body must make sure that these persons in charge of the patient exposure respect all the requirements of the BSS:
  - How can it reach that point, what are the means?
  - What are the measures to take in the event of non-respect of these standards?
  - And what are the limits?

Evidence of BSS Requirements Implementation

- The Regulatory Body shall deliver authorizations only if all the requirements of the regulation are satisfied
- The regulations require that the acceptance of the requests and granting of the authorizations is conditioned by the satisfaction of all the requirements, including those related to the protection of the patients which are:

- For the radio diagnosis:
  - Conformity of the types of generators with the purpose of the intended examinations (Radio Diagnosis, Paediatric Radiology , Interventional Radiology,
  - Conformity of the equipment with the standards the EEC, IEC or equivalent local standards
  - Availability of the qualified personnel able to handle the equipment, to check regularly the quality of the functioning…

- Availability of means to minimise failure of the equipment or human error
- Availability on the machines of means to control the patient dose and its traceability
- Availability of the means of protection of the sensitive organs (lens of eyes, breast, thyroid, gonads)
- Special devices for children immobilisation is necessary

- For Nuclear Medicine:
  - Conformity of the material
  - Availability of necessary competencies
  - Availability of the means of control of radionuclide activities administered to the patients
  - Measures to be taken to protect the other patients
  - Measures to be taken if any error of patient or dose or radionuclide happens

- For Radiotherapy

– Conformity of the equipment
– Availability of necessary competencies
– Availability of means of protection of the patients
– Availability of the requirement for the programming and the simulation of the treatments
– Availability of means for calibration of the sources, for evaluation of patients doses and
– Means to avoid the incidents or accident and to respond to eventual emergency

When to verify compliance with the requirements

- At the time of the evaluation of the requests of authorization or licence or at the time of the notifications and registry
- During technical controls at import, during commissioning, acceptance tests and functioning
- During the other inspection
- And at the renewals of the authorizations

What to verify during the inspections

RB inspectors shall check during various controls and inspections:

- The conformity of the equipment with the conditions defined in the authorizations
- The good functioning and maintenance and quality control of the authorized equipment
- The evidence of personnel qualification (diplomas, training in the imaging or therapy techniques and training in Radiation Protection)
- Existence of person in charge of Radiation Protection and the evidence of this responsibility and of his defined tasks

- Existence of medical physicists, of radiopharmaceutical specialists and specialists in Dosimetry
- The training programs and their conformity with the requirements of the Regulatory Body
- The management of quality: procedures of the execution of the examinations (choice of the parameters of exposure, patient dose determination factors and records)
- The traceability of the maintenance and quality control of the equipments, calibration of the sources, records of the incidents or eventual accidents and their declaration to the Regulatory Body

- Use of clinical information and data available of previous examinations
- Existence and implementation of the guides of diagnostic imaging, interventional, Nuclear Medicine or Radiotherapy indications,
- Existence and implementation of the Reference Levels
- Existence and use of the means of the protection of the sensitive organs ,
- The traceability of the technical breakdowns or incidents or overexposure of patient and their follow-up, and evidence of declaration to the Regulatory Body.
- System of patient and referent doctors information

Enforcement of the regulations

- Non-conformity must be noted by the inspectors to take necessary measures which could range according to importance of the infraction from
  - Sensitizing to the need for protection of the patients,
  - Authorization suspension or cancellation
  - Other measures to be determined by the Regulatory Body and regulations

Limits to the regulatory control of the BSS requirements R P P implementation

- Justification of the exposure, prescription and realization is the responsibility of the Clinicians, Radiologists, Doctors in Nuclear Medicine or Radiotherapy.
- The Regulatory Body inspection may be unable to demonstrate excessive prescriptions, examination accepted and realized by complacency, or after loss of the initial documents or after transfer of patients to anther hospital without documents ...

