Assessment and promotion of safety culture in medical practices using sources of ionizing radiation: the Cuban experience.

Rubén Ferro Fernández *, Alba Guillén Campos and Alma Arnau Fernández

National Center for Nuclear Safety, 28 No. 504, Miramar, La Habana, Cuba

Abstract. The lessons learned from several radiological accidents in medical and industrial practices using sources of ionizing radiation show that a fragile safety culture in the organizations and human error were the most important contributors to such events. The high contribution of human factors to safety in the radiotherapy treatment process have been also revealed by the results of a recent study, a Probabilistic Safety Assessment to this process conducted in the framework of the Extra-budgetary Programme on Nuclear and Radiological Safety in Iberian-America. However no significant actions are noticed around the world to investigate and develop methods and techniques to assess and promote a strong safety culture in those practices, unlike other sectors such as nuclear power, chemical, commercial aviation and oil industries. The Cuban Nuclear Regulatory Authority has under way a National Program for Promotion and Assessment of Safety Culture in organizations using sources of ionizing radiation. As part of this program, during 2007, a pilot study was carried out. Two Radiotherapy and Nuclear Medicine Units were chosen for this pilot study, where managers and specialists were interviewed, a safety culture survey was executed and a final report was prepared with several recommendations both for Regulators in designing their regulatory strategy on safety culture for medical practices and for users to increase their level of safety culture. This paper describes the methodology used to organize, prepare, execute and report the results, findings and recommendations of this kind of review, the benefits and main difficulties found during this endeavor and the perspective and suggestions that, in opinion of the authors, are important to be taken into account in the field of radiological safety culture in the near future.

KEYWORDS: Safety Culture, Radiotherapy, Cuban experience

1. Introduction.

The lessons learned from several radiological accidents in medical and industrial practices using sources of ionizing radiation show that a fragile safety culture in the organizations and human error were the most important contributors to such events. The high contribution of human factors to safety in the radiotherapy treatment process have been also revealed by the results of a recent study, a Probabilistic Safety Assessment to this process conducted in the framework of the Extra-budgetary Programme on Nuclear and Radiological Safety in Iberian-America [1]. However no significant actions are noticed around the world to investigate and develop methods and techniques to assess and promote a strong safety culture in those practices, unlike other sectors such as nuclear power, chemical, commercial aviation and oil industries.

The Cuban Nuclear Regulatory Authority has in course a National Program for Promotion and Assessment of Safety Culture in organizations using sources of ionizing radiation. As part of this program, during 2007, a pilot study was carried out. Two Radiotherapy and Nuclear Medicine Units were chosen for this pilot study, where managers and specialists were interviewed, a safety culture survey was executed and a final report was prepared with several recommendations for Regulators in designing their regulatory strategy on safety culture for medical practices and for users to increase their safety culture level. The following sections describe the methodology used to organize, prepare, execute and report the results, the main findings and recommendations of this kind of review, the benefits and main difficulties found during this endeavor and the perspective and suggestions that, in opinion of the authors, are important to be taken into account in the field of radiological safety culture in the near future.

2. Radiological safety culture.

The first step in the organization of the safety culture assessment was to establish what radiological safety culture means. The assessment team brought the proper definition established in the Cuban regulation “Radiological Basic Safety Standards” issued in 2002 as a Joint Resolution by the Ministry

* Presenting author, E-mail: ferro@orasen.co.cu
for Science, Technology and Environment (CITMA) and the Ministry for Public Health (MINSAP), which states:

*Safety Culture is the assembly of characteristics and attitudes in organizations and individuals, that work with sources of ionizing radiation, which establishes that, as an overriding priority, protection and safety issues receive the attention warranted by their significance.* [2]

Inside this definition the terms *protection* and *safety* were considered as established in the Basic Safety Standards [3] issued by International Atomic Energy Agency (IAEA) as follows:

*The protection of people against exposure to ionizing radiation or radioactive substances and the safety of radiation sources, including the means for achieving such protection and safety, such as the various procedures and devices for keeping people’s doses and risks as low as reasonably achievable and below prescribed dose constraints, as well as the means for preventing accidents and for mitigating the consequences of accidents should they occur.*

3. Methodology for the safety culture assessment

Due to the lack of a known methodology for assessing radiological safety culture it was necessary to draft a methodology taking into account: first, the experiences in this field in other sectors like the nuclear power generation, oil industry and; then, the features of the use of sources of ionizing radiation.

