

# National Program of Radiation Protection of Patients (Argentina)

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## Abstract

The medical radiation are undoubtedly the most important contribution to human exposure to ionizing radiation. Statistics indicate a growing trend in the number of practices as well as the amount of services particularly for Intervention cardiology. The quality of practice, justification and optimization are now an important issue for the scientific and regulatory bodies. Since the adoption of Directive 97/43/EURATOM, and the realization of the Malaga Conference most European countries have implemented action plans for radiation protection of patients, including the seeking of consensus regarding the optimization dose and the criteria for justification.

In this context, and convened by the Nuclear Regulatory Authority was held in our country, December 10, 2004, the first Conference on Patient Radiation Protection (PRP) in order to install in the medical community an active discussion on this topic. Then came a series of activities that today constitute the National PRP is sustained and driven by medical societies in the country and in particular the Argentine Society of Radiology and the Society of Radiation Protection.

Basic objectives of the PRP program:

- 1) Justification: The study is performed only when imaging studies are needed. (Refferal Guide)
- 2) Optimization of practice: That studies be carried to the doses received by the patient are the minimum necessary.
- 3) Prevention of risks: To avoid the occurrence of accidents and serious injuries in interventional procedures establishing quality systems and standards for the practice.
- 4) Training and Education: Including the prescribing physician and the whole team of interventional cardiology. (Recertification)
- 5) Dissemination of PRP criteria to the entire medical community

Results: PRP program has reached a reasonable maturity and this year marks the 6th Day of PRP at the National Academy of Medicine and 4 Regional Symposia one of which is dedicated to intervention in all specialties.

Conclusion: The establishment of national PRP is an appropriate measure that can systematically improve the quality of care in all specialties that used ionizing radiation. The active participation of medical and technicians societies is essential for program success.

Strategies to cope with different interests within society are described. Main problems, failures and difficulties are also described.

**KEYWORDS:** *Radiation Protection of Patients; Procedures; Quality System; certification*

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## Introduction:

The technological explosion that has occurred in recent decades has multiplied geometrically and use of medical imaging has helped to achieve earlier diagnosis and more accurate.

Modern equipment can detect small functional abnormalities in only a few seconds with a precision and accuracy unthinkable some years ago. This has resulted in the detection of disease in earlier periods (which makes them more effective treatments) in the detection of previously unknown processes (which allows to apply appropriate treatments), in reducing the incidence of some diseases, and reducing the occurrence of certain complications in the course of many others.

It is true that this increased use of imaging methods have increased exposure to the radiation. But while the radiation risks have increased, much more has increased the quality of life of the population due to

medical advances in both diagnosis and treatment.

So it must be said that there is no conflict between the radiological hazards and medical practice. Whenever benefits are much greater than the risks involved when procedures are implemented within the standards of good medical practice.

All medical acts should be judged according to the equation benefit / risk. Address this issue by emphasizing only the increased use of diagnostic techniques and their possible harmful effects is to look at only one side of the equation.

Emphasize the increased use of diagnostic methods over the years as a problem in itself, is like worrying about the increased use of antibiotics from 1920 (when infectious diseases were not effective treatment) or the surgery since the introduction of anesthetic procedures.

Technological development has brought new indications for imaging methods, and the evolution of medical and surgical treatment requires more and better diagnostic and prognostic information in the past. Of course this leads to a more expensive medicine, but while the equation benefit / risk is to the favorable side, should be understood that it is an expense that must be assumed.

The problem of increased use of diagnostic or therapeutic action is when they are not indicated. In this case, the equation benefit / risk is negative, because the benefit is zero, and the patient only takes risks. We know that everyone is asking for unwarranted diagnostic tests, which unnecessarily expensive medicine and forth, also unnecessarily, patients at risk. But this is no exception to other causes of malpractice, such as drug administration is not justified, or performing unnecessary surgical procedures.

This is what we must attack: misuse. Whenever there is a medical indication, the benefit outweighs the risk. There is one question that usually comes: How many CT scans may be a patient in your life?. The answer is, as you need. If a patient has a chronic illness that requires regular tomographic controls suffer severe head trauma, you can not refuse a CT scan with the argument that has been done many: the risk to have an undiagnosed brain injury (and therefore untreated) is much greater than the risk of that CT will increase the percentage of chance of developing a cancer in the future.

