IAEA-TECDOC-1494

Case studies in the application of probabilistic safety assessment techniques to radiation sources

Final report of a coordinated research project
2001–2003

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The originating Section of this publication in the IAEA was:

Radiation and Transport Safety Section
International Atomic Energy Agency
Wagramer Strasse 5
P.O. Box 100
A-1400 Vienna, Austria

CASE STUDIES IN THE APPLICATION OF PROBABILISTIC SAFETY ASSESSMENT TECHNIQUES TO RADIATION SOURCES

IAEA, VIENNA, 2006
IAEA-TECDOC-1494
ISBN 92–0–104206–X
ISSN 1011–4289

Printed by the IAEA in Austria
April 2006

FOREWORD

Radiation sources are used worldwide in many industrial and medical applications. In general, the safety record associated with their use has been very good. However, accidents involving these sources have occasionally resulted in unplanned exposures to individuals. When assessed prospectively, this type of exposure is termed a ‘potential exposure’.

The International Commission on Radiological Protection (ICRP) has recommended the assessment of potential exposures that may result from radiation sources and has suggested that probabilistic safety assessment (PSA) techniques may be used in this process. Also, Paragraph 2.13 of the International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources (BSS) requires that the authorization process for radiation sources include an assessment of all exposures, including potential exposures, which may result from the use of a radiation source.

In light of the ICRP's work described above, and the possibility that PSA techniques could be used in exposure assessments that are required by the BSS, the IAEA initiated a coordinated research project (CRP) to study the benefits and limitations of the application of PSA techniques to radiation sources. The results of this CRP are presented in this publication. It should be noted that these results are based solely on the work performed, and the conclusions drawn, by the research teams involved in this CRP. It is intended that international organizations involved in radiation protection will review the information in this report and will take account of it during the development of guidance and requirements related to the assessment of potential exposures from radiation sources. Also, it is anticipated that the risk insights obtained through the studies will be considered by medical practitioners, facility staff and management, equipment designers, and regulators in their safety management and risk evaluation activities.

A draft version of this report was prepared during the third Research Coordination Meeting of the CRP that was held in Mexico City in May 2003. This draft report was further elaborated by V.N. Dang of the Paul Scherrer Institute, Villigen, Switzerland. The IAEA officer responsible for this publication was E. Reber of the Division of Radiation, Transport and Waste Safety.

EDITORIAL NOTE

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CONTENTS

1. INTRODUCTION

1.1. Background

Probabilistic safety assessment techniques have been applied since the 1970s in the nuclear industry, first to nuclear power plants (NPPs), and then to research reactors. The techniques have also been applied successfully to other potentially hazardous endeavors, such as aerospace applications, oil and chemical industry plants, offshore platforms, and railroad networks. The success of these techniques, expressed as an effective reduction of the risks for the analysed installations as a consequence of these studies, supports their use in a range of domains.

Radiation sources are used throughout the world for a variety of purposes, in industry, medicine, research, and education. As noted in Ref. [1], many are in the form of sealed sources where radioactive materials are permanently sealed in a capsule or closely bonded and in a solid form. The risks posed by these sources and materials vary widely, depending on such factors as the radionuclide, the physical and chemical form, and the activity. Unless breached or leaking, sealed sources present a risk from external radiation exposure only. However, breached or leaking sealed sources, as well as unsealed radioactive materials, may lead to contamination of the environment and the intake of radioactive materials into the human body. Radiation sources also include machine-produced sources of radiation such as linear accelerators used in radiotherapy, diagnostic X ray units and non-medical electron beam irradiators. Radiation emitted by these devices is the primary radiation hazard associated with their use.

In general, facilities that use radiation sources are designed, built and operated according to high safety standards. As a result, the overall safety record of radiation source facilities has proven to be very good. However, sometimes accidents do occur. These episodes are often caused by human errors, but can also occur due to the failure or malfunction of equipment or safety systems, or, more generally, a combination of these elements. When assessed prospectively, exposure to individuals that may result from accidents is termed a 'potential exposure'.[1]

International Commission on Radiological Protection (ICRP) Publication 60 [3] includes, and ICRP Publication 76 [4] further develops, recommendations that dose limits and constraints should be supplemented by risk limits and constraints that take account of a potential exposure assessment and the probability of various types of harm from the resultant dose. ICRP Publication 64 describes a framework with which to judge the acceptability of potential exposures [5]. Examples of the application of this framework to several radiation sources are provided in ICRP Publication 76. In these examples, because of the probabilistic character of the events or sequences of events leading to accidents, probabilistic safety assessment (PSA) techniques were used to analyse scenarios that could cause potential exposures.

Paragraph 2.13 of the International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources (BSS) [2] further requires that the

[1] Potential exposure is defined specifically in the glossary of the International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources (BSS) [2] as an "exposure that is not expected to be delivered with certainty, but that may result from an accident at a source or owing to an event or sequence of events of a probabilistic nature, including equipment failures and operating errors."

authorization process for radiation sources include an assessment of all exposures, including potential exposures, which may result from the use of the source.

In this context, the IAEA initiated a coordinated research project (CRP) to study the benefits and limitations of the application of PSA techniques to radiation sources. PSA permits not only risk estimation, but also may allow for qualitatively identifying the weak points of a certain facility or practice. When quantitative information is available, a PSA yields a ranking of the different contributors to the overall risk. In a broader sense, PSA is a systematic approach to understanding what can go wrong, the consequences of failures, and the likelihood of each event or combination of events will cause an accident.

About safety and security

The studies reported in this publication deal with the **safety** of radiation sources, i.e. the prevention of accidents and the mitigation of accident consequences that will result in the protection of people against exposure to ionizing radiation or radioactive materials. Accidents involving radiation sources are most often caused by equipment failures and/or human and organizational failures at a facility using a source. Two main applications of radiation sources are industrial irradiation and medical applications. In industrial applications, the risks to facility personnel and to the public are of concern. In medical applications, the risks to the patient are the primary concern, in addition to the risks to facility personnel and to the public.

Risks from failures in radiation source **security**, which refers to measures to prevent unauthorized access to, and loss, theft and unauthorized transfer of, radiation sources, are not in the scope of this work.

1.2. Objectives

The overall objective of this report is to present the results and experiences from a CRP on the application of PSA techniques to radiation sources. (It should be noted that this information is based solely on the work performed, and the conclusions drawn, by the research teams involved in this CRP.) In the CRP, PSA techniques were applied by each team to a selected sample of medical and industrial applications of radiation sources.

The aims of this publication are:

- to report on the technical issues, work performed, and main results of the CRP,
- to summarize the major risk insights obtained through this work, highlighting also the strengths and weaknesses of current PSA procedures and processes and the benefits of the use of PSA techniques,
- to provide recommendations as to how PSA may be used by users, manufacturers and regulators of radiation sources to improve the safety of their operation,
- to report on the applicability of PSA techniques, and to provide guidance and recommendations for future safety studies of radiation sources, and
- to present an overview of the studies performed within the framework of the CRP and to present the final reports of the participants.

1.3. Coordinated research project participants and facilities studied

Six countries participated in the CRP: Argentina, Canada, China, Cuba, Mexico, and the United States of America. An overview of the studies performed as part of this CRP is presented in Table 1.

1.4. Structure of this report

This report is structured as follows:

Section 2: Overview of PSA and its techniques. Challenges for the application of these techniques to radiation sources. A graded approach to safety assessment. Value of qualitative techniques for characterization of the risk profile of the facility and the derivation of safety insights.

Section 3: Summary of the major safety insights obtained in this work.

Section 4: Main findings on the application of PSA techniques for characterizing and quantifying the risks related to radiation sources. Recommendations for future applications of PSA techniques. Suggestions for future activities regarding the safety of radiation sources.

Annex I: Synopses of each of the exploratory studies performed as part of the CRP. Description of their scope, overall approaches and techniques used, and main results. Information provided regarding recommendations on the application of PSA techniques to industrial and medical sources.

Table 1. Coordinated Research Project Overview

Country	**Organization**	**Principal investigator**	**Radiation source application studied**	**Facility location**	**Study type**
Argentina	Universidad Nacional de Cuyo	J. H. Báron	Cobalt teletherapy	FUESMAN, Argentina	Process and task analysis, HRA
Canada	MDS Nordion	N/A[a]	Industrial irradiator	N/A	PSA
China	Laboratory of Industrial Hygiene, Ministry of Health	K. Wei	Cobalt teletherapy	China	FMEA, human factors evaluation with relative risk ranking, event tree analysis, fault tree analysis
Cuba	Centro Nacional de Seguridad Nuclear (CNSN)	J.J. Vilaragut Llanes	Cobalt teletherapy	UOPR, Pinar del Rio, Cuba	PSA
Mexico	Comisión Nacional de Seguridad Nuclear y Salvaguadias (CNSNS)	A. Huerta-Bahena[a]	Industrial irradiator	Tepeji del Rio, Mexico	PSA
United States of America	University of Wisconsin, Madison	B. Thomadsen	Brachytherapy	US & International	Human error analysis or reported events, partial-scope PSA

[a] Canada and Mexico worked on a joint study for an irradiator in Mexico. A. Huerta-Bahena of CNSNS was the principal investigator for the study. J. Mardian of MDS Nordion collaborated with the Mexican team and provided technical expertise on industrial irradiators.

2. PROBABILISTIC SAFETY ASSESSMENT FOR RADIATION SOURCES

The aim of this section is to present an overview of PSA techniques and of the procedures for performing a PSA. The methodological challenges for the application of PSA to radiation sources are discussed.

2.1. Risk and probabilistic safety assessment

The term risk is frequently defined as the set of answers to three related questions, for instance in Refs [6], [7], [8]:

(1) What can go wrong?
(2) How likely is it?
(3) What are the consequences?

Usually, the first question is answered by identifying undesired events or conditions that may lead to negative consequences to human life, health, property, or the environment. The second question is answered by developing a model that estimates the probability or frequency of undesired events resulting from failures of components, or human actions or errors. The third question is addressed by assessing the consequences of the undesired events.

The PSA methodological framework is a set of techniques (methods) for systematically answering these questions. PSA permits not only risk estimation, but also helps to qualitatively identify the weak points of a specific facility or practice. When quantitative information is available, the assessment provides a ranking of the various contributors to the overall risk, and in a broader sense, a systematic approach to understanding what can go wrong, the consequences of failures, and the likelihood of each single event, or combination of events, that have the potential to lead to an accident.

2.2. Probabilistic safety assessment techniques

The techniques that are most frequently associated with the PSA framework are event trees for scenario or accident sequence modelling, and fault trees for modelling the contributors to the failure of equipment and systems. These methods can be considered the core of the PSA; however, the PSA 'toolbox' includes other methods and tasks. Some of these techniques may also be used in risk assessments and safety management activities independent of a PSA. Selected techniques are briefly described next.

Process tree analysis. Process trees follow the procedures involved with a process and illustrate the interrelationships between the steps. Process trees help locate critical steps in a process, and when combined with records of failures, highlight where corrective actions should fall.

Fault tree analysis. Fault tree analysis is a deductive technique and graphical representation for analysing the ways in which an undesired outcome may occur. In PSAs, fault trees are used to analyse the failure of a system function (systems analysis). In some cases, fault trees can also be used to analyse the undesired outcome directly. Starting from the undesired outcome or failure, the ways in which this event can occur are listed and systematically decomposed.

Event tree analysis. Event trees are used to analyse and represent the sequences of events leading to an undesired outcome. An event tree is an inductive analysis which starts with an initiating event and moves progressively through the successive responses of the systems and human actions, describing the corresponding results in terms of success (upper path of the branch) or failures (lower path of the branch). Probabilities are assigned to the event tree headings, usually by means of the fault tree analysis. This allows the overall probability of undesired outcomes resulting from the accident sequences to be calculated.

Failure modes and effects analysis (FMEA). At the level of the facility, FMEA may be performed to identify failure scenarios, i.e. potential accident initiators. This is done by systematically reviewing the failure of each system or component in terms of its potential consequences. At the level of individual systems, an FMEA may be useful in identifying failure contributions to be modelled in fault trees.

Task analyses. Task analyses refer to the qualitative analyses performed to characterize personnel actions that may be safety-relevant. A task analysis examines performance requirements and performance conditions including procedures, job aids, and ergonomics with the aim to identify potential errors. Task analysis is performed for actions in routine operations, maintenance and testing. In addition, task analyses may be performed to identify and characterize actions in response to abnormal events. In a PSA framework, task analyses are typically part of human reliability analysis (HRA).

Review of experience. The experience of the facility under study or of similar facilities is reviewed to provide inputs both to the development of PSA accident scenario models and to the reliability data analysis. With regard to accident scenario modelling, the review of experience contributes to the identification of equipment and human failures, and potential scenarios (and classes of scenarios). Information from the analysis and reporting of abnormal events, precursor events, and previous accidents is relevant. Some pertinent techniques *are root cause analysis* and *precursor analyses*.

In support of the development of a reliability database, equipment failure data and the results of periodic testing and post-maintenance testing are relevant. These data can be a very useful input to model quantification if it is systematically collected.

Additional techniques that may be performed in the framework of a PSA range from relatively simple tools used mainly for qualitative analyses (e.g. the Hazard and Operability (HAZOP) technique and 'What-if' analyses) to more elaborate qualitative/quantitative techniques. A variety of techniques may be available for specific elements of the PSA, e.g., human interactions analysis.

Some fundamental references on PSA and its techniques are [9], [10], [11], [12]. The general procedures and specific techniques described are typically oriented to performing PSAs for NPPs. Correspondingly, the guidelines are aimed for large automated plants, with multiple levels of redundant or diversified safety and mitigation features, i.e. defence in depth.[2]

Within the PSA, *quantification* refers to both a) the estimation of probabilities for equipment failures and human actions, as well as to b) the calculation of the expected frequencies of undesired outcomes, which is based on integrating the equipment and human action

[2] Defence in depth refers to the application of more than one protective measure for a given safety objective, such that the objective is achieved even if one of the protective measures fails.

probabilities within the PSA model. For quantification, there exist databases of generic data. For instance, Ref. [13] includes generic component reliability data for PSA applications for research reactors.

PSA techniques can be applied, however, to many facilities other than complex systems with multiple layers of defense and automatic systems. For these facilities, a conventional PSA may not always be the best choice (either because of technical, staffing, data or budgetary reasons). In such cases, individual PSA techniques or various combinations of techniques may be applied.

Even for NPP PSAs, risk evaluations are generally performed starting from rather simple techniques (e.g., FMEA), proceeding to more complex models (e.g., fault trees and event trees), and finally going deeper with specific techniques for specific aspects that have been found to be critical.

2.3. Methodological challenges for the application of probabilistic safety assessment to radiation sources

A number of methodological challenges arise in applying the conventional PSA framework and techniques to assess the safety of radiation sources. A selection of important challenges is discussed in this section.

A large spectrum of undesired outcomes. The potential undesired outcomes associated with the safety of radiation sources in radiation therapy, and industrial applications fall into a large spectrum. These include both radiation exposures to the personnel operating the facility or device and exposures to the public; in the case of medical applications, the undesired outcomes include a variety of accidental medical exposures[3] to patients. For example, the Cuban study considered a broad spectrum of undesired outcomes from the practice of cobalt teletherapy. This study developed probabilities for public exposures (around 1×10^{-10} per year); occupational exposures (around 1×10^{-4} per year); and accidental medical exposures (with "undesired dose to normal tissue" and "unirradiated portion of the target" being the most prevalent). The release of radioactive material inside or outside irradiator facilities is an additional concern that was considered in the Mexican study. In contrast, PSAs for NPP applications focus on a wide range of accident scenarios that lead to a limited number of undesired outcomes (principally, damage to the core or spent fuel); the consequences of accident scenarios to the public and to the environment are then estimated.

For each type of outcome, the PSA framework readily accommodates a range of undesired outcomes. For accidental medical overexposures, for instance, the range of outcomes could be defined from a few percent of the prescribed fractionated dose to multiples of the prescribed dose. Similarly, a range of outcomes for radioactive material releases can be defined in terms of the released quantities. In each case, the aim is to distinguish among accidents with minor,

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[3] Accidental medical exposures are defined in Section II.29 of the BSS [2] as being:

(a) any therapeutic treatment delivered to either the wrong patient or the wrong tissue, or using the wrong pharmaceutical, or with a dose or dose fractionation differing substantially from the values prescribed by the medical practitioner or which may lead to undue acute secondary effects;

(b) any diagnostic exposure substantially greater than intended or resulting in doses repeatedly and substantially exceeding the established guidance levels; or

(c) any equipment failure, accident, error, mishap or other unusual occurrence with the potential for causing a patient exposure significantly different from that intended.

N.B. Accidental medical exposures are sometimes referred to informally as 'misadministrations'.

significant, and severe outcomes and consequences. Since the potential scenario initiators, the accident sequence evolutions, and the availability and reliability of the defences, etc. may differ for each type of undesired outcome; PSAs that address multiple types of outcomes may require a comprehensive set of analyses for each.

Central role of human actions in facility processes. In general, facility equipment is comparatively simple and the degree of automation is low. Therefore, the actions of facility personnel are central to the radiation source applications in the scope of this CRP. In the medical application of radiation sources, for example, normal operations (the treatment of patients) involve a large number of actions by personnel from a variety of disciplines. The clinical radiation therapy process, for example, is complex and involves multiple steps requiring human actions as shown in Figure 1. It should be noted that this flow chart only describes the radiation therapy planning process in terms of the major divisions of work that must be completed, and each of these requires numerous and sometimes complex actions by personnel.

Reliance on human checks and administrative measures. In conjunction with the low degree of automation, the safety of the processes relies to a large degree on human checks and administrative measures.

For example, in the American study, the van der Schaaf Taxonomy (SMART) was used to classify human errors that caused treatment delivery errors in brachytherapy. [14] As seen in Figure 2**,** the dominant failure mode was "Verification failure", followed by "Intervention" (which was scored if someone simply erred).

Large variety of potential accident initiators. Although defence in depth is implemented for the critical human actions of the facility processes and for the main devices, there are nevertheless a large number of potential accident initiators. A number of critical human actions may be covered by self-checking, and their failure can lead directly to undesired outcomes.

2.4. A graded approach to risk evaluation — matching levels of effort and risks

The main goal of a graded approach, as applied to risk evaluation, is that the levels of analysis effort should be proportional to the potential risks. A graded approach is applicable to the overall effort and level of detail, and the allocation of resources within a risk evaluation.

At the overall level, the IAEA criteria for the categorization of radioactive sources may be useful in establishing the upper range of potential consequences [1]. It defines five categories of sources from Category 1, high risk or 'extremely dangerous', to Category 5, 'not dangerous', based on the potential harm to human health that these pose if not managed safely (and securely).[4] For each category, a definition is provided for both individual sources and dispersed radioactive material.

