

Continuous Improvement of the Regulatory Framework for the Control of Medical Exposure

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Abstract

Background: One of the key elements to guide the improvement of the regulatory control is the availability of a self-assessment tool for regulatory performance. Although there is general guidance on self-assessment for regulators and users (IAEA), there is a need for more specific advice on how to address challenges and difficulties faced by regulatory bodies, when regulating radiation protection of patients. Examples of these challenges are the need for regulatory initiatives, in cooperation with health and education authorities, professional bodies and equipment suppliers, and to put in place necessary elements that are beyond responsibility of individual users of radiation, to enable them compliance with safety standards. **Purpose:** within the programme of the Ibero American Forum of Nuclear and Radiation Safety Regulatory Organizations, a project to develop such a self assessment tool for the regulatory control of medical exposure has been designed. **Method:** national experiences in transposing and enforcing the international radiation safety standards, as to how the requirements are included in national regulations are reviewed. Further, difficulties to the implementation of safety requirements are analyzed and a self assessment approach and possible regulatory solutions are presented. **Results and discussion:** In this study the following documents are being produced: 1) Transposition of international requirements into national regulations in the six countries of the Forum, 2) difficulties to implement and enforce the requirements, 3) guidance on self assessment of regulatory framework for medical exposure, 4) suggested contribution to the revision of international radiation safety standards.

Keywords: regulatory, medical exposure, self assessment, continuous improvement.

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1. Introduction

Medical uses of radiation bring unquestionable benefits to diagnosis and treatment of disease. These benefits increase continuously, due to the fast development of new technologies and techniques on one

hand and to the need to make the benefits available to developing countries. Every day more than ten millions of diagnostic radiology exams, hundred thousand nuclear medicine exams and more than thousand patients are treated with radiation [1]. As a result of this use, medical use of radiation is the largest exposure from man-made radiation sources [2]. Radiological risks range from trivial to serious depending on the type of application.

General radiography still accounts for about two thirds of all x-ray imaging. Wide variations in dose, up to two orders of magnitude, for many procedures resulted in increasing attention to determine how to ensure patients receive no more dose than necessary. Surveys of patient doses and image quality, and reference levels are a means of reducing doses while keeping diagnostic confidence. Countries using this approach have seen substantial decreases in these doses.

Conventional films are being replaced by digital techniques. These techniques have the potential for reducing dose, given their higher sensitivity. However, in the short-term, doses are likely to increase since higher patient dose usually means improved image quality; even though this improved quality is not always necessary for diagnosis. Also, with digital radiology, it is very easy to obtain (and delete) images, so there is a tendency to obtain more images than necessary.

The use of relatively high-dose procedures such as computed tomography (doses higher than conventional radiography), has been steadily increasing over the years, as new technology allows faster image acquisition and improved image quality. This is associated to a substantial increase in population exposure. In addition, in some countries there is a trend for promoting CT for early detection of diseases in asymptomatic patients, without being referred by a physician, and oblivious of the substantial dose involved.

Interventional procedures using x rays provide the highest exposure to individual patients among all imaging procedures with the possibility for radiation injuries. It has been reported that the severe injuries can be avoided or the severity could be largely reduced.

New complex radiotherapy techniques have been developed, such as beam intensity modulation, image guided radiotherapy, breathing gated radiotherapy, tomotherapy, radiosurgery, new treatment planning systems, virtual simulation and “all inclusive” electronic information systems, which pose new challenges from the safety view point. Severe, unintended exposures have been reported and continue to occur and preventive measures are of high priority.

Regulatory work has to be done in this context and radiation protection principles and requirements are to be applied in all these areas. There are a series of international documents [3,4,5] dealing with the elements of a national infrastructure for protection and safety, and the subjects to be addressed and questions to be asked to evaluate quality and effectiveness of the regulatory body in the various areas of responsibility (regulate, authorize, inspect, request corrective measures and, if necessary, enforce them). However, there is a need for reference documents with practical solutions and answer to the questions asked.

In the preamble of the International Basic Safety Standards for the Protection against Ionizing Radiation and for the Safety of Radiation Sources (the BSS) [3] the need was recognized to “provide facilities and services that are essential for radiation protection and safety, but are beyond the capabilities required of the legal persons who are authorized to conduct practices”. To meet certain regulatory requirements, there is a need for qualified and certified medical and paramedical staff, which is not available in a number of countries, for arrangements for generic justification of practices and techniques, calibration at a standards laboratory, quality audits, diagnostic reference levels, dissemination of lessons from accidental exposures, and assessment of safety of new technologies and equipment.

These are all elements which cannot be generated by the users individually not by the Regulatory Body alone. It needs cooperation, agreements, and arrangements with other institutions

(educational, health, labour and customs) and professional bodies in order to create and maintain the infrastructure. To make compliance with regulatory requirements possible, the regulatory body needs to take a proactive approach. On the other hand, the provision of such elements at the national level “does not detract from the ultimate responsibility for radiation protection and safety borne by the legal persons authorized to conduct the practices”.

