

**RISK MANAGEMENT AND RADIOLOGICAL SAFETY IN  
HEALTH CARE**

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## 1. Introduction

The health care sector is an extensive and complex sector. Most likely, it is the largest single employment sector in Europe, where a large range of very different tasks and jobs are carried out. It therefore contains a large number of hazards and risks and complex occupational, safety and health management problems.

Health care interventions are intended to benefit patients, but they can also cause harm. The complex combination of processes, technologies and human interactions that constitutes the modern health care delivery system involves an inevitable risk of adverse events that can – and too often do – happen. Treatment errors in medicine are classified under various names including “treatment misadministration’s,” “treatment incidents,” “treatment accidents,” “unusual occurrences,” “treatment discrepancies,” and “adverse events.” In 2000, the Institute of Medicine in the United States published a detailed report on treatment errors in medicine, entitled “To Err is Human: Building a Safer Health System” (Kohn et al., 2000). The Report defines treatment errors as “the failure of planned action to be completed as intended” (i.e. error of execution) or “the use of a wrong plan to achieve an aim” (i.e. error of planning).

It was estimated that there were about 44 000 to 98 000 people in the United States who died annually from medical errors. These deaths represented more than annual deaths from motor vehicle accidents, or number of patients who died from breast cancer, or deaths from AIDS. The estimated total annual cost of these errors was \$38 to \$50 billions per year. The most common types of errors were categorized as being related to “technical” (44%), “diagnosis” (17%), “failure to prevent injury” (12%), and “use of drugs” (10%).

The Institute of Medicine report prompted a number of legislative and regulatory initiatives designed to document errors, which occurred during medical procedures and to start the search for solutions. These initiatives were further catalyzed by the second IOM report entitled “Crossing the Quality Chasm: A New Health System for the 21st Century” (National Academy Press, 2001), and the AHRQ Report on Critical Analysis of Patient Safety Practices (Shojania et al., 2001) which highlighted safety as one of the fundamental aims of an effective health care system.

Not only patients, but also all occupational groups in the medical sector may face hazards. The main risk factors are well documented (WFILWC, EF/95/27/EN). They include musculoskeletal loads, biological agents, chemical substances, radiological hazards, changing shifts, work rhythms and night work. violence from members of the public, accidents at work, etc.

Additionally to the general safety systems there is a special system for radiological safety of medical devices and for radiation protection of patients and medical personnel. In this paper, radiological protection is considered within the system approach, in order to underline, that risk assessment and effective health and safety management are the key to preventing and reducing patient and healthcare-worker exposure to any kind of hazard. This include also the safety of medical devices and systematic assessment of direct and indirect consequences of particular technologies and threats against patient safety due to misuse, overuse or under use of technology.

## 2. Radiological hazard

### 2.1. Biological effects of exposure to ionising radiation

When ionising radiation passes through matter, energy is imparted to the matter in the process of ionizing of atoms. This energy is quantified in terms of dose. In biological tissues, the process of changing atoms through ionization also changes the molecules containing those atoms and it may thus cause damage to the cells containing those molecules. If cellular damage does occur, and it is not adequately repaired, it may either prevent the cell from surviving and reproducing, or it may result in a viable but modified cell. The two outcomes have different implications for the organism as a whole, the former being associated with deterministic effects and the latter with stochastic effects.

Deterministic effects occur when the dose exceeds a given threshold in short time. The severity of the effects is proportional to the dose, although the dose threshold is organ specific. Acute exposure to very high radiation doses such as might arise in the course of radiotherapy or as a consequence of an accident, can lead to tissue injury. Depending on the conditions of the exposure, this might induce effects such as erythema, sterility or – at sufficiently high doses – death within a few weeks or months. Other effects such as cataracts might occur over a

period of years. These effects generally arise only at high doses, which are generally rare and in may arise only in very specific situations. However, in the case of radiotherapy and the most complex interventional radiology procedures, high doses that exceed the threshold for tissue injury may be unavoidable because at lower doses the therapy or intervention would be not successful.

Stochastic effects are probabilistic in nature (i.e., their frequency increases with received dose), but their severity is independent of the dose. The main stochastic effect is initiation of carcinogenic process. Therefore, the main impact on health following exposure to moderate or low radiation doses is an increased risk of cancer in later life. The duration of the latency period is typically 5 to 15 years from the date of exposure depending on organ and tissue.

In addition to cancer, there are suggestions from studies of the Japanese A-bomb survivors and of patients given radiotherapy that the risk of cardiovascular disease might be increased following radiation exposure.

The second type of stochastic effects are mutations and hereditary effects associated with them. This has been observed in animal experiments but has been difficult to document in humans.

## 2.2. General rules of radiation protection

Radiation protection is concerned with the protection of individuals, their progeny and populations against possible detrimental effects of radiation. The basic quantity in the system of radiological quantities and units is absorbed dose, which is the amount of energy transmitted by ionizing radiation per unit mass. Absorbed dose is measured in grays, Gy (1 Gy = 1 J/kg).

The development of biological effects depends not only on the absorbed dose, but also on the specific type of radiation. Therefore, the quantity equivalent dose has been introduced, in order to take this difference into account, by applying radiation-specific weighting factors. The weighting factor for gamma and beta radiation is equal 1, while that for alpha particles and neutrons may reach 20, depending on the particle energy (ICRP Publication 60, 1991). Equivalent dose is measured in sieverts (Sv).

In cases involving non-homogenous irradiation (e.g., the exposure of various organs to different doses), it is useful to calculate an effective dose, i.e. the sum of doses in particular organs or tissues, multiplied by weighting factors, which take into account the radiation sensitivity of each tissue and organ (ICRP Publication 60, 1991).

For all practices (continuing and proposed), the exposure to radiation has to be controlled through justification, optimization and dose or risk limitation.

Justification involves a demonstration that there is a net benefit from a practice which leads to exposure to radiation. Most often, the justification process is conducted when a new practice is proposed and various design options are considered. Only the options which can be expected to do more good than harm are selected. The considered benefits and detriments should encompass all aspects of the proposed practice, so the decision-making process covers far more than radiation protection alone and should involve all appropriate governmental and societal decision-making agencies. Justification is also required when existing practices are under review, particularly if new information is available concerning their efficacy or their consequences.

The optimization is performed in order to make the best use of resources in reducing radiation risks, once a practice has been justified. The broad aim is to ensure that the magnitude of individual doses, the number of people exposed, and the likelihood that potential exposures will actually occur should all be kept as low as reasonably achievable, economic and social factors being taken into account (ALARA principle). In essence, optimization involves the examination of a suite of possible strategies, ranked in order of reduction in detriment. The optimum will have been reached when any further step to reduce the detriment would involve a deployment of resources that is out of proportion to the consequent reduction. Optimization is principally involved in the design process for the detailed operation of a practice, but the general principles of optimization should always be borne in mind in day-to-day administration of radiation protection procedures.

Limitation of dose or risk is used to place bounds on risk to individuals so that risks do not exceed a value which is considered acceptable for everyday, long-term exposure to radiation. As it is assumed that the probability of stochastic effects increases with dose with no threshold, dose limits do not and cannot define a demarcation between 'safe' and 'unsafe'. Consequently, it is not sufficient merely to ensure that individual doses do not exceed the limits: they should be controlled through optimization to be as low as reasonably achievable. Conversely, it

is not a matter of undue concern for a person's health if, on occasion, that person's dose slightly exceeds the dose limit, although it would certainly be cause for investigative action if this occurred during normal working operation of a practice. There are exceptional circumstances, such as in emergencies or accidents, in which the voluntarily-taken exposures may exceed the annual dose limits.

All medical exposures should be subject to the principles of justification and optimization in a medical context. Dose limits, which are employed to restrict occupational and public exposure to radiation, are not appropriate for patients undergoing diagnosis or therapy. The physician responsible for the patient will determine the appropriate medical care. However, recommended guidance levels (IAEA, 1996) for medical exposure for particular procedures may assist in optimising patient dose.

For doses received by a patient undergoing medical diagnosis or therapy, there are two levels of justification. First, the medical practice involving exposure to radiation should be justified in principle. Second, each procedure should be subject to a further, case-by-case justification by the clinician who is responsible for the management of the patient and who determines that the exposure is necessary for diagnostic or therapeutic purposes.

### **2.3. Hazard associated with the use of medical radiological equipment**

Medical radiological equipment can be grouped according to the three major radiological disciplines – diagnostic X-ray equipment, equipment for nuclear medicine and radiotherapy equipment.

For diagnostic X-ray equipment, the following characteristics of the devices are usually listed as being associated with radiation protection of the patient:

- radiation quality related to radiological application,
- limitation and indication of the extend of the X-ray beam,
- relationship between X-ray field and image reception area,
- leakage radiation,
- focal spot to skin distance,
- attenuation of the X-ray beam,
- primary protective shielding related to radiological application.

There are three diagnostic techniques that need a special consideration These are mammography, computed tomography (CT) and interventional radiology.

In mammography, the X-rays has to be used for assuring a life saving diagnosis when applying a relative high dose with low energy X-rays. Consequently, the main issues addressed for the radiological safety are the X-ray quality and accuracy of operating data. Compared to general X-ray equipment, in mammography the tolerances for generating and filtering the X-rays, and for accuracy of automatic exposure systems are much smaller.

The application of CT equipment is spreading out extremely fast, due to its advantages in imaging capabilities. The today's capability of presenting near real time imaging makes it possible to use the CT equipment also for interventional procedures. On the other hand the CT examinations are associated with relatively high doses, often over the whole body of the patient. Therefore, the rules of justification and optimization of exposure should be strictly followed in these examinations.

Interventional radiology is a fast growing field of applications and includes more and more complicated procedures. This leads to a significant increase of the doses to the patients and to the medical staff. Therefore, there are special safety elements, e.g. the tolerances defined for the correspondence of X-ray field size and image reception are usually smaller than for general X-ray equipment, because the small fields are often used, especially at cardiovascular examinations.

Another source of hazard can be formed by improper subsystems or components which are intercepting the X-ray beam and play an important role for the radiation protection of the patient. Among theme, there are X-ray grids, image intensifiers, X-ray cassettes, screens and films.

Diagnostic equipment in nuclear medicine does not expose directly the patient to any particular danger other than regular electrical or mechanical hazards. The particular issues in this case are the performance standards for different modalities used in nuclear medicine. The danger comes from delivery to the patient of radiopharmaceuticals, necessary for the diagnostic procedure. Since underdose or overdose may result in sub-optimum image and in false diagnosis, the exact activity of the radiopharmaceuticals must be measured by

radionuclide calibrators and the measures against incorrect delivery of radio-pharmaceuticals to the patient have to be introduced.

Safety requirements in radiotherapy differ significantly from those in diagnostic X-ray. They include systems to protect the patient against incorrect dose, incorrect beam geometry and excessive radiation leakage. Also treatment planning systems are important for ensuring the accurate delivery of the radiation to the tumour. The safety requirements concerns the algorithms used and the minimum requirements for the users manual, in order to allow the proper choice during the treatment planning process.

### 3. Risk management

#### 3.1. General Definitions

The most important definitions used in this paper are listed below:

Hazard - Potential source of harm to the patient or user.

Harm - Physical injury or damage to health of people, property or environment.

Risk - A combination of the severity of the harm and the probability of occurrence.

Risk Analysis - Systematic use of available information to identify hazards and estimate the risk.

Risk Evaluation - Judgement, on the basis of risk analysis, of whether a risk which is acceptable has been achieved in a given context based on the current values of society.

Risk Control - The process through which decisions are reached and protective measures are implemented for reducing risks to, or maintaining risks within, specified levels.

Risk Management File - A set of records and other documents, that are produced during a risk management process.

Adverse Event – Any injury caused by medical care. Identifying something as an adverse event does not imply "error," "negligence," or poor quality care. It simply indicates that an undesirable clinical outcome resulted from some aspect of diagnosis or therapy.

Near miss is an event or situation that could have resulted in an accident, injury or illness, but did not, either by chance or through timely intervention.

According to the above definitions, hazard is a potential for an adverse event, a source of danger. Risk is a measure of the combination of (1) the hazard; (2) the likelihood of occurrence of the adverse event; (3) the severity or overall impact. Risk assessment begins with risk analysis to identify all possible hazards, followed by risk evaluation to estimate the risk of each hazard. In general, risk assessment is based on experience, evidence, computation, or even guesswork.

Concerns regarding patient safety, variable health care quality and increasing health care costs have led to the introduction of clinical management tools that have their origins outside of the traditional health care sector. The degree of regulation imposed on any device or practice is proportional to the potential hazard associated with this device or practice. This approach is known as risk management.

#### 3.2. Swiss cheese model

There are many models of complex systems and their malfunction but the most popularly in medicine is so called Swiss Cheese Model of systems failure. The key terms of the model are "active errors" and "latent errors" introduced by James Reason. (Reason, 1990; Reason, 2000).

Active errors occur at the point of contact between a human and some aspect of a larger system (eg, a human-machine interface). They are generally readily apparent (eg, pushing an incorrect button, ignoring a warning light) and almost always involve someone at the frontline. Latent errors (or latent conditions), in contrast, refer to less apparent failures of organization or design that contributed to the occurrence of errors or allowed them to cause harm to patients.

Sometimes, errors are classified as "slips" or "mistakes". Mistakes reflect failures during attentional behaviours, or incorrect choices. Attentional behaviour is characterized by conscious thought, analysis, and planning, as occurs in active problem solving. Therefore, mistakes typically involve insufficient knowledge, failure to correctly interpret available information, or application of the wrong rule. In contrary to mistakes, slips are associated with failures of schematic behaviours or lapses in concentration (eg, overlooking a step in a routine task due to a lapse in memory, an experienced surgeon nicking an adjacent organ during an operation due to a

momentary lapse in concentration). Thus, choosing the wrong diagnostic test or ordering a suboptimal medication for a given condition represent mistakes. A slip, on the other hand, would be forgetting to check the chart to make sure that a drug is ordered for the right patient.

Distinguishing slips from mistakes serves two important functions. First, the risk factors for their occurrence differ. Slips occur in the face of competing sensory or emotional distractions, like fatigue, and stress. Mistakes more often reflect lack of experience or insufficient training. Second, the appropriate responses to these error types differ. Reducing the risk of slips requires attention to the designs of protocols, devices, and work environments—using checklists so key steps will not be omitted, reducing fatigue among personnel (or shifting high-risk work away from personnel who have been working extended hours), removing unnecessary variation in the design of key devices, eliminating distracting devices (eg, phones) from areas where intense concentration is needed, and other redesign strategies. Reducing the likelihood of mistakes typically requires more training or supervision.

The Swiss Cheese Model (Fig. 3.1) was developed in order to illustrate how analyses of major accidents and catastrophic systems failures tend to reveal multiple, smaller failures leading up to the actual hazard (Reason, 2000). The point is that no single barrier is foolproof. Each of them has "holes" like in the Swiss cheese. The model characterizes the organizational latent factors such as staff training, policy decisions, resource allocation etc. It also allows a medical intervention to be broken down into a number of steps (slices of cheese), identifying confounding or contributing factors at each step in the process. Confounding factors are illustrated as the "holes" in the slice of Swiss cheese and represent the problems or errors that might contribute to failure of the overall system and result in an adverse patient event. An individual human error represents only one hole in a single step or "slice." Usually, an adverse event may occur only when several holes line up and the path of the intervention, unfortunately, falls through them at every step. It is very important to remember that for some serious events even rare cases of harm will be unacceptable.

In reality, the "slices" form a dynamic system with permanently moving "holes". Moreover, the slices of cheese and the location of holes in them are not independent of each other. This can be easily observed in emergency situations when several safety checks may fail down or be bypassed. In health care, such failure modes, in which slices of the cheese line up more often than one would expect if the locations of their holes were independent, occur distressingly commonly. In fact, many of the systems problems discussed by Reason and others—poorly designed work schedules, lack of teamwork, variations in the design of important equipment between and even within institutions—are sufficiently common that many of the slices of cheese already have their holes aligned. In such cases, one slice of cheese may be all that is left between the patient and significant hazard [<http://psnet.ahrq.gov/glossary.aspx>].

