The practical implementation of Safety Culture

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Abstract. When, during the review of the Chernobyl accident, the INSAG Committee introduced the term “Safety Culture”, the latter was rapidly widespread. Later on, as a result of activities sponsored by the IAEA, the original Safety Culture concept was extended to include a large number of issues that are typical requirements of a Quality Assurance Program and, thus, the understanding and application of the term became more difficult.

Unfortunately, the way in which certain organizations approached this topic has not contributed to find the appropriate actions for its implementation.

Safety Culture is not mentioned at all in ICRP-60, even if the significance of its attributes is acknowledged in a few paragraphs (p. 233 and 247).

The IAEA’s Basic Safety Standards deal with the requirements for Safety Culture and for Quality Assurance as absolutely individual issues; however, Safety Culture should be considered as a part of the Quality System.

The EURATOM 97/43 Directive, used in the European Community for preparation of regulations for medical practice, although inspired in ICRP-73, does not even mention Safety Culture; however, it reads (Art. 11) that: “The main emphasis in accident prevention should be on the equipment and procedures in radiotherapy... Working instructions and written protocols and quality assurance programmes are of particular relevance for this purpose.” This deserves the following reflection: accidents have occurred when the procedures applied were correct and the equipment was operating properly; however, inadequate actions were taken. INSAG-4 reads: “procedures and good practices are not sufficient if applied mechanically…”

Increasing personnel training is not enough if, at the same time, there are no activities aimed at enhancing their attitude towards quality and safety.

Risk perception is not the same among all of us and, therefore, our attitudes towards prevention can be different: there are different perceptions concerning the probability of occurrence of a given event, the consequences of an event upon our health, the influence of our performance upon safety, the effectiveness of procedures, etc.

If risks are perceived differently, the ways in which we will react in case of an accidental event will also be different and they will have an influence upon our attitudes and behaviours towards compliance with a given prevention procedure…

The following scheme are used in this paper to explain Safety Culture Implementation:

1. Analysis of the original Safety Culture concept (Social-Technical Systems)
2. The relationship between Risk Perception and Safety Culture
3. The role of Safety Culture within a Quality System
4. The original reasons for the introduction of the Safety Culture concept
5. Its definition and the exaggerated encompassing framework assigned to it lately
6. A parallel with the current situation in the conventional industry
7. The practical difficulties faced by regulatory authorities in its assessment
8. Its particular importance in the medical applications of radiation
9. Strategies for the practical application of Safety Culture
10. How can we stimulate personnel participation and motivation
1. Analysis of the original Safety Culture concept (Social-Technical Systems)

Safety Culture is a quality or attribute applied to production organizations and, therefore, it is convenient to analyze what is the structure of an organization. Production organizations are composed by two elements of a very different nature, which cannot be managed in the same way:

♦ Elements that we can label as "technological", such as equipment, premises, documents, materials and tools used for production; and,

♦ The persons composing the organization, which we can label as "the human or social element". "Human" because it involves people and "social" because it involves the behaviour or the way in which people interact and communicate with each other.

Therefore, the most appropriate name for it is a "Social-Technical System" in which failures and errors can originate in any of its two constituents, which must be controlled jointly.

It must be noted that, in their beginnings, Quality Systems were oriented almost exclusively to the technical issues of the organizations.

By means of the Quality Assurance programs, a careful, methodical and systematic monitoring was performed for each one of the stages and elements in the production process, checking that prevention was duly applied to any failures in equipment units, materials or procedures.

With regard to the second element, the social component, the training programmes were exclusively aimed at improving the individuals' technical knowledge and at providing them with further and better information, while the examinations and evaluations carried out allowed to assess whether they had, indeed, acquired the technical knowledge required for the performance of their tasks.

**However, human errors do not occur only due to lack of knowledge.** Individuals may incur in errors because they are absent-minded, because they have a conflict with their supervisor, because they are not motivated or because it just does not suit them to work well on that very day.

Even if with goodwill and predisposed to perform a task, individuals' attitudes may be conditioned by emotional and psychological factors affecting their capabilities for prevention or detection of failures.