- Implementation of ALARA principle may not be respected when using interventional or new techniques known as radiant
- Repetitive examinations may be not documented without traceability and may be ignored by responsible persons or inspectors
- Abusive indication may exist even if there are other alternatives (ultrasound or MRI) “for iconography”…
- Non-systematic follow-up of the patient skin doses organs dose if any overexposure is noted

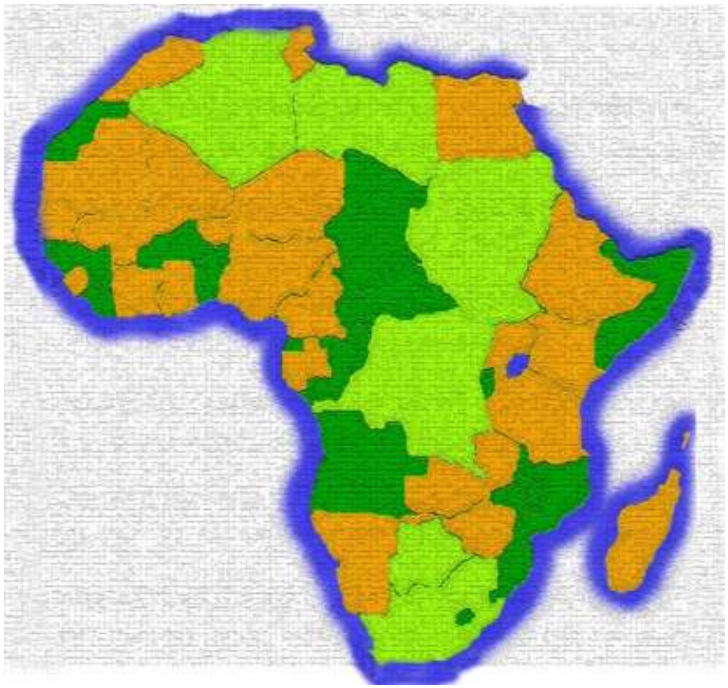
The solution to these problems is directly related to:

- Academic level of education of radiation protection
- Ethics
- Spread of safety culture
- Involvement in elaboration and application of guidance of professional society
- Importance of continuous training and its validation
- Efficacy of quality management program

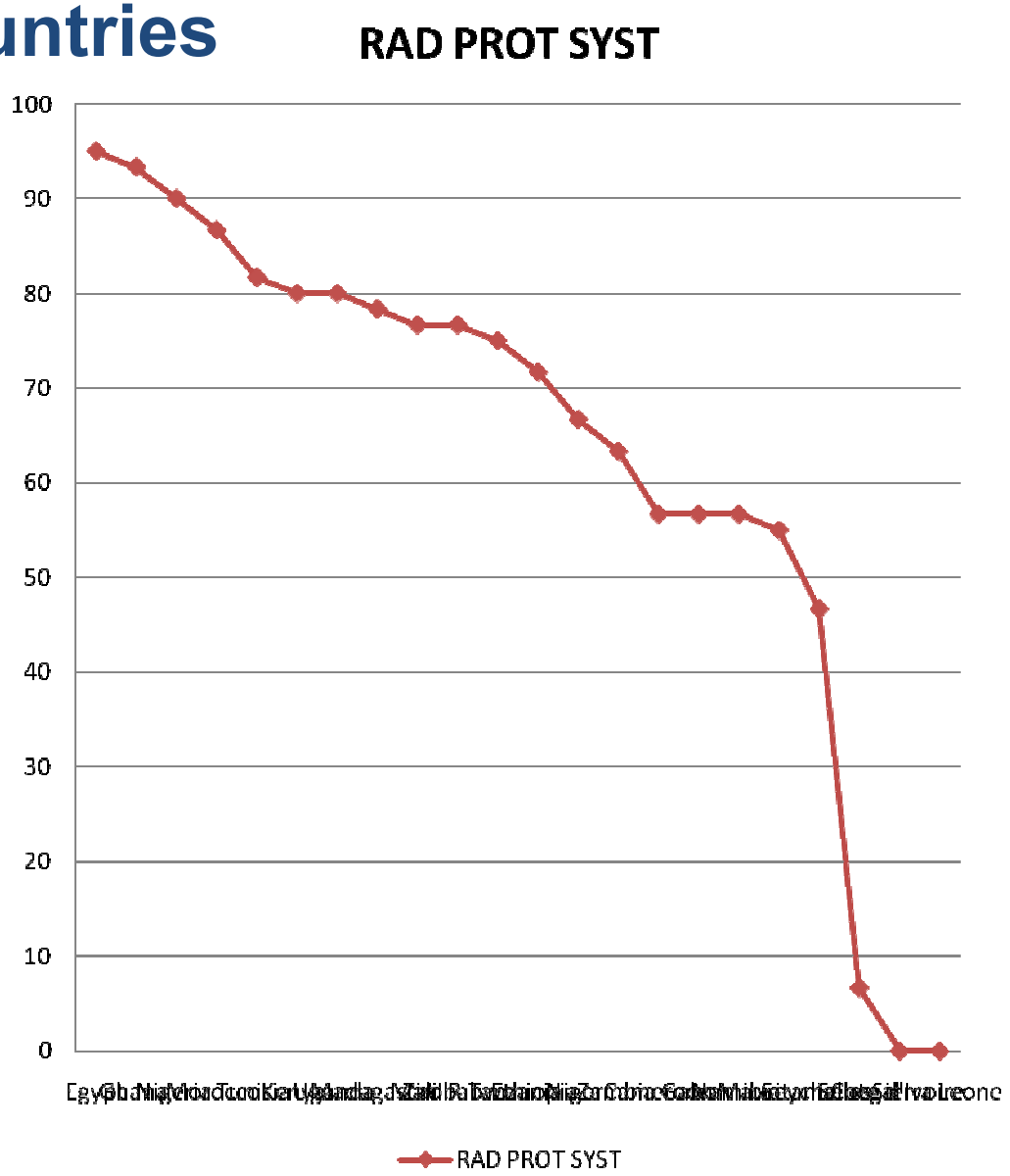
- Role of Organizations as IAEA, WHO, Radiological and Specialties societies working together with RB in the elaboration of guidance for the choice of procedure and their promotion by regulation.
- Role of Training required by the regulations necessary for all categories of health care personnel concerned.
- Role of Regulatory body in including patient protection items during medical installations inspection program
- Importance of enhancement of material and human resources given to radiation protection department
- Importance of cooperation between professional bodies, regulatory bodies and authorities

