REGULATORY FUNCTIONS AND MEDICAL EXPOSURE

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INTRODUCTION

Must the patients subject to medical radiation practices be protected ?
What does the protection of patients means ?
Who must protect the patients ?
Is it not a sole responsibility of physicians ?
These are some of the questions this paper attempt to discuss.

MEDICAL EXPOSURE

Last international recommendations on radiation protection assign new emphasis to *medical exposure*, the expression used by the International Commission on Radiation Protection to name the exposure of patients to radiation for diagnostic or therapeutic purposes (1). The International Atomic Energy Agency, the World Health Organization, the Pan American Health Organization and other international organizations (2) have shown similar concern for medical exposure as for ocupational and public exposures. These are signs of a remarkable evolution toward a better protection of the patients.

Medical exposures have some particular characteristics:

a) Patients are *intentionally* exposed to radiation. Benefit from medical practices can not be obtained unless patients receive some dose of radiation (*necessary dose*).

b) Dose limits are not applicable because benefits and risks of radiation has to be evaluated on the same individuals and therefore there is not room for inequity..

c) Optimization has a lower constrain (necessary dose) while optimization of ocupational and public exposures has upper constrains (dose limit or another constrains)

d) Justification and optimization principles apply to medical exposure. They are more closely interrelated than in any other aplication of radiations. To be justified a medical exposure must produce some *benefit* to the patient health. Bennefit depends on the *right prescription* of the practice and the *good quality* of its performance it is to say optimized performance. A medical practice that has not been optimized may have poor quality and provide no benefit to the patient and therefore should not considered to be justified. Prescriptions rely exclusively on *human factors* (the knowledge and experience of physicians). Performance rely on human factors (mainly physicians and physicists) and on *physical factors* (proper equipment, its maintenance and calibration, rigth treatment planning, etc.)

e) Diagnostic practices involve relative small individual doses and very large collective dose. (3) Significant part of collective dose attributable to diagnostic practices in most countries could significantly be reduced without loss of benefit (4) through a better justification and optimization of procedures. Diagnosis is the field of radiation applications where the most substantial reduction of collective dose may be achieved at very low cost.

f) Therapy procedures involve large individual doses and the efficacy of treatments depends on the accuracy and distribution of doses in a very sensitive way. Significant part of therapy procedures may be inefficient due to a poor accuracy in delivering doses to the tumor or failures in protecting normal tissues.

g) Potential exposures asociated to medical sources have to be considered (5). Accidents caused by medical sources are a significant proportion of radiological accidents. Along last fifty years 38 % of deaths in radiological accidents were produced by medical sources (6) and most of them were patiens.undergoing radiation treatments. These only are the recognized accidents. Most of them were caused by significant deviations from prescribed doses. However it is well known that even a small deviation from the prescribed dose (10% for instance depending on the type of tumor) may cause a significant reduction on the cure probability. Unles good quality control procedures are implemented it is quite feasible that nobody realize that a significan fraction of treatments are carried out whith smaller probability of cure than what correspond to a good technique. Where is the boundary between an accident and a bad practice ? Is it a matter of

perception ? Many patients may not have positive reactions to radiation therapy (what may signify death) due to lack of good quality treatments. Should those situations be considered accidents or bad practices ? Radiation therapy is probably the field of radiation applications where more lifes can be saved through a human and physical resources of good quality.

h) There is not public perception of risk from medical sources . Since they are associated with preservation or recovery of health they seem to be inherently good. Medical practice with radiation sources may be carried out with great impunity.

REGULATORY AUTHORITY

Since dose limits are not applicable to medical exposure physicians have unlimited freedom to irradiate patients Regulatory authorities have to decide how deep their regulation on medical exposure should go. Whatever the decision be it will imply some sort of interference with medical practice. .

Regulatory Authorities, when are not the same as Health Authorities may find some conceptual dificulties to aplly regulations on medical exposure.. That means a sort of self constrain to impose requirements because they may collide with medical practice freedom

There can no be restrictions on medical procedures prescriptions Regulations on medical exposure can be oriented to enforce quality improvement through three main tools: by promoting good expertice of the human resources involved, by promoting the use of adequate equipment and techniques and by promoting quality control procedures.

ARGENTINE EXPERIENCE

Argentina started their regularory activities on Radiation Protection in 1958 when the National Atomic Energy Commission (CNEA) iniciated the promotions of radioactive material applications. The first regulations stablished the basic principles of the license process "to attend public utility reasons and to prevent the possible harm of nuclear trasmutation and reactions" (7).