Serge Prêtre stated: "Men are amphibious beings who live simultaneously in two worlds: the arid world of facts and the sea of symbols. Actually, facts should prevail over symbols; however, often, the opposite occurs". [1]

On the other hand, in addition to individual work by people, teamwork is required through cooperation among the various sectors in the organization. Teamwork will be more or less efficient depending on the human relationship and communication existing among the people involved in the team.

People's attitudes and motivations are influenced by the conditions of the physical and social environment in which they performed their activities that, in turn, can be modified by the group of people itself and, especially, by the management.

It is worth mentioning that the technical issues of production organizations have always been better controlled than the human and social issues; the latter have not been considered in their full extent. Perhaps, people thought that this was not an issue to be dealt with in the labour environment or in a production enterprise. Anyhow, undoubtedly, the control and attention to technological issues is far simpler, easier to attain and less compromising than improving the social issues in an organization.

Whichever the reason for this situation, it is a fact that the safety of a facility cannot be guaranteed by appealing only to the quality of the equipment and to the technical knowledge of people; there is the additional the need to look after the quality of the social ensemble of the people involved and of
interaction among them. This need, intrinsic in our human condition, is valid in a nuclear power plant and in a modest radiodiagnosis service.

The origin of the "Safety Culture" concept can only be explained through this type of analysis and is the logical consequence of the failures experienced in looking after the above-mentioned issues.

2. The relationship between Risk Perception and Safety Culture

Even when all the technical issues are well under control and the training is correct, a single inadequate attitude can bring along an error involving the failure of the prevention system. Therefore, increasing personnel training is not enough if, simultaneously, no activities are performed to improve their attitude towards quality and safety.

Risk perception is not the same in all individuals and, consequently, their attitudes towards prevention can be different.
- There may be a different perception concerning the probability of occurrence of an event, depending on the individual's confidence on the working hypotheses.
- There may be a different perception concerning the consequences of an event upon our health.
- There may be a different perception concerning the influence of our performance on safety.
- There may be a different perception concerning the effectiveness of the procedures, etc.

If the perception of risk is different, the way of reacting before an accidental event will also be different. If we are not fully aware of the way in which our actions can affect safety, we will not be able to take the necessary actions to prevent accidents. Knowing about the existence of a risk is not enough; we must know its actual magnitude, how the risk is related to the activities we perform and which is the effectiveness of the applicable preventive measures and procedures. All of these factors have an influence upon our attitude and behaviour concerning compliance with a given prevention procedure.

Another important issue is the perception of the working environment in which the person is involved because the organization's culture has an influence upon an individual's culture. When everybody has a positive attitude with regard to responsibility and prevention, this attitude will probably be transmitted to an individual in a rational or unconscious way. Somehow, individual attitudes depend on the collective culture in the organization and, thus, rules, behaviours and habits are gradually acquired either by a friendly nature or by esprit de corps. If an individual observes that his/her colleagues work carelessly or do not comply with the established rules, his/her risk perception will be of a lower magnitude; contrarily, if his/her colleagues are cautious in the performance of their tasks, his/her risk perception can increase.

Risk perception is both rational and subjective and, even if basically resulting from one's own experience, to a greater or lesser extent, it can be influenced by the culture and the values prevailing in the organization where the individual performs his/her duties.

The person responsible for the safety of a facility must identify and evaluate the personnel's risk perception in order to minimize the subjective elements and attain a level of perception that is strongly bound to reality.

Additionally, the existence of labour conflicts within the organization has proved to be the cause for attitudes and behaviours adverse to safety, such as showing discomfort before a situation undesired or considered unfair. For instance, if a person feels that the rules of the organization are not fair or that supervisors are not competent, he or she might not follow the procedures because, in his/her opinion, they are unfair or because he/she has no confidence in their effectiveness.

Then, three levels of knowledge and attitude towards risk can be defined:
1. Awareness of the existence of risk.
2. Awareness of how one's own activities influence the control and prevention of risks.
3. Acceptance and acknowledgment of the importance of complying with the established rules for risk prevention.

The person responsible for safety must evaluate which is the personnel's awareness and attitude towards risk and, consequently, take the necessary measures using the training, motivation and personnel involvement tools in accordance with the prevailing situation. An important issue is the participation of all the personnel, to the extent of their possibilities, in the preparation of the procedures for risk prevention.

