

The keys for success in the application of Quality Systems in Nuclear Medicine and Radiotherapy

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INTRODUCTION

The main objectives of radiation protection in medical applications are:

- a) **Preventing accidents (potential exposures) and**
- b) **Attaining doses as low as it is reasonably achievable (optimization).**

Both planning and the use of preventive or quality systems are essential in the fulfillment of such objectives. “*Planning*” is definitely required both for prevention and for optimization. Planning implies scheduling the activities to be performed in order to comply with the established goals, through an efficient use of the available resources.

The quality of planning depends on the information available. Anyone planning needs to have, at least, the following information:

- ◆ the possible situations and scenarios during operation;
- ◆ the antecedents of the task to be performed and those related to it;
- ◆ the behavior of all the elements involved in the system, as a result of the tests performed;
- ◆ the errors or failures liable to occur; and
- ◆ what to do in case of deviations and incidents.

Once the sources of error and the eventual causes for the postulated accidents have been established, a **Program of Operating Actions** must be put in place in order to reduce the probability of occurrence of the foreseen failures and errors.

The set of all the operating actions, regulations and activities to be carried out for preventing failures is called **Preventive System** or “**Quality System**”.

This simple and easy-to-apply scheme may lead to significant progress in the implementation of quality systems and to minimizing errors in treatment planning and dose management. This, in turn, can improve results and decrease the complication and relapse rates.

This presentation is aimed at **analyzing the factors favoring an effective implementation of a Quality System**, as well as the factor that may hinder such implementation.

TERMINOLOGY MISUSED

It should be noted that certain confusion has arisen in the terminology used in this field: “Quality Assurance” and “Quality Control” are often erroneously used as synonyms. Additionally, Quality Control is often related only to physical issues and, fundamentally, to the equipment. The presentation of this topic, even in some publications issued by prestigious international agencies, is highly confusing. Quality assurance programs appear as mere lengthy and detailed checking lists of the equipment being used. On the other hand, the “Quality Assurance” contents of the training programs for nuclear medicine and radiotherapy specialists, proposed by such agencies, are very elementary and appear as a part of Quality Control.

The application of Quality Systems in medical practice is not as widespread as it is desirable. The topic—which is so significant for attaining high-quality diagnoses and radiotherapy—is not included in the programs of events for specialists in radiology, nuclear medicine and radiotherapy.

Justification for not applying a quality system takes diverse forms:

- ◆ Quality systems generate excessive paperwork.
- ◆ They are only useful for major facilities.
- ◆ Complying with the regulatory standards is enough.
- ◆ Costly specialists or advisors are required.
- ◆ Quality systems are unnecessary if work is well done.
- ◆ Quality standards do not apply to actual problems, etc., etc.

Criticism arose in some countries where the corresponding regulatory agencies applied the same quality requirements used for nuclear power plants. Part of that criticism is correct, while other is exclusively addressed to designs of Quality Systems that, sometimes, are definitely inappropriate for the actual needs of a given facility.

This indicates that recipes that are good for some may be inadequate for others and this is the root of the problem.

Technological progress in medicine is constant and practice is modified day after day. Therefore, in order to face the various circumstances rapidly and avoid accidents, “dynamic and intelligent” quality systems become essential.

QUALITY SYSTEMS AND QUALITY CONTROL

As defined in the dictionary, a “system” is “a set of elements acting in a coordinated manner to comply with a given function”. Any production organization is a “social-technical system” constituted by elements, such as equipment, machinery, documents, materials, tools used in production (technical elements) and a group of people working in the organization (social elements).

Since failures may originate in any of the elements of the system, whether material or human, preventing failures requires a set of actions to control all the elements in the system and their interrelation.

This set of coordinated actions constitutes the Control System. If is to be controlled, it should then be named “Quality System”. (Quality Assurance is just one Quality System)

As opposed to the above, Quality Control does only involve some of the elements in the social-technical system, such as the condition of the equipment.

This wording confusion is not simply a semantic problem. The use of “quality control” applied exclusively to part of the tasks brings evidence of only “gross errors”, while deviations between the desired therapeutic goal and that actually reached cannot be detected.

Additionally, the absence of quality systems makes it virtually impossible any comparison among the treatment schemes applied in different services and even among different techniques applied in the same service.