Example of African countries

SELF-ASSESSMENT QUESTIONNAIRE ABOUT RADIOTHERAPY REGULATION STATUS AMONG FNRBA MEMBERS



PARTICIPATING COUNTRIES



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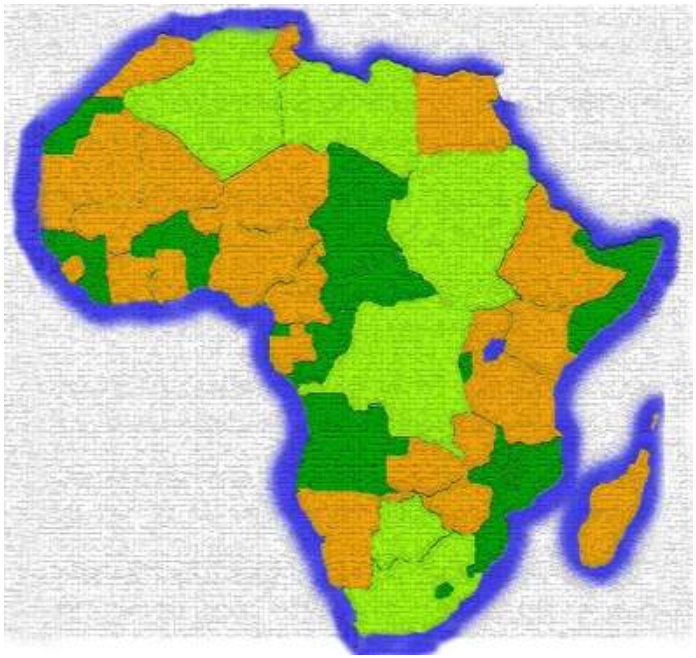