3. The role of Safety Culture within a Quality System

The structures of Quality Systems are highly variable and depend on the characteristics of each organization. Nevertheless, there are three activities shared by all Quality Management systems:

1. **Quality Planning**: which involves fixing the quality objectives and defining the production or service-rendering processes and the resources to be used.

2. **Quality Control**: a fundamental activity, including all the tasks aimed at complying with the quality requirements.

3. **Quality Assurance**: involving all the actions aimed at making customers confident of the fact that there is compliance with all the requirements, primarily by establishing a Documentation System used as a proof and "objective evidence" of the quality activities performed within the organization (Formal Quality).

Some modern Quality Management systems do also include activities for **Quality Improvement** aimed at a continuous improvement of the organization's capacity to comply with all the established requirements (effectiveness of the organization) and to attain economy in the resources being used, thus attaining the objectives with the least possible effort (efficiency). This policy does not only lead to fulfilling the Quality goals but also to do so for a lower cost and in a shorter time. [2]

What is the role of Safety Culture in a Quality System?

Undoubtedly, the qualities and attributes of Safety Culture contribute towards making people, and the organization as a whole, act with greater effectiveness and efficiency, thus improving their performance in reaching the objectives, which, in our case, are those aimed at enhancing safety.

Attributes such as "a sense of responsibility", "being cautious" or "having a watchful attitude" are human qualities that, evidently, allow to improve the organization's efficiency and, certainly, to reduce the probability of occurrence of failures and accidents... Focused with this particular approach, Safety Culture represents a valuable tool in making quality systems both effective and efficient, and this is fundamental in the facilities and circumstances in which safety is an invaluable requirement.

4. The original reasons for the introduction of the Safety Culture concept

In the '70s, most nuclear power plants in operation had implemented Quality Assurance Programmes for the control of their activities. There was the understanding that Quality Systems were essential for the safety of the facilities and Regulatory Authorities demanded their implementation as a necessary requirement for obtaining the Construction or Operation Licenses.

As a significant record, it can be noted that, when the Three Mile Island accident occurred in March 1979, the Kemeny Commission, appointed by the Government of the United States to study the problem, reached the conclusion that:
"one of the main causes of the accident was the lack of an adequate implementation of the Quality Assurance Program"

The Quality Assurance / safety relationship was established in a very clear and conclusive way...

A few years later, the Chernobyl accident occurred and, as in the previous case, a Review Committee was created and integrated by experts who had to determine the causes of the accident. In this case, the response from the Safety Committee (INSAG), regarding the quality systems, was as follows: "The mere existence of a Quality Assurance Programme is not an adequate guarantee in preventing accidents and even the compliance with all the procedures and good practices is not enough if they are performed mechanically and without conviction..." and that "the main cause of the event was the lack of an appropriate 'Safety Culture'."

The INSAG message was very clear and stressed the remarkable importance of the individuals' attitudes and motivations in the good performance of any tasks performed, although primarily in so far as safety is concerned. [3]

5. Its definition and the exaggerated encompassing framework assigned to it lately

The INSAG defined Safety Culture as follows:

Safety Culture is a set of characteristics and attitudes of an organization and the individuals involved, establishing as first priority that the activities performed will deserve special attention in accordance with their importance concerning Nuclear Safety.

Considering the particular features of the new concept, which could give way to subjectivities, some controversies arose concerning its interpretation and, consequently, the INSAG issued a second and far bigger document, where the scope and the practical application of Safety Culture were explained in greater detail. [4]

Additionally, the IAEA organized several technical meetings to discuss its meaning and applications and, later on, created an advisory and support team that prepared a "Manual for the application and assessment of Safety Culture", called "ASCOT Guidelines" [5], which was profuse in examples and is widely diffused in the nuclear community.

As a result of this multiplier process, the initial Safety Culture concept was broadened to include a large number of issues related to Safety that are not only referred to individual attitudes but also to the regular activities in a Quality Assurance Programme, such as:

- Establishment of training programmes
- Compliance with the established procedures
- Definition of responsibilities for each one of the individuals within an Organization
- Establishment of clear authority lines
- Performance of periodical reviews of the working documents
- Etc., etc.