EVOLVING FROM QUALITY ASSURANCE TO SAFETY CULTURE

Earlier, quality systems were oriented almost exclusively to the technical issues in the organization. Quality assurance programs involved a careful, methodic and systematic monitoring of every stage –and every element in the production process, verifying the due prevention of any failures in equipment, materials or procedures.

For instance, the training programs were devoted to providing individuals with an improved technical knowledge by providing them with additional and better information. The exams and evaluations performed allowed assessing whether such technical knowledge had been actually gained. This does not refer exclusively to the nuclear industry; usually, both schools and universities apply the same criterion, providing and checking only the acquisition of technical knowledge.

However, the reason for human errors is not only lack of expertise. Individuals can make mistake because they are absent-minded, due to conflicting relations with their supervisor, because they are not motivated or, simply, because they just do not care how well they perform the job.

This means that a due control has always been exerted upon the technical issues in production organizations, while the *human and social aspects* were not focused with the same dedication. Perhaps people thought that this was an organizational issue, which could not be modified through training.

This traditional approach has evolved strongly during the last few decades and, essentially, because of the impact of the Japanese industry’s postwar evolution upon the Western World. Then, new criteria were developed for the management of production organizations. Thus, in addition to technical knowledge, emphasis was made on improving the attitudes, motivation and predisposition of the personnel in an attempt to attain quality and excellence in production.

The key for the success of modern Quality Systems is the stimulation of people, at all levels, motivating them to fulfill the goals of the organization. This modern system for organizational management was named “Total Quality Management” (TQM). In such quality system, the idea of “totality” arises from the facts that, *all the workers must participate and all the production matters must be included in the control system.*

Some Argentine hospitals have also implemented Total Quality Systems and two of them deserved the National Quality Award; however, this was a partial experience and was not extended to all services.

In the nuclear industry, a particularly transcendental event produced a radical change in the way in which quality had been traditionally managed: the Chernobyl accident. The Technical Committee in charge of assessing the causes of the accident established that:

The mere existence of a quality program is not an appropriate guaranty for preventing accidents... even compliance with all the procedures and the application of good practices are not enough if they are carried out mechanically and without conviction. Both the attitudes and motivations of individuals and the

Organization Culture are important. Since then, the latter has been called “SAFETY CULTURE”.

The message was “if we want to apply due control to the whole system, we must not forget some of the elements involved in the same: individuals, their attitudes and their relationship with the tasks they perform”.

This position assumed by the INSAG Committee meant a **paradigmatic change**. Ten years before, another similar reviewing committee, the Kemeni Commission, had stated: “the TMI-2 accident occurred due to failures in complying with the Quality Assurance Program” (!)

Unfortunately, a critical accident had to happen for creating awareness on the importance of this issue; however, on the other hand, this circumstance led to the dissemination of this message, extensively, throughout the nuclear community.

QUALITY ASSURANCE / SAFETY CULTURE: SUPPLEMENTARY CONCEPTS

The application of the safety culture allows completing a quality system with the psychological and social elements that had not been taken into account by the pioneers of quality assurance. Therefore, safety culture involves supplementary elements that cannot be absent from a modern quality system.

The implementation of a quality assurance program must include the necessary elements for stimulating and motivating individuals in the organization and facilitating teamwork. This remark is applicable to both large companies and the simple radiodiagnosis service in a hospital.

Safety culture—which is essential for the success of a quality system—is not easy to verify because it contains some “intangible” elements. The latter cannot be evaluated with the tools usually employed in regulatory inspections or in quality audits. For this reason, regulatory authorities are reluctant to apply requirements whose compliance they will be unable to verify.

Currently, this situation has led to the coexistence of two counteracting attitudes within the nuclear community. On one hand, although with scarce concrete results, the importance of safety culture is being emphasized; on the other, quality systems are implemented without even mentioning safety culture.

Anyhow, without going deeper into this topic (so as to avoid intensifying the polemics), the methodology proposed herewith is aimed at overcoming—in a practical manner—some of the difficulties that may arise.

THE IMPLEMENTATION OF QUALITY SYSTEMS IN HOSPITAL SERVICES

The key for the development of a good quality system is the performance of a detailed analysis of the processes by the personnel responsible for the corresponding tasks. Then, the working conditions and procedures must be established and, finally, the results must be monitored.

Avoiding the use of “foreign recipes”, just because they worked well somewhere else, is highly important. Each facility has its own problems, which are related to its own system and personnel. Consequently, no rules or principles can be extrapolated automatically to another situation with guaranteed success! Besides, the analysis of the process is very constructive among workers and obliges them to think about safety issues.(safety culture)

Below is a brief description of the items considered as highly significant for the successful preparation and implementation of such program.