2. Objectives

This project has a double overall objective: 1) to present options and practical solutions to enable regulatory programmes to become effective, making it possible for users to meet regulatory requirements on radiation protection and safety, and 2) to facilitate regulatory body’s self-assessment of performance on the control of medical exposure, thus contributing to its continuous improvement.

3. Method

The approach taken in this project consists of four actions: 1) the regulatory programmes of the FORO’s countries regarding medical exposures were analyzed. The analysis included the legal frameworks, the scope of the responsibilities of the regulatory bodies involved in patient radiation protection in each country, the regulatory infrastructures and the regulatory frameworks considering the transposition and implementation of the requirements of the BSS for medical exposure; 2) as a result of this analysis, the most common difficulties and obstacles in the national programmes were identified; based on the findings from 1) and 2), a document was written to assist regulatory bodies on self-assessment, with options and solutions to overcome the difficulties and obstacles found in step two, so as to enable users of radiation in medicine to comply with the safety standards; finally, 4) with these findings, a set of suggestions to improve the international safety requirements of the BSS are drawn as a contribution to the BSS revision process, which is currently ongoing.

4. Results

The implementation of the project has produced the following outcomes, in terms of difficulties, weaknesses of the regulatory programmes and the national infrastructure, and solutions towards compliance with BSS requirements and equivalent national regulatory requirements

4.1. Regulatory system

4.1.1. Division of regulatory responsibilities

Regulatory responsibility for different practices or different aspects of radiation protection and safety may be divided between different authorities. Regardless of the division of regulatory responsibilities, the preamble of the BSS states that the government must ensure that all aspects are covered [3]. However, division of responsibilities may lead to somewhat artificial separation. For example one regulatory body may be responsible for radioactive materials and another one for radiation generators, with the result that one and the same facility with both types of devices is regulated by two or more different bodies, responsible for regulating radiation protection and safety. Another example is that one authority is responsible for therapeutic applications and another one for radiology equipment for imaging, which brings new difficulties in radiotherapy, where increasingly extensive use of imaging equipment is made

In the absence of a systematic coordination mechanism among these regulatory bodies, there may be inconsistencies in regulatory requirements, in approaches to licensing, in inspection frequencies, in enforcement policy, in priorities for patient safety and even different safety culture in the regulatory bodies as such, with the appearance of contradictory opinions. All this may increase the administrative burden of users and not contribute to safety and in summary, may weaken the governmental credibility.

Understanding and coordination among regulatory bodies requires commitment and cooperative agreements at the highest level, in order to make coordination effective. The subjects of these agreements should cover the following aspects:

- Harmonization of the regulatory framework in order to minimize gaps and overlaps
- Coordination of the authorization and inspection process in order to reduce redundant administrative burden to users. A regulatory flow diagram of the authorizations and other regulatory actions would contribute to this coordination.
- Exchange of information in order to collect scattered information, provide feedback to inspection programmes, alerts on non-compliance and to have access to sensitive information related to accidental exposure of patients
- Joint activities to disseminate and promote safety culture, which should contribute to a solid national regulatory system.
- Joint regulatory policies, including enforcement, in order to strengthen national programmes on radiation protection of patients.

4.1.2. *Graded approach*

The current BSS [3] [paragraph 2.33] establishes that “technical requirements shall be applied when appropriate and to an extent commensurate with the magnitude and likelihood of the exposures expected from the practice or source”, which could be called a graded approach. This requirement is not specifically developed in the appendix on medical exposure, although more specific requirements to establish a graded approach in therapeutic, interventional and diagnostic procedures would be beneficial to use resources in an effective manner. A categorization of sources according to risk has also been published [6]. Subjects for a graded approach would be

- Degree of detail required for safety assessment for authorization, inspection frequency and follow-up on deficiencies
- Training programme for the staff of the various practices
- Degree of presence and involvement of qualified experts such as medical physicists, with full dedication in therapeutic applications and frequent availability in interventional procedures
- Degree of requirements on clinical dosimetry, including individual dose determination for therapy with unsealed sources
- Efforts to avoid accidental exposure and radiation injuries
- Degree of details for informed consent of patients. For high-dose therapeutic and interventional procedures, the informed consent should be in writing.

A graded approach to the system of authorization and inspection helps optimize regulatory efforts with a prioritized scheme of control. With a graded approach, facilities with higher risk, such as radiotherapy with new technologies, may benefit from more complex and proactive safety assessments, such as probabilistic methods and risk matrix approaches, also adapted and used in other projects of the FORO.

4.1.3 *Enforcement issues*

Social pressure makes difficult to restrict operation of a medical activity. This social scrutiny asks for optimized, balanced and sound enforcement actions, based on the principle of “do more good than harm”. A credible and respected regulatory body should base enforcement actions on the following pillars:

- Solid generic safety assessments of the radiological medical practices and techniques

- Specific inspection programmes designed on a risk based graded approach
- Competent and well trained staff with specific knowledge on the medical activities and hospital environment
- Institutional support at the highest level for the technical decisions

4.2. Closing gaps in national infrastructures

4.2.1. *Responsibilities for medical exposure and availability of qualified staff*

In many parts of the world, especially in developing countries, the inexistence of qualified professionals who are crucial to patient safety remains an unresolved issue. Moreover, compliance with regulatory requirements on medical exposure depends on the availability of qualified and certified radiation oncologists, nuclear medicine specialists, technologists and medical physicists.