Naturally, all the original and specific elements of Safety Culture, labelled as "intangible qualities", were maintained, including:

- acting with utmost caution,
- keep a watchful attitude,
- apply sound judgment,
- be fully aware.

As a result of this broader scope, most of the activities performed are related to Safety Culture and, therefore, its implementation demands highly diverse skills and capacities. Any activity that is not performed adequately can affect safety; however, each activity has its own and distinctive features and requires particular handling in order to avoid failures and deviations.
On one hand, scientific, technological and applied engineering knowledge is required and, on the other, knowledge is required on humanistic sciences, such as sociology, labour relations, social psychology and training of human resources.

Establishing criteria and working methods that can be applied to all the hierarchical strata and to all the issues involved in Safety Culture is a hard task. Therefore, for convenience, the problem can be divided into a group of elements that can be managed more easily by specialists, in order to attain effectiveness.

6. A parallel with the current situation in the conventional industry

In the conventional industry, Quality Assurance Programmes had experienced a certain discredit due to failures in their application, i.e.,

a) Almost always, a large number of documents were generated, often unnecessarily, without taking into account people's capacity to read them.

b) More emphasis was placed on the inspections and reviews of the documents than in quality incorporation to the product (further increases in control were considered to be always a good measure for improving quality).

c) Difficulties in evaluation of efficiency were encountered in the Quality Assurance Programme and, thus, the continuous improvement and review process, which was one of the requirements of the Programme, were hindered.

The traditional approach to Quality Assurance has evolved strongly during the last few decades, fundamentally as a result of the impact produced in the western world by the post-war Japanese industry. It was then that new criteria arose for the management of production organizations and, in addition to technical knowledge, emphasis was made on improving people's attitudes, motivations and predisposition towards attaining quality and excellence in production.

Precisely, the key of the success in the modern quality systems results from stimulating people, at all levels, in order to motivate them to attain the organization's objectives. These modern systems for the management of organizations were collectively named as "Total Quality Management" or "TQM".

The Total Quality systems are based on a principle establishing that the greatest efficiency in an organization is attained when all the personnel, without exceptions, participates actively in attaining the established quality and productivity goals. The participation of the personnel is stimulated by the organization, where a working environment is generated considering that people constitute the fundamental value in attaining quality. The participation of the personnel is evaluated periodically and is acknowledged by the management by means of appropriate stimuli. This philosophy is equivalent to the intrinsic criteria of Safety Culture originally developed by the INSAG, looking forward to improving people's attitudes and positive approach, avoiding the compliance with orders and requirements in a mechanical manner and without conviction.

7. The practical difficulties faced by regulatory authorities in its assessment

The Culture of an Organization is defined as the set of ideas, habits, thoughts, beliefs and other non-written rules that people share and use in making their decisions. Individual attitudes are influenced by the culture of the organization, the latter creating rules that are incorporated by individuals.

Risk perception depends on the personal experience and on the influence exerted by the labour or social environment.

The INSAG defined Safety Culture as a set of "intangible elements" of a subjective nature that, nevertheless, result in tangible signs and results. Influencing the culture of an organization implies, above all, an ethical responsibility. It is a complex task that requires diverse non-conventional
capabilities. A Safety Culture assessment cannot be made by means of a conventional audit or regulatory inspection.

The appearance of this new concept implies that the regulator will be faced to non-traditional scenarios and situations, obliged to make decisions that cannot be based on previous experiences and required to apply other criteria and other evaluation methods.

Definitely, Safety Culture has been an important challenge for regulatory agencies that, although convinced of its importance, are unable to find the suitable mechanisms for imposing its application...

"There is no point in issuing a standard or a regulatory requirement whose compliance cannot be verified by means of a conventional evaluation and which cannot result in an objective evidence demonstrating its compliance, as it occurs in an audit."

An exactly identical situation arises when the Quality Assurance systems are compared with Total Quality systems or TQM. While the former include Requirements and Standards that can be audited and certified, the latter do only contain "Recommendations" that are not auditable or certifiable and, therefore, compliance with the same remains to the users' judgment. Examples of this statement are the "requirements" in the ISO 9001 Standard (Quality Assurance) and the "recommendations" in the ISO 9004 Standard (Total Quality).

