Sustainable quality systems for every Health Service

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Abstract: The implementation of a Quality system is an indispensable requirement to assure the protection and the radiological safety, especially in those facilities where the potential risks are important. One of the "general conclusions" of the Conference of Malaga (to achieve the RPP) is also the implementation of quality systems.
Lamentably the great majority of the Services of Health in the world, more than 95 %, has not nowadays any formal quality system but only any elements what can be named a " natural quality system " that includes protocols of work, records of several processes, certified of training of the personnel and diverse practices that are realized in systematic form but that not always are documented.
Most health services do not have the necessary means available to adhere quickly to international standards.
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 the public hospitals.
The scenario described represents a challenge for the Regulatory 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?"
Due to these circumstances a "Basic Guide" has developed for the implementation of a quality system in every Health Service that takes the elements as a foundation of the standard ISO - 9000:2000 and the standard for systems management GSR-3 of the IAEA.
The criteria and the methodologies are showed in the presentation.

KEYWORDS: quality systems; protection of patients; quality standards.

The current situation of health services

Implementing a quality management system (QMS) is a prerequisite for ensuring the protection and radiological safety, particularly in those facilities where the potential radiological risks are important.
The recommendations of the Congress of Malaga on Radiological Protection of Patient also included as the basic requirement to have an integrated QMS to other management systems.
The vast majority of Health Services in the world, over 95% do not currently have any formal QMS.
In general in the Health Services exist some elements of what can be termed a " natural quality system " that includes some protocols, records of certain processes, programs upgrade staff skills and various practices that are conducted in a systematic manner but which are not always properly documented.
Moreover these health services are not trained or qualified personnel to carry out a project for certification and accreditation on QMS and many do not have the resources to hire an outside advice, particularly the Public Hospitals.
The regulatory authorities can not require certification against a standard of quality because the costs involved can not be faced by all of the facilities.
A decrease in the level of the requirements or vagueness of them can affect the quality of health benefits is therefore not advisable.
The scenario described is complex but very real and represents a major challenge for all the regulatory authorities that must work in a coordinated manner.
The challenge for regulatory authorities is: how do we ensure that facilities meet an acceptable standard of quality without demanding an budget effort out of their reach? In other words: how to design a sustainable quality standard?
At this point it is important to the alternative choice in terms of standard of quality and their approach.

Regulatory approach and Analytical Approach

The methodologies used in the design of QMS can be grouped into two categories: a traditional regulatory approach, and another more modern, the analytical approach.

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The regulatory approach is the implementation of all requirements of a given standard without necessarily proceed to a preliminary analysis of the processes themselves.
The criteria are linked to control elements or activities in an organization or productive activity and to each element is assigned a control criterion
The first quality standards were designed with an argument similar to the following:

1. Throughout company performed a series of activities to produce a product
2. Each of these activities can be a source of mistakes and detours
3. We need to monitor each individual activity to control all the organization.
4. We must establish control measures for each of these activities.

This will set all the criteria of quality such as design, supply, management of documents, records, materials management, organization, measuring instruments, non-conformity, and so on. Besides establishing a criterion for determining overall control periodically to control specific criteria are actually applied in each of the organization's activities through audits or self assessments.

What are the weaknesses of the regulatory approach? The criteria for controlling the various activities are based on experience and as the first standards were developed by the manufacturing industry of great importance the criteria were designed to respond to the particularities of this organizational structure and its specific problems and therefore its application in the areas of services was conditional.
While every organization is engaged comparable activities (purchases, tests, records, etc.). The relative importance, complexity and relevance of them is totally different
The regulatory approach was introduced in the 60's, particularly in the United States and some European countries using a set of national standards for quality assurance which did not differ mostly in their philosophy although the definition of activities had different scope and nuances.