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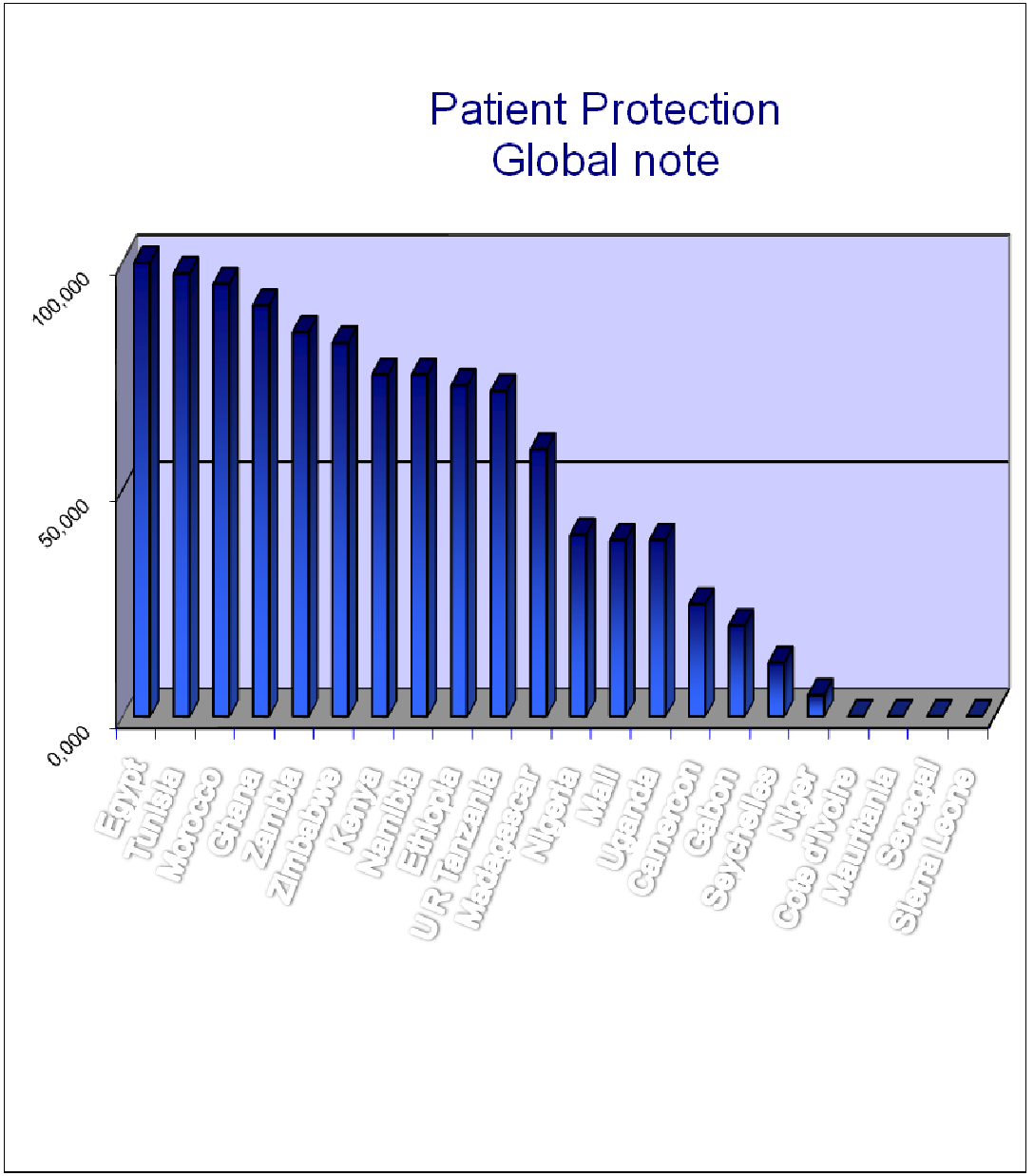

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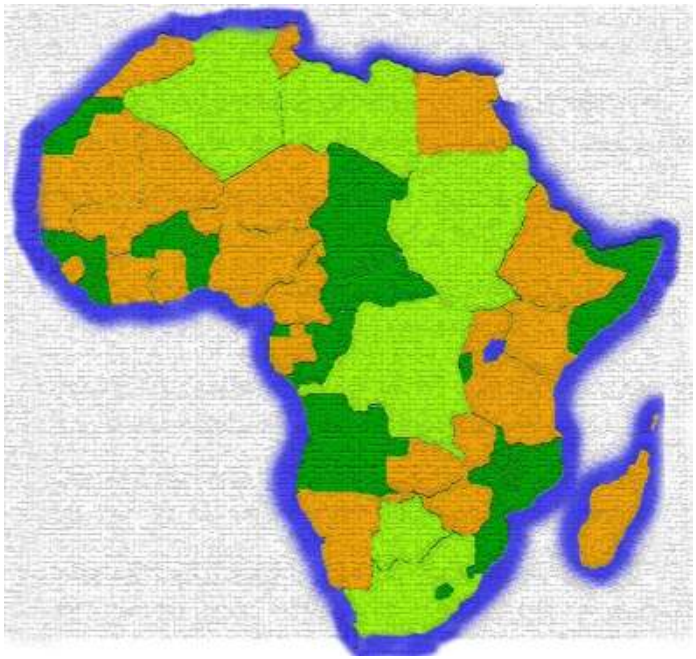