3.1 Purpose of the Assessment

To determine the safety culture level in the relevant organizations with medical practices using ionizing radiation, starting from the identification of items called artifacts, espoused values and, basic assumptions in the behavior of individuals and of the whole organization, through the application of several assessment techniques simultaneously, to produce, as a result, several recommendations and suggestions to improve current practices in the facility and achieve a higher level of radiological safety culture.

3.2 Scope of the Assessment

The assessment was applied to two hospitals operating medical practices that involve radiation sources, considering the following:

- The radiological safety culture assessment involved the whole hospital operating radiation services. The main focus was on top level management commitment and leadership.
- The radiological safety culture was assessed in detail in the different radiation services in the hospital, included in the study, i.e. Radiotherapy and Brachytherapy and Nuclear Medicine.
- The assessment included mainly the radiological safety culture of workers with respect to themselves and, in some degree, their radiological safety culture with regard to patients and public.

3.3 Organization of the Assessment

The assessment process was carried out following the scheme showed in Figure 1.

3.3.1 Preparatory phase:

Its purpose is to allow the assessment team to familiarize with the facility to be assessed and with the criteria and approach to be used during the assessment, in accordance with the characteristics of the practices in the facility.

* Presenting author, E-mail: ferro@orasen.co.cu
3.3.2 Execution Phase:

Is the assessment process itself and consists of four steps: application of assessment techniques; information processing; documentation and; feedback to facility management.

3.3.3 Post-assessment phase:

Includes the elaboration of a Final Report of the assessment and, the analysis of the evaluation process itself in order to improve it for future studies.

3.4 Assessment Approach

- Due to the lack of this kind of assessment in the radiological sector, the experiences were considered from other sectors like nuclear power generation; oil industry and; medical care.
- The assessment involved the two main components of safety culture defined by INSAG-4 [4]: the framework created in the organization and the attitudes and responses of the individuals of the organization to that framework.
- The assessment was oriented to find facts related to artifacts, espoused values and basic assumptions in order to obtain a global picture of the safety culture in the organization.
- Knowing in advance that the radiological safety culture is poorly developed in the practices with radiation sources, the assessment focused mainly on items related to management commitment and leadership and, on the elements of the safety management systems, which could highly contribute to the level of the safety culture.
- The results were presented to the facility as recommendations.
- A safety culture scale was applied, experimentally, for future comparisons.

* Presenting author, E-mail: ferro@orasen.co.cu
3.5 Assessment criteria

A total of 39 safety culture characteristics were used, as reported in the literature [5], to relate findings to one of the levels of culture model:

- Artifacts: 29 characteristics
- Espoused values: 5 characteristics
- Basic Assumptions (Beliefs): 5 characteristics

With those findings the level of safety culture at the facility was classified by two criteria:

3.5.1 Organizational maturity:

Reflects the stage of organizational development with regard to how the organization focuses the radiological safety [5]:

- Stage 1: Regulation based
- Stage 2: Goal based
- Stage 3: Continued improvement

These levels were determined by 12 parameters derived from [5].

3.5.2 Safety Culture Level:

Reflects the level of safety culture by other scale based on the safety culture maturity model used by Ashcroft et al. (2005) to develop the Manchester Patient Safety Framework [6]:

- Level 1: Pathological
- Level 2: Reactive
- Level 3: Calculative
- Level 4: Proactive
- Level 5: Generative

These levels were determined by 20 critical parameters for every level.

3.5 Assessment techniques

In order to obtain the information needed for the assessment, several techniques were applied in parallel or separately. Each technique has different contribution to findings from different levels of culture model as shown in the Table 2.

Table 2: Contribution of several assessment techniques to findings of each level of culture model

<table>
<thead>
<tr>
<th>Technique</th>
<th>Contribution</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Artifacts</td>
</tr>
<tr>
<td>Initial meeting with top level management</td>
<td>High</td>
</tr>
<tr>
<td>Facilities walk-around</td>
<td>High</td>
</tr>
<tr>
<td>Facility documentation review</td>
<td>High</td>
</tr>
<tr>
<td>Safety Culture Checklist</td>
<td>High</td>
</tr>
<tr>
<td>Safety culture Survey (questionnaires)</td>
<td>Low</td>
</tr>
<tr>
<td>Interviews</td>
<td>Low</td>
</tr>
</tbody>
</table>

* Presenting author, E-mail: ferro@orasen.co.cu
4 Results of the assessment

The main results of the radiological safety culture assessment of this pilot study are briefly described as follows.

4.1 Main data of consulted sample

Table 3 contains brief information of the sample consulted during the study. In spite of the effort of the assessment team to involve the majority of the personnel of the facilities in this pilot study the results show that the people involved were approximately 60% of the total.