The more complete and mature expression of the regulatory approach is ISO-9000 versions in 1987 and 1994, which contains 20 control criteria for the same amount of activities in an organization. To contemplate the implementation of the standard organizations that do not perform certain activities, the standard is presented in three levels (9001/2/3) of which only the first level includes all activities and hence all the control criteria .
To facilitate the implementation of ISO-9000: 94 to the Health Services were designed other standards that changed the terminology or the language but not the basic structure of the standard so that the changes were only cosmetic. For instance changed the concept of customer by the patient.
The inappropriate use of these standards in various health organizations led to the design of quality systems inefficient.
The application of this approach in health services was always a difficult task because the specific activities of a Hospital are therefore very different from those of manufacturing industries and it is generally required the involvement of engineers for advice doctors in designing procedures.

Characteristics of some health services with the regulatory approach (ISO Certificates 9001:94)
The Regulatory Authority carried out regulatory inspections to certificates Health services and found evidence of an excellent management of non specific processes to the health service, such as air conditioning, elevators and fire prevention and excessive zeal in elements associated with comfort during the patient stay in the service, such as coffee service, the projection of videos, furnishing comfort, elegance of health, decoration, colour and quality of aprons used by patients for conducting studies, administrative management, to admit the patient, and so on.

Instead major faults were detected in matters relating to the conduct of diagnostic processes or radiotherapy, upgrade staff skills and control devices for monitoring and measurement.
It was noted the following diversions:

- Frequency of testing equipment very low regard for recommended values
- Radiation monitor without the calibration.
- Radioactive sources without the shield
- Lack of updated register of sources movement.
- Lack of procedures in very important processes (eg, for brachytherapy)

If we analyse the causes of the imbalance between the control processes and conduct some critical support processes and control of the administrative processes of the service can be determined that there are two important factors:
The misuse of the concept of client / patient that defines the requirements.
The system design management counselling by professionals who are unaware of the essence of the services of health care.
The conceptual mistake that does not apply quality management to the realization of medical practices.

The misuse of the concept of client / patient:

a) The term "customer" was developed in activities where their meaning and significance is obvious: the buyer of a car, a pen, a refrigerator or a hamburger has all the knowledge and skill necessary to determine the attributes that may require or demand product.
   These attributes are evaluated by the customer with the simple use of their senses. Customer satisfaction is the primary value of the product. The customer dissatisfaction and product disables defines not quality. There is another element of value that he can compare.
b) However in the case of a health service the situation is totally different. The patient is not always qualified to evaluate all the characteristics of quality of service that he receives and generally focuses on attributes related to interpersonal relationships, comfort, and others not directly related to the scientific-technical quality of service received…
c) Neither the prescribing physician (the doctor that perform the prescription) has the qualification to assess the quality of the service but just a perception of the quality of results. Working conditions, the alignment of equipment and diagnostic devices can only be evaluated on the spot during the process and retrospective and quality of service depends on these operating conditions.
d) No entity that provides social security cover or have the financial facts needed to evaluate the quality of provision unless it decides to conduct a technical audit appropriate, but overall objectives and interests are different.
e) In the end this situation stems from an extrapolation of incorrect concepts and approaches that may be appropriate for an activity but should not be extended to other scenarios and situations without a prior assessment of the circumstances.
f) Hence, it is essential to emphasize used as input for the design of a QMS assessing the present and future needs of customers-users and potential rather than their expectations.
g) In cases where direct client is not always adequately qualified, it is necessary to have a defender of the rights of the patient and prescribing physician and should be resorted to the figure of the Competent Authority appointed precisely to protect the interests of population and represent him in the role of control that otherwise can not be done.
h) If the concept of authority was taken into account by business certification is likely that some deviations observed in certificates health services had not been produced.

The design of management system for professionals who do not come from the Health System: The GSC of a health service should be designed by a professional with a thorough understanding of the processes and detailed medical diagnosis and treatment. Otherwise the GSC will have weaknesses in the essential processes that determine the quality of medical service. Experience shows that when the design is done by other professionals overturn the emphasis on control and verification of administrative processes and neglecting support processes essential realization.