However, it is imperative to take all necessary measures to protect the patient to retain the benefits reducing the risks. This is the goal of programs Patient Radiation Protection (PRP), which exist in the world from the recommendations in the first PRP Congress held in Malaga, Spain in 2001. These recommendations led to various laws and policies in Europe and the United States, and initiating various activities in many countries.

In Argentina, the Nuclear Regulatory Authority in 2004 organized the first Conference on PRP, where they organized "working groups" began systematic, receiving strong support of the Argentina Society of Radiology and Radiation Protection Society Argentina. These activities resulted in the development of the Argentine Patient Radiation Protection.

The main objective of this program is to prevent unjustified doses, practices to optimize the doses involved are as low as possible, so that medical practice does not unduly increase the risk of radiation exposure of the population.

For this, it works in the training of medical personnel on Radiation Protection in the implementation of quality systems, and adequate supervisory structure and regulatory control.

PRP Argentine Program is conducted by a Joint Committee of Professional Associations involving the use of ionizing radiation in medicine and has **6 objectives**:

**1 - Justification:** It is important that the public knows that imaging studies that involve risk is justified only if the examination is medically indicated. To achieve this goal in 2006 Argentina Radiology Society

prepared a "Guide of Recommendations for the Indication of Studies of Diagnostic Imaging," in order to support the prescribing physician. This guide contains the most common clinical cases and a recommendation of the diagnostic study most appropriate for each case. Currently the guide was given to the scientific societies that gather prescribers to review and update together.

The participation of the prescribing physician in this process is critical because it has been determined that the principle of "justification of the practice" is the most important to prevent the risk of the public.

**2 - Optimization of practice:** Once the studies are justified is intended that these be carried out in optimal conditions for the doses are as low as possible. This is very important that teams are well maintained, calibrated and are used most suitable operating parameters for each study.

**3 - Prevention of Accidents (potential risks):** Radiation therapy can result in failures that cause the patient to receive a dose greater than or less than required, and both cases should be avoided. These accidents are generally caused human errors, and have occurred in many countries although fortunately not ours. Also in "Intervention" using fluoroscopy equipment, can produce some serious injuries. It is important staff training, the presence of specialized personnel, and design of quality systems involving all staff.

**4 - Training:** The medical team must have an appropriate qualification. This is very important for new medical specialties that are using fluoroscopy equipment without having received adequate training in radiology and radiation protection. The principles of radiation protection must be included in the curricula of medical careers in specialized courses, and professional certification programs.

**5 - Dissemination of PRP criteria:** In order to make appropriate dissemination of PRP criteria throughout the country, including the general public, are held courses, seminars and workshops at all levels. Last year we developed the 6 th Day Patient Radiation Protection, as part of the 57th Argentine Congress of Radiology, with the participation of numerous related scientific bodies.

**6 - Structure of control and monitoring:** In order to establish a control system that encourages good practice and correct the deviations, there have been proposals to the competent authorities to establish permanent Radiological Protection Services in hospitals.

People should not hesitate to complete the studies prescribed by a doctor, because when you meet the criteria of justification and optimization benefit is much greater than the risk.

Specialized professional associations are working on this issue on a continuous, intense and responsible task.

The implementation of the above mentioned aims in the society where we live requires the design of strategies for overcome the disadvantages and resistances generates by any new change.

The strategies must rely on a staggered planning that begins with the conviction of the medical community of which the benefits overcome at length the economic costs of the efforts to be performed.

Medical irradiations are undoubtedly the most important contribution to human exposure to artificial ionising radiation. Since its initial use Computed tomography has continued to evolve. Statistics show a growing trend in the number of practices as well as the number of installations.

Computed tomography is a powerful diagnostic tool, much more than any other imaging test; an extraordinary anatomical display that can be rendered in perfect 3D models, but medical x-rays also cause cancer. Just one body CT scan increase 1 in 1000 the chance of developing cancer, and the risk in children is even higher.