TEN RECOMMENDATIONS FOR THE ELABORATION OF A QUALITY SYSTEM (OR FOR THE REVIEW OF AN EXISTING ONE)

1. Approaching the task step-by-step and through minor activities

When a project for the elaboration of a quality system is started, the first steps should be devoted to the activities or working processes posing the biggest problems and, therefore, providing greater opportunities for improvement.

Only when results have been obtained with regard to a given task or sector, the evaluation of another area can be started, profiting of the lessons learned and correcting mistakes. Thus, an important impact upon the tasks performed in the service can be prevented. Conflicts between the development of the system and the routine work carried out in the service must be avoided.

The task is performed within a given sector, but the rest of the Service must be informed of what is being done, so that everybody is informed all the time.

2. Participation by all the staff

A successful task depends fundamentally on the participation of all the personnel. There are no exceptions concerning the people who may contribute to the analysis and evaluation tasks, including the auxiliary staff and those in charge of housekeeping.

Participation by all the staff in the evaluation tasks, at the various corresponding levels in each case, is basically aimed at assessing failure risks and the preventive actions for their avoidance or mitigation. However, there are other far more important benefits:

- ◆ Workers get to know and understand the weaknesses involved in the processes and their impact upon safety, as referred to both productivity and quality.
- ◆ Workers learn how to write procedures.
- ◆ Workers are trained in handling calculation tools.
- ◆ Workers learn about the purpose and the importance of safety measures.
- ◆ Workers understand why there is a need for procedures and the degree of detail required in each case.
- ◆ Workers understand why records are important.
- ◆ Workers become aware of the importance of learning and training.

Automatically, workers acquire the sense of ownership concerning the tasks they perform and are motivated to generate initiatives (safety culture)

3. The goals shall always include quality, but also productivity and safety

Success cannot be expected from a quality system that does not include productivity, quality and safety, simultaneously. This is the way to gain support from the patients, from the hospital management and from the regulatory authority.

Quality assurance programs have been very much criticized, among other things, for ignoring the consideration of costs.

During the analysis of a process, the failures affecting each one of the above elements must be detected. For instance, the concrete goals of a radio-diagnosis service must be:

- a high-quality image,
- the lowest possible cost,
- the shortest time required for the examination and
- the lowest possible dose incurred by both the operator and the patient.

4. The analysis of "processes" (principal and secondary)

All the activities performed in a service must be divided and subdivided into major and secondary processes in order to facilitate their analysis and their detailed evaluation. For instance, in a radiotherapy service, the main process can be subdivided into six secondary processes:

- ◆ The patient's identification data (diagnosis, treatment prescribed, reports on previous treatment, traces in the patient, etc.)
- ◆ Assessment of the patient's anatomy (mistakes in defining the irradiation boundaries, positioning of the patient, definition of critical organs, delimitation of inhomogeneities, etc.)
- ◆ Definition of the target volume (shape and location, movement in organs or tissues due to circulation, respiration or patient's movements, etc.)
- ◆ Treatment planning (errors in beam data, algorithms, software and hardware in computerized planning, etc.)
- ◆ Treatment management (errors in the calibration of treatment units, positioning of the patient, erroneous

treatment parameters, etc.)

- ◆ Follow up during a certain period, results obtained, appearance of side effects or sequelae.

In turn, for every “secondary process”, the analysis must include the review of all the elements involved:

- ◆ The **equipment**: diagnosing units, treatment units, measuring instruments, planning and simulation equipment (hardware and software), verification systems and techniques, etc.
- ◆ The **personnel**: number of qualification of the participating physicians, physicists and technicians.
- ◆ The **procedures**: including the specification of tasks and responsibilities, communication among staff members, records, etc.
- ◆ The **materials**: shields, accessories, collimators, consumables, reagents and drugs.

For each task, an assessment must be made of the errors and failures that may occur, of their impact upon results and of the way to avoid them.

(Quality can only be affected by errors and failures. If all the failures in a quality system could be avoided, such quality system would be perfect).