In particular, medical physicists have responsibilities to meet the requirements on calibration of radiation beams and sources, clinical dosimetry, and quality assurance. They are unavailable in many countries and there are two reasons for this situation: 1) there is no programme of education and on-the-job training established in many countries, and it may be unfeasible to maintain such programme at a national level, where only a small number of professionals is required; 2) sending professionals abroad for education and on-the-job training often results in losing them because they prefer to stay in the country where they have been trained, particularly if the profession is not even formally recognized as a health profession in their own countries.

It is the responsibility of governments to be aware of these difficulties and to make provisions for a system for education, to have in place a process of accreditation, to formally recognize the staff as health professionals and to put in place a programme to keep in the country the staff that is crucial to safety. Although the approval of training on radiation protection falls under the responsibility of regulatory bodies, the education of staff in their own profession does not. Nevertheless, without availability of safety critical professionals in the country, regulatory requirements can not be met.

For these reasons, the regulatory body needs a proactive approach to work together with educational institutions, the health authority and professional societies in order to formally establish means to educate safety critical professionals and certify and recognize them as health professionals. The regulatory body should play a major role in this process, since it is the only authority with the information and knowledge of the safety implications of not having the necessary qualified experts and of the magnitude of the problem. In countries in which the number of hospitals, for example radiotherapy departments, is too small to maintain an educational programme cooperation with other countries and a joint strategy may be necessary.

4.2.2. *Justification of practices*

Justification of medical practices and techniques requires a judgment of benefits and risks. The regulatory body for radiation protection is normally not responsible for making judgments on the benefits of diagnosis and treatment with radiation. A sensible approach to generic justification of a given practice or technique and for a health screening programmes on asymptomatic patients at national or local level would be to obtain approval by the health authority in consultation with professional societies and regulatory body, the latter being in charge of evaluating or providing judgment on the risks of the application of radiation.

Since the primary benefit of medical exposure is for individual patients, decisions for individual exposure is up to the patient and his/her doctor, the latter bearing the responsibility to do more good than harm [7, 8]. However, professional bodies should provide guidance on appropriateness

criteria for each type of examination and treatment. This guidance can be used as reference by doctors prescribing and performing the procedure. There is recently a trend to promoting certain screening diagnostic medical exposures by some hospitals and clinics, leaving the decision for patients to make. This approach is called “self-referral”. An example of it is a total body scan for health screening, a technique with relatively high exposure.

These evaluations, judgments, guidance material and approaches to deal with controversial issues such as self-referral, are issues requiring participation of health authorities, regulatory body, medical professional societies and patient societies. They can only be dealt with in cooperation and with well coordinated programmes. The regulatory body, responsible to enforce compliance with requirements on patient protection needs to be proactive to develop institutional relations, permanent forums, ad-hoc task groups and other arrangements to make compliance with the regulatory requirements on justification possible.

4.2.3. Optimization of protection

4.2.3.1. Protocols for calibration and quality assurance

The first international conference on patient protection in 2001 [9] and the resulting Action Plan [10] concluded that requirements for medical exposure should be performance oriented and that details should be covered by guides, which can be adapted to the rapid evolution of equipment and techniques.

There are a number of protocols in different parts of the world and the language and abbreviations as well as the nomenclature in the formulas may not be entirely consistent. A misinterpretation and incorrect use of one of these variables and parameters may cause serious accidental exposure, especially in radiotherapy. Each professional will tend to use a different protocol, depending on the country he/she has more contact with. It is cumbersome for the regulatory body to monitor safety in these circumstances

The regulatory body should be proactive and work with professional bodies, encouraging them to adopt one of the protocols, preferable an international one, because international protocols are the result of an extensive harmonization work of the existing bibliography worldwide [11,12,13]. In this way, the adopted protocol becomes the recognized one by the health authority and the regulatory body and professional societies as a national consensus. This provides a unified approach, a common terminology and parameters, which facilitates regulatory control, assistance among hospitals, training, external verification and double checks and quality audits as needed.

4.2.3.2. Metrology arrangements for calibration of dosimetry instruments

The BSS requires that dosimetry equipment be traceable to a standards dosimetry laboratory. A valid calibration certificate is, therefore, an essential element to safety. To maintain traceability over time, dosimetry equipment needs to be recalibrated periodically. The process of sending, calibrating and returning the dosimetry equipment should be completed in a short period of time, because hospitals need the equipment permanently available for regular measurements.

There are a number of issues that may cause delay, such as administration, budget, transport, waiting time in the laboratory, return. This is aggravated in countries where there is no national laboratory, and equipment needs to be sent abroad for calibration. Experience has shown that equipment may be retained in customs for months or even import fees may be requested in both countries.