8. Its particular importance in the medical applications of radiation

Safety Culture is not mentioned specifically in some documents related to Radiological Protection or to the prevention of accidents in medical applications of radiation.

The ICRP-60 contains hardly any clear reference to Quality Systems, while Safety Culture is not mentioned specifically, although some expressions appear that can be interpreted as references to this topic.

In the chapter dealing with the implementation of the recommendations, among the requirements for management, there is a quite explicit reference (p. 247), when it reads: "a safety-based attitude must be fostered among all those involved in the operation" and, further on, "what can be attained through training and the acknowledgment that safety is an individual responsibility and an issue concerning the top management". In its section dealing with responsibilities and authority (p. 233), there is a clear statement reading that "the procedures, instructions and other administrative requirements are not enough to attain a good radiological protection level, everybody must consider safety as a daily task to be performed". This is quite similar to the expressions used by the INSAG.

The ICRP-73 refers explicitly to Safety Culture (p. 123), when reading that "procedures and instructions are very important but not enough to attain an adequate safety standard if the attitudes known as Safety Culture cannot be introduced in the personnel". There is also a statement indicating that Safety Culture is very important and that it must be maintained permanently by means of concrete actions carried out by the Management.

Draft 10 of the ICRP, prepared for "The prevention of Accidents in Radiotherapy", does not mention the issue of Safety Culture.

The IAEA's Basic Safety Standards (BSS-115), in its chapter referred to practices, deals with three sets of requirements referred to Safety Culture, Quality Assurance and Human Factors. It does not include any requirements aimed at fostering or stimulating the personnel's participation or involvement; however, it establishes concrete requirements for training in diverse technological areas.

The EURATOM 97/43 Directive, used by the countries of the European Community in the preparation of their regulations for medical practices, although inspired in the ICRP-73, does not mention Safety
Culture. Contrarily, in its Art. 11, it reads that "in the prevention of accidents, utmost attention shall be paid to the equipment and procedures and that, to this end, the written instructions and protocols are particularly important".

The reflection to be made is that several accidents have occurred while the correct procedures were being used and the equipment units were operating properly; however, inadequate actions were carried out. In the accident occurred in the United States in 1992 with a High Dose Rate Brachytherapy unit, in which one patient died and several people were overexposed, the source got loose and remained inside the patient,..., the three attending technicians noticed the sound and light alarm generated by the radiation detector inside the treatment room, but they assumed that the instrument was malfunctioning and did not perform any verification...

There are many other examples of this attitude involving the assumption of false alarms. In the accident occurred at the University Clinical Hospital of Zaragoza, the last barrier for the detection of the problem was the energy indicator in the unit's command panel, which was operating correctly; however, the abnormal value indicated was attributed to a malfunctioning of the monitor.

A lot of good work is being done in the development of Training Programs for medical practice and there is really plenty of bibliography available. However, training is not enough to avoid all sorts of accidents. Many accidents have occurred and "were not due to the lack of experience but to an excess of experience, resulting from excessive confidence and, consequently, to a loosening of the safety measures.

9. Strategies for the practical application of Safety Culture

Any new concept or cultural change to be introduced requires a methodology supporting it and allowing to its implementation... otherwise, Safety Culture will be only a simple expression of desire or a good humanistic message full of good intentions, but without any possibilities for success.

Safety Culture, as described in INSAG-4, involves a set of attributes that can be clearly split into two sub-groups:
1) The attributes involved in a Quality Assurance System
2) The specific and characteristic attributes of Safety Culture affecting people's attitudes and behaviours.

Some examples of the first group of attributes are:
- To comply with the established procedures
- To define the responsibilities of each individual within the Organization
- To establish Training Programs

In order to consider all of these attributes, a Quality Management System must be implemented. A model that can be used is the international ISO 9000 Standard in its 2000 version.

Some examples of the second group of attributes are:
- acting with utmost caution,
- keep a watchful attitude,
- apply sound judgment,

In order to consider this second group of attributes, which are "specific and characteristic" of Safety Culture, the personnel's involvement and development must be stimulated and promoted in order to attain a positive attitude towards safety and facilitate team work. A model that can be used by the management can be found in the Recommendations of ISO 9004 Standard, in its version 2000, and, particularly, the recommendations under item 6.2 referred to personnel training and involvement.