5. Profiting of both internal and external “operating experience”

There are three important sources of information that must be taken into account for accident prevention planning:

- a) A detailed and systematic analysis of the processes—including all the participating elements— aimed at predicting the eventual consequences that may arise from their failure.
- b) The “operating experience” of the facility, including both the failures that caused accidents and those without any consequences. An analysis must be made of the causes of such events and of the actions taken for avoiding reoccurrence. (In order to profit of this source of information, it is important to establish a failure registration and evaluation system).
- c) The analysis of accidents and incidents occurred in other similar facilities, in order to establish whether they are applicable to the facility under study. Radiotherapy is an activity involving major risks and several accidents—some of them with fatal consequences— have occurred. Additionally, the risk of insufficient doses is also a significant risk for radiotherapy patients. Appendix 1 contains a listing of the most common causes of accidents in this field.

Accidents can also occur in nuclear medicine and in radiodiagnosis, although they produce minor consequences due to the magnitude of the radioactivity involved.

6. Preventive, control and mitigation measures

Once the possible sources of failure in each process and the eventual causes of the postulated accidents have been identified, operating measures must be established to prevent or reduce their probability of occurrence or to mitigate their damage.

This is the most important task and the establishment of *simple, effective and economic preventive measures* depends on the experience of the evaluator.

7. "Grading" preventive measures and "defense in depth"

The magnitude of the actions taken for preventing errors and failures shall be commensurate with the impact of such error or failure upon the quality of the results and the doses incurred by the patient and by the operator (grading).

The greater the importance of the damage to be avoided, the greater shall be the magnitude of the preventive measures and the greater the degree of **“defense in depth”**

In order to ensure greater effectiveness in the prevention system to be applied, safety measures are required considering the possibility of a failure in the preventive measures!

This “overpreventive” attitude is called “Defense in Depth Criterion” and involves “foreseeing failures in the measures taken to prevent failures”. Their degree of redundancy shall be proportionate to the magnitude of the risk to be avoided.

8. Discussions within the work team

The preventive measures proposed by an analyst shall be reviewed with the Head of the Service and with all the members of the team. Depending on the subject, consultation may be required with physicians, physicists and auxiliary staff from other units experienced in the process under study.

Discussions on the measures to be taken are also useful in prompting and stimulating teamwork (Safety Culture).

9. Involvement by the hospital's service Management

The process of change begins when the Management considers that the ideas and objectives may be convenient for the organization, that a method can be developed for their application and that the costs involved justify, at least, starting with a small-scale task. Later, after an evaluation of the results, a decision can be made regarding continuity.

Consequently, the Service Head must be involved throughout the work program development process, including the initial motivation of the staff to assume the task, the establishment of the organization's values and the evaluation of the results obtained.

10. The Quality Program and its implementation

The set of preventive, control and mitigation measures established by the work team constitutes the facility's Prevention Program or Quality Program that is to be implemented.

The set can be structured as convenient. Measures can be classified for the various processes, by subject area or following the classical structure of the Quality Assurance Criteria (i.e., those established in the 50-C-Q or ISO-2001 Standards).

Appendix 2 introduces the Prevention Program of a Nuclear Medicine Service that does not follow any pre-established structure.

The implementation of the program can be started on a partial basis, upon completion of the analysis and evaluation of a given process, or after it has been totally completed.

For the final evaluation of a program, comparison with programs applied in other similar services is advisable (**Benchmarking**), as well as an analysis of the reasons for the differences encountered. In addition, reference documents (Rules and Regulations), such as checking lists, can be used to verify the quality of the established program.

Once a quality system has been implemented in a hospital service, it can also be used conveniently, as a "**leading case**", for other services.

After the Quality Program has been implemented, careful attention must be paid to any changes occurring in the service (people, procedures, equipment or materials), which can modify the initial conditions under which the evaluation was performed ("**change analysis**").

CONCLUSIONS

The elaboration or review of a Quality Program through an evaluation of the processes by the personnel involved in the service has proved to be successful and to contribute to the enhancement of Safety Culture.

During the performance of the tasks —and especially in teamwork—, both the professionals and the technicians enhance their specific training, acquire greater involvement in the tasks and become more aware of the weaknesses in the process and of the actual validity of the procedures.

From a regulatory point of view, it is highly important that those responsible for a given practice are the ones who establish the rules, verify their effectiveness and readjust them in accordance with the obtained performance.

Medical practice contains certain issues that involve a series of difficulties. One of them is the interface among the various medical care services and the Hospital's management. As a general rule, this leads to the existence of "blurred responsibility" areas. This situation is yet more conflictive when services are contracted on a temporary basis.