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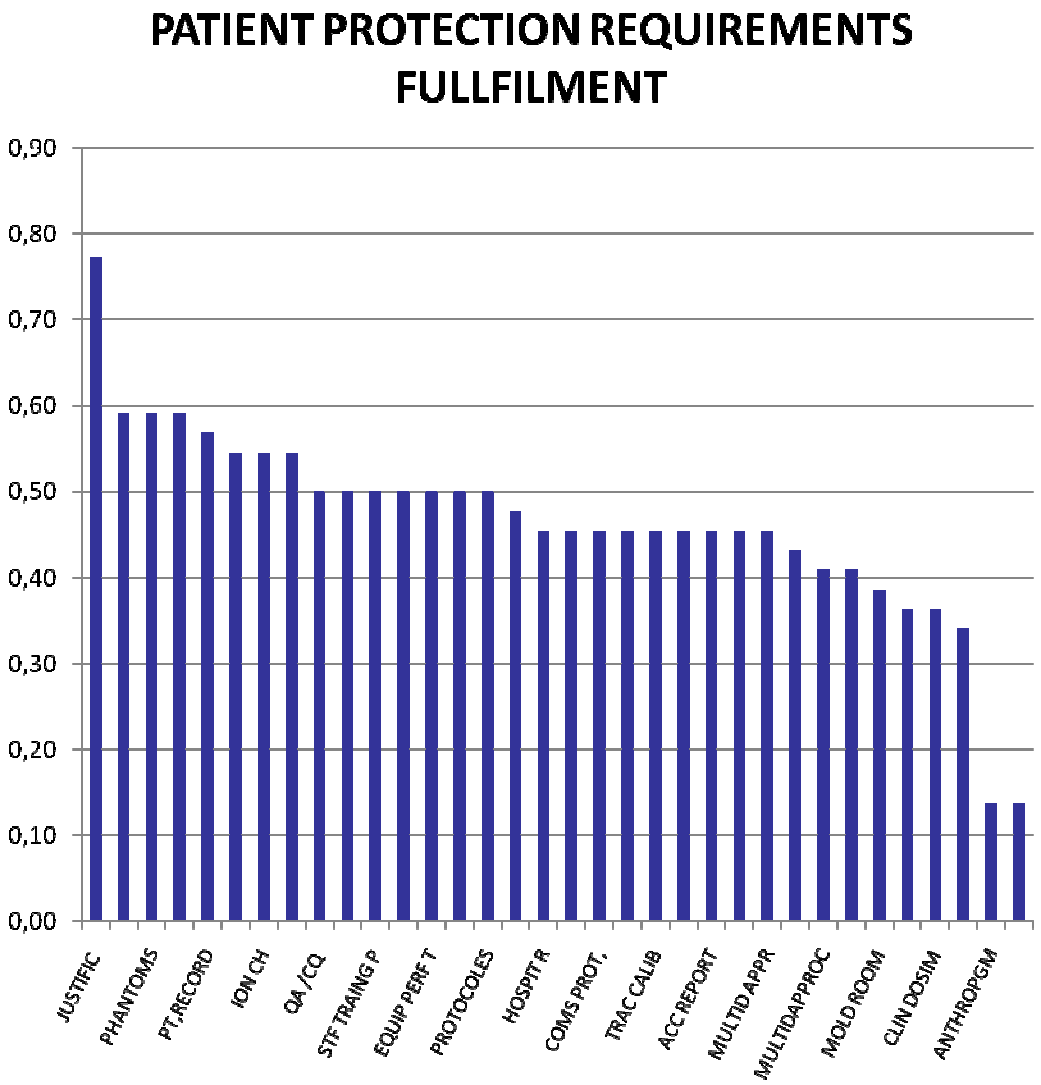

Conclusion -1-

- BSS are currently being updated with strengthening of radiation protection of patients
- Radiation Protection of Patients is new for certain countries in progress in many others
- To meet the Requirements defined in the BSS
- Radiation Protection Professionals are called to have sustainable programme for safety culture protection procedures in all kinds of patient exposure and to show their commitment for present and future challenges

Conclusion -2-

- For Regulatory Bodies: Working together and sharing knowledge may help to fill the gap between countries and
  - to elaborate National Regulation related to medical exposure,
  - develop inspections procedures,
  - guidance levels,
  - quality control and training of medical and paramedical professionals, interactions between scientific societies


thank you