Table 3: Main characteristics of the sample consulted during the assessment.

<table>
<thead>
<tr>
<th>Type of Practice</th>
<th>Medical</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of facilities</td>
<td>2</td>
</tr>
<tr>
<td>Radiation services</td>
<td>Radiotherapy; Brachytherapy; Nuclear Medicine</td>
</tr>
<tr>
<td>Type of personnel</td>
<td>Hospital Top Level Managers</td>
</tr>
<tr>
<td></td>
<td>Managers of Radiation Services</td>
</tr>
<tr>
<td></td>
<td>Professionals and Technical staff of</td>
</tr>
<tr>
<td></td>
<td>radiation services</td>
</tr>
<tr>
<td>Number of visits</td>
<td>6</td>
</tr>
<tr>
<td>Interviews with</td>
<td>2</td>
</tr>
<tr>
<td>Hospital top level manager</td>
<td></td>
</tr>
</tbody>
</table>

Profile of the sample by groups of individuals

<table>
<thead>
<tr>
<th></th>
<th>Potential Sample</th>
<th>Processed sample</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Radiotherapy and</td>
<td>72</td>
<td>41</td>
<td>52,6</td>
</tr>
<tr>
<td>Brachytherapy</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nuclear Medicine</td>
<td>37</td>
<td>18</td>
<td>48,6</td>
</tr>
<tr>
<td>Managers</td>
<td>12</td>
<td>7</td>
<td>58,3</td>
</tr>
<tr>
<td>Total</td>
<td>121</td>
<td>69</td>
<td>57,4</td>
</tr>
</tbody>
</table>

Profile of the sample by specialties

<table>
<thead>
<tr>
<th></th>
<th>Processed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Managers</td>
<td>7</td>
</tr>
<tr>
<td>Physicians*</td>
<td>9</td>
</tr>
<tr>
<td>Medical -Physicist</td>
<td>7</td>
</tr>
<tr>
<td>Dosimetrist</td>
<td>3</td>
</tr>
<tr>
<td>Radiation therapist**</td>
<td>17</td>
</tr>
<tr>
<td>Nuclear medicine technician</td>
<td>12</td>
</tr>
<tr>
<td>Nurse</td>
<td>4</td>
</tr>
<tr>
<td>Technician-Radiopharmacologist</td>
<td>1</td>
</tr>
<tr>
<td>Auxiliary***</td>
<td>1</td>
</tr>
<tr>
<td>Technician****</td>
<td>0</td>
</tr>
<tr>
<td>Not defined</td>
<td>8</td>
</tr>
<tr>
<td>Total</td>
<td>69</td>
</tr>
</tbody>
</table>

4.2 Main radiological safety culture findings

The overall assessment of all the facts and results of the study allowed the assessment team to detect and identify several areas of the facilities that should be improved in order to achieve a higher radiological safety culture level in their daily work. These findings were mainly related to the following items:

* Presenting author, E-mail: ferro@orases.co.cu
Hospital top level management commitment with radiological safety
Visible leadership of the hospital management with regard to radiological safety in their services
Priority of radiological safety with respect to other demands of the Hospital services
Radiological safety policy of the facilities; awareness by personnel
Resources for radiological safety
Regular review of radiological safety status at top level meetings in the facility
Personnel involvement in radiological safety
Informed culture on radiological safety
Reported culture on radiological safety
Organizational learning culture on radiological safety culture
Personnel dosimetry
Patient safety

The findings and results of the study revealed that, at present, these two facilities are at the lowest level of organizational maturity, i.e. at level of regulation based, because the philosophy and policy of radiological safety in both of them are based mainly in achieving radiological safety by merely complying with the applicable regulations. According to the safety culture level, the assessment team allocated these two facilities at a reactive level with very few elements of calculative approach.

5. Main conclusions

- The radiological safety culture at practices using radiation sources could be assessed using such an experience in other sectors with proper and careful adaptations.
- The methodology designed and used in this study should be a starting point for more well-developed and sophisticated tools for the assessment a radiological safety culture in the practices using radiation sources
- Considering the high contribution of; human factors, and especially, of safety culture shortcomings; to the occurrences of radiological events in medical and other radiological practices it is urgent to join effort worldwide to promote and support several initiatives in this topic in the framework of national, regional and international organizations.

6. REFERENCES

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* Presenting author, E-mail: ferro@orasen.co.cu


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* Presenting author, E-mail: ferro@orasen.co.cu