It is necessary to put in place mechanisms to expedite the process and facilitate compliance with regulatory requirements on traceability. These elements and arrangements go beyond the capabilities of individual users. There is here another opportunity for the regulatory body to be proactive and work together with the standards dosimetry laboratory, (for example organizing timely campaigns), or

with the customs authority to facilitate export and import. It may be also necessary to have cooperative agreements with another country with national laboratory. Contacts between the regulatory bodies and agreements between countries may make this process possible.

4.2.3.3. Reference levels and mechanisms for their establishment

The (BSS) [1] requires the use of guidance [reference] levels by medical practitioners in the process of optimization. These levels provide guidance on what is achievable with current good practice, and are to be applied with flexibility to allow higher exposures if these are indicated by sound clinical judgment.

In countries, such as the UK, where reference levels have been developed and applied for about 12 different types of examinations, a survey showed dose reduction of 30% and another survey performed about five years later, showed an additional reduction of 20% [14]. This significant reduction is primarily due to increase in awareness of radiation doses and optimisation of the radiology practices throughout the country.

It is well recognized that there are some circumstances in which overzealous reductions in patient dose can have a deleterious effect on image quality, which would be detrimental for patients. Methods for monitoring image quality are, therefore, required [15, 16, 17,18, 19, 21]. This ensures that guidance [reference] levels are associated with acceptable images and that any actions on patient doses resulting from applying guidance [reference] levels do not result in a loss of diagnostic confidence. This is why the BSS also requires that optimization is done taking into account norms of acceptable image quality established by appropriate professional bodies and relevant guidance [reference] levels for medical exposure. The BSS further establishes that guidance [reference] levels are to be established by relevant professional bodies in consultation with the regulatory [body].

The Action Plan on the Radiological Protection of Patients [10] indicates that guidance [reference] levels should be established locally. Differences in training, sensitivity of image receptors and quality control may cause differences, which can not be suddenly changed by imposing guidance levels from other countries. In order for medical practitioners to be able to use guidance [reference] levels they have to be established by professional bodies in consultation with the regulatory body. Establishing guidance levels is complex, and requires coordinated effort, and possibly a step-by-step approach, from a pilot exercise to a broader survey. Thus, the Regulatory Body should be proactive to get this process running and to monitor the use. Collaborative effort and agreements with the health authorities and professional bodies is essential. A review of the different approaches to reference levels worldwide is provided in [21].

4.2.3.4. Arrangements for acceptance of equipment

The BSS requires users to ensure that equipment conforms to international IEC and ISO or equivalent national standards, which also evolve with time and place increased requirements. Manufacturers have subsidiary responsibilities for the compliance with the BSS. They should contribute to facilitate generic safety assessments of specific components or complete equipment systems [5]. The generic assessment would be documented and such documentation of approved equipment is available in several of the industrialized countries. It is important for the user to ensure, before placing an order, that the equipment to be ordered “type approved” or carries a certificate of compliance with the IEC or nationally recognized equivalent standards in the country of use.

There are a number of difficulties associated with compliance with these BSS requirements, since old equipment may not comply with current IEC standards. Second hand equipment is some times donated, purchased, imported may not meet the standards either.

An inventory of equipment and its state of compliance should be made and an action plan with appropriate timing and deadlines may be needed. Again, a cooperative effort between the regulatory body, the health authority, manufacturers, and professional societies is required to develop

acceptability criteria and testing and a proactive approach of the regulatory body to move forward is crucial.

4.2.3.5. Arrangements for external audits

The BSS requires licensees to put in place a comprehensive programme of quality assurance for medical exposure, including the verification of relevant physical and clinical aspects. One of the problems to implement a complete programme is the difficulty of having external audits. The scope of the audit and the specialists to take part of an external audit is still a question of debate. The next question is the availability of audit results to the regulatory body, taking into account that external audits contain clinical aspects of medical practice, not necessarily related to regulatory requirements and that interference with medical practice may occur.

A suitable strategy to solve this problem would consist of cooperative agreements among the regulatory body, the health authority and professional societies on external audits regarding the presentation of reports. Subject of these agreements would be the application of risk-based graded approach and a method of reporting, in such a way that aspects related to regulatory requirements be filed separately. The risk-based graded approach would help select the relevant audit report subjects, starting by the risk of an accidental exposure (radiotherapy) or radiation injuries (interventional procedures) or diagnostic examination with higher exposure, for example computed tomography, or examination with a large impact to collective dose to the population. In this way these aspects can be provided to the regulatory body upon request without interference with other clinical aspects of the medical practice.

4.2.3.6. Database for disseminating lessons to avoid accidental exposure

BSS requirements include the investigation of accidental medical exposure, the adoption of corrective measures to prevent them in future and the report to the regulatory body, the patient and his/her doctor. Knowledge of information on a previous accidental exposure can help prevent a similar event in the future.

Not only can the knowledge of accidental exposure help prevent other events. Also near misses without consequences can provide important lessons to others. Sharing this knowledge is essential but obtaining this information is not straightforward. The staff of a hospital involved in a near miss may not be willing to share it because of fear that it may trigger actions by the hospital administrators or by the regulatory body. Reassuring confidentiality in this type of reporting is essential. There are some well known anonym reporting systems such as Radiation Oncology Safety Information System (ROSIS) collecting events with no consequences.