Anyway, the discussion of radiation risks must be tempered because the recognition of their benefits.

The quality of the practices, their justification and optimization are today a subject, which is relevant to scientific circles and regulating organisms.

Today many medical associations of radiology are extremely concerned about the increase of unjustified doses, which have determined an increase in cancer in the population.

After the adoption of Directive 97/43/EURATOM and the Malaga Conference, most European countries have implemented action plans for the radiological protection of the patient including the search for consensus in relation to optimize doses and the criteria for justification. One example is Guide PR/118 for applying for diagnostic tests.

### **Beginning of RPP activities in Argentina**

On 10 December 2004, activities began within this framework, when the first Seminar on **Radiation Protection of Patients (RPP)** took place, with the aim of opening an active debate on the subject within the medical community. Doctors in the fields of Radiodiagnosis, Nuclear Medicine and Radiotherapy were present as well as representatives from the Ministry of Health, regulatory organisms and different professional associations. During the Seminar, Guide PR/118 was presented and through a teleconference Dr. Michel Bourguignon, the Assistant Director of the Authority of Nuclear Safety in France presented their experience for the adaptation and adoption of these guides, which had been carried out in France.

After the first seminar, “4 work groups” were set up in Radiodiagnosis, Radiotherapy, Nuclear Medicine and Radioprotection for pregnant women and systematic activities were begun which received firm institutional support from the Argentine Society of Radiology. They ended with the elaboration of a “Program of Radiation Protection of the Patient” which is still implemented.

### **Program of Radiation Protection of Patients**

The analysis of the existing situation determined that achieving some of the established aims could be too much for the willpower and/or amount of available economic resources and so it was decided to fix more realistic short term goals which could be achieved quickly, using the funds available to advance modestly but constantly without causing false expectations.

Aims such as the implementation of systems of quality in all health services, achieving top training for professionals and technicians all over the country, determining reference levels and achieving the use of protocol in all diagnostic tests through images, all require great effort and cannot be achieved immediately.

### **Adaptation to technological innovation:**

The rapid advances which are present in Medicine today, both in equipment and work protocol, determine that “*norms and regulations never arrive on time*” which is why it is paramount that health services have “*systems of dynamic quality and continual improvement*” that can be adapted quickly to changes.

**Intervention Radiology:** The problem of interventional radiology is that every day there are more specialists non-radiologists that use different technologies without having a suitable preparation and training in radiological protection.

This determines an increase in the damages that are produced in the patient from erythema or radiodermatitis up to ulcers that need surgery.

The situation is more risky even for the patient and the operator when there are used equipments that are not designed neither prepared for interventional radiology.

There was done a systematic work of control of the doses received by the patient and the operators during different practices of interventional radiology in several Services of the City of Buenos Aires.

The target of the work was to establish guidelines, reference levels and protocols of work for the radiological protection of the patient that they could be applied in other services, especially for those services led by specialists non-radiologists.

The results were also used for designing the questionnaires of the program of re-certification.

There was done the follow-up of different conditions of work in order to optimize the operative parameters minimizing the risks of radiation, reducing the doses of the patient and simultaneously that of the operators.

## **Details of the activities carried out and state of the project:**

### **1) Justification**

The aim is to improve clinical practice supporting the prescribing doctor's task by developing a "Guide for Prescription Criteria" to improve the link with the professional responsible for the test. The aim of the justification of the practice is that "the benefit obtained is more important than the damage occurred" and to avoid unnecessary radiation on patients.

Guide PR/118 in Spanish of the European Community was used as a basis as too the equivalent Guide in French prepared by the French Society of Radiology (SFR) with the support of the National Office of Nuclear Safety (DGSNR) and the National Agency of Accreditation in Health (ANAES).

In order to be able to adapt it to the particular practices developed in the country, 11 committees of experts were set up through the Argentine Society of Radiology.