An organization can attain greater efficiency when the personnel participate in the fulfilment of the safety, quality and productivity objectives. For this purpose, the personnel's participation is stimulated
by the organization, evaluated periodically and acknowledged by the management by means of appropriate stimuli.

The personnel participates in the whole process:
• in the initial tasks for motivating the personnel in this subject,
• in the establishment of the organization's values
• and in the preparation of the situational diagnosis,
• and of the working methods towards change,
• and in the execution of concrete activities for improvement and the evaluation of results.

10. How can we stimulate personnel participation and motivation?

The top management must do with the appropriate tools for stimulating and prompting the personnel's motivation towards the quality and safety objectives.

Some elements contributing to stimulate the personnel's participation and involvement are the following (extracted from Kaoru Ishikawa's book):
♦ Having a possibility for promotion within the organization.
♦ Receiving stimuli and acknowledgment for the tasks performed.
♦ Being informed of what is happening and of what is being written.
♦ Being fully aware of their responsibilities.
♦ Being qualified for their tasks.
♦ Working in an environment of confidence.
♦ Participating in the formulation of objectives.

The most relevant document to be used as a guide to improve personnel involvement and participation is the new ISO 9004 Standard in its 2000 version. Also applicable are the criteria established for the National Quality Prizes, which are very similar to each other. Examples are the criteria for the Deming Prize in Japan, the Malcolm Baldridge Prize in the USA or the National Quality Prize in Argentina. [6]

The new ISO 9004 Standard, version 2000, contains a series of recommendations suitable for personnel implication, awareness and training, particularly in its items 6.2.1 and 6.2.2.


It must be kept in mind that the Quality Assurance Standards were prompted by the needs in the large-sized manufacturing industries and, consequently, the criteria established were originally designed as a response to the activities in such organizational model. Although comparable activities are performed in all organizations (purchasing, tests, records, etc.), their relative importance, complexity or relevance can be extremely different and require a different approach. The previous version of the ISO-9001 Standard, which is still in force, contains 20 pre-established criteria or rules and responds to the described model.

For this reason, the extrapolation of such Standards for their application to health-care services has always been a difficult task because they are not adaptable to their needs and require external advice in order to generate a large number of formal documents. This is why they have lost some prestige and some health-care service managers state that "Quality Programmes are unnecessary when a job is well done" or "complying with the Regulatory Standards is good enough".

The new 2000 version of the ISO-9000 Standard represents a radical change in the philosophy and the methodology to be used, because the approach is primarily based on the analysis of the processes of the facility itself and, therefore, it suits exactly the specific features of the facility. Besides, any the Criteria and Rules contained in the Standard can be excluded at the user's judgment when they are
not applicable or when irrelevant. Consequently, it becomes a customized tool for the activities being performed.

**Participation of the personnel in the preparation of the Programme**

The participation of the personnel, at all levels, is essential for the success of a quality management programme, precisely because it contributes to the set-up of safety culture. The process of analysis is a good training tool because it prompts people to think about the safety issue. This topic is particularly important, for instance, in interventionist radiology, where the techniques are more and more often used by specialists in other branches of medicine who have no prior training in Radiobiology or Radiological Protection.

The following advantages arise during the analysis of the processes:

- The weaknesses of the processes and their impact upon quality, safety and productivity are identified (awareness on the implication of errors).
- The importance of the procedures and of the required degree of details is understood.
- The importance of records and the need for training are assumed.
- Automatically, the "sense of membership" is acquired during the performance of the tasks, which motivates the generation of initiatives for quality improvement (Safety Culture).
- The discussions on the measures to be taken stimulate "team work" (Safety Culture).

Every medical service has its own particular problems, depending on their personnel, resources and health-care infrastructure. Therefore, all their capabilities should be conveniently used in the design of the most appropriate Quality System for the individual circumstances.

During the development of this tasks, and especially through team work, the professionals, technicians and officers improve their specific training, assume a greater commitment with their tasks and become aware of the weaknesses of the processes and of the actual importance of complying with the procedures. (Safety culture...)

**References**

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