The Regulatory Body should take the initiative in designing a strategy, together with the health authority and professional societies for radiotherapy, interventional radiology, interventional cardiology and medical physics to stimulate communication and dissemination of information to prevent new events in the future.

4.3. Summary of suggested cooperation with other authorities and professional bodies

In the sections 4.2 and 4.3 a number of recommendations are given to the regulatory body to address gaps in regulatory and radiation protection infrastructures by means of cooperative approaches with other regulatory bodies, health authorities, professional bodies, manufacturers, customs authorities and patient societies. In addition cooperation with other countries may be necessary.

These recommendations are summarized in the following Table

Institutional agreement	Aspects to be covered	Main institutions directly involved
a) Fostering education and training for human resources on patient protection	<ul style="list-style-type: none"> ● Availability and recognition of the specialties for the professionals involved in patient protection ● Existence of a mechanism for their accreditation. ● Training of referring physicians prescribing medical exposure. ● Inclusion of radiation protection into medical curricula at degree level ● Training of specialists not directly involved in using radiation. ● Continuous professional education of medical and non medical staff 	Regulatory Body (RB), Health Authority (HA), Education Authority (EA), academic institutions and professional certifying agencies.
b) Fostering i of the various medical practices using radiation	<p>Inclusion of qualified experts in the health staffing</p> <p>Sufficient staff with responsibilities for protection and safety concomitant with work load.</p>	Regulatory Body (RB), Health Authority (HA), Education Authority (AE), Labor authority (LA), professional bodies for physicians, physicists and technologists
c) Facilitating mechanisms for justification of medical radiological practices	<ul style="list-style-type: none"> ● Development of standards ● Development or adoption of medical protocols for justification of medical exposure for diagnostic and interventional procedures. Special emphasis on sensitive groups (pediatric, pregnant and chronic patients) ● Development of guidance related to justification, such as appropriateness criteria for medical exposure ● Safe introduction of new technologies 	Regulatory Body (RB), Health Authority (HA), medical professional bodies
d). Fostering the establishment of diagnostic reference levels (DRL)	<ul style="list-style-type: none"> ● Inventory of equipment for diagnostic radiology and interventional procedures using X rays ● Dose surveys ● Specific training on establishing and using DRL ● National database on patient dose data 	Regulatory Body (RB), Health Authority (HA), medical professional bodies of radiology, interventional procedures using X rays, standards dosimetry laboratories, Universities
e) Fostering calibration and quality assurance programmes for the medical radiological	<ul style="list-style-type: none"> ● Metrology infrastructure to facilitate traceability in the calibration of radiation sources and beams used for medical 	Regulatory Body (RB), Health Authority (HA), medical professional bodies, standards dosimetry laboratories, suppliers of medical

Institutional agreement	Aspects to be covered	Main institutions directly involved
practices	exposure and for dosimetry equipment <ul style="list-style-type: none"> ● Adoption of protocols for calibration of sources and beams for clinical use ● Infrastructure for monitoring patient exposure ● Quality criteria for diagnostic images ● Protocols for recording physical and clinical data. ● Existence of preventive maintenance programmes ● External audits 	equipment and radioactive sources
f) Fostering the establishment of acceptability criteria for medical radiological equipment	<ul style="list-style-type: none"> ● Criteria for obsolete and old equipment (extension of “life”) ● Criteria for decayed radioactive sources for clinical use ● Import and manufacture of equipment in compliance with internationally recognized standards (IEC) or equivalent national standards ● Recommendations to use equipment incorporating devices for determination of patient doses 	Regulatory Body (RB), Health Authority (HA), medical professional bodies, suppliers of medical equipment and radioactive sources
g) Establishment of constraints for the release of patients treated with radionuclides or permanent implants	<ul style="list-style-type: none"> ● Environmental surveys and of socio-cultural conditions ● Writing recommendations (I-131) 	Regulatory Body (RB), medical professional bodies, for nuclear medicine and radiotherapy
h) Strengthening the metrological infrastructure and strategy for calibrations	<ul style="list-style-type: none"> ● Arrangements for calibration abroad when there is no laboratory in the country ● Agreements and arrangements with customs authority for export and return of dosimetry equipment abroad ● Arrangements for calibration campaigns and optimization of resources to satisfy the need 	Regulatory Body (RB), Health Authority (HA), Customs Authority (CA), standards dosimetry laboratory, medical physics society
i) Fostering emergency preparedness to deal with radiological accidents involving patients	<ul style="list-style-type: none"> ● Training in the early diagnosis of radiation injuries for the network of assistance in the case of an emergency 	Regulatory Body (RB), Health Authority (HA), Other institutions involved in emergency response
j) Establishment of a national database of radiological incidents and accidents	<ul style="list-style-type: none"> ● Awareness raising ● Assurance of confidentiality of the information ● Computer and information 	Regulatory Body (RB), Health Authority (HA), medical professional bodies for radiotherapy and interventional procedures using X rays