Finally, it must be noted that, in medical applications involving radiation, —both in radiotherapy and in radiodiagnosis— **the Quality of the results depends on the judgment of the physicians** responsible for the diagnosis and for image interpretation. The quality of medical judgment —very important as far as the result of the process is concerned— can be reviewed periodically through the application of a **peer-review** mechanism.

ATTACHMENTS : Appendix 1 and 2

APPENDIX 1

SINGLE FAILURES OCCURRED IN RADIOTHERAPY ACCIDENTS

- Failures in the calibration of the irradiation system.
 - Failures in the alignment of the irradiation equipment.
 - Failures in operators' training that led to a faulty interpretation of the operating parameters.
 - Failures in training on how to face abnormal situations.
 - Computerized systems that were not tested for all the possible operating conditions.
 - Errors in equipment maintenance and control before their startup.
 - Unawareness of failures occurred in other facilities and of their causes.
 - Failures in the assessment of the dose rate, whether superficial or in-depth.
 - Failures in communication between the hospital's physicist and the oncologist.
 - Lack of attention to the equipment operating parameters.
 - Lack of attention to alarm signals and failure indications.
 - Lack of permanent control of the patient's positioning.
 - Failures in the interpretation of the operating parameters.
 - Failures in the elaboration of the procedures.
 - Treatment applied to the wrong patient due to failure in his/her identification.
 - Error in the irradiation of the selected anatomic area.
 - Use of wrong irradiation sources.
 - Brachiotherapy sources stuck in the tubules.
 - Failures in the calculation of radioactive decay.
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DOUBLE FAILURES RESULTING IN RADIOTHERAPY ACCIDENTS (weakening of the "defense in depth")

- Failure in the manufacturer's control + failure in receiving inspection.
 - Wrongly delivered instructions + failure in operator's training.
 - Failure in computerized planning + lack of knowledge on the system by the operator.
 - Failure in treatment planning + failure in the detection of clinical signs of overexposure or underexposure.
 - Failure in the operating procedure + lack of attention in the control of operating parameters.
 - Failure in the operation + lack of supervision.
 - Failure in supervising irradiation + lack of control over the disposal of clothes and wastes.
 - Failure in the equipment + disbelief in protection alarms.
 - Errors in equipment calibration and alignment + errors in dosimetry.
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APPENDIX 2

PREVENTIVE PROGRAMME IN A NUCLEAR MEDICINE SERVICE (TOPICS CLASSIFIED BY SUBJECT AREA IN A NON-CONVENTIONAL MANNER)

- **Qualification and training requirements for professional, technical and auxiliary staff.**
- **Instructions for the service's waste management.**
- **Maintenance manuals of the imaging diagnosis equipment units.**
- **Requirements for the personal in charge of equipment inspection, control and maintenance.**
- **Manual of Working Protocols.**
- **Equipment testing and verification book.**
- **Standards for the control of superficial contamination.**
- **Periodical monitoring plan and routine checking lists.**
- **Instructions for the control during the reception of radiopharmaceuticals.**
- **Book for the inventory of reagents and drugs.**
- **Registration of patients and tests performed (computerized).**
- **Regulations for personnel monitoring.**
- **Plan for intercalibration of radiodiagnosis equipment.**
- **Book / Register of sources and calibration patterns.**
- **Listing of technical publications for permanent consultation.**
- **Book for the registration of failures and minor errors.**
- **News log book.**
- **Instructions for emergencies both in the service and outside.**

Note: The use of the expression "Preventive Program" instead of "Quality Program" in hospitals involves a cultural connotation, as well as a strategic approach. In the medical environment, lack of quality can be criticized, but "lack of prevention" is unacceptable. Nevertheless, obviously, the important issue is not the name given to the program but its contents.

(h) Applications of nuclear medicine in thyroid, liver, gastro-intestinal tract, kidneys, heart, lungs, brain and bones, in tumour imaging and in infections: " Anatomy, physiology and typical patient presentation" cannot even justify broad courses that encompass radiotherapy. This makes it difficult for a physicist who may be working alone in an institution to gain the necessary experience by working alongside nuclear medicine technologists. There are no established guidelines for training in nuclear medicine physics. In the case of other professionals, the IAEA provides mechanisms for vocational. 2.4.7. Suggested syllabus for the training of medical physicists in nuclear medicine. (a).