The Analytical Approach ***(Management processes with a systemic approach)***

Over time the needs of various other organizations prompted the emergence of a number of methodologies that all share a common analytical approach heavily in the design of preventive actions.
The analytical approach is based on detailed analysis of production processes themselves to identify the causes of failures and detours in order to prevent them, which are used various tools and methodologies work of greater or lesser complexity.
The analytical approach has been developed primarily for identifying root causes and resolving problems in specific productive organizations and are not comparable to other activities. Such is the case of chemical industries, food, nuclear power plants, armaments, the Automotive industry, etc..

Instead of defining activities they start from the processes that are unique to each organization. The processes may include some general activities but not all activities are part of all processes.
Examples of methodologies based on the use of assessment tools systematic processes are as follows:

- **HazOP**: (Identification of risks and operational problems in Chemical Plant). This methodology is investigating the detours that may arise in business processes using a multidisciplinary team of experts that analyzes in detail the causes and consequences that may occur in the operational parameters for each node of the plant in order to devise preventive measures necessary.
- **FME:** (Technical Analysis Modes of failure and its consequences originally developed for some military activities in the MIL-STD-1629) This methodology identifies the purpose of a trial and then sequentially modes of failures, its consequences, the severity of damage, mitigation actions that followed, root causes, its probability of occurrence and detection and defines certain values that enable quantify the risk to design the necessary preventive actions.
- **DMAIC**: (Methodology for improving the performance systems used in Six Sigma, both for production processes such as administrative or commercial) is a model that uses statistical tools to dramatically improve the efficiency of a process chosen. It clearly defines a process that is liable to be improved to get all the data the same, statistically analyze the information, redesigning the process and control the new results in a cycle of continuous improvement.
- **PSA:** (Security Analysis probabilistic used for risk analysis of Nuclear Power Plants) very elaborate technique that begins with the identification of all "events start" of any kind which could lead to an accident, the development of trees events that link the events start with the accidental scenarios, quantifying the probability of occurrence using fault trees and the final estimate of the probability of an accident is usually determined that the merger of the reactor core.
- **HACCP** (Method of risk analysis and critical control points which is used in the food industry) technique that analyzes the potential risks of all kinds related to the development of a food and points of the production process where control can be more effective to establish control measures and limits on the parameters of process needed to prevent risks.
- **ISO-9001:2000 (General Criteria):**The general criteria (4.1)of ISO-9001:2000 applies the analytical approach.

  The Standard requires:
  a) identify the processes.
  b) determine the sequence and interaction of these processes,
  c) determine the criteria to ensure that control processes are effective,
  d) ensuring the availability of resources for the operation and process control
  e) and then measure and track.

  While there is no clear recommendation to conduct an analysis of the processes it is essential to determine control criteria.

  The rest of the standard reduces the regulatory approach to management processes, strengthens the role of leader and an increased emphasis on the processes of monitoring and measurement and appropriate use of data as well as continuous improvement and taking corrective actions and preventive over its predecessor version 94
- **Standard IAEA - GS-R3** (for the Control of management practices and nuclear radiation): The requirements of this rule are similar to those of ISO 9001:2000 but provides much more clearly the need to analyse and assess the processes for identifying risks and how to prevent them ... and then, it is the best standard for our purposes.

In fact all these methodologies and / or analytical tools are quite comparable and complementary as they have sole objective discover the root causes for designing preventive measures with tools that are sequential, iterative, systematic and statistics generally.
The methodological differences are due to the nature of the risks involved and the different scenarios that determine different goals. If the risks are different the tools are as well.

Regulatory advantage of analytical approach: When an organization is limited to meet a specific standard issued by the Regulatory Authority is somehow delegating responsibility to risk assessment and decide on preventive measures necessary in itself Regulatory Authority ...