Head and Neck: Dr. José Luis Sanromá and Dr. Ezequiel Salas; Spine and Locomotor system: Dr. Guillermo Azulay and Dr. Marcos Hjelt; Circulation: Dra. Patricia Carrascosa and Dr. Pérez Arenasa; Chest: Dr. Juan Carlos Spina and Dr. Eduardo Diez; Digestive: Dr. Salvador Merola and Dr. Alberto Seehaus; Kidneys and Urinary: Dr. Gustavo Saubidet and Dr. Alejandro Beresňak; Gynaecology and Obstetrics: Dr. Diego Elías and Dra. Fernanda Dovasio; Breast: Dr. Roberto Rojas and Dr. Gustavo Mandler; Orthopaedics: Dr. Osvaldo Velán and Dr. Rubén Gonzáles Villaveirán; Cancer: Dr. Juan Mazzucco and Dra. Adriana Dieguez; Pediatrics: Dr. Fernando Gentile and Dr. Roberto Pittaluga.

The Guide has already been evaluated and adapted to local practices and is being judged by the associations of the specialities which order the tests such as paediatrics, orthopaedics, intensive care, nephrology, rheumatology etc so as to attain their approval.

Given the importance of having a system to measure the effect of the new Guide on prescriptions for radiological tests, 10 common syndromes which require image tests (pediatrics and adults) were chosen in order to assess the type of tests that are ordered before and after the application of the Guide in public and private hospitals as well as through medical schemes and insurance.

This first aim of "guaranteeing justification" is carried out in four stages:

- ❑ The issuing of the Guide was validated and approved by professional associations and then presented in the National Radiology Congress in 2007 (Stage completed)
- ❑ A second stage of diffusion, information, promotion and training in the use of the Guides for all professionals using it. (Stage completed)
- ❑ A third stage of evaluation of the obtained results and the presentation of a report to the health authorities justifying its issuing as a legal requirement.
- ❑ A fourth stage consisting of the Guide being issued by the acting authorities ensuring its full use in all health areas and making sure that doctors not following the recommendations, do so. Its use would be compulsory but not its strict application as the decision is always up to the doctor based on the analysis of each individual case.

The rational use of the techniques of diagnosis through images will contribute to the suppression of unjustified tests, a simple measure which is an efficient use of radioprotection. Prioritizing the principle of justification seems to suggest a change in paradigma in the current approach to the radiation protection of the patient. In this way the prescribing doctor acquires new relevance, who, together with the specialist in diagnosis through images, radiotherapy or nuclear medicine, will be responsible for the application of the principle of justification.

### **2) Optimising Radioprotection:**

The aim of optimising practices is for tests to be carried out through techniques that ensure minimum irradiation for the patient without affecting the quality necessary for the image. Several difficulties related to the large quantity of equipment with out of date and imprecise information were pinpointed.

Based on statistical research carried out in 6 provinces 15,000 pieces of equipment (Rx and TC) have been counted plus approximately 350 centres of nuclear medicine making an estimate of 25,000 in the country.

Ensuring that all these health services have personnel qualified in RPP and that all the equipment operates in the right conditions, is a difficult task, which requires appropriate strategies. Although it is compulsory to register the parameters used in each test in the country, in fact this is not always complied with and the health authorities do not always have the resources to control all the services efficiently. This situation makes the carrying out of statistical research on the true practices and techniques in the country difficult.

The parameters of radiation are established by technicians in accordance with the protocol of traditional bibliography, with the teaching of their professors or with techniques established by the manufacturers of the equipment.

These techniques are not necessarily good enough to be able to obtain images of good diagnostic quality using a lower dose of radiation for the patient.

One of the proven factors which most affects this dose received by the patient is the repetition of tests. In Argentina at the present time, there is no register of parameters of radiation used on each patient in tests of ionising radiation although generally there are registers which allow the analysis of the quantity of x-rays either for tests repeated for some reason: incorrect posture of the patient, lack of quality control of the equipment, fixed parameters which do not coincide with the real parameters etc.

This second aim “Optimizing Radioprotection” is carried out in four stages:

- ❑ Collection of information used locally and in other countries in order to develop different studies, such as operative parameters, reference levels, work protocol, quality control, registers etc (Stage in completion)
- ❑ A second stage of analysis of the existing information by groups of specialists in order to produce “Manual of work protocol” to minimize the dose involved both in the patient and the operators and public (Stage in development)
- ❑ A third stage of quantitative evaluation of the results obtained in order to present a report to the authorities and:
- ❑ a fourth stage consisting of the issuing of recommendations by medical associations and/or authorities for the full use of the Manual of work protocol.