[4] The IAEA categorization of radioactive sources is intended only to support risk-informed decisions related to both the safety and security of **radioactive sources**. Therefore, the categorization scheme is not relevant for **machine-produced sources** of radiation such as X ray machines and particle accelerators.

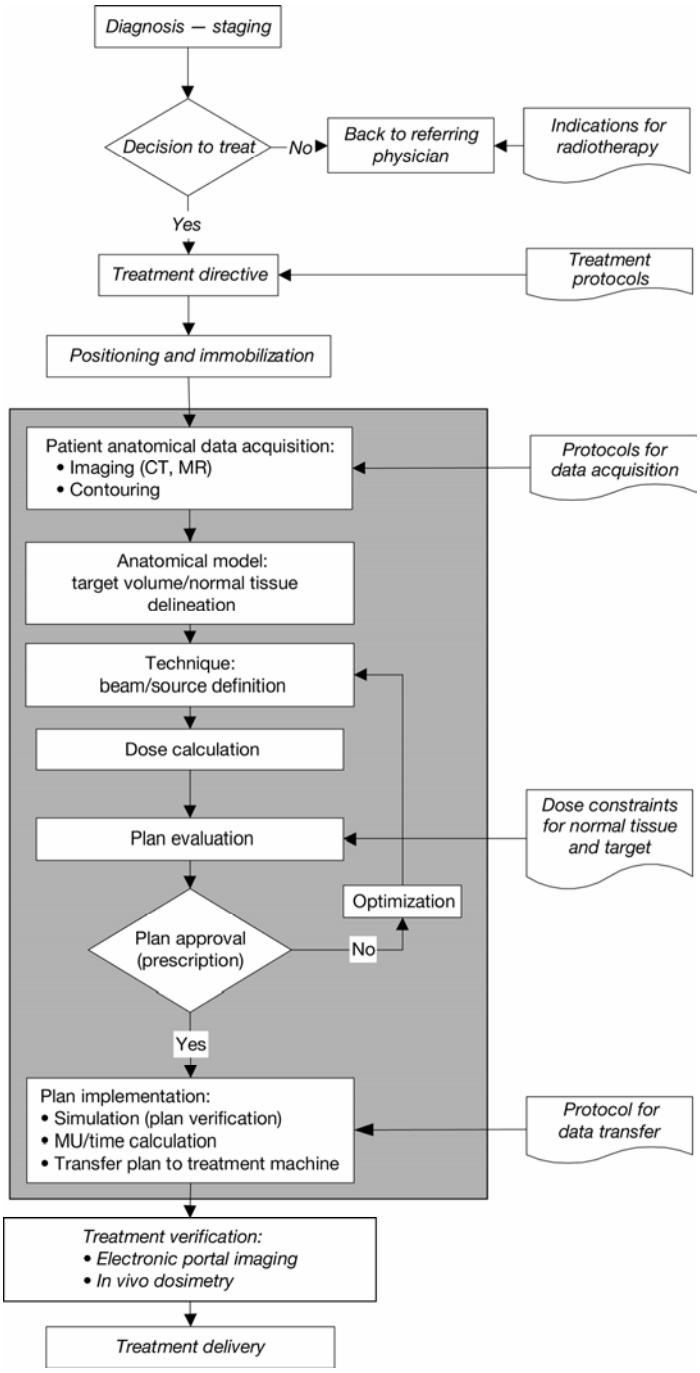

Fig. 1. Steps in the radiation therapy planning process [15].

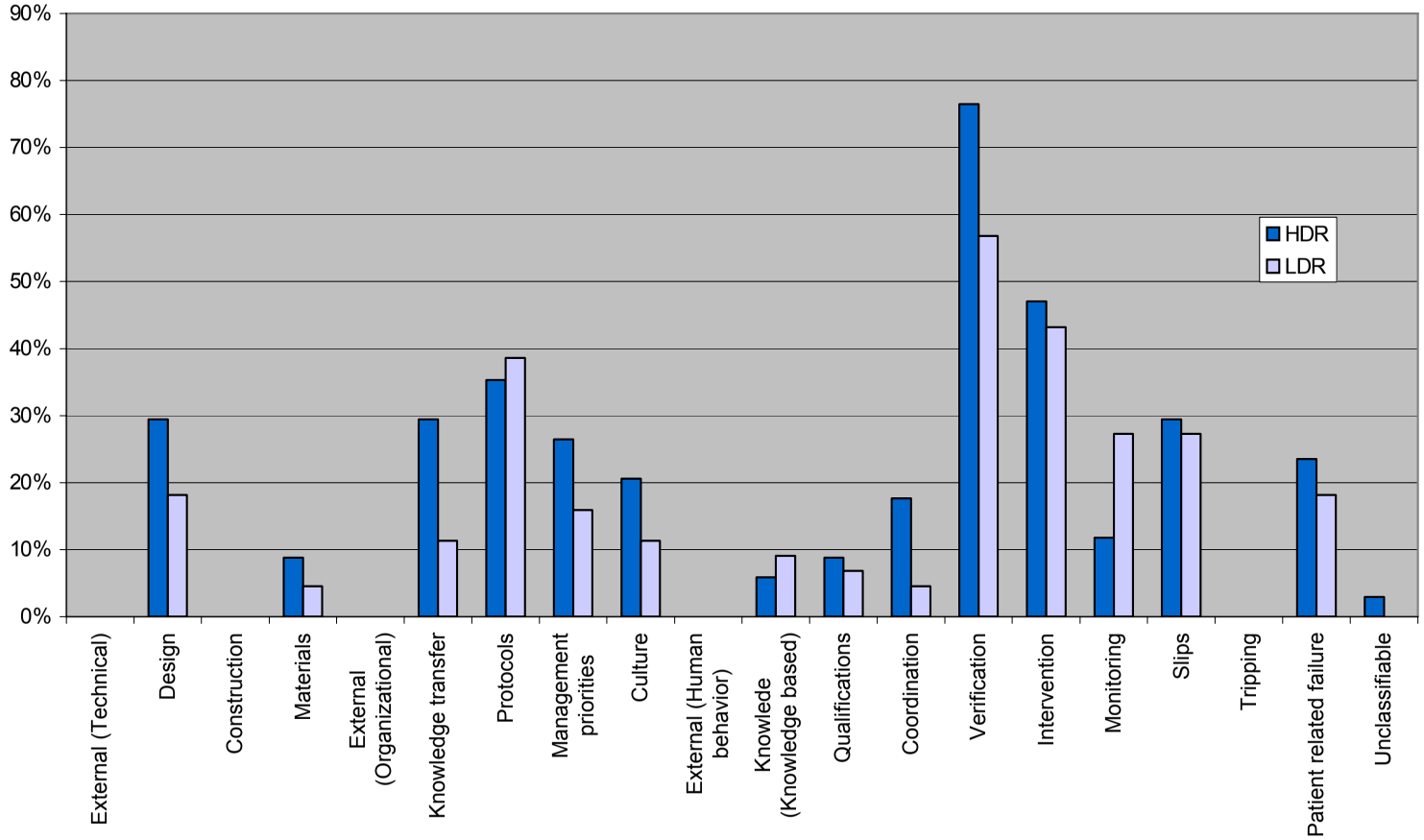

Fig. 2. SMART Human Error Model (Pinball Method) (American Study [14].)

An ‘individual source’ is a radioactive source that can be picked up or otherwise handled, including solids such as metals, ceramics, and sealed containers of powders, liquids, or gases. Radioactive source facilities typically involve (one or more) individual sources.

For practices involving radiation sources with low potential harm, the application of sophisticated or detailed PSA techniques may be too costly. For higher-risk radiation sources, a graded approach can be used to allocate resources within the risk evaluation, in order to make the best use of limited resources and ensure that higher-risk issues are not overlooked. It should be noted that, according to the classification of radioactive source practices presented in Ref. [1], the practices examined in the studies of this CRP involve high-risk sources, i.e. Category 1 for industrial irradiators and cobalt teletherapy, and Category 2 for medium and high dose rate brachytherapy.

For the allocation of resources within a PSA, the elements of a graded approach include:

— a scoping analysis of the facility as a whole, i.e. including equipment, personnel, organization, and also operations such as maintenance, in order to identify the main potential hazards and general scenarios. The use of semi-quantitative methods and coarse estimates may be helpful at this stage;
— the use of the results of this analysis to select the hazards and scenarios to be subjected to more detailed analyses and modelling, ensuring that higher-risk contributors are not overlooked; and
— appropriate emphasis on potentially valuable qualitative analyses. In many cases, these may identify relatively simple measures that can improve the safety of a facility. Especially for facilities without an existing risk evaluation (qualitative or quantitative), modest efforts may identify measures that can reduce risk.

In general, a quantitative risk model should be the objective. In spite of lacking data or uncertainties, the quantitative model can be useful as a tool to integrate the results of qualitative analyses, to evaluate the importance of the identified risks and their contributors, and to assess the effectiveness and potential benefits of safety improvements.

2.5. A variety of facilities

While radiation source facilities present common methodological challenges for the application of PSA, it should be emphasized that the facilities may be different in a number of ways that are safety-relevant. Elements other than the design of the technical equipment affect the risk of individual facilities; moreover, these elements may differ in significant ways among facilities of the same type.

Some of these elements include the organization of the processes, the ergonomics of the tools used in connection with the practice, personnel training, maintenance and testing programs, and administrative and organizational configurations and characteristics. Therefore, risk evaluations of the same model of irradiator in use at different facilities, or the performance of similar radiotherapy practices at different hospitals with different staff and within different organizational and training programs would be expected to yield different results.

The structure of a risk evaluation and the selection of techniques to apply may vary, depending on the objectives of the study, the budgetary and technical constraints, and the availability of the proper information and data.

3. MAIN RISK INSIGHTS OBTAINED AND APPLICATION OF RESULTS

This section highlights the main risk insights obtained in the CRP studies at a more general level. These constitute potential safety issues that may be considered by practitioners, facility staff and management, equipment designers, and regulators in their risk assessment and safety management activities.

The facility- and practice-specific character of PSA results and safety insights obtained in the CRP studies should be emphasized. These are the product of analyses that reflect the organization of processes, facility design (layout, structures, systems, and components), and maintenance and operational practices in a specific facility or practice. In particular, the results concerning the dominant contributors to risk in terms of scenarios, equipment failures, and human tasks, as well as the resulting conclusions for safety management should not be directly used for other facilities and practices.

3.1. Industrial irradiators

This section, which is derived from the results of the Mexican study, provides a list of the major contributors to the risk of undesired outcomes that were identified for industrial irradiators and some suggestions for addressing these issues:

- For the high exposure end state, the most important contributors are various events leading to "stuck source" initiating events and (common cause) failure of the access control interlock relays allowing operator access to high dose areas. For radwaste release, the important contributors include failure of the fault detection relays such as the area monitor and failure of radiation monitors.
- Faults related to inaccurate indicators of the position or movement of radioactive sources figure greatly in initiating events that lead to undesired end states.
- Experience data show that the failure of micro-switches, which positively indicate source rack position, has played a significant safety role. Improvements in the design of the facility studied have reduced the contribution of this failure; for plants with micro-switches of older or other designs, the importance may be much larger.
- Some longer-term scenarios involve the accumulation of radioactive material in the pool sediments and inadequate radiation surveying of the sediments before release.
- Periodic surveillance programs may not detect the failure of some components of safety-related systems, such as access interlocks and area radiation monitors. In the CRP study, the appropriate function of the access interlock system was not assured against some failures. This can occur with systems that are not often used or with failure modes that are not easily detectable.
- The accurate assessment of current plant conditions by irradiator operators after an unusual condition is indicated by safety systems is a potential initiating event for undesired outcomes. One scenario would involve the incorrect interpretation of manually operated radiation survey instruments after a fixed radiation monitor indicates the absence of high radiation levels.
- The specific situations that are (as well as related situations that are not) detectable by an alarm function should be an element of training.
- Because the failure to use, or incorrect use of, various procedures is an important contributor to accidents, procedures need to be reviewed so they efficiently address the most frequent *operational* events and situations in a clear and efficient manner.

— Presentation of the rationale underlying the steps required by a procedure may be a useful element of training. Likewise, feedback on the usability of procedures should be solicited from the facility staff; again, the aim should be to ensure that the procedure helps rather than hinders the operating staff.

3.2. Medical practices

Three of the CRP studies dealt with cobalt teletherapy and one study dealt with brachytherapy. The brachytherapy study provides more general insights because it covers international experience with brachytherapy. As a result, the insights may be applicable to a wide range of medical applications of radiation sources. Unsealed sources such as therapeutic and diagnostic radiopharmaceuticals were not studied in the CRP. And, it should be noted that the application of PSA techniques to these sources could be a more complex task and could characterize negative outcomes that are more complicated than with sealed sources.

As can be expected due to the large component of human actions in medical practices, most of the risk insights relate to human performance. These insights are associated with the treatment process, its quality assurance (control) steps, and the quality assurance of the device and facility. The insights concern:

— the character of significant scenarios,
— human factors as they relate to task, job, and process design, and
— equipment design and ergonomics.

Although many of the resulting insights involve human performance and quality assurance issues, it should be emphasized that the application of PSA techniques was essential in selecting the areas and tasks to examine in the risk evaluation. Many of the insights resulted from qualitative analyses performed in the course of the PSA. The PSA was helpful in:

— modelling the relationships between errors, the defences in place, and the undesired outcomes,
— communicating this model of risk and its contributors to the facility staff, and
— identifying sensitive and critical tasks to review.

3.2.1. Character of scenarios

This section discusses some of the features of the scenarios in medical practices that are important contributors to risk:

— Equipment reliability tended not to be a major factor. However, when involved, it was associated with the more severe consequences. In addition, equipment failures produced environments conducive to human performance failures.
— The experience data were particularly sparse for events involving underexposure and the failure to irradiate the complete target volume. It should be noted that these are probably underreported in experience reports.
— Events tended to happen most in connection with actions with the least time available for their completion.
— There are few defences in place for errors in many of the large number of tasks that are routinely performed in medical practices. As a result, some of these could lead directly

to undesired outcomes. Figure 3, which was adapted from the American study, demonstrates how human errors can lead directly to undesired outcomes. [14]

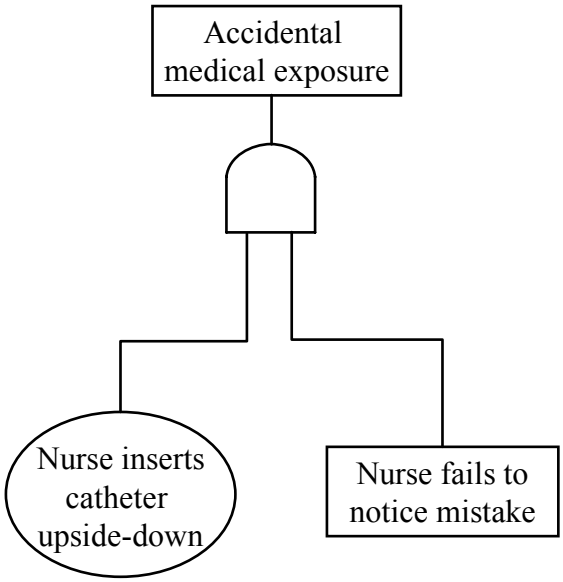

Fig. 3. Fault tree for a typical medical event (adapted from American study [14]).

— Lack of training and procedures covering unusual conditions frequently contributed to events:
  (1) The experienced events often showed many abnormal situations were not detected, often even though many indications pointed to these situations.
  (2) The response to abnormal situations often included actions appropriate for normal conditions, but not for the conditions of the event.
— The coverage of abnormal situations and unusual or unexpected events in the training program should be examined. The training should address both the detection of these situations as well as the response to these situations. Risk evaluations and the PSA model may be a useful input to this training.

3.2.2. Human factors, and task, job and process design

Job and process design play an important role in accident scenarios:

— Staff workloads need to be managed carefully in the process design, considering not only a routine workload, but also periods of high workloads. To reduce the impact of high workloads on risk:
  o Staffing for independent control and verification tasks should be assured, even for peak workloads.

- Day-to-day scheduling should allow for unexpected increases in workload. High workload periods should be identified and the process design should allow the attention to safety issues to be increased during these periods.
- Technology such as computerized aids may provide some solutions to reduce workload. However, these may introduce new failure modes that need to be assessed in a risk evaluation.

— Communication among staff members, especially between disciplines, was an important issue. Some training addressing the work performed by other disciplines may help to identify potential problems.

— A substantial amount of data that varies from patient to patient must be dealt with repetitively by the staff:
  - Job and process design should aim to avoid potential interruptions.
  - Workplace design and physical layout should avoid distracting factors.

— Quality assurance programs should cover the comprehensive radiotherapy process.

— For critical tasks, independent checks should be considered in addition to self-checking. For example, as seen in Figure 4, the results from the Cuban study indicated that error probability may be reduced by a factor of 40 through the implementation of redundant checks of tasks related to the physical planning of cobalt teletherapy treatments. Process models and PSA may be helpful in identifying tasks that should be checked (and to some degree, in evaluating the potential risk reduction). Checks that have a 'keyhole' function, i.e., those that may detect a wide variety of preceding errors, deserve particular attention. In addition, the process design should consider the potential to rely excessively on the correctness of previous checks.

— The effectiveness of verification procedures (when properly carried out) can be an issue.

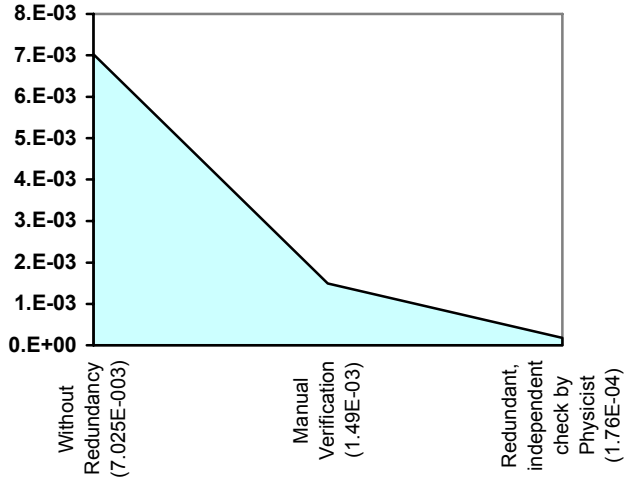

Fig. 4. Effect of redundant checks on error probability in the physical planning of cobalt teletherapy treatments (Cuban study).

— The experience data show that changes in the staff treating a case increases risks. This can occur as a result of staff changes or changes in the patient's schedule (coming on a different day or different time of day). The qualitative analyses suggest that 'special', patient-specific requirements, or changes during the case may not be transmitted to the person, e.g. not documented.

- It is worth noting that, in consultation with the staff, risk reduction may be achieved by (welcomed) changes to the job or process design. However, the addition of new requirements may not have the expected, desired effect on the overall safety of the process. The sensitivity results of the PSA may be useful in evaluating the safety impact of the measures under consideration.
- The Chinese team performed a Task Analysis of initiating events attributed to human error in the cobalt teletherapy treatment process. Tasks were defined as discrete units of opertor behavior or cognitive activity having a discernable starting point, duration and end point. Experts in radition oncology, medical physics, risk assessment and design engineering for cobalt units were requested to qualitatively and quantitatively characterize error probabilities associated with these tasks and their consequences. The Task Analysis resulted in a relative risk profile analysis that provides a basic means for identifying the most likely risk contributors and their relative importance. Figure 5 shows a relative risk ranking for 20 relatively high-risk tasks. The numbers along the abscissa of the figure refer to the numbers assigned to specific tasks. The highest-risk tasks were 2.2 (review of the use of departmental equipment for an unusual situation), 3.5.1 (performance of central axis dose calibration), 9.2.2 (monitor patient on visual TV monitor) and 3.1.2.1 (placement of treatment table, gantry and collimator angle to pre-established standard portion for iso-centrality and output checks).
- Specific results relating to the types of human errors that can occur are provided in Figure 6, which shows the results of a Failure Modes and Effects Analysis that was performed by the the Cuban research team to identify the causes of human errors with significant consequences in cobalt teletherapy treatments.
- An example of specific results from the American research team that used process tree analysis to examine brachytherapy events that occurred between 1980 and 2001 is presented here: [14]
  - For LDR cases where dosimetry followed placement (such as most intracavitary applications), this analysis found the following characteristics for the events:
    - Errors in four steps accounted for 52% of the events:
      - Selection of the sources to place into the applicator,
      - Loading of sources into the applicator,
      - Using the required units when entering data into the computer, and
      - Fixing the sources in the applicator, or applicator in the patient.
    - Most steps in the branches “Source loading,” and many along “Dose/time calculation” and “Treatment termination” had errors.
    - For LDR cases where dosimetry preceded placement (most interstitial implants), errors occurred only in source preparation (usually ordering), and source placement into the implant (usually a failure to monitor the placement closely enough).
    - For HDR brachytherapy, by far the most common step with failure was entering the treatment distance (14 of the 45 evaluable events of this type), usually not changing the default value. However, some events occurred in almost all steps in treatment unit programming and delivery.
    - Dose specification during treatment planning accounted for 5 of the 45 events. The only problems with source strength in the events studied happened when entering the calibration data into the treatment-planning computer.

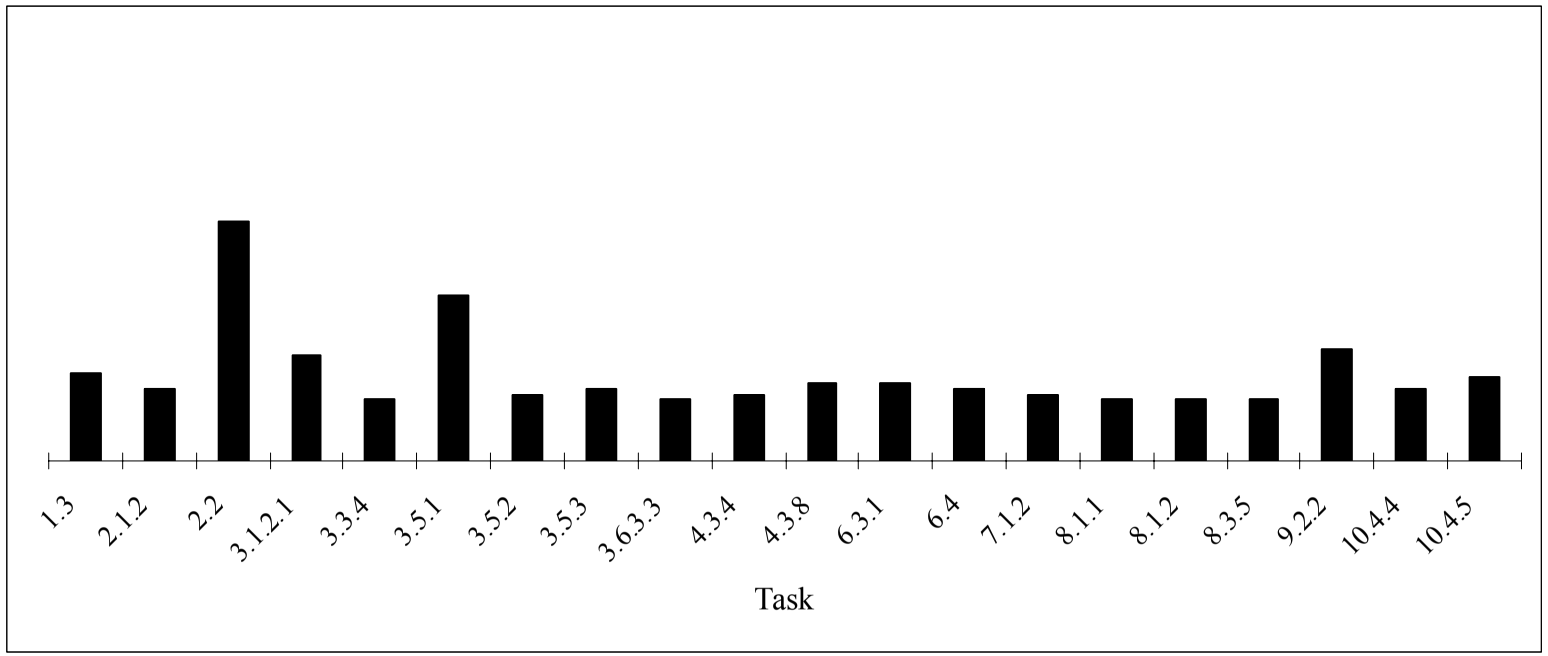

Fig. 5. Relative risk profile for Co-60 teletherapy tasks (Chinese study).

(The numerals along the abscissa are task identification numbers. See text for descriptions.)

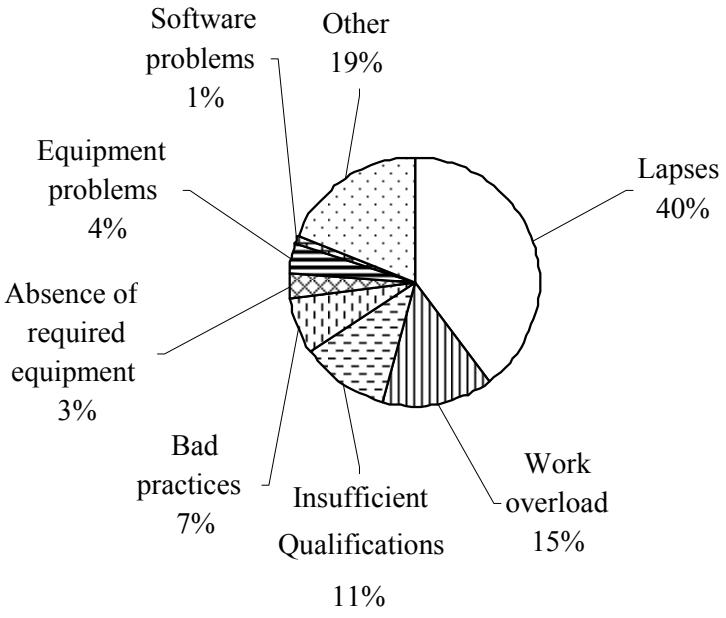

Fig. 6. Main causes of human error in cobalt teletherapy treatments identified through the use of FMEA (Cuban study)

3.2.3. Equipment design and ergonomics

The ergonomics of equipment and related issues contributed to a large fraction of the reported events.

The analysis of brachytherapy experience data showed that equipment design had a large effect on human failures. In general terms, these issues also apply to teletherapy equipment. Equipment manufacturers should pay closer attention to human factors in design:

- Some events attributed to human failures are closely connected to issues with equipment ergonomics. For instance, differences in the norms of operation in equipment produced by different manufacturers may result in manipulation errors.
- The use of the appropriate (measurement) units when entering data, e.g. calibration data, into a computer or piece of equipment contributed to treatment errors. In some cases, this was compounded by differences in the units required for the inputs to different pieces of equipment or displayed by equipment.
- The use of values calculated by software without adequate verification contributed to errors.
- Closer attention to human factors in the design of equipment can significantly reduce risks. Some specific problematic equipment design characteristics include:
  - default settings without verification features,
  - keypads that differ slightly, and subtly, from standard calculator keypads, and
  - formats for data that differ from that normally expected by the user.
- Warnings for parameters outside an expected range may help equipment users identify some errors. In addition, selected values calculated by software should be displayed such that technicians / medical physicists may verify these against their own experience.

— Design features for positioning equipment, templates, blocks, filters, and the like, that will not allow incorrect placements (e.g. upside-down, rotated, etc.) could prevent errors.
— Specific to brachytherapy, the American team found that treatment errors may be caused by devices for loading sources that allow the sources to fall out easily.

In the Chinese study, FMEA was used to identify failure scenarios of cobalt teletherapy units. This led to the identification of potential vulnerabilities in the following safety systems:

— The door information sensor in the door interlock subsystem had a much higher failure probability (1×10^{-4} per demand) than the other components of the subsystem.
— The collimator subsystem was found to be a weakness because of the relatively high failure probability of some of its components (1×10^{-5} per demand); these included the cross-hair indicator, and field size and field rotation sensors.
— Some components of the optical subsystem such as the field lamp, light scale, and laser positioner have a high failure probability (1×10^{-5} per demand) and a high failure consequence.
— Four components of the table lock subsystem including the iso-rotation lock, column rotation lock device, lateral movement lock device and long-movement lock device had high failure probabilities (1×10^{-5} per demand) and high failure consequences.

3.3. Conclusion of the use of risk insights

The general safety insights summarized in this section as well as the specific results presented in Annex I should be regarded as potential issues to consider in safety management, regulation, and risk assessment studies. Due to the differences in practices and facilities, it is likely that the ranking of the issues will differ significantly in another facility. The conclusions and recommendable risk reduction measures will correspondingly differ.

The caution and advice of the brachytherapy study team concerning the use of the results provides a good summary:

> The ‘users’ in brachytherapy include a wide variety of specialists, such as radiation oncologists, medical physicists and nurses. Each specialist has a role in establishing the procedural protocol for treating patients. Every facility performs the procedures slightly differently, so the direct application of the findings from this study, or an analysis at any facility, will have limited application at another. However, the conclusions certainly serve as a warning of hazardous actions or situations that any facility should consider and address. The general conclusions from this study should guide the design of quality management to prevent the propagation of errors that could result in an error in the treatment.

4. GENERAL CONCLUSIONS AND RECOMMENDATIONS

Section 4.1 presents the conclusions from the application of PSA techniques to radiation source facilities. Useful safety insights and recommendations for safety improvements were obtained. A number of difficulties and challenges were experienced. These are summarized together with their implications for PSA applications in the remainder of this section. The

overall assessment of the CRP study teams is presented in Section 4.2. Section 4.3 discusses a number of recommendations for performing future PSA studies for these types of facilities. Finally, some suggestions for future work that will support the performance of PSAs of radiation source facilities and improve their safety are briefly discussed in Section 4.4.

4.1. Conclusions and findings

4.1.1. Probabilistic safety assessment techniques — applicable and useful

The research conducted within the framework of this CRP demonstrated that PSA techniques could be successfully utilized to identify safety concerns at facilities and activities that use radiation sources. At the outset, the challenges for the application of PSA included:

- the large spectrum of undesired outcomes, including unintended exposures of patients at radiotherapy facilities, and of the personnel and public for all facilities,
- low automation and reliance on human checks and administrative measures,
- the dominant share of human tasks in the processes of medical practices and facilities, and
- a large variety of potential accident initiators, resulting from the reliance on human processes and the low degree of automation.

The studies have identified the areas where so-called classical PSA techniques could be applied directly as well as those areas where significant adaptation or supplemental analyses were needed. Despite a number of difficulties experienced by the study teams that are summarized in subsequent sections, PSA techniques proved to be a powerful tool to:

- identify and delineate the events or combination of events that may lead to undesirable end states,
- assess the expected probability of occurrences of such combinations, subject to large uncertainties in the data,
- systematically consider the effectiveness, strengths and weaknesses of the equipment, human, and organizational features of the system as they relate to safety, and
- identify modifications to the facility and its operational and safety management procedures that might lead to improved safety.

The major benefit of PSA is that it provides a consistent and integrated model of facility safety based on information about facility design, operating practices, operating histories, component reliabilities, human behaviour, and health effects. In practice, PSA aims to achieve completeness in defining possible mishaps, deficiencies and facility vulnerabilities, producing a balanced picture of significant safety issues across a broad spectrum.

Many of the difficulties experienced in the exploratory applications of PSA to radiation source facilities arise because the overall PSA approach, the main body of application practice, and the methodological guidance are to a large degree oriented to systems that combine technical complexity and a large degree of automation and redundancy. An additional challenge for the studies was the lack of equipment and human reliability data. The recommendations discussed in Section 4.3 proved to be useful in circumventing or dealing with these difficulties. At the same time, it is worth noting that, as PSA is applied to different types of systems, the techniques of the approach will continue to develop. These difficulties

and challenges will become less problematic as the experience from novel applications of PSA grows and new methods and models adapted to these are created.

4.1.2. Safety insights

All of the CRP studies were successful in obtaining useful safety insights, which were used to evaluate and recommend safety improvement measures. In some cases, the facilities have already implemented these measures, and while this process is in progress at others.

Synopses of each of the studies and their main results are presented in Annex I. The safety insights that are obtained are facility-specific and therefore cannot and should not be transferred directly to other facilities; instead, they identify generic areas of concern or issues.

In Section 3, the major risk insights have been generalized as issues for the practitioners, operating personnel, managers, regulators, and equipment and facility designers to consider in their risk evaluations and other activities.

It is worth noting that many of these insights and recommendations were obtained from the qualitative techniques performed as part of the PSA. In this way, useful results could be obtained despite the lack of data and data uncertainties, which in some cases were significant obstacles to the quantitative analysis.

4.1.3. Challenges for performing probabilistic safety assessment for radiation source facilities

Some challenges with the application of PSA techniques to radiation source facilities include significant difficulties in identifying initiating events and accident scenarios, selecting data on equipment reliability parameters, and modelling human errors. These difficulties resulted from the broad scope of undesired outcomes and the large role of human tasks in the facility processes.

Large number of human tasks in some of the processes. Medical radiotherapy practices are to a large degree human processes. Table 2 provides a list of the tasks and key staff members from various disciplines involved in the treatment of a patient. The Cuban participants in the CRP estimated that the number of routine, directly safety-relevant manual steps, tasks, and subtasks for cobalt teletherapy exceeded 40 000 per year. Some of these tasks are performed many times every day. Similarly, a process tree that follows the entire treatment process for high dose-rate, remotely afterloaded brachytherapy is presented in Figure 7. In this figure, each bough represents a major division of the process. Off each bough are branches representing components of the major divisions. Finally, the leaves on the branches correspond to small functional steps. The numerals indicate the number of events occurring on that leaf. While HRA has always been a part of PSA as applied in NPPs, the human component formed a small factor. In other industries, human factors play a relatively larger role; however, in medical settings, the human component dominates.

Lack of systematically collected experience data. For industrial irradiators as well as medical radiotherapy practices, there is only a limited amount of information on operational and equipment experience. Although more significant accidents have been described in a range of reports, the lack of systematically collected data on incidents, near-misses, as well as on the numbers of successful procedures (e.g. the number of patients treated successfully with a procedure) make a definitive assessment overview of potential issues and scenarios difficult to achieve.

Differences among practices (facilities). Even among facilities using the same medical therapy, e.g. among different cobalt teletherapy facilities, there are differences in the operational procedures, practices, and training. Although PSAs are facility-specific, these differences make it difficult to draw from the generic experience both in selecting the issues emphasized in each study and in building scenario models.

Lack of equipment and human reliability data. Although the databases of generic data compiled for NPPs include some of the component types needed in radiation source PSAs, reliability data are not available for other component types. Also, the available data may not reflect the operating conditions for these facilities.

Human reliability data is an issue for most PSA applications; for radiation source facilities, which have processes involving many frequently performed tasks, the probabilities for omissions estimated by various methods may not be applicable. In part, the difference may arise from recovered vs. raw error rates. The lack of data on human performance specifically for medical settings was a significant hurdle for the studies.

Large expected significance of errors of commission. In PSAs for highly proceduralized and automated systems, the omission of required actions has been the main focus, with errors of commission (EOCs) receiving increasing attention only more recently. The studies found that this incremental approach, starting with omissions primarily and adding EOCs, is unsuited to the scenarios in radiation source facilities. Many omissions are likely to be recovered while EOCs appear to be significant contributors to accident scenarios.

4.1.4. Adaptation and supplementation of probabilistic safety assessment procedures

PSA studies include seven main analysis tasks, from familiarization and the definition of the scope to model quantification. These tasks are listed in the left column of Table 3.

The performance of a PSA study, as described in various guidance documents [9], [10], [11], [12], generally consists of a fairly proceduralized series of steps. This structure of PSA steps is based on a broad base of application experience, primarily for NPPs. Because the plants have common underlying safety concepts and, in some cases, similar system designs, the potential vulnerabilities and scenarios may also be shared. Thus, a new PSA study for an NPP can benefit from this information and be organized according to a 'template'. In addition, generic lists can help to ensure that a study is comprehensive and systematic in its scope; for instance, a list of generic initiating events consists of the initiating events that have been identified in other PSAs for similar NPPs. When applying PSA methods to a new area or industry, PSA procedures must be adapted and supplemented with the aim to identify the major potential risk contributors and to orient the analysis efforts towards these. These changes to PSA procedures fall into two main groups:

(1) emphasis on a phased implementation of the study, making use of scoping analyses and intermediate results to orient the study, and
(2) the increased use of qualitative analyses to provide a broad basis for the study.

The supplemental actions associated with each of the PSA tasks are listed in Table 3. These are discussed in more detail in Section 4.3, Recommendations for future PSA studies.

Table 2. Key staff functions in clinical radiation therapy [16]

Tasks	Key staff
1. Clinical evaluation	Radiation oncologist
2. Therapeutic decision	Radiation oncologist
3. Target volume localization	
Tumour volume	Radiation oncologist and medical physicist
Sensitive critical organs	Radiation oncologist
Patient contour	Medical physicist
4. Treatment planning	
Beam data-computerization and computation of beams	Medical physicist
Shielding blocks, treatment aids, etc.	Dosimetrist/mould room technician
Analysis of alternate plans	Radiation oncologist/medical physicist
Selection of treatment plan	Radiation oncologist/medical physicist/dosimetrist
Dose calculation	Dosimetrist
5. Simulation/verification of treatment plan	Radiation oncologist/ simulator technician
6. Treatment	
First day set-up	Radiation oncologist/dosimetrist/ therapy technician
Localization films	Radiation oncologist/therapy technician
Daily treatment	Radiation therapy technician
7. Evaluation during treatment	Radiation oncologist/nurse
8. Follow-up exams	Radiation oncologist/nurse

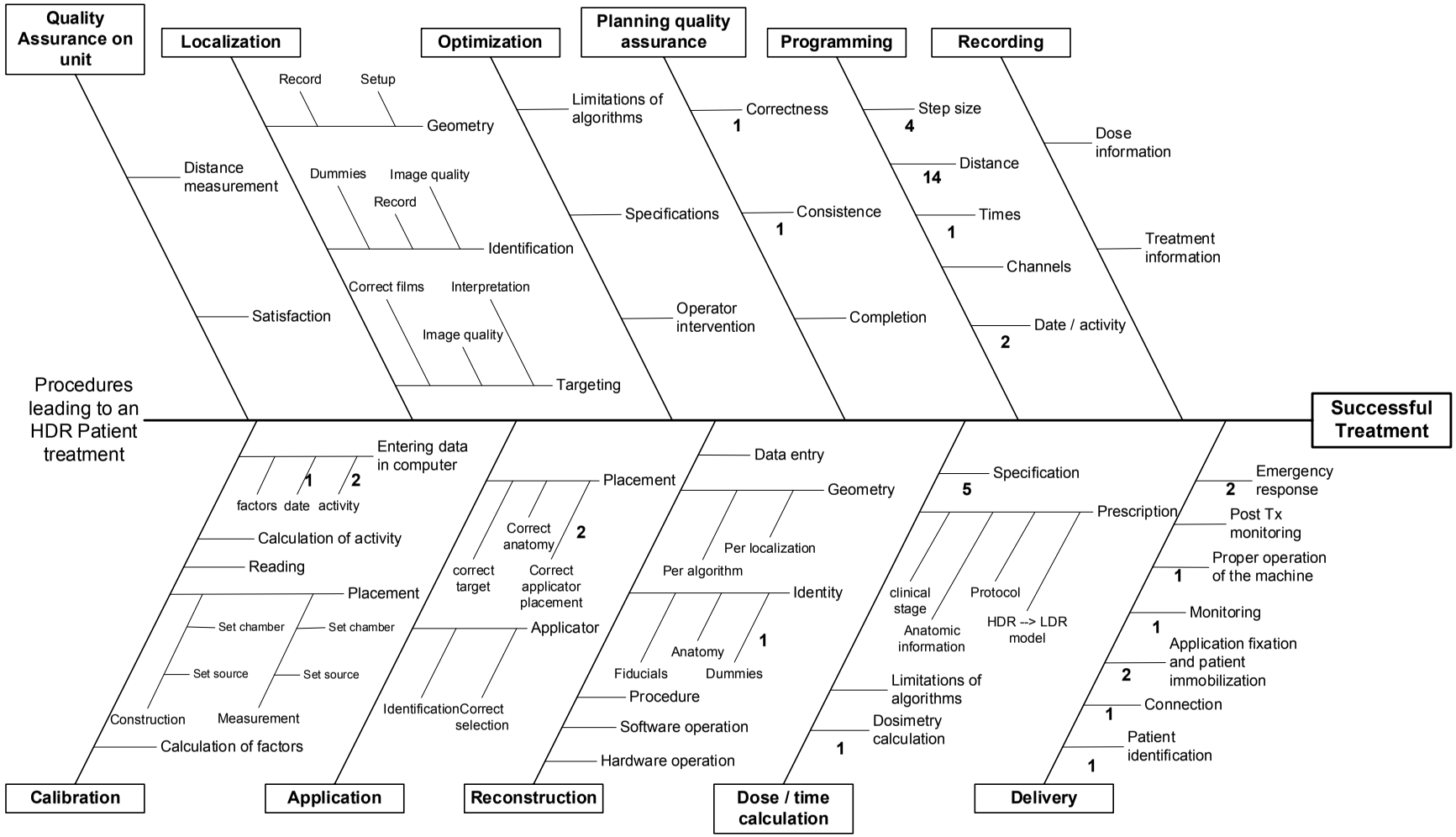

Fig. 7. Process tree for brachytherapy (American study [14]).

Table 3. Extensions to PSA tasks in PSAs of radiation sources

PSA tasks	Supplemental actions used in PSA studies for radiation source facilities
Familiarization and definition of scope	– Qualitative scoping to determine priority of undesired outcomes
Initiating events	– Extensive reviews of previous accidents and incidents, FMEA
Accident sequence and systems modeling and analysis	– An integrated model such as a fault tree may be developed to combine accident progressions and system and human response
Human reliability analysis	– Extensive task analysis to characterize diverse set of performance conditions – Emphasis on identification of potential 'error-forcing conditions' and errors of commission
Reliability data	– Survey of failure events to compensate for lacking systematic data collection
Model quantification	– Increased emphasis on sensitivity analysis due to uncertainties in data

4.1.5. Qualitative analyses

Although a quantitative orientation characterizes PSA procedures, qualitative analyses are an integral element of these procedures. They provide a comprehensive basis for the estimation of probabilities and for the identification of safety insights. For the facilities studied within this CRP, the qualitative analyses were essential in view of the following:

- Insights from previous studies were not available, requiring more scoping-level analyses.
- Even when such studies were available, the significant differences among the facilities, in particular, among the medical practices, would suggest caution as far as the general application of study results from a specific facility.
- Errors of commission and performance conditions where human errors become very likely (error-forcing conditions) both contribute significantly to the risk. Although these types of errors are relatively difficult to quantify with existing HRA quantification, qualitative analyses to identify potential errors of commission were used successfully in the CRP studies and provided valuable insights.

For some facilities or classes of undesired outcomes, qualitative analyses may be sufficient to obtain safety insights. A graded approach, discussed below in Section 4.3.3, is suggested because the additional efforts needed to construct a quantifiable model and to obtain an adequate set of reliability estimates may be quite substantial. At the same time, the results of the qualitative analyses can be very useful and may identify minor modifications that can improve the safety level.

In the present work, a variety of qualitative and quantitative approaches have been followed. Qualitative analyses underlie all quantitative analyses; the main issue is whether data were

adequate to quantify the insights of the qualitative analyses. For some facilities, the study or parts of the study did not include quantification.

Even when the availability of data is less than optimal, the use of PSA modelling techniques such as fault trees and event trees are nevertheless recommended. They provide an overall structure to organize and integrate the results from the various types of analyses.

Quantification using screening probabilities for human errors was found to be useful. Screening probabilities are conservative (pessimistic) error probabilities that are used to determine on a preliminary basis whether the human errors are potentially significant. Those errors or tasks that are potentially significant are subjected to more detailed analyses while further analysis for the remaining errors may be omitted. Appropriate values of screening probabilities depend on the specific PSA application since they are related to the expected level of performance. The use of screening probabilities helps to prioritize on a coarse level the issues identified in qualitative analyses as well as ensuring that resources are directed to the key problems. This means that, even without a quantified PSA, many conclusions can be drawn and an effective improvement of facility safety can take place.

4.2. Overall assessment by the study teams

The search for reliability data applicable to the facilities studied in the CRP represented one of the major challenges encountered by all of the teams. In the very early stages of the studies, it became very obvious that applicable data for essential aspects of risk evaluations were lacking. Another major challenge was the application of HRAs. This was a complex and problematic application. A variety of approaches were used to overcome the challenges, resolve the problems, and obtain meaningful results.

In the area of industrial irradiators, the Mexican-Canadian team performed a PSA for an irradiator located in Tepeji, Mexico. The team was able to obtain sufficient data from irradiator users and to apply the data to the Tepeji irradiator. The success of the PSA process is confirmed by the outcome of the study. The analyses provided meaningful insights on the risk of radiation exposure to the irradiator operators, and indicated the areas where risks could be reduced. These were addressed by relatively minor changes in equipment, processes, procedures, and operation.

Medical practices were addressed by three research groups that applied PSA techniques to cobalt teletherapy units. A fourth team dealt with brachytherapy, which is discussed in the next paragraph. The Cuban team performed a PSA for a cobalt unit located in Pinar del Rio City in Cuba, the Argentinean team applied PSA techniques to a cobalt teletherapy unit located in Mendoza, Argentina, and the Chinese team applied PSA techniques to two cobalt teletherapy units located in China. All three teams were unable to acquire any data on incidents resulting in unwanted events and equipment failure. Despite the lack of facility-specific data, all three teams were able to complete their studies, each using a different approach. Based on the results, the application of PSA techniques can be viewed positively. The analyses provided meaningful insights on the risk to patients, operators and public. Although no facility-specific data were available and used in the analyses, the use of generic data and the emphasis on relative risks were sufficient to obtain useful results.

In the case of brachytherapy, the American team conducted interviews with hospital personnel where events had happened and obtained over 250 records. The team applied PSA techniques to some of the cases and obtained meaningful results. As was the case with cobalt teletherapy

units, there were no specific data available on total number of procedures performed to be used in the analyses. The team used their own estimated data in order to complete the analyses. The results of the analyses were useful in identifying recommendations that can reduce the risks to the patients, the operators and the public.

On the basis of their experience with the application of PSA techniques to radiation sources and the useful results obtained, each team highly recommends the use of PSA techniques. While all five teams discovered that in most cases there were not sufficient data to ensure a completely facility-specific quantitative analysis, the analyses performed clearly provided useful information pointing to the weak points of a specific piece of equipment, process or operation.

4.3. Recommendations for future probabilistic safety assessment studies

This section presents a set of recommendations to be considered in performing a PSA study for radiation source facilities. Table 4 presents a summary of the key ideas related to these recommendations, which are discussed subsequently.

Table 4. Overview of recommendations for performing future studies

Issue addressed by recommendation	**Key ideas**
Establishing objectives and scope	Initial scope should be comprehensive, phased and graded approach
Selection of the project team	Multidisciplinary, stakeholders
Graded approach	Matching effort and potential consequences
Study phases and use of preliminary/intermediate results	Broad qualitative base, screening analyses, use of early results to prioritize
Use of other safety assessments, PSA studies	Help identify potential issues to analyse, caution in using models and results of other studies
Analysing human actions and potential errors	Errors of commission (EOCs)
Data for equipment and for human actions	Surveys, screening estimates, sensitivity and importance analyses
Use and communication of results	Focus on recommendations

4.3.1. Establishing objectives and scope

The overall objective of applying PSA techniques to radiation source facilities is to characterize the risk, including the most important contributors, and to identify possible modifications to facility equipment, processes, procedures and training that will improve safety. Understanding the relative importance of safety insights and evaluating the effectiveness of potential safety improvement measures are motivations for applying the quantitative perspective associated with PSA techniques.

In establishing the objectives and scope of a PSA study for radiation source facilities, the following overall recommendations can be made in light of the experience obtained in this work. These recommendations and generally recognized good PSA practices are coherent. In general terms, they would also apply to any novel application of PSA.

— Studies should be initiated with a very broad, comprehensive scope for the facility and its processes as well as for the undesired outcomes to be considered. A comprehensive initial scope is important to ensure that the study does not inadvertently exclude important potential hazards and undesired outcomes, given the limited information on the risks from these facilities (e.g. from earlier studies) as well as the significant differences among the facilities (including facilities of the same type).
— A graded approach should be applied to safety assessment. The main idea of a graded approach is to match the level of effort with the potential hazards and risks. This approach should be considered both in terms of the whole facility as well as the processes within the facility. As discussed in Section 2.4, the aim is to avoid a thorough analysis of low-risk scenarios while overlooking other higher-risk contributors. A graded approach as applied to radiation source facilities is discussed in Section 4.3.3.
— Organize the PSA study in phases, which are progressively more detailed. In general, all of the aspects of the facility in the comprehensively defined scope will not be analysed at the same level of detail and effort. The focus of the early phases of the study should be to systematically consider the entire facility and to identify the main hazards and risks. The use of qualitative analyses, screening values, and sensitivity and importance analyses in these phases is discussed further in Section 4.3.4.
— Although the availability of data for equipment and human actions was a significant issue, a quantifiable PSA model should be an objective in most cases. A quantitative approach is essential to allow the prioritization of issues and to provide an understanding of sensitivity. This prioritization is useful for the study; it helps to orient the PSA study itself, e.g. to expend efforts on reducing the uncertainty of important parameters while maintaining screening values for unimportant ones. In addition, importance and sensitivity information also supports the evaluation of the resulting safety insights and recommendations for facility and process modifications.
— The study should aim to obtain both qualitative and quantitative results. The results of qualitative analyses included, in many cases, safety improvements that required few resources to implement and made sense to implement regardless of the final PSA results.

4.3.2. Selection of the project team

Regarding the selection of a project team for the performance of the PSA, the experience gained in this CRP is as follows:

— The team must include persons sufficiently familiar with facility procedures. These persons need to be able to understand the processes and break them into their component parts as well as to evaluate the validity of assumptions made.
— It should not be assumed that a person who has a role in a procedure will be able to understand all of the other roles. Therefore, the team needs participation both from persons who have an overview of the procedure and from those who perform the individual tasks.

— The project team will also need persons experienced in PSA. A number of the challenges experienced in these exploratory studies should be anticipated when future studies are performed. Although PSA techniques are conceptually simple, considerable experience is needed for an effective and accurate application of these techniques.
— Finally, close participation of facility personnel enhances the implementation of PSA study results. A PSA study is a complex set of models and the detailed understanding of team members will help in the communication of the safety insights and add to the practicality of recommended safety improvement measures. As stakeholders in the PSA process and in the facility, they can also promote the acceptance of the recommendations.

4.3.3. Graded approach

The principle of a graded approach to risk evaluation is that the level of effort should be proportional to the potential risks, as introduced in Section 2.4. This principle is applicable to both the overall study and to the allocation of resources within the study. The essentials of the approach include:

— consideration of the upper range of potential consequences resulting from the practice in the definition of the overall scope and aims of the study. The IAEA radioactive source category according to the definitions in Ref. [1] may be a useful input for this process.
— an initial, systematic, but relatively simple analysis of the facility as a whole. In this initial, scoping analysis, it is important to aim at a 'complete' picture of the potential risks posed by a facility. Each undesired outcome, the groups exposed to these risks, and the spectrum of operations and maintenance should be examined. For this purpose, qualitative or semi-quantitative methods and rough screening estimates may be useful.
— a scoping analysis of the complete facility that identifies the main potential hazards and general scenarios for which detailed analyses should be performed. The aim is to ensure that potentially important risks are not overlooked.
— a selective quantification effort. In this regard, a model quantified with coarse screening values (conservative, pessimistic probabilities) can indicate the scenarios and parameters where it is worthwhile to expend efforts to obtain better estimates. The final model may retain screening values for less sensitive and important parameters.
— an appreciation that the safety insights from qualitative analyses may be sufficient indicators of safety-significant issues for some facilities or classes of undesired outcomes. Qualitative analyses can in many cases identify relatively simple modifications to the facility, its processes, and procedures that can improve safety.

Given that the estimation of probabilities is a crucial issue for the application of PSA to radiation source facilities, an important question for managing the effort is whether to aim for a quantifiable model. The additional effort needed to construct a quantifiable model and to obtain an adequate set of reliability estimates may be quite substantial.

For all but the lowest risk category sources and simplest facilities and models, a quantitative model provides noteworthy advantages: it allows a better integration of the results of different techniques, it provides indications of the relative importance of hazards and risks, and it allows the priority and the effectiveness of the options for safety modifications to be evaluated.

In connection with the graded approach, it should be noted that, in Ref. [1], the sources used in the radiation source practices examined in this CRP are classified as high risk, i.e. Category 1 for industrial irradiators and cobalt teletherapy, and Category 2 for medium and high dose rate brachytherapy. It should be emphasized that this categorization focuses **on the potential harm from the radioactive source** itself rather than on the risk from the overall facility.

Of course, the assigned radioactive source category has implications for the potential risks of the facility. The potential harm associated with low risk sources is by definition limited. In contrast, for sources in the higher risk categories, the risks of the facility may not be dominated by the most important perceived hazards. A tendency to focus on, and to thoroughly analyse the areas of the practice and issues that are better understood should be avoided. The risk evaluation should be aimed at assessing the safety management of the more evident safety-relevant aspects of the facility as well as identifying safety issues in other areas.

The risk evaluation should address the use and maintenance of the facility comprehensively. For instance, in the industrial irradiator, there are potential risks during normal operation as well as during configuration and maintenance activities. Thus, it is important to define the initial scope broadly and to consider a spectrum of groups that are exposed to the risks, e.g. patients (for medical facilities), operating personnel, maintenance personnel, as well as the public.

4.3.4. Risk evaluation phases and use of preliminary/intermediate results

The need to organize a risk evaluation study in phases is related to the graded approach; more resources are allocated to the issues that are more critical to the safety of the facility and to risk evaluation. A phased approach ensures that resources are used effectively, with minimal resources expended on non-essential issues.

The phases should be structured generally as follows:

- An overall analysis of the whole facility is first performed to identify a broad range of undesired outcomes, general contributing factors and scenarios, and safety-related facility features and measures. This analysis should be comprehensive and relatively simple, and may emphasize qualitative results.
- The greatest perceived risks should be identified early on, but other aspects of the practice with risks that may be less obvious should be identified and evaluated.
- Given that the estimation of probability parameters will generally be problematic for these types of facilities, a preliminary quantification based on coarse, conservative values can highlight the parameters for which more effort should be expended to refine the estimates. For the less important parameters, these coarsely estimated values may continue to be used in subsequent iterations. (The issue of estimating probabilities for equipment reliability and human actions is discussed below in Section 4.3.7.)
- Sensitivity and importance analyses are used at each study phase to identify the issues to be analysed in detail and the models requiring refinement. The development of the model should be oriented to address the more important issues. The uncertainties in some areas and the conservatism of some estimates may not be significant from an overall perspective.

— The probabilities of the undesired outcomes may be finally calculated and the dominant contributors and safety insights identified. The model can be used to prioritize safety improvement measures.

Qualitative analyses are performed in the earlier phases of risk evaluation, as a means of defining the detailed scope of the analysis, and in the subsequent phases, in support of the quantitative analyses. It is worth noting that in spite of the generally quantitative orientation of PSA, the products of qualitative analyses have intrinsic value and should be considered part of the results of the study.

In summary, the organization of the study in phases is intended to limit, in a methodical and traceable manner, the issues that must be analysed, in order to ensure that the required effort is kept to a reasonable level. This is crucial for both the reliability data issues and the qualitative and quantitative analysis of human actions; it also takes modelling and data uncertainties into account.

4.3.5. Use of safety reports and studies, other probabilistic safety assessment studies, and accident analyses

In both the initial risk evaluation phases aimed at defining the scope and subsequent analyses, helpful sources of information include safety reports, safety analyses, PSA studies for related practices, and information on past accidents and incidents.

The safety reports on other facilities may identify additional issues relevant to safety that may be considered in risk evaluation. For various reasons, these reports may vary in scope, content, and level of detail; consequently, they provide a broader basis for risk evaluation.

PSA studies for similar or related practices, if available, may provide hints for modelling specific aspects of the practice and identify methodological issues and possible solutions. These include the exploratory studies of this CRP. Recommendations for the performance of future PSA studies are summarized in Section 4.3. These recommendations are further elaborated upon for industrial irradiators and medical facilities in Sections I-4 and I-6, respectively, of Annex I.

A review of information on past accidents and incidents can highlight specific scenarios and potential initiating events or classes of initiating events, especially given that lists of generic initiating events applicable to radiation source facilities are not available. This review should consider a broad range of facilities, including facilities that may be significantly different in terms of design and operation. This information complements the results of facility-specific analyses such as FMEA.

In all of the above cases, the main value of the information is:

— to raise safety issues (hazards, initiating events, environmental and ergonomic factors, procedures and training) that have been relevant in the same practice or in similar processes,
— to provide lists of accident and event causes that may help in identifying scenarios and initiating events to be addressed in the PSA,
— to identify other sources of information and data, sometimes including an evaluation of their relevance and usefulness, and

— in some cases, safety management measures may provide options for addressing similar issues for the practice being studied.

Due to the different types of radiation source practices, as well as the large differences among practices of the same type, the results of the PSAs and other safety analyses for other facilities should be interpreted with a great deal of caution due to their facility-specific character.

4.3.6. Analysing human actions and potential errors

The analysis of human actions in a PSA has the aim to identify the potential errors that should be included in the PSA model, to estimate the probabilities of these errors, and to identify possible safety improvements. This section provides recommendations for the analysis of human actions and potential errors at radiation source facilities, focusing on identification and qualitative analysis. Data issues and quantification, for both equipment and human reliability data, are addressed in the next section.

The CRP participants found that the methods typically used in PSAs to identify and to qualitatively and quantitatively analyse human actions required significant efforts to adapt them for use in radiation source studies. This is because the techniques for the analysis of human actions are mainly oriented to PSA applications for highly automated, technologically complex systems with diverse and redundant equipment such as NPPs. Although task analysis is used to some extent to identify human actions and errors to include in the model, the accident sequence analysis and systems analyses, which focus on the equipment, largely determine the actions modelled in the PSA.

Some characteristics of radiation source facilities that impact the analysis of human actions are presented here:

— Radiation source facilities typically have low levels of automation. Processes are designed around human interactions and control and is highly manual, resulting in a relatively large number of tasks and error opportunities.
— Multiple types of undesired outcomes may be of interest. Risk evaluation needs to consider the potential risks to patients (medical practices), operating or treatment personnel, maintenance personnel, and the public.
— The procedures and the process are less formally defined and controlled, compared with large, complex technical systems such as NPPs.[5] Consequently, informal practices and circumventions, which may be unintentional or intentional, need to be identified and analysed.
— The radiation source (the hazard) may be moved manually, for instance, in maintenance. This increases the number of situations to be analysed.

Specific to medical practices:

— The treatment process includes a number of tasks with relatively high frequencies (in normal operation), for which errors pose a direct risk.

[5] Some reasons for this are that the magnitudes of the undesired outcomes are much smaller for radiation sources than for NPPs, and the need for the practices to be flexible, e.g. in terms of scheduling.

— A number of groups, coming from different disciplines and organizational units, are involved in the patient treatment process.

It is worth noting that the risk evaluation of many radiation source facilities includes the most demanding requirements for HRA. Ref. [17] defines and characterizes four levels of HRA as shown in Table 5.[6] For the time being, the risk evaluation of a facility with a Category 1 or 2 radioactive source (IAEA categorization [1] as discussed above in Section 2.4) is in fact the "evaluation of a novel system with high risk potential and with human involvements". In this case, the recommended level to aim for is the most resource-intensive: Level-3 HRA, 'HEA-driven HRA, within PSA'. Note that Level-4 HRA does not include quantitative analysis and would generally have a more limited scope; consequently, it does not represent a higher level of effort than Level-1 through Level-3.

Table 5. Levels of human reliability analysis and recommendations

	Description	**Definition and recommendation**
Level 1	PSA-driven task-based HRA	Tasks (PSA human actions) identified solely by PSA *Practiced, but not recommended*
Level 2	(Level 1) + targeted task analysis	Task analysis is carried out for scenarios identified by PSA *Minimum recommended*
Level 3	HEA-driven HRA, within PSA	Human Error Analysis (HEA) used to identify tasks, quantification at action level *Recommended level to aim for when evaluating a novel system with high risk potential and with human involvements*
Level 4	Qualitative HRA	HRA process used without quantification and impact assessment Can help identify causes and the error-reduction potential *Usually used to address a known human performance problem*

Source: derived from [17], p. 318.

In a Level-1 or a Level-2 HRA, the identification of the actions to include in the PSA is based on the defined human-machine system response to initiating events. In the Level-2 HRA, task analysis is performed on these scenarios; in other words, the human performance challenges in these scenarios are also examined. Both of these levels of HRA rely on the completeness of the accident scenarios defined in the PSA.

In contrast, when the PSA accident scenarios have a dominant human contribution as well as when the scenarios are not well understood, the scenarios and the human role in the scenarios have to examined at a more fundamental level. In a Level-3 HRA, a Human Error Analysis

[6] These 'levels of HRA' are not correlated to the PSA Levels (Level 1, 2, or 3) for nuclear power plants, which are defined based on the consequences that are examined. In Level 1 PSA, the core damage frequency is calculated; in Level 2 PSA, the accident progression to the 'source term' is analysed; finally, Level 3 PSA estimates the consequences to the public and the environment.

(HEA) is recommended. The HEA is a more comprehensive qualitative analysis that is performed to identify tasks to include in the PSA and to define the PSA scenarios.

The 'onion framework', shown in Figure 8, lists a range of issues that may need to be addressed in the HEA and defines these as HEA levels. Table 6 [17] provides criteria for determining the required HEA level. For radiation source facilities, the responses to these criteria show that all six levels need to be addressed to some degree. The answers are all 'yes' except for the next-to-last criterion about the availability of maintenance data. Level 5 (which includes errors of commission (EOCs) and rule violations) and Level 6 issues are beyond the scope of most quantitative HRA analyses. Level 5 and Level 6 issues are best addressed by reviewing and evaluating safety training, safety culture, and operational practices in terms of whether situations do occur at the facility in which safety rules and procedures may not or do not have the highest priority.

In summary, these criteria and recommendations from [17] suggest that, for radiation source facilities, a Level-3 HRA, an HRA in which an HEA is performed, is needed and that the HEA needs to cover all 6 HEA levels.

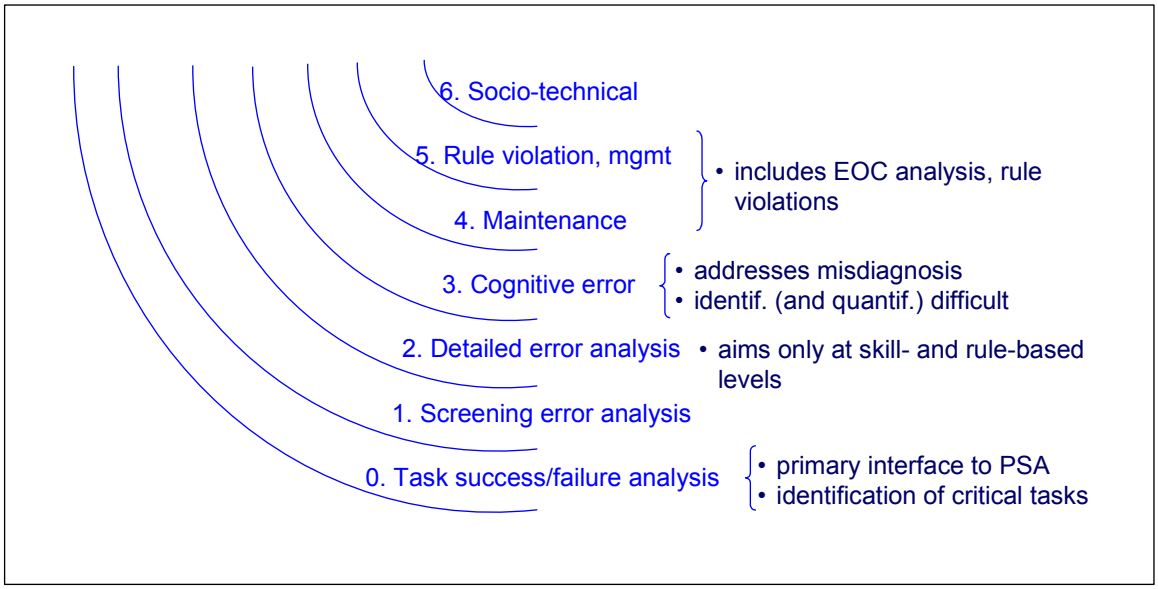

Fig. 8. The 'onion framework', a multi-levelled approach to HEA [17].

Table 6. Criteria for selecting the qualitative 'onion framework' analysis level

Criteria / Questions	**If yes,**
Are the PSA and the number of tasks large?	Screening at **level 0 or 1**, backed up by **levels 2-5** for sensitive tasks
Is the PSA for a novel system with a high hazard potential and high degree of human involvement?	**Levels 2-4**, also implement and review safety culture
Does a cognitive error potential exist?	**Level 3**
Is there any evidence (from operational experience) of rule violations?	**Level 5**
Is reliable maintenance-failure data available?	Data may be used. ***If no***, **Level 4** for a subset of tasks to determine the appropriateness of the available maintenance data
Do people carry out tasks that can directly affect safety and undesired outcomes?	**Level 6**

Source: [17], p. 119.

Recommendations for the analysis of human actions

The use of radiation sources is intensive in human actions; therefore, the analysis of human actions and potential errors should represent a larger proportion of the effort compared with the PSAs of facilities that are more complex and automated. The experience of the exploratory studies suggests that the analysis of human actions may require at least 50% of the effort, compared to the usual 10% in other PSAs. For this reason, implementing a phased approach and applying screening techniques are essential strategies. A few recommendations about the analysis of human actions are provided:

- A review of past experience and accidents can help to identify critical issues and error-prone tasks that should be examined in the PSA. The study on brachytherapy experience [14] provides examples of methods that can be useful in such a review.
- Analysing the treatment process, including the human facets of the process, is important as a basis for the project team members and the facility personnel to discuss and analyse the practice. For medical treatments, a patient-centered perspective may be helpful to define the scope, i.e. the analysis of the process focuses on the interactions with a given patient.
- The radiation source practices examined in the CRP studies have a low degree of automation and the associated processes have a substantial number of human actions. In the case of the medical practices, the process involves persons from different disciplines and organizational units. In general, a relatively large number of tasks must be subjected to task analysis, and special attention must be paid to the tasks where different disciplines interact.
- At the level of the facility and the overall PSA model, screening quantification of the evolving PSA model should be used repeatedly to identify those actions for which

qualitative and quantitative analyses are needed (task analysis and estimation of human action probabilities).
For medical practices, these are particularly resource-intensive due to the number of routine tasks and error opportunities, and the number and diversity of involved personnel.

— Operational and production constraints should be identified and their potential impacts on the performance of the tasks should be assessed. Defining a nominal scenario and considering variants of the scenario, as recommended in the ATHEANA method [18] was found to be useful. For instance, the Argentine participants in the CRP defined the variants in terms of operational variants (e.g., a short notice change to the order of patients, addition of patients) and considered how the scenario may change and the changes of the personnel behaviour.
— The analysis of human tasks should aim to identify the 'coping' and 'optimizing' behaviours of personnel under pressure. These behaviours may not themselves be 'erroneous', but can reduce the effectiveness of recovery opportunities.
— Because the practices are designed around human interactions and checking, the risks due to errors in communication are an important issue.

Communication aspects that need to be considered include:

— information content, e.g. identity of patient, location of target, treatment parameters,
— mode of communication: oral, written, graphical, etc.,
— representation of the content: notation, conventions and standards for representing the information, and
— background and training of the persons communicating, since the discipline and the organizational unit to which each belong may influence the choice of mode or of representation.

The process tree used in the American team's brachytherapy study, shown in Figure 2 (above in Section 4.1), was found to be a useful representation of the nominal treatment process. This qualitative analysis focuses on nominal process, i.e. all of the steps that are routinely performed during the treatment. This representation can highlight the more challenging tasks of the personnel and the types of error that may occur. The actual errors and their consequences are not addressed at this stage. This representation of the process may also be used to identify the communication among personnel that is required.

4.3.7. Data for equipment and human actions

The availability of data for equipment reliability and for human actions represented a major problem for most of the exploratory studies. For equipment failure data, the problem stems from the fact that reliability data have not been collected for the equipment examined in the studies, as it has been for components in systems for which reliability analysis and PSAs have been historically performed. Human reliability data is an issue for PSA applications in all areas; while some data are available for execution errors, probabilities for personnel decisions are generally difficult because they depend strongly on the industry and its approach to safety management, on training and practices in a given facility, and on the specific situation in which the human action is taken.

As discussed above, risk evaluation has to be structured carefully in order to compensate for the lack of data and to ensure that the estimation of data remains manageable. In nearly all

cases, a quantitative PSA model is recommended for risk evaluation. The development of a quantitative model helps to integrate the results of the various techniques. In addition, it provides the means to prioritize safety insights and to identify safety improvements with the largest impact. (The exceptions are facilities with very low risk radiation sources.) A list of insights gained through the studies is provided:

— A screening quantification of the preliminary PSA model is recommended, using rough, conservative estimates of the input probabilities.
The objective of this type of quantification is to prioritize the data issues and to focus the data analysis on the equipment and human events that are important and to which the results are sensitive. Events that are unimportant and to which the results are not sensitive do not need to be quantified further; note that these should usually be retained in the model and documented.
— Screening quantifications may need to be repeated as the PSA model evolves. If possible, the final PSA model should not contain conservatively estimated events that are important; these estimates may distort the risk profile and overstate the relative risks associated with these situations. The importance and sensitivity results from the quantification of the final model should be used to verify that these estimates are only used for events with low importance and sensitivity.
— Sensitivity analyses are recommended because of the large uncertainties associated with the data. In addition, for important components and human actions, these analyses shed light on the effect of, improving the performance of this equipment or of the personnel on these tasks, and improving the quantitative estimate of the failure probability.
— If resources are not available for a facility-specific data analysis, coarse screening values may be used as a fallback. Combined with importance and sensitivity analyses, the results can still be useful if interpreted with caution. They can also be used to identify what data should be sought in the future.

Equipment and component data

For much of the equipment and component data, the primary source of information will be generic data. Generic data represents the failure data for a component at a large number of facilities, sometimes in different industries. Some sources of generic data include Ref. [13] for research reactors, Ref. [19] for NPPs, and Refs [20] and [21] for the offshore oil industry and process industry. Operating conditions refer to the level of demands placed on the equipment, the environmental setting in which it is used, as well as the frequency and quality of maintenance. The conditions reflected in the generic data may be more or less adverse than in the facility being studied; therefore, possible differences in operating conditions should be identified and corresponding adjustments to the failure rates should be made.

The facility's own experience should be evaluated and taken into account. For standby components and systems, the results of regularly performed tests may help to estimate or bound the failure probabilities. For operating components and systems, an estimate of the hours of active operation may be helpful. In both cases, but especially for the latter, it is important to examine whether failure events may have been unintentionally excluded or forgotten. Success statistics should be interpreted with particular care. A useful product of the review of facility experience is the identification of failure modes. In some cases, it may also provide important information about human errors associated with the operation (maintenance, or testing) of the equipment.

A survey of failure events and operating experience at similar facilities may be useful, as was performed in the industrial irradiator study of this CRP. Such a survey is particularly valuable in the identification of failure modes to consider.

It is clear that the analysis of generic data, facility experience, and the integration of this information into a failure rate for each component in the PSA model are resource-intensive. Conservative estimates should initially be used in a screening quantification in order to define the priorities for data analysis. Given limited resources, conservative estimates may be the only option. Without a more facility-specific data analysis, the numerical results of a PSA should not be overly emphasized. The prioritization of the contributors to risk may be inappropriate and lead to the wrong conclusions.

An effort to systematically collect data subsequent to the PSA should be encouraged, in particular, for the parameters that are risk-significant (important) and to which the model is sensitive. This effort should be aimed at validating or improving the estimates used in the model.

Data for human actions

The estimation of probabilities for human actions and errors is a difficult problem in many domains in which PSA is applied. Some data are available for tasks that involve manipulations, following written or oral instructions and procedures, and the reliability of various forms of checking, e.g. by a supervisor. The data in the THERP handbook [22] for these so-called 'execution' tasks, which have been derived with significant input from expert judgments, have been shown to be relatively dependable for NPP applications, e.g. in Ref. [17]. In this domain, as in any domain, these estimates need to be adjusted for performance shaping factors, a process for which the handbook also provides some support.

On the other hand, very few data are available for the estimation of the decision component of human actions in a PSA. Decision tasks are highly dependent on specific situations; in this light, the concept of generic data is problematic in itself. THERP provides estimates in the form of time reliability curves for the diagnosis (decision) tasks in NPPs based on expert judgment; however, the type of situations covered by this expert judgment model are unlikely to be encountered in radiation source PSAs.

Here are several specific points that should be considered when applying PSA techniques to radiation sources:

- A useful survey of available human reliability data is given in Ref. [23]. It discusses the THERP data and other sources of data, as well as applications other than the nuclear power industry.
- A good overview of HRA that emphasizes qualitative analysis as well as HRA quantification methods is Ref. [17].
- The THERP data for 'execution' tasks are generally the closest analogue to 'generic' data for human actions.
- For the highly frequent tasks, e.g. those routinely performed daily, that are encountered in radiation source practices, due to the large human component in routine radiation source operation, the coarse screening probabilities used for NPP PSAs (failure probabilities usually between 0.1 and 0.5 per demand) are not practical. These need to be estimated on the basis of the experience at the facility.

— The estimation of failure rates based on facility experience should include a good degree of conservatism unless the data are formally and systematically collected. A clear distinction should be made between error-free performances and errors that were recovered (through self-checking or detected by someone else). Errors that are relatively frequent, but mostly recovered should be highlighted; these are clearly the vulnerable tasks and the recovery mechanisms may be among the first to fail in non-routine situations.
— Coarse screening probabilities (between 0.1 and 0.5 per demand) are an appropriate first approximation for the detection of off-normal or unusual conditions, the detection of errors (by someone else), the performance of non-routine tasks, performance in non-routine situations, and responses to abnormal situations.
— The potential dependence among human actions needs to be systematically evaluated and quantified. An inadequate treatment of this dependence is likely to significantly distort the results of the risk evaluation. The THERP model of dependence remains the most commonly used approach to quantify dependence. At least a low level of dependence should probably be assessed for most actions that are somehow related, unless the tasks are known to be performed by different techniques and designed to be independent. Self-checking, an important feature of medical practices, should probably be assigned moderate to high dependence while low to moderate dependence may be applied to verifications performed by an independent checker using a different technique.
— Although the analysis of errors of commission (EOCs) are not routinely performed in NPP PSAs, the exploratory studies of this CRP found that a qualitative analysis of EOCs was useful in highlighting potential safety issues. In particular, several studies found that off-normal situations or variants of the nominal process should be systematically evaluated. This is analogous to the analysis of scenario variants as recommended in the ATHEANA method. In variant situations, the probabilities of human errors, for instance, of omitting a redundant check, may be significantly higher. If such cases are identified, the probability of the situation variant will need to be estimated, while the human action probability will be high (0.1 to 1.0).

PSA steps in light of human action data issues

In addressing human action data issues, in particular in facilities (practices) with a large human action component, a strategy based on the following steps can be recommended to focus the risk evaluation on the important risk contributors and safety issues. In these facilities, both the qualitative analyses and quantitative analyses need to be focused on the actions and tasks with a significant potential risk. This strategy needs to be combined with a similar strategy for equipment data issues.

(1) *Initial high-level task analysis to identify error opportunities at the scenario level.* This task analysis focuses on the nominal treatment process. These opportunities may be integrated into a preliminary PSA (scenario) model.
(2) *Screening quantification of the preliminary PSA model*. In this step, the error opportunities are assigned coarse screening values, e.g. failure probabilities on the order of 0.1-0.5 per opportunity, unless there is experience data that may help bound these values. The recovery opportunities should also be conservatively modelled (with probabilities of the failure of recovery on the order of 0.5 for each separate opportunity). The purpose of this step is to prioritize the error opportunities that require more detailed analyses and to identify those error opportunities for which the human and technical

safety measures, e.g. checking and supervision steps, and interlocks, are generally adequate. Importance and sensitivity measures should be considered.

(3) *Detailed qualitative analysis of the personnel tasks associated with each retained error opportunity.* This step may show that the opportunity for this type of error may exist at several parts of the task or in several tasks. In addition, for each task, it may identify opportunities for errors of other types. For each of the new errors, recovery opportunities need to be identified as well.
This step leads to a refinement of the PSA model and provides the qualitative basis for quantifying human actions. In addition, safety improvement measures may be identified.

(4) *A screening quantification of the refined PSA model.* This screening would be as in Step 2. While a similar approach may be used for the screening values, the purpose of this step is to determine the error opportunities for which it is worthwhile to perform a detailed quantitative analysis in order to obtain better probability estimates.

(5) *Quantification of human actions*. A detailed HRA is then required for those actions that are significant in terms of PSA importance measures or sensitivity measures.

(6) *Best estimate quantification of the PSA model*. The final quantitative results of the PSA include importance and sensitivity measures obtained with the best estimates. These measures are needed to identify the dominant contributors and safety issues and to evaluate the need and priority of safety improvement measures.

4.3.8. Improving safety — use and communication of probabilistic safety assessment results

The application of PSA to radiation source practices yields results that may enhance the overall safety level of these installations. It should be noted that PSA results do not, by themselves, constitute a demonstration of the adequacy of the safety level of a radiation source practice. Instead, its results complement the fulfillment of current safety standards, which are based on experience and summarize good practices.

The estimated frequencies of undesired outcomes, calculated by means of the PSA model, are just one component of the quantitative results. To obtain insights into the safety of the facility requires identifying the features of the processes and equipment that contribute to the quantitative results and ranking their contributions. More generally, the risk profile includes the dominant scenarios or situations, the equipment failures including failure modes, and the critical personnel tasks and potential errors. The calculated importance measures for the contributors are the quantitative component of the risk profile and provide the basis for the ranking of the contributors. The principal importance measures, Fussell-Vesely or fractional contribution, the Risk Achievement Worth or Risk Increase Factor, and the Risk Reduction Worth or Risk Decrease Factor, support different types of safety management decisions. In addition, the quantification of uncertainties and sensitivities provides additional insights on the PSA model and its results.

Measures to improve safety should be formulated based on the identified risk and their contributors. The range of risk-reducing measures can include:

— modifications to the equipment or operation of the facility (its processes),
— review, improvement, or development of procedures and checklists to support the personnel in their tasks, as well as the associated personnel training,

— improvement of safety management processes. These include identifying critical components for maintenance and testing, reviewing the frequency and scope of maintenance and testing, and monitoring the critical aspects of the facility, and
— the collection of information and data or performance of issue-specific studies to address uncertainties in the model or its parameters.

The frequencies of undesired outcomes and other quantitative results need to be interpreted with a great deal of caution due to the significant uncertainties expected for the application of PSA in new domains and facilities. With this caution in mind, the importance and sensitivity results in particular were found to be helpful in prioritizing risk-reducing measures that are expensive or extensive. However, the risk profile should not be used to disregard the safety of any treatment step or equipment.

It should be noted that the exploratory PSAs of the project also identified other, simpler measures that made meaningful contributions to reducing risks. Finally, the study may also show that the current safety features and measures relevant to specific high-profile aspects of a practice are adequate.

The inclusion of facility personnel on the PSA team and their involvement should be highlighted as essential, not only for the development of the PSA model, but also for the development of safety insights and recommendations for risk reduction measures. In this final stage of the work, these stakeholders can ensure that the recommendations are practical and effective. Through their expertise, they will ensure that the results and recommended measures are understandable to the facility personnel and management and facilitate the adoption of the recommended measures.

4.4. Suggestions for complementary activities in support of radiation source safety

This section briefly presents some suggestions for activities that may contribute to the reduction of risks in radiation source practices, and facilitate the performance of PSA studies for other radiation source practices.

4.4.1. Reducing risk in radiation source practices

The teams participating in the CRP concluded that the safety of the practices they examined would benefit from:

— the sharing of safety insights and vulnerabilities, including the development of action plans to address these. PSA could be useful as a common approach and frame of reference.
— the compilation of good practices for the operation of radiation source practices and their safety management. (Some compilations for medical practices do exist, e.g. [24], [25], [26], [27].)
— the exchange of good practices on the modification of processes when introducing technological solutions, e.g. computer aids in medical settings, and the positive and negative experiences with these.

4.4.2. Facilitating future probabilistic safety assessment studies of radiation source practices

The challenges for the exploratory PSA studies of the CRP stemmed from the broad scope of risks in each radiation source practice, the relatively high frequency and relevancy of human actions, and the general lack of qualitative information and data specific to radiation source facilities. The following suggestions address PSA training, the development of guides and checklists specific to radiation source PSAs, and qualitative and quantitative data:

— *Development of training material and courses on the application of PSA for radiation source safety.* An introduction to PSA tools and techniques in radiation source safety applications aimed at facility staff would be helpful, because of their role in safety management.
— *Development of checklists and procedures for the PSAs of radiation source practices.* Simplified techniques are particularly needed to perform the extensive qualitative analysis that is needed in the PSAs of radiation source practices.
— *Systematic, structured review of experience for specific radiation source practices.* A review of this type that was performed by the American research group for brachytherapy was valuable in identifying generic issues to consider in the facility-specific PSA.
— *Collection of statistics on types of treatments.* The collection of statistics on types of treatments (per practice and across practices) would allow better use of the information provided in accident and event reporting.
— *Studies on personnel performance in industrial and medical settings where radiation sources are used.* There is a need for more information on several topics including: a) the efficiency of various types of checks and the underlying factors, given the strong dependence of medical processes on the judgment and checking of the staff; b) the incidence of omissions in medical settings; and c) tendencies related to the evolution and use of informal procedures.
— *Guidance on screening values for tasks and situations.* Guidance should be developed on appropriate screening values for the types of tasks and situations encountered by the personnel in radiation source practices.
— *Equipment probability data.* The collection of equipment reliability data in the operating environments of radiation source practices would improve the accuracy of PSA studies.

4.5. Overall conclusion

In this CRP, PSA techniques were applied in the risk evaluation of a diverse set of radiation source practices. While by no means comprehensive, this set included both medical radiation source practices and an industrial irradiator. It is worth noting that significant differences among the facilities were found, even among practices of the same type. At the same time, generic safety and PSA issues were identified, which applied to all practices.

The application of PSA techniques resulted in safety insights for each of the practices. Probability values estimated with large uncertainties were used in the studies in which an overall quantification could be performed. In spite of these uncertainties, a quantitative approach is highly recommended because it supported a prioritization of the risk contributors and consequently of the recommendations for risk reduction. In addition, during the performance of the studies, the results of intermediate quantifications of the PSA model

provided valuable insights for determining an appropriate level of detail for the different parts of the PSA model. For instance, the quantitative information was essential in prioritizing the scenarios to examine, the personnel tasks to analyse, and the data to be sought.

An overview of each study and the resulting safety insights is presented in Annex I. With the exception of the American study, which deals with a sample of international experience with one type of radiation source practice, the facility-specific character of these results should be emphasized. A more general summary of the major risk insights is presented in Section 3. Other facilities may benefit from reviewing whether the general and facility-specific issues that are raised are applicable to them.

The recommendations for future PSA studies of radiation source practices presented in this section are based on the experiences obtained in the exploratory studies. The strongly positive experience of the study teams can be used to recommend the performance of a PSA, or at least an application of PSA techniques, as an element of safety management in radiation source facilities.

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ABBREVIATIONS

ATHEANA	A Technique for Human Event Analysis
CNSNS	Comisión Nacional de Seguridad Nuclear y Salvaguadias (Mexico)
CNSN	Centro Nacional de Seguridad Nuclear (Cuba)
FMEA	Failure Modes and Effects Analysis
HDR	high dose rate (type of brachytherapy)
HEA	human error analysis
LDR	low dose rate (type of brachytherapy)
HRA	human reliability analysis
NPP	nuclear power plant
PRA	probabilistic risk assessment (alternate term for PSA)
PSA	probabilistic safety assessment
QA	quality assurance
THERP	Technique for Human Error Rate Prediction

ANNEX I. OVERVIEW OF PSA STUDIES CONDUCTED AS PART OF THE COORDINATED RESEARCH PROJECT

I-1. Introduction

Annex I was written by the participants in this CRP during the third Research Coordination meeting that was held in Mexico City in May 2003. A generic description of the facilities and practices that were studied as part of the CRP is presented, as well as recommendations concerning the application of PSA techniques to radiation sources and common aspects of the medical applications that were studied. The majority of this annex is comprised of brief descriptions of each of the studies that were performed as part of the CRP. Table 1 provides an overview of the reports that are summarized in this Annex.

Table 1. Final reports of the CRP studies

CRP Final Report	Synopsis Location	Study subject	Participating Country
Probabilistic Risk Assessment Associated with the Operation of An Industrial Irradiator Installation.	I-3.1	Industrial irradiator	Mexico[a]
Methods and Procedures To Apply Probabilistic Safety Assessment (PSA) Techniques to the Cobalt-Therapy Process. Cuban Experience.	I-5.2	Cobalt teletherapy	Cuba
ATHEANA Application to Human Error Issues in Cobalt Therapy (Argentine Experience).	I-5.3	Cobalt teletherapy	Argentina
Investigation of Appropriate Methods and Procedures to Apply PSA Techniques in Safety of Radiotherapy and Industrial Irradiation Facilities	I-5.4	Cobalt teletherapy	China
Towards Probabilistic Risk Assessment in Brachytherapy	I-5.5	Brachytherapy	USA

[a] Canada and Mexico worked on a joint study for an irradiator in Mexico. A. Huerta-Bahena of CNSNS was the principal investigator for the study. J. Mardian of MDS Nordion collaborated with the Mexican team and provided technical expertise on industrial irradiators.

I-2. Generic descriptions of facilities and practices studied in the coordinated research project

The following general descriptions of the radiation source facilities or practices examined in the exploratory PSA studies are taken from Annex I of Ref. [I-1].

Irradiator facilities are relatively few in number, and contain very high activity sources to sterilize foodstuffs, medical products and supplies, and for other specialized applications. The sources used in performing the irradiation of the material vary in physical size, some being large or others being pencil-sized, and each facility will contain many such sources. The facilities that contain the irradiation sources are specially designed, often including thickly shielded walls, interlocks, and other protective equipment. Other irradiators are self-shielded and are used in research applications or for blood irradiation.

Teletherapy units are commonly found in medical institutions, such as hospitals or clinics. The physical dimensions of the source are relatively small, with generally a cylindrical (few cm in diameter by several cm long) shape. The source is contained inside a large shielding device. Most Co-60 teletherapy units contain a single source that can be moved around a patient. Fixed multi-beam teletherapy units (Gamma Knife) focus gamma radiation from an array of over 200 Co-60 sources on brain lesions. The facilities within which the units are located are usually specifically designed and include thick shield walls and have other protective equipment, due to the high activity source strength.

Brachytherapy applications are of three slightly different varieties. These are generally referred to as low dose rate (LDR) brachytherapy, medium dose rate (MDR) brachytherapy, and high dose rate (HDR) brachytherapy. These applications use sources that may be small physically (less than 3 mm in diameter and only a few mm to a few cm long), and thus are susceptible to being lost or misplaced. HDR and MDR sources, and some LDR sources, may be connected to a long wire attached to a device (a remote after-loading device). The after-loading device may be heavy, due to the shielding for the sources when not in use, and the device may be on wheels for transport within a facility. The remote after-loading device may also contain electrical and electronic components for its operation. Brachytherapy sources are located in hospitals, clinics and similar medical institutions, and such facilities may have a large number of sources.

Teletherapy units are used for *external beam radiation* while brachytherapy is an alternate term for *internal radiation therapy*. The following descriptions are quoted from Ref. [I-2], which presents radiation therapy principles. Radiopharmaceuticals are not addressed in this project.

— **External beam radiation**, in which the radiation is focused from a source outside the body onto the area affected by the cancer.
— **Internal radiation therapy or brachytherapy**. With internal radiation, small radioactive wires or pellets, about the size of a grain of rice, are directly implanted into the tumour (interstitial radiation) or into a cavity close to the tumour (intracavity radiation). These can be permanent or temporary. Imaging tests such as X-rays, ultrasound, or CT scans are used to assist the doctor in putting these in the correct place. The permanent pellets, sometimes called seeds, emmit radiation for several weeks or months. Because they are so small and cause little discomfort, they are simply left in place after their radioactive material is used up. Another type of treatment, high dose rate (HDR) brachytherapy, uses needles containing radioactive material. These will be left in place for less than an hour. The radioactive source travels through the needles to the tumour.

The advantage of brachytherapy is the ability to deliver a high dose of radiation to a small area and is useful in situations that require a high dose of radiation or a dose that would be more than the normal tissues could tolerate if given by external beam.

I-3. Study of an industrial application

I-3.1. Industrial irradiator (Mexico)

I-3.1.1. Objective and scope

The objectives of this study were to investigate the value of state-of-the-art PSA for the safety assessment of industrial irradiators; to characterize the risk associated with the operation of the industrial irradiator; to identify and evaluate safety improvements; and to apply risk insights to develop specific inspection and surveillance procedures.

The PSA was performed for an industrial irradiator facility in Tepeji, Mexico. This facility is an IR-201 Heavy-Duty Tote Irradiator, a Category IV panoramic irradiator, which uses sealed sources containing Co-60. It has been designed and installed by MDS Nordion and is operated by NGS, Inc. The irradiator is used for the sterilization of medical products, cosmetics and foodstuffs, by exposure to a high dose of gamma radiation. The irradiator fulfils the requirements of Safety Series No. 107 of the IAEA [I-3].

The sources in the irradiator are doubly encapsulated Nordion Type C-188 Co-60 'pencil' sources with a total activity of 1.15 MCi (April 2000). These sealed sources are inserted into subassemblies called modules, which are assembled in a rigid stainless steel source rack. The source rack is 4 modules high by 5 modules wide. Each module has a capacity of 42 sealed sources. When less than this number is required, the remaining spaces are filled with non-radioactive 'dummies' in order to get the required dose distribution. The Mexican irradiator has two source racks, one with 8 modules and the other with 12 modules, each with an independent elevator system. The irradiator is designed to contain a maximum of 3 MCi.

The scope of the PSA includes normal irradiator operation and the source movement time frame. Therefore, source loading and unloading, and maintenance activities were excluded from the scope of the project. Internal initiating events (i.e. product movement failures, process systems failures, etc.) were covered by the study. External initiating events, such as external flooding, fire, and earthquake were excluded from the analysis.

I-3.1.2. Resources

The human resources devoted to this project involved three PSA analysts with strong backgrounds in the application of PSA to NPPs and a design engineer from MDS Nordion with extensive experience in the design and operation of industrial irradiators. During the development of the project, extensive support was provided by plant personnel.

I-3.1.3. Undesirable end states

In NPP PSA, the core damage frequency or the containment failure frequency are the typical end states of accident sequences. For an industrial irradiator PSA, accident sequence end states should be identified. The undesirable end states for this industrial irradiator PSA were defined in terms of *overexposure* of facility employees and of *release* of radioactive material.

The overexposure-related undesirable end states were defined by various amounts of absorbed dose to individuals, e.g., a whole body exposure of from 3.4 – 4.5 Gy. To address source leakage, two kinds of material were considered, water-soluble and insoluble. For releases of radioactive material resulting from source leakage, the undesirable end states were defined in

terms of the concentrations of radioactive material in liquid effluents and solid radioactive waste.

I-3.1.4. Approach used – techniques found useful

The application of PSA was approached in a similar manner to the way it is with NPPs. The tasks involved the identification and grouping of initiating events, the development of fault and event trees, the development of a failure database, the performance of a human reliability assessment and accident sequence quantification.

- Operational experience and major accidents occurred in irradiator facilities were reviewed in order to identify initiating events. An initiating event for an industrial irradiator was defined as an event that creates a disturbance in the plant operation that requires the irradiator to be shut down. In order to have a complete initiating event analysis, a systematic identification of potential failures in equipment and system by means of a Failure Modes and Effects Analysis (FMEA) was performed.
- An event tree is an inductive analysis which starts with an initiating event and moves progressively through the successive responses of the systems and human actions, describing the corresponding results in terms of success (upper path of the branch) or failures (lower path of the branch). Probabilities are assigned to the event tree headings by means of the fault tree analysis. This allows assessment of the overall probability of the accident sequences. Detailed event trees have been developed for the seven initiating events.
- Fault trees were developed for eight systems included as event headers in the event trees. The top-down technique was used to develop the fault trees. The level of detail for the fault tree models covers basic components (valves, relays control, electrical fuses, etc.). Support systems such as air supply, electrical source, etc., were modelled as part of each front line system fault tree. Human actions were incorporated in the fault and event trees and were modelled using human reliability techniques.
- Due to the lack of plant-specific failure data, information from the oil, chemical and nuclear industry were used to compile failure data for components. The frequency for initiating events was estimated using the plant logbook. In order to get a specific database, MDS Nordion staff performed a component failure survey covering each (MDS Nordion) irradiator facility.
- The Technique for Human Error Rate Probability (THERP) [I-4] was used to analyse operator response to accident sequences. The analysis considered as much as possible the differences (behaviour, stress, available time to respond) between NPP and irradiator operation. In addition, the ATHEANA method [I-5] was also used for two accident sequences; in these analyses, the HEART method [I-6] was used to quantify human error probability and was combined with the equipment failure probability.
- Sequence quantification was performed using the SAPHIRE (System Analysis Programs for Hands-on Integrated Reliability Evaluations) computer code [I-7]. The SAPHIRE code combines fault tree logic with event tree logic in order to get the sequence logic and the minimum cut sets for each sequence. The minimum cut sets represent the lowest combination of equipment failures and human errors that can lead to an undesired end state.

I-3.1.5. Methodological challenges

The principal challenges in performing the PSA for this irradiator facility were:

- Data availability.
- Human Reliability Analysis (HRA).

Worldwide operational experience with industrial irradiators indicates that the incidents with more serious radiological consequences have been caused by human errors. Various methodologies are available to systematically analyse human reliability; however, most of them were developed to analyse human performance in a NPP, in which the level of stress, the time available to perform tasks, and other performance conditions differ from the conditions typical of industrial irradiators.

With regard to HRA, the ATHEANA method was used to identify potential error-forcing contexts in two sequences. Compared with the THERP results for these sequences, the results of the quantification based on HEART did show an increase in the human error probability due to the error-forcing contexts. The advantage of the ATHENA method is the identification of specific error-forcing contexts and its use to improve operator training programs due to the significance of these human actions.

I-3.1.6. Main results

The quantitative results of the PSA for the industrial irradiator facility are presented in Table 2.

Table 2. Quantitative Results

End State	**Frequency per plant-year**
high dose exposure (> 4.5 Gy)	1.1E-7
release to drain beyond the regulatory limits (3E6 Bq/m3)	4.8E-7
release of radwaste beyond the regulatory limits (0.3 Bq/g).	5.6E-5

For the *high dose exposure* end state, the dominant accident sequence is:

- Initiating event of 'Product movement failure',
- Source stuck by cylinders failure,
- Human error to recognize the source position,
- The common cause failure of safety interlock relays, and
- Operator error to use portable survey meter.

For the end state, *release of radioactive waste*, the dominant sequence is:

- Initiating event of leaking sealed sources with a significant amount of insoluble Co-60,
- Operator error in checking radiation level in sediments of pool.

For the end state, *release of radioactive material*, the dominant sequence is identical, with an operator error to check the radiation level in the pool water (rather than in the pool sediments).

The risk significant components were the control relays of the Control Access System, whose operational status is not tested.

I-3.1.7. Recommendations concerning the application of probabilistic safety assessment techniques to industrial radiation source applications

— Because of the lack of facility-specific component failure data, generic data from the oil, chemical, and nuclear industries were used; however, these data needed to be adapted.
— A survey of component failure experience was performed for MDS Nordion irradiator facilities around the world. The data from this survey are inherently biased because they are self-reported. However, this qualitative information can be very useful, e.g., through the use of failure modes observed during service conditions.
— The review of international operational experience showed that a majority of accidents have occurred during normal operation with the most significant risk associated with the movement of the source during the start-up or shutdown of the irradiator.
— PSA studies have only been performed for a limited number of industrial irradiation facilities; therefore, generic lists of potential initiating events and accident scenario types are not available. A review of operating experience could be very helpful in developing this information. This review should consider a broad range of facilities, including facilities that may be significantly different in terms of design and operation. This information would complement the results of facility-specific analyses such as FMEA.

I-4. Studies of medical applications

I-4.1. Common aspects of medical applications

Medical applications of radiation sources include two broad areas: *diagnostic* and *therapeutic*. Generally, the amount of radiation used, and the resultant risk of overexposure to patients, personnel and members of the public, is much less for diagnostic applications than with therapeutic applications. Therefore, the inclusion of therapeutic applications in this CRP was a higher priority than diagnostic applications.

In therapeutic applications, there are also two main practices that use radiation sources with the potential to cause significant radiation damage. The first of these is *teletherapy*, where a radiation beam is directed to a patient from an external source. The second is *brachytherapy*, where physically small radiation sources are inserted in the patient's body.

Therapeutic applications require many separate actions to be performed by staff members from various disciplines. (See Table 2 in the main text.) These range from diagnosis of a condition to be treated, specification by a physician of a certain radiation therapy, planning of the dose treatment, patient and equipment set-up, and irradiation (usually during several sessions). There are also several control steps along the process (i.e., second physician opinion, checking of the simulation results, set-up checking, patient follow-up after several sessions, etc.). It is worth mentioning that guidance exists that presents a body of 'safe practices' relevant to radiotherapy. This guidance underlies the conception of the treatment

and safety management processes used in radiotherapy practices. Examples of such guidance publications include [I-8–I-11].

In both teletherapy and brachytherapy, there are various specific practices that are used, for example cobalt radiotherapy, linear accelerator radiotherapy, etc. for teletherapy; and high- and low-dose brachytherapy. The selection of the appropriate irradiation technique is usually determined by the type of disease to be treated and the preference of the oncologists who prescribe the therapy.

Both teletherapy and brachytherapy have been addressed in the present CRP. Cobalt teletherapy was analysed by three different teams (Cuba, Argentina and China) while high-dose brachytherapy was analysed by the American team.

All of these practices have some common aspects:

- For therapeutic uses of radiation, the most common undersired outcomes are accidental medical exposures (See Footnote 3 of the main text for definition).
- Accidental medical exposures may either be isolated events (i.e., affecting only one patient during one exposure of a treatment) or systemmatic (i.e., affecting one or more patients during the course of their treatment).
- If used incorrectly, radiation sources have the potential to expose workers and members of the public to doses in excess of prescribed limits. (Teletherapy sources are typically classed in Category 1 while high and medium dose rate brachytherapy sources are classed in Category 2 [I-1].)
- The practices are performed in a hospital environment.
- The equipment used is of high quality.
- In the radiotherapy process, many individuals or groups participate in the administration of the treatment (i.e., physicians, medical physicists, technicians, administrative personnel, etc.).
- The participating personnel come from different disciplines and are often assigned to separate functional/administrative units.
- As a consequence of the previous two aspects, the contribution of human errors to the overall risk is relatively high. However, if quality control measures are implemented in which individuals and groups check each other's work, the risks from human errors may be mitigated or eliminated.

A synopsis of the research performed by each of the participating teams that examined radiotherapy practices follows:

I-4.2. Cobalt teletherapy (study 1 - Cuba)

I-4.2.1. Objective and scope

The general objective of this study was the safety evaluation of the performance of cobalt teletherapy by the Oncological Unit of Pinar del Rio (UOPR) in Pinar del Rio, Cuba, in a systematic, exhaustive and structured way. The evaluation included the application of different techniques and tools of risk identification to investigate the root causes that may lead to accidental exposures to the public, workers and patients, and related accidental sequences during the different stages of the therapeutic treatment (from medical diagnosis up to administration of the treatment).

The specific objectives of the PSA included the evaluation of equipment and human actions that contributed to an increased risk of undesirable end states with the purpose to:

- identify the dominant sequences of cobalt radiotherapy accidental medical exposures;
- identify critical process deficiencies,
- identify weaknesses in practices, procedures and training,
- develop a more complete understanding of the causes and contributing factors that result in accidental medical exposures, and
- provide assessment of efforts to eliminate and/or mitigate accidental medical exposures, i.e., regulations and quality assurance.

I-4.2.2. Resources

The research team was composed of personnel with significant knowledge of the practice of cobalt teletherapy, including specialists in oncology, medical physics, cobalt teletherapy unit maintenance, PSA and Human Factor Assessments specialists; and regulatory personnel specialized in medical practices. The study was completed in two years.

I-4.2.3. Undesirable end states

The PSA started with the definition of undesired end states to be included in the study. Accidental medical exposures were defined as: higher than desired dose to intended volume; lower than desired dose to intended volume; radiation dose to normal tissue outside intended treatment volume, including the wrong patient or body part; unirradiated portion of intended target volume; and non-homogeneous dose to the intended target volume.

Accidental medical exposures are also classified into different categories of error in terms of the extent to which the error is likely to affect individual treatments, individual patients, or all the patients treated with a specific unit. In other words, an episodic error affects a single daily treatment; a programmatic error impacts a larger portion of the patient's treatment; and a systematic error affects all patients treated on a specific unit.

In addition to the risks to patients, unacceptable outcomes in cobalt teletherapy also include occupational and public exposures.

I-4.2.4. Approach used

The methodological tools used in the analysis were Failure Modes and Effects Analysis (FMEA), Event Trees and Fault Trees. These tools were used to evaluate occupational, public and medical exposures during cobalt teletherapy treatment. However, the primary focus of the study was on accidental medical exposures.

The use of classic PSA methodology requires that accident-initiating events be defined. These initiating events represent the starting point of many different accident sequences and delineate the initial conditions for these sequences. The complete list of root causes of the initiating events was determined with the FMEA risk identification tool.

Equipment failure modes and human errors were evaluated for each system and treatment stage in more than 25 brainstorming meetings that were aimed at obtaining an exhaustive list of the deviations that could produce significant adverse outcomes. More than 260 human errors and equipment failures that can cause accident-initiating events were identified. These

root causes of initiating events were grouped in 46 types that can be modelled by means of individual event trees, based on their safety functions and similarity of the success criteria of the defence in depth associated with those functions. By grouping these events, the number of event tree models was reduced to a manageable number without losing any significant information.

Separate events trees were constructed for each initiating event group. Each event tree had a different structure since the initiating events were grouped according to mitigation requirements. Fault tree models were constructed for each top event. The fault trees were developed with a sufficient level of detail to include specific components. In addition to hardware faults, the fault trees included human errors committed in response to accidents and those associated with the treatment.

Generic equipment failure probabilities and typical human error probabilities from available databases were used to quantify the outcome of each accident sequence. The initiating event and top events from one fault tree were combined to analyse the accident sequences. After combining the appropriate models, a Boolean reduction was conducted by computer software to produce sequence cut sets.

I-4.2.5. Methodological challenges

For cobalt teletherapy, there are many undesirable end states with significantly different consequences that make the accident scenarios more complicated to examine than is the case with most applications of PSA.

Human performance makes a significant contribution to accidental medical exposures. A large number of manual steps, tasks and subtasks are performed many times a day, reaching more than forty thousand times per year. Therefore, frequencies per year of some initiating events in cobalt teletherapy may be much higher than in the classical application of PSA to NPPs.

Reports of accidental medical exposures are relatively rare. Therefore, the use of the data in PSA is limited, even more so when the error affects just one patient (episodic or programmatic), or when the accidental medical exposure results in less radiation dose than was intended. The self-analyses of causes of accidental medical exposures vary among facilities both in detail and accuracy.

Some data already exist in a variety of forms regarding the number of accidental medical exposures that occur; however, data on the number of successful treatments performed are not formally reported. Such data are necessary to quantify probabilities of undesirable end states.

I-4.2.6. Main results

The study established that PSA techniques may effectively and reasonably determine the risk associated with the cobalt teletherapy treatment process, though there are some weaknesses in the methodology for this kind of study requiring further research. These weaknesses are due to PSA's traditional orientation toward complex hardware systems designed to operate with a high level of automation (e.g. NPPs) while the cobalt teletherapy treatment is a relatively simple hardware system with a significant human multi-disciplinary interrelation. There are still practical limitations in methods, models and data for evaluating human performance, human dependence and organizational and managerial issues.

Several findings were analysed concerning the cobalt treatment process. Regarding the probabilities of undesirable end states, the lowest exposure probabilities correspond to public exposures during the treatment process; around 1E-10 per year.

Using conservative data, the frequency of occupational exposure events is around 1E-4 per year.

Regarding the patient, the frequency of accidental medical exposures depended on the extent to which the error affected the treatment of one patient, or all the patients treated on a specific unit.

The current PSA does not provide an estimate of the absolute frequencies of accidental medical exposures. Nevertheless, it indicates where and why the more frequent accidental medical exposures will occur with respect to the overall frequency. Sensitivity analyses were performed to determine the influence of certain tasks or critical stages on the results.

The principle of defence in depth is well-implemented in the cobalt unit design as well as in some critical tasks of the cobalt teletherapy process (e.g., calibration during commissioning). However, some of the stages of the treatment process do not satisfy the defence in depth concept; as some initiating events have no accident sequences and lead directly to damage states.

I-4.3. Cobalt teletherapy (study 2 - Argentina)

I-4.3.1. Objective and scope

The general objective of the project was the evaluation of the potential of PSA techniques to characterize the risk of the TERADI800 cobalt teletherapy unit, which operates in FUESMEN, in the city of Mendoza, Argentina. This unit was manufactured by Invap (Argentina) and operates in a medical service, where several other diagnostic and therapeutic services exist.

The fulfillment of this objective resulted in:

- The understanding of the practice and its overall analysis from the risk perspective, by using all the experience and data that could be acquired,
- An assessment of which parts of the analyses can be performed satisfactorily with conventional PSA tools, and
- The exploration of new alternatives to conventional PSA techniques to address areas where conventional PSA techniques could not be easily applied.

The scope of the study changed as the project progressed. This was the consequence of the application of a graded approach (also see Section 2.4). The first step of the study was the understanding of the facility design and operation. An overall qualitative screening of contributors to risk was performed, and from there it was decided to restrict the scope to the risk to patients, and also to focus the study on the analysis of human errors that may contribute to the overall risk.

A secondary general objective was also pursued, which was the integration of service personnel in the analyses and in the use of intermediate results.

I-4.3.2. Resources

The team that executed this study included three PSA analysts with experience with PSA application to NPPs, research reactors, and other hazardous industries. None of them had any experience with cobalt teletherapy. The three members of the team belong to the Cuyo National University.

The initial objective to integrate medical personnel into the analysis team was not possible, mainly due to the time schedules of these individuals. However, an agreement was made to conduct interviews with the medical personnel, and to enable an assessment of all the steps of the practice, either in the form of written reports, photographs, and/or service walk-throughs.

For the analysis, the code SAPHIRE [I-7] was used by the analysis team, as well as computers, a digital photo camera, and office space.

I-4.3.3. Undesirable end states

The first part of the study was devoted for an overall analysis of the facility, its operation and all the possible contributors to risk. Three different groups of potentially affected persons were identified:

— Patients,
— Workers, and
— Members of the public.

The risk associated with the latter two was estimated to be negligible in comparison to the risk to patients; also, it was judged that this risk could be evaluated using standard techniques. Therefore, it was decided to concentrate on the risk to patients.

This being the case, the risk to patients comes mainly from accidental medical exposures.

The overall risk assessment also indicated that a large contributor to risk may come from human errors; therefore, the focus of the study was re-directed toward these errors.

Under these considerations, it was not necessary to define more finely the undesired end states, but to try to identify, understand, and evaluate the contribution of human errors to any of the undesired end states.

I-4.3.4. Approach used

As mentioned above, the approach used was motivated by work to obtain an initial, overall understanding and analysis of the service. This was done by analysing the operational diagram of the service itself, identifying its components, and constructing an operational model of the service.

This model allows for an understanding of the different steps that are carried out from the moment a patient is recommended to the oncology service by a physician. These steps include the diagnosis of the site to be treated by an oncologist, the dose prescription, the calculation of the necessary radiation to give the desired doses by a physicist, the simulation of the radiation treatment in a simulator, the specification of fixing devices, blocks, filters, etc., by the

physicist, the construction of these devices by a technician, the set-up of the patient, the irradiation, and the follow-up.

Besides, there are several check points in the process, and iterations when found necessary. There is also a dependence on image-diagnostic products (i.e., x-rays, tomographies, etc.) and an overall dependence on the calibration personnel.

The complexity of the service operational scheme, the large number of different persons with different backgrounds and the interactions among them, make room for a large number of human errors that may contribute to the risk.

During several facility walk-throughs, several errors were identified and recorded, which confirmed that the greatest emphasis should be placed on human error analysis.

Under these circumstances, standard human reliability analyses techniques (i.e., THERP [I-4]) were explored, and critically compared with modern techniques (in particular, ATHEANA [I-5]).

Several errors were analysed with ATHEANA, with successful identification of the primary contributors to the undesired outcomes, but with no success in the quantification process.

I-4.3.5. Methodological challenges

The general methodological challenge was to evaluate if the application of a conventional PSA approach and its techniques (i.e., that for a NPP) would be effective in identifying, representing and quantifying the risks associated with the application of cobalt teletherapy.

Despite the fact that some aspects of cobalt teletherapy can be analysed with these standard techniques with relatively good results, it became clear to the project team that the most relevant contributors to risk (i.e., human errors and, among them, errors of commission) were not adequately represented and would not be adequately quantified in a conventional PSA approach.

The challenge for these kinds of facilities is that there are many errors that, by themselves, could lead to an undesired end state. For example, an error in the diagnosis of a certain disease may lead to the unnecessary irradiation of a patient; an administrative error when calling the patient to be irradiated may cause the irradiation of the wrong patient; and so on.

This being the case, the methodological challenge was how to treat these errors, as well as errors of commission that have many potential opportunities to occur in a facility that is not automated like a NPP, and where the end states are so dependent on human actions.

It is important to mention also, that there is virtually no data to quantify any of these errors, for cobalt teletherapy as well as in generic databases.

I-4.3.6. Main results

The main results of this project are qualitative.

— The first result is the fact that, for the purpose of analysing the safety of the service, PSA techniques and, above all, a risk-based perspective, proved to be useful in identifying the most relevant contributors to risk.

— Secondly, the study found that it was possible to carry out a conventional application of an NPP-like PSA. However, it was recognized that many techniques of this application needed to be re-interpreted. For example, initiating events and event trees were not found to be very useful, as well as the 'minimal cut set' concept, given that many individual errors may lead directly to an undesired end state. In this sense, the service does not have a defence in depth concept comparable to that of NPPs and therefore, the event trees are usually trivial.
— Human errors and, among them, errors of commission were judged to be large contributors to risk.
— It was found that there does not exist a sufficiently developed method to identify, characterize and quantify these errors. However, several insights were gained from first and second generation HRA methods.
  - In particular, ATHEANA was found to be very useful when combined with task analysis. However, the use of ATHEANA required specific adaptations for the service under study, provided that this method was developed also for NPPs.
  - The availability of data for the inputs to the HRA models was another problem. The ATHEANA approach has been found useful in the sense that it tries to quantify the probability of a certain context where the error may occur, rather than the probability of the human error itself.
— A main result of the performance of the study is a consistent (but qualitative) reduction of the risk of the practice, provided that the identified errors have been communicated to the appropriate personnel, and specific actions to reduce the likelihood of these errors have been taken.

I-4.4. Cobalt teletherapy (study 3 - China)

I-4.4.1. Objectives and scope

The general study objective was the evaluation of PSA techniques to assess the level of safety of two types of cobalt teletherapy units made in China, applying different techniques and tools of risk to identify areas for improvement. The units that were studied were the GWXJ 80 (or GWGP80) and the FCC-7000 (or 8000). The general objective aims at extending and widening the understanding of important issues that affect the safety of cobalt teletherapy treatment. By doing so, design or operational problems can be identified and areas for improvement or future study can be identified.

Related to the general study objective of identifying areas for improvement, the specific objective and corresponding uses of PSA are:

— Identification of accident sequences. The initiating events, hardware failures and human errors are identified that can lead to undesirable end states.
— Identification of system components and human actions important for safety. Analysis of the results of PSA leads to the assessment of the relative importance of the various systems, components and operating procedures.
— Human factor analysis and human error assessment for the cobalt teletherapy process.

The scope of the PSA study considered only in hardware failures of cobalt units and human errors in the cobalt teletherapy treatment process that affected the risk to patients. It does not include risks to members of the public and workers.

I-4.4.2. Resources

The work team is composed of system analysts from two manufacturers, PSA specialists from Tsinghua University, and specialists in radiation oncology and medical physics from two cancer hospitals, as well as some scientific researchers from a national institute.

The information used for the study came from two cooperating radiotherapy unit manufacturing plants and from some hospitals. Some members of the research team visited the plants and more than 20 hospitals that use cobalt teletherapy units.

I-4.4.3. Undesirable end states

For accidental medical exposures, the criteria used to define undesirable end states are dose variance of a certain percentage (compared with the prescribed treatment), dose to the wrong site, or dose to the wrong patient. It should be noted that these criteria are based solely on a deviation from a prescribed dose, i.e. these end states do not necessarily imply an adverse effect on a patient's health.

In general, six categories of undesirable end states were defined for the risk evaluation:

— Dose to intended volume higher than desired,
— Dose to intended volume lower than desired,
— Dose to normal tissue outside intended volume (includes the wrong patient or body part),
— Portion of intended target volume not irradiated,
— Dose distribution in target volume different than intended, and
— Premature, uncontrolled or unplanned exposure to patient.

Regarding error pervasiveness, three levels were defined in terms of the extent to which the error is likely to affect individual treatments, individual patients or all patients treated on a given cobalt teletherapy unit.

In this study, the defined undesired outcomes did not consider occupational and public exposures.

I-4.4.4. Approach used

Before the event tree and fault tree analysis was applied, a very good understanding of the system operation, as well as the operation of its components and the effects of their failures on system success is necessary. Such knowledge and understanding can be achieved through a FMEA.

The analysis for the two models of cobalt teletherapy units proceeded as follows:

(1) Performing an FMEA,
(2) Selection of initiating event group,
(3) Constructing fault trees, and
(4) Constructing event trees.

Human performance made a significant contribution to accidental medical exposures. Therefore, it is important that the reliability of humans be included in the risk assessment

process. The approach taken in identifying human errors is through the use of human factor evaluation as it relates to the cobalt teletherapy process, including the following steps:

— A data collection plan,
— Function and task analysis,
— Definition of risk assessment criteria,
— Export judgment and risk task analysis, and
— Relative risk ranking and profile analysis.

In addition to the PSA, a separate analysis of an occupational exposure event on 2 January 2002 in He Nan province, China, was performed. The process for conducting the analysis involved tree models as follows:

— Developing a generic error model,
— Fault tree modelling, and
— Event tree modelling.

I-4.4.5. Methodological challenges

The purpose of this study is to evaluate the use of PSA in developing risk-based medical devices with radiation sources. Traditional methods used in assessing risk in NPPs may be inappropriate to use in assessing medical radiation risks. NPP PSAs are machine-oriented with a human failure component associated with critical machine failure events.

In assessing the risk of administering an incorrect radiation dose to a patient, the primary source of failures seems to stem from the actions of people and only secondarily from machine failures. This basic difference has led to the development of a person-centered approach to risk assessment that yields relative risk profiles. This person-centered approach to risk assessment includes a hierarchy of steps:

— Identify the critical human and machine processes and sequences,
— Evaluate hazards to patients,
— Perform a modified task analysis, and
— Develop relative risk profiles for each task sequence.

There are potential limitations in the traditional risk assessment methods for the medical use of radioactive material. It is due to:

— Data associated with specific top events or their causes may not be readily available and could require the gathering of additional reliability data. For risk assessments, the data must include the number of failures and the number of successes in order to get a ratio. However, success data are not reported; therefore, the data are statistically very limited with respect to use in risk assessments.
— In many cases, required additional data such as human error data can be developed through consultation with relevant experts, but this area represents one of the weakest parts of risk assessment.
— Risk assessment, as a technology, has been applied to NPP operations since the mid-1970s. Its application to the medical use of radiation sources is still developing and

some components of the methodology require improvement, such as data requirements, modelling requirements and special considerations for medical risk assessments.

I-4.4.6. Main results

FMEA

A FMEA for the two types of cobalt teletherapy units was found to be a very useful preliminary step to system model development (e.g. fault trees). It is a systematic method for analysing and clarifying the effects of component failure on the system function.

For the GWXJ 80 (or GWGP 80) type unit,

— 5 systems, 35 subsystems and 175 components were defined.
— Three levels of severity in the FMEA study were developed for the two types of units. 51 components were assigned level 1 severity. For these, based on the experience of engineers and maintenance reports, the estimated component failure probabilities ranged from 1 E-4 to 1 E-7.

For the FCC-7000 (or 8000) unit,

— 6 systems, 28 subsystems and 132 components were defined.
— 79 components were assigned level 1 severity. The estimated component failure probabilities for these ranged from 2 E-4 to 1 E-10, using the same approach as for the other unit.

According the FMEA for the two types of units, initiating events can be grouped in such a way that all events in the same group impose essentially the same success criteria as well as the same special conditions and thus can be modelled using the same event (or fault) tree analysis. It is noted that *these event models contain equipment failures only* and do not include human error events.

Human factor evaluations (HFE)

A series of human factors evaluations was undertaken to better understand the contributing factors to human error in the cobalt teletherapy process. The study focused solely on function and task analysis vis-à-vis teletherapy activities. A basic process using existing techniques for identifying the most likely risk contributors and their relative importance was developed. The output of this approach was the development of relative risk rankings and profiles for specific tasks.

The following five steps in HFE methodology were used to identify and assess the likely high risk tasks: (1) Data collection; (2) Function and task description; (3) Definition of risk assessment criteria; (4) Expert judgment and risk task analysis; and (5) Relative risk ranking and profile analysis. In this study, the experts were professionals experienced in the cobalt teletherapy practice. Preliminary estimates from 10 experts were collected to estimate the error probability and consequences for each task.

The data resulting from the application of function and task analysis include system data, task data and risk data. The system data include details about potential hazards and abnormal modes of operation. The task data help characterize potential errors. The risk data include

relative estimates of human errors and consequences of undesired outcome. The risk data are manipulated into relative risk ranks and profiles.

Altogether, 103 discrete tasks were identified as integral components of the cobalt teletherapy process. These tasks were grouped into 10 discrete functions. Relative risk profiles and distributions were developed which offered insights into the critical tasks of the cobalt treatment process. Plots of the relative point estimates of probability, consequence and its risk are provided, referred to as risk profiles, allowing comparisons of risks among tasks. These relative risk profiles aid the identification of the high-risk, high-consequence or critical tasks, without requiring an absolute quantification of probability, consequence and risk for each task.

The relative risk profiles showed that several of the highest risk tasks are associated with three functions of the cobalt teletherapy process: pre-treatment planning session (Function No. 2), treatment and safety equipment checks adjustments and maintenance (Function No.3), and treatment administration (delivery) (Function No. 9). It further indicated that the highest-risk tasks are

— Task 2.2, review the use of department equipment for unusual situations,
— Task 3.5.1, perform central axis dose calibration,
— Task 9.2.2, monitor patient on visual TV monitor, and
— Task 3.1.2.1, place treatment table, gantry and collimator angle to pre-established standard position for iso-centrality and output checks.

In conclusion, the results show that the performance of relative risk profiling for cobalt teletherapy may be most effective in medical applications of radiation that are not highly structured or have limited databases of experience. The relative risk techniques used to study cobalt teletherapy can identify weaknesses in treatment processes.

I-4.5. Brachytherapy

I-4.5.1. Objectives and scope

The objectives of this study were to

— Establish the conditional probabilities for errors in the various phases of the brachytherapy treatment process, and
— Find particular aspects of brachytherapy where improvements in quality management or increasing safety procedures would reduce the likelihood of errors in such treatments.

The study investigated the brachytherapy procedure generically, and not as practiced in any particular facility. This study only considered safety with respect to the patient, ignoring the potential for accidental exposure to the general public or excessive exposures to the staff of radiotherapy facilities.

I-4.5.2. Resources

The information used for this study came from reports of errors in brachytherapy treatments gathered by the US Nuclear Regulatory Commission (NRC) and the International Atomic Energy Agency. The NRC accepts neither reports involving errors in prescribing treatments,

nor in diagnosis or defining the treatment targets. Thus, the analysis contains no information about errors of these types. The team assembled for the analysis included a medical physicist, a radiation oncologist, two industrial engineers, four industrial engineering students (in succession), and a quality improvement specialist.

I-4.5.3. Undesirable end states

The reports upon which this study was based fell into events considered 'misadministrations', defined as:

- Treatment delivered to the wrong patient,
- The dose delivered to the target being wrong by greater than 20%,
- Treatment to the wrong site,
- Failure to remove a source for a temporary implant,
- Treatment with a leaking source, or
- Treatment using the wrong radionuclide.

Actual injury to the patient was not a criterion for inclusion in the database, and only one event resulted in significant near-term patient injury, although the course of a patient's treatment might have been compromised.

I-4.5.4. Approach used

The analysis for three forms of brachytherapy (high dose-rate 'HDR' brachytherapy, low dose-rate 'LDR' temporary application brachytherapy, and low dose-rate permanent implant brachytherapy), proceeded as follows:

- Making a process tree, [1]
- Creating a qualitative failure mode and effects analysis,
- Building a fault tree,
- Clarifying the details of each event in the database,
- Performing a root cause analysis for each event,
- Indicating on the process tree and the fault tree the steps at which the failures occurred that resulted in the event, and
- Determining the conditional probability for a failure at each branch of each tree per event.

In addition, the natures of the failures for each event were classified using three error taxonomies.

[1] A process tree follows the flow of the entire treatment process. Each bough represents a major division of the process. Off each bough are branches, representing components of the major divisions. Finally, the leaves on the branches correspond to small functional steps. Detail can be added in finer branches as is useful for analysis. Each step in the process tree must be completed successfully and correctly for an error-free treatment. A process tree applies to the procedure for all patients undergoing that particular treatment. If an accidental medical exposure happens, at least one of the steps involved failed to be executed correctly (and possibly more).

I-4.5.5. Methodological challenges

Compared with PSA for power plants, the analysis for a medical procedure differs in several very important aspects.

- The first is the very high component of human actions. Almost no events resulted directly from mechanical or electronic failures (although such failures produced environments conducive to human performance failures).
- Projection of expected failure rates remain elusive because the actions frequently are complex sequences, often without a fixed or standard combination or order and also with undetermined recovery mechanisms.
- The frequency of events is low, so few branches of any tree garner many scores, and many branches show no errors. While the conditional probability for errors along no branch would be zero, many branches have no data to indicate the magnitude of its respective probability.
- Finally, the total number of treatments delivered during the period of the study, most with no error, remains unknown, and likely unknowable. Thus, only conditional probabilities, that is, the probability that an error happened in a particular step given that an event happened, could be calculated, rather than the absolute probabilities. The lack of absolute probabilities prevents the performance of a complete PSA.

I-4.5.6. Main results

Risk analysis tools common in industry provide useful information for error reduction in medical settings, although the tools often work less effectively in medical applications because of the very high component of human actions, and modification of such techniques could improve their efficacy. Tables were prepared with the conditional probabilities for each step that had recorded events. Even with the small numbers of events, the tables clearly show the most hazardous phases of the treatments.

General conclusions from the brachytherapy study

The general conclusions include:

- Events usually have multiple causes;
- Failure to consider human performance in the design of equipment led to a large fraction of the events;
- Verification procedures often were ineffectual;
- Many events followed the failure of persons involved to detect that the situation was abnormal, often even though many indications pointed to that fact. Once identified, the response often included actions appropriate for normal conditions, but inappropriate for the conditions of the event;
- Events tended to happen most with actions having the least time available;
- Lack of training and procedures covering unusual conditions frequently contributed to events;
- New procedures, or new persons joining a case in the middle present increased hazards.
- The data provided insufficient detail to assess the influence of environmental shaping factors (such as time of day), but there is a slight indication that the effects mirror those in other settings.

The particular results from the process tree analysis and fault tree analysis are presented in Tables 3 and 4.

Table 3. Results from process tree analysis of brachytherapy event reports

LDR	HDR
For LDR cases *where dosimetry followed placement* (such as most intracavitary applications), the process-tree analysis found the following characteristics for the events: **Errors in four steps accounted for 52% of the events**: — Selection of the sources to place into the applicator, — Loading of sources into the applicator, — Using the required units when entering data into the computer, and — Fixing the sources in the applicator, or applicator in the patient. Most steps in the branches 'Source loading' and many along 'Dose/time calculation' and 'Treatment termination' had errors. For LDR cases *where dosimetry preceded placement* (most interstitial implants), errors occurred **only in source preparation** (usually ordering), and **source placement** into the implant (usually a failure to monitor the placement closely enough).	For HDR brachytherapy, by far the most common step with failure was entering the treatment distance (14 of the 45 evaluable events of this type), usually not changing the default value. However, some events occurred in almost all steps in treatment unit programming and delivery. Dose specification during treatment planning accounted for 5 of the 45 events. The only problems with source strength in the events studied happened when entering the calibration data into the treatment-planning computer.

Table 4. Results from fault tree analysis of brachytherapy event reports

LDR	HDR
For LDR brachytherapy, **three quarters of the errors were during treatment delivery**, where as a percent of total number of LDR events: — 26% because the wrong strength sources were used ('source loading error'); — 12% because the sources were never placed in the applicator correctly ('Incomplete loading'); — 11% because the patient removed the sources and the staff didn't notice or correct; and — 8% because the physician placed the applicator incorrectly. Of the 12% of the events where the sources never were correctly placed, 83% involved failure during loading the ovoids of a Fletcher-Suit style cervical applicator (usually with the sources falling out of the buckets). The failures for **the remaining quarter of the events occurred during treatment planning**, notably: — 15% of events with errors in calculation (11% due to incompatible units); and — 8% of errors due to incorrect source strength entry.	**Two-thirds of the errors occurred during delivery of the treatment**. Of those: — 40% of events resulted from the failure to change the default value for the treatment distance (listed as 'Error in transcription', of which the default-value error was the only example encountered); — 10% happened because of a problem with the source drive mechanism ('Source fails to progress'); — 7% occurred because the applicator shifted in patient; — 5% involved incorrect connections between the applicator and the treatment channel. **One-third of the errors arose during treatment planning**, with: — 16% of errors in calculation, but of various types; — 7% of errors due to incorrect source strength entry (of which, all were failure to enter new source information into a computer); and — 7% of errors during localization.

I-4.6. Recommendations concerning the application of probabilistic safety assessment techniques to medical radiation source applications

The general challenges for the application of PSA techniques to radiation source applications were outlined in Section 2.3. Information about the specific challenges encountered by each of the CRP research teams that studied medical practices has been presented in Section I-5. In light of the experience of these teams, this section presents some recommendations specific to medical practices for conducting PSA or applying PSA techniques in risk evaluations.

— Consider the patient first as the person most at risk from medical uses of radioactive materials, followed by a facility's personnel and then the general public.

— For patients, include all of the possible undesired outcomes. It is worth noting that the delivery of an insufficient dose or the failure to deliver the prescribed dose to the entire target volume may be under-reported in the literature.
— Include (to the extent possible) as wide a range of the therapeutic steps as possible. Many risk contributors may come from diagnosis, planning, set-up, inadequate checking/verification (failures of the steps related to control), as well as from equipment failures.
— Perform as complete a human error analysis (HEA) as possible. The experience shows that the risk associated with radiation therapy is strongly associated with the performance of the human tasks in the process. The limitations of quantitative methods, i.e. of the quantification aspects of HRA, motivate a deep qualitative analysis.
— Experience demonstrates that a risk evaluation identifies quite large risk contributors while it is being performed; the transmission of these 'lessons learned' to the responsible persons serve both to reduce the associated risk, as well as to enhance their commitment in the risk evaluation process.
— Try to involve closely the radiotherapy personnel in the study. The broad spectrum of tasks and disciplines often means that few persons have deep knowledge in all areas of the service. Use the interim results to enhance the safety of the radiotherapy service and motivate participation in the study.
— A significant problem for the selection of initiating events in medical settings is that many actions fall into a long continuum of actions and reactions throughout the process. In some of the studies, significant resources and several techniques were used to ensure the completeness of the initiating events selection.

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