On the other hand, implementing a QMS, according to analytical approach, for example according to the requirements of ISO-9001: 2000, or the Standard IAEA - GS-R3 oblige the organization to identify processes and their interaction design methods (procedures) for effective monitoring and implementing the actions necessary to achieve results and improve continuously.
This means that the organization took out his responsibility and Regulatory Authority operates in the background, reviewing control measures, which is in the interest of safety practice and hence on the quality of people's lives and the confidence inside and outside the health organization regarding its ability to meet as planned.

Staff participation in the design of QMS (creation of a Safety Culture)
The involvement of employees at all levels is critical to the success of a programme of quality management because it helps to establish the Culture of Security.
The analysis process is very educational as it suggests the problem of security. This issue is particularly important, for example in the Interventional Radiology where techniques are used increasingly by specialists from various branches of medicine without any prior training in Radiobiology or Radiation.

During the task of analyzing the processes are obtained the following advantages:

- There are weaknesses in processes and their impact on the quality, safety and productivity. (is aware of the implication of errors)
- It is understood what is the importance of procedures and the degree of detail required.
- It understands the importance of records and the necessity of learning and retraining.
- It automatically acquires "ownership" in carrying out this task, which motivates to generate initiatives towards improving the quality **(Safety Culture)**
- The discussion of measures taken to stimulate "teamwork" **(Safety Culture)**

The Perception of Risk is not the same in all people and their attitude towards prevention may be different and this is important for security.
This difference may relate to:

- The probability of occurrence of an event according to the trust that is taken into the working hypotheses
- The consequences of an event on our health
- The influence of our proceed in security.
- The effectiveness of the procedures, etc..

If the perception of risk is different, different is how to act before an accidental event.
If we do not have clear conscience about the way in which our actions may affect the security we can not take measures to prevent accidents. It is not enough to know that there is a risk we must know its actual size, that form is related to the activities we do, and what is the effectiveness of preventive measures and procedures.
That depends on the attitude and behavior to the completion of a procedure to prevent determined.

Each Medical Service has a particular problem that depends on its staff, its resources and hospital infrastructure, so it is desirable to use all its capabilities to design the quality management system that is more appropriate to their own circumstances.
When carrying out this task, and especially on teamwork, professionals, technicians and assistants improve their specific training, acquire greater commitment to the task and made aware of the weaknesses of the processes and the real importance of complying with the procedures . (Safety Culture)

The simultaneous use of two approaches: the analytical approach and regulatory approach:
The new version of ISO-9001: 2000 can be considered a standard hybrid that contains the two approaches: its General Criteria (4.1) respect the analytical approach as well as distribution and content of many paragraphs (Ex: Monitoring and 8.2.3 measurement processes). and instead there are other criteria that includes traditional and follows a regulatory approach to control all elements of the system following the "criteria of control activity" (Ex: Control of documents (4.2.3) and records (4.2. 4).
Of course it is possible to use the two approaches in a complementary manner in the design of quality management system.

It should emphasize that if based on an analysis of the processes are taking all precautionary measures and the methodology is properly documented, is met with the requirements laid down any rules by reference.

The application of analytical approach requires a thorough knowledge of the processes while the regulatory approach requires greater knowledge and experience in the use of quality standards. This is important with regard to the use of external consultants to the organization and therefore has implications for the cost of system design.

The QMS of a health service should be designed by professionals with a thorough understanding of the processes and detailed medical diagnosis and treatment. If required tutoring or professional external advice it is necessary that should meet the mentioned qualification.

Annex - Example of Regulatory GUIDELINES

Regulatory Guidelines for the implementation of a Quality Management System

The Guide proposal is based on the analytical approach and use of the general criteria of the ISO 9000:2000 series of standards and criteria of the GS-R-3 which increases the simplicity of regulatory requirements without affecting the achievement of the quality objectives.

To get the Spanish version including the complete Regulatory Guidelines please send a mail to: rodolfotouzet@gmail.com