Institutional agreement	Aspects to be covered	Main institutions directly involved
	technology support <ul style="list-style-type: none"> ● Use of information for prevention, quality improvement, training and continuous professional development 	

4.4. Summary of dissemination of safety culture related information

An essential element of the regulatory programme for the control of medical exposure is a policy of proactive dissemination of information on safety and regulatory issues to improve radiological protection of patients. The dissemination strategy should identify audiences, messages and means to disseminate. Information is one of the most powerful tools for the regulator in order to foster and consolidate a safety culture. Budgetary provisions for the dissemination programme are essential. The considerable expertise required for the sophistication of radiation protection in medical practice, and its importance, given the fact that it is the largest man-made exposure from man-made radiation sources, should be reflected in the budget. Funds should be also sufficient to cover all sectors involved in radiological medical practices.

Audience	Main information	Method
Patients	Existence of the regulatory framework Basic and specific simple information	web, leaflets, informative campaigns
Users of radiation, medical and paramedical professionals	Legislation, regulations, guidance and authorization conditions Forms and questionnaires Informative notes from the manufacturers on safety issues General information on protection of patients Information on incidents and accidental exposures	Web, mailing, workshops, bulletins, institutional publications, meetings
Health authority	Responsibilities and implications of the radiological protection of patients	Forums, round tables, institutional communications, working meetings
Professional bodies	Role of professional societies in the regulatory process for the radiological protection of patients. General and specific technical information on the radiological protection of patients	Workshops, forums, mailing, working meetings, round tables, congresses, round tables, institutional communications, Web
Policy-makers	Needs for the radiological protection of patients and consequences in case of lack of it or its degradation Need to provide a balanced budget to sustain programmes on the radiological	Institutional communications and presentations Public dissemination

Audience	Main information	Method
	protection of patients Need for policy of cooperation with other national organizations (mainly the health authority, education authorities and academia centers)	
Decision-makers (directors, managers, hospital administrators)	Compliance with regulations on the radiological protection of patients, Need for support to users of radiation Their responsibilities to foster and implement safety culture	Meetings, workshops, Web
Manufacturers and administrators	Need to comply IEC standards or national equivalent standards Conditions of acceptability of equipment	Institutional communications, meetings, workshops, forums, Web
Maintenance services	Awareness raising of the implications of maintenance errors with medical equipment on the radiological protection of patients	Institutional communications, meetings, workshops, forums, Web
Media	Public information on the radiological protection of patients, relevant information in cases of radiological accidents involving patients	Institutional communications, interviews, articles, Web,

4.5. Self-assessment of regulatory framework and continuous improvements

The IAEA radiation safety appraisal and support to Member States [22,23] refers to the need for the regulatory body to hold institutional relations. This criterion can be considered accomplished when coordination and cooperation at national level have been established and maintained with other authorities, intervening organizations, customs, law enforcement, professional societies, universities and technical services, as appropriate. This includes the formal and clear definition of respective responsibilities and functions. At the appraisal the following question is asked:

Does the regulatory body advise and co-operate with other relevant national authorities in relation to the implementation of the regulatory programme ... ?

Criteria from the IAEA Thematic Safety Area on Protection in Medical Exposure of the IAEA [23] refer to the need for cooperation with professional societies, suppliers, although there is no mention of the health authority.

In the work done under this project institutional relations and cooperative agreements have been addressed in full detail with about 43 evaluation questions on the subjects described in 4.2 and 4.3 of this report. This is the first time that institutional relations are considered in such detail. These kind of detailed questionnaires have been prepared for various aspects of the regulatory programme such as the regulatory framework, selection and training of the staff of the regulatory body and the authorization and inspection system for radiological medical practices. The goal is to assist the regulatory bodies in a self assessment process designed to analyze their ability to design and implement strategies for making regulatory programmes in the medical area efficient and effective. The proposed evaluation system is aimed at finding out not only “what” to do but “how” to do it.

4.6. Contribution to the review process of the International Basic Safety Standards

Important remark: these suggestions are the result of the work done by the authors and do not necessarily represent the position of the FORO's countries or of the FORO as such.

1. The current International Basic Safety Standards establish requirements for registrants and licensees only, not for governments or for regulatory bodies, because the BSS are based on the presumption stated in its preamble, that governments already discharge their responsibilities for protection and safety, by having legislation in place, a regulatory authority established and a national infrastructure for radiation protection and safety. The revised Standards should address governmental responsibilities and obligations of the regulatory body by means of explicit requirements.
2. Requirements should be included on the need for the regulatory body to reach cooperative agreements with health authorities, professional bodies, manufacturers, customs authorities and patient societies, in order to make provisions, which go beyond the capability of individual users, thus enabling them to comply with regulatory requirements. In addition, cooperation with other countries may be necessary for calibration of dosimetry equipment abroad when necessary.
3. Generic justification for practices and techniques requires the judgment on their benefits by health authorities and the risks considerations by the regulatory authority. Professional bodies may provide complementary guidance on appropriateness criteria for different diagnostic and therapeutic procedures. Requirements on governmental arrangements for justification are needed in the revised BSS, as well as clear assignment of responsibilities to referring physicians and medical radiological practitioners for individual medical exposures.
4. A graded approach should be incorporated in the revised version of the BSS, in order to allocate more resources where the risk is more important, ranging from high-dose therapeutic applications and interventional procedures down to low-dose simple diagnostic examination. Requirements for a graded approach are needed for both regulatory bodies and users of radiation. The tasks directly affected by the level of risk are listed in 4.1.2.
5. There should be requirements on governments to provide for educational programmes for the professionals needed for medical exposure. In particular, these programmes should address accreditation and recognition as health professionals for certain paramedical staff with substantial responsibilities for patient protection, such as medical physicists.
6. The current BSS takes for granted that national infrastructures provide for essential services, including standards dosimetry laboratory. In the revised BSS, requirements for governments should be included to provide this service or to make arrangements with customs authorities and with laboratories in other countries, in order to enable hospitals to maintain calibration of their radiation sources and beams used for medical exposure traceable to a standard dosimetry laboratory, through calibrated dosimetry equipment.
7. Requirements should be placed on the health authority and the regulatory bodies to work together with relevant professional societies for the establishment of diagnostic reference levels to be used as part of optimization of protection.
8. Requirements on the regulatory body should be included to foster safety culture in the country by establishing and maintaining a system of safety relevant information for parties affected by its decisions, medical and paramedical staff, the public, patients, manufacturers and other interested parties.
9. A requirement on the regulatory body should be included in the revised BSS to foster the establishment, in cooperation with the health authority, relevant professional societies, manufacturers and users, of a data base and mechanism for collection and timely dissemination of

information of lessons from incidents, near misses and accidental exposures, particularly from interventional procedures and therapeutic use of radiation.

10. A requirement on the regulatory body should be included, to establish, in consultation with health authority and relevant professional societies, criteria for acceptability of equipment, its useful life and obsolescence of medical radiological equipment.
11. A requirement on the regulatory body should be included, to establish, in consultation with the health authority, donors and the relevant professional societies, criteria for acceptability and tests of second-hand equipment to be used in radiological practices in medicine. The criteria should address the subsequent quality control and maintenance in order to ensure protection and safety while in use.
12. A requirement on registrants and licensees should be included to inform patients on risks associated to medical exposures, in a way that is commensurate to the risk specific procedures, following the risk-informed graded approach proposed in point 4.

5. Discussion and conclusions

This study has analyzed the degree of transposition and application of the International Basic Safety Standards in the FORO's countries, has identified potential gaps in infrastructure, which pose obstacles for users to comply with regulatory requirements and has provided solutions to these weaknesses. The main findings of the study are the followings:

- Division of responsibilities, ambiguities in the competences of regulatory bodies, and gaps in national infrastructure are a major challenge to ensure compliance with requirements. If the ambiguities in the law and gaps in infrastructure are too large and look overwhelming to regulators governments are responsible to look into these obstacle and assign responsibilities. On the other hand, the regulatory body needs to be proactive in searching for mechanisms to overcome these difficulties and to vigorously move towards ensuring compliance with regulatory requirements.
- Most weaknesses of the regulatory system and gaps in infrastructure can be overcome with a framework of institutional relations and cooperative agreements with other governmental organizations, such as health, education and labour authorities, calibration laboratories and custom authorities, as well as stake holders such as professional bodies, manufacturers. These relations and agreements should put in place mechanisms to enable users to comply with regulatory requirements. In particular, intense and continuous collaboration of the regulatory body with the health authority is crucial for patient protection.
- The regulatory body should use its limited staff and resources in an effective manner following a risk-informed graded approach. This approach provides a good sense for priorities in terms of risks, "devoting more effort where it is more needed", choosing the type of facilities and sources to initiate the inventory, the degree of detail for authorization, frequency and intensity of inspections, enforcement and follows up on safety deficiencies.
- The graded approach is not only important for regulators, but it is equally important for requirements on users. The need for presence of qualified experts, and patient exposure control, double-check procedures, quality control and audits, is higher in facilities with higher risk, such as therapeutic applications and interventional procedures.
- There is a delicate balance between regulating / monitoring medical exposure and interfering with medical practice. A sensible approach, based on performance oriented regulations, combined with guidance and cooperation with professional societies on protocols, quality assurance and audits, may achieve effectiveness with a minimum of interference. The common-sense approach is to do

what is really necessary. The principle of “doing more good than harm”, is also applicable to enforcement actions.

- It is not sufficient to monitor “what” is done at the facilities; it is also important “how” it is done, the degree of commitment by administrators, managers and workers, their attitudes and other indicators which bring provide confidence on safety well before any enforcement action becomes necessary, are essential items.
- Safety is not only mere compliance with requirements. It is also doing the job with full knowledge, attention, alertness, due thought, positive attitude and a proper sense of accountability. All these features together are elements of a good safety culture. The regulatory body needs to be proactive by means of a policy and a system for providing and exchanging safety information to and with stakeholders. This approach may anticipate potential problems and help remove them before they become safety threats.

With these elements in place and effectively implemented, the strength, credibility and confidence in the regulatory system may be achieved

REFERENCES

- [1] INTERNATIONAL ATOMIC ENERGY AGENCY. Report of the steering panel on the Action Plan on the Radiological Protection of Patients. IAEA, Vienna, 2008.
- [2] UNITED NATIONS SCIENTIFIC COMMITTEE ON THE EFFECTS OF ATOMIC RADIATION. UNSCEAR 2000 Report to the General Assembly, with Scientific Annexes, United Nations, New York, (2000)
- [3] FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS, INTERNATIONAL ATOMIC ENERGY AGENCY, INTERNATIONAL LABOUR ORGANIZATION, OECD NUCLEAR ENERGY AGENCY, PAN AMERICAN HEALTH ORGANIZATION, WORLD HEALTH ORGANIZATION, International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources, Safety Series No. 115, IAEA, Vienna (1996).
- [4] INTERNATIONAL ATOMIC ENERGY AGENCY. Legal and Governmental Infrastructure for Nuclear, Radiation, Radioactive Waste and Transport Safety. IAEA. Safety Standards Series, No. GS-R-1. IAEA, Vienna (2000).
- [5] INTERNATIONAL ATOMIC ENERGY AGENCY, Radiological Protection for Medical Exposure to Ionizing Radiation. Safety Standards Series No. RS-G-1.5. IAEA, Vienna (2000).
- [6] INTERNATIONAL ATOMIC ENERGY AGENCY, Categorization of Radioactive Sources. IAEA-TECDOC-1344. IAEA, Vienna (2003).
- [7] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Radiological Protection and Safety in Medicine, Annals of the ICRP, **26** 2, Pergamon Press, Oxford, UK (1996).
- [8] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION. Recommendations of the ICRP .ICRP Publication 103. Ann. ICRP 37(2–4).2007
- [9] INTERNATIONAL ATOMIC ENERGY AGENCY. Proceedings of the International Conference on the Radiological Protection of Patients. IAEA, Vienna, 2001.
- [10] INTERNATIONAL ATOMIC ENERGY AGENCY. International Action Plan on the Radiological Protection of Patients. Approved by the Board of Governors and endorsed by the General Conference in September 2002. IAEA, Vienna (2002).
- [11] INTERNATIONAL ATOMIC ENERGY AGENCY. Absorbed Dose Determination in Photon and Electron Beams: An International Code of Practice, IAEA-Technical Report Series No. 277, Second Ed, IAEA, Vienna (1997).

- [12] INTERNATIONAL ATOMIC ENERGY AGENCY, Absorbed Dose Determination in External Beam Radiotherapy: An international Code of Practice for dosimetry based on standards of absorbed dose to water, IAEA Technical Report Series 398, IAEA, Vienna (2000).
- [13] INTERNATIONAL ATOMIC ENERGY AGENCY. Dosimetry in diagnostic radiology: An international Code of Practice. IAEA Technical Report Series 457, IAEA, Vienna (2007).
- [14] HART D, HILLIER MC, WALL BF, SHRIMPTON PC, BUNGAY D. Doses to patients from Medical X ray Examinations in the UK - 1995 Review. National Radiation Protection Board, NRPB-R289, Oxford, Chilton, UK (1996).
- [15] EUROPEAN UNION, Council Directive 97/43/Euratom of 30 June 1997 on health protection against the dangers of ionizing radiation in relation to medical exposure, and repealing Directive 84/466/Euratom, Official Journal of the European Commission Rep. L 180, Luxembourg (1997) 22-27.
- [16] EUROPEAN COMMISSION. European Guidelines on Quality Criteria for Diagnostic Radiographic Images. EUR 16260. Luxembourg, EC (1996).
- [17] EUROPEAN COMMISSION. European Guidelines on Quality Criteria for Diagnostic Radiographic Images in Paediatrics. EUR 16261 Luxembourg, EC (1996).
- [18] EUROPEAN COMMISSION. European Guidelines on Quality Criteria for Computed Tomography. EUR 16262 Luxembourg, EC (2000).
- [19] EUROPEAN COMMISSION. European Guidelines for Quality Assurance in Mammography Screening, 2nd Edition Luxembourg, EC (1996).
- [20] EUROPEAN COMMISSION. Referral guidelines for imaging. Radiation Protection 118. Luxembourg (2001).
- [21] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Diagnostic reference levels in medical imaging: review and additional advice, Annals of the ICRP, **31** 4 (2001) 33-52, Pergamon Press, Oxford, UK.
- [22] INTERNATIONAL ATOMIC ENERGY AGENCY. Thematic Safety Area for Technical Cooperation Projects. Regulatory Infrastructure. IAEA, Vienna, 2006
- [23] INTERNATIONAL ATOMIC ENERGY AGENCY. Thematic Safety Area for Technical Cooperation Projects. Control of Medical Exposures. IAEA, Vienna, 2006
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