However, there is no point in establishing work protocol without a minimum of quantity control of the equipment, which will at least ensure that the real operative parameters correspond to the indications of the instruments. This is why training and accreditation of those responsible for the maintenance of the equipment should be carried out at the same time. Work on awareness is being done for this reason through their different associations.

### **3) Preventing potential exposure**

The “general conclusions” of the Conference of Malaga show two basic elements to achieve the RPP: training and coaching as well as the **implementation of quality systems**, the latter being particularly important to prevent potential exposure, especially in those installations where potential risk from radiation is greater.

Most health services do not have the necessary means available to adhere quickly to international standards, so a standard which ensures the existence of the essential elements in a quality system must be designed to then be able to obtain automatic and accessible accreditation for all health services. One cannot demand something that only a few can comply with when it is likely that 90% of the Health Services in Argentina and in the rest of the world do not have a formal quality system available yet.

At the same time the health services do not have either qualified or trained personnel to lead a certification or accreditation project and most of them do not have the resources available to hire external consultants, especially public hospitals.

The scenario described represents a challenge for the Regulating Authorities who must determine “how to ensure that installations comply with an acceptable standard of quality without it placing an impossible strain on their budget?”

The methodology used in the design of quality systems can be divided into two categories: Reglimentary Approach and Analytical Approach.

The Reglimentary Approach is the application of the requirements of a given standard without necessarily going through a previous analysis of their own operative processes.

Each requirement is linked to an element or activity which is developed in the productive organization and each activity is assigned a “criteria control”. The reasoning is the following: “if each activity can be the source of failure or error, then each one should be controlled individually so as to control the group of activities of the organization”.

In this way, “**criteria control**” appears: design control, supply control, document control, register control, material control etc etc.

On the other hand, the Analytical Approach is based on the “**detailed analysis of specific processes**” to identify the causes of the failure and deviation and to then prevent them which is why different tools and methodology are used to a greater or lesser complexity.

Within this approach we can find methodologies which use **systematic evaluation tools for processes**, such as HazOp, FMEA, DMAIC, APS, HACCP, 8D, ANOVA and others. The new version of the ISO-9001:2000 is a standard hybrid one which contains two approaches: its General Criteria (4.1) requires the identification and analysis of the processes and the rest of their contents including requirements for controlling the system following “criteria for control per activity”.

In the design of the Basic Guide general criteria (4.1) of the ISO 9001 : 2000 were used. The application of the Analytical Approach requires deep knowledge of the processes while the Reglimentary Approach requires greater knowledge and experience in the use of the standards of quality. This is important as far as the use of external consultants in the organization is concerned and has a great influence on the cost of the design of the system.

Basically, it is considered that: “If the detailed analysis of the processes is carried out as well as the necessary preventive measures of control and the work is documented, it is not necessary to comply with the other requirements”.

This third aim “Prevention of potential exposure” is carried out in four stages:

- ❑ Design of a Guide to implement a basic system of quality (Stage in completion)
- ❑ A second stage of diffusion of the Guide through professional associations.
- ❑ A third stage of quantitative evaluation of the results obtained in order to present a report to the health authorities and the Argentine organism of normalization (IRAM)
- ❑ A fourth stage consisting of the formal issuing of the Guide by the normalization organism and the health authorities.

The systems of quality are necessary but not enough to prevent human error arising from lack of motivation and from attitudes of those who have an incorrect perception of the risks, which is why the implementation of the Safety Culture is absolutely necessary. The use of the analytical approach in the design of the system of quality together with the participation of personnel allows the Safety Culture to be encouraged and developed effectively.

#### **4) Some foreseen complementary activities to be carried out within the RPP program.:**

The effective participation of professionals and technicians in the development of the RPP of the patient is a key aspect for its success, which is why the initial awareness work is very important.

It should be pointed out that the Guide of prescription criteria does not cover high complex clinical profiles, which should be resolved appropriately by the prescribing doctor and the doctor responsible for the test.