Since that time individual and institutional authorizations were granted by the Regulatory Authority (CNEA) when specific requirements were fulfilled. There are evidences of concern about the protection of patients in that regulation. Physicians had to have specialized education and proper training to be authorized. "Medical facilities had to have adecuate means for a clinic attention of patients." .

Further regulations preceisely defined.the requirements to obtain authorization to utilize radioactive materials or accelerators in medical practices (8). These include specialized courses and training periods of about three years. Those requierements are still in practice and were important steps toward good quality medical exposures. Unquestionably these requierement interfere severily with the profesional freedom of physicians to use ionizing material in medicine. However as this process was accompanied by a true leadership in research and education from the same institution that applied the regulations there was a good degree of acceptation. Another important factor was the fact that every authorization request has been analyzed by an advisory committee integrated by experts in the use of ionizing radiation; most of them physicians or physicists specialized in medical application of radiations. So petitioners have been judged by their peers.

Ap to 1980 institutional authorizations were granted after verification of generic radiation protection and safety measures mainly considering the protection of workers and public There was not special regulation on physical aspects to assure good quality medical exposure.

In 1980 an additional regulation was adopted jointly by the CNEA and the Public Health Secretariat (SSP) exclusively to promote the improvement of medical exposure quality in radiotherapy and nuclear medicine.(9). This regulation was previously discussed with the most representative physicians and physicists in the fields of radiotherapy and nucler medicine.. Their main requirements are:

a) specifications of some characteristics of equipment to avoid excessive obsolescense.
b) specifications on maintenance and quality control of equipment
c) use of complementary equipment for simulation and calibration
d) specifications of minimun set of units to integrate radiation therapy faccilities to cover the most frequently techniques in teletherapy and braquitherapy.
e) minimun set of units to integrate nuclear medicine faccilities to cover the most common diagnostic techniques.
f) composition of minimun staff of physicians, physicists and technicians..
g) need for authorizations renewal every five years.

This regulation was thought as an evolutionary process since periods of time were allowed to fulfill the requirements..

Had the Regulatory Authority of Argentina (CNEA) enough power to enforce such a regulation ? The fundamental regulation (7) gives it sufficient faculties to regulate the conditions for granting individual and institutional authorizations. However, since the 1980 regulations on radiotherapy and nuclear medicine advanced significantly in the field of medical exposure it was though that the support of the Public Health Authorities (SSP) would help to achieve acceptation among physicians. As a consequence of an agreement signed between the Public Health and Regulatory Authorities the regulation was jointly enforced by these two institutions mainly through the regulatory faculties of the Regulatory Authority. As stated in the text the SSP "requires the concurence of CNEA to enforce the regulation." It must be noticed that Regulatory and Public Health Authoriies have kept an excelent level of cooperation in Argentina.

In 1994 Argentina updated its basic standards and the concept of medical exposure was incorporated as well as the optimization of medical exposure through the proper utilization of equipment and techniques (10). In 1995 the Regulatory Authority was separated form CNEA. The new institution is the National Nuclear Regulatory Entity (ENREN) and all the regulatory faculties were transfered to it. However there has been different interpretations on whether the ENREN has the same faculties as CNEA had to enforce the existing regulations on medical exposure. At present this is a matter of analysis. This an example of institutional caution to act in the field of medical exposure even when there has bee a generalized acceptation of requierements imposed by the 1980 regulations.

However a good degree of cooperatrion between the new Regulatority Authority and the Public Health Authority will most probably warranty the continuation of a policy unquestionably positive for the protection of the patients, avoiding an involution on the achieved goals.

CONCLUSION

Medical exposure is the field of radiation protection with the largest possibilities for reducing unnecesary doses and consequently negative effects of radiation without associated benefits. It also has the greatest posibilities of increasing benefitial consecuences of medical radiation sources by improving diagnostic and therapeutic techniques quality. Therefore Regulatory Authorities should not be absent in this field.

But they should not act alone. Regulations on this matter should not be prepared without the intervention of physicians and physicists with recognized expertise on medical aplications of radiations Cooperation of Public Health Authorities is most desirable. Even when the Public Health Authorities may not have operative capacity to enforce regulations in some countries Public Health Organizations have the faculty of judjing what is benefitial or not in the medical practice.. Agreement between Public Health and Regulatory Authorities may result in a sinergistic combination of resources. International Organizations have provide good example of cooperation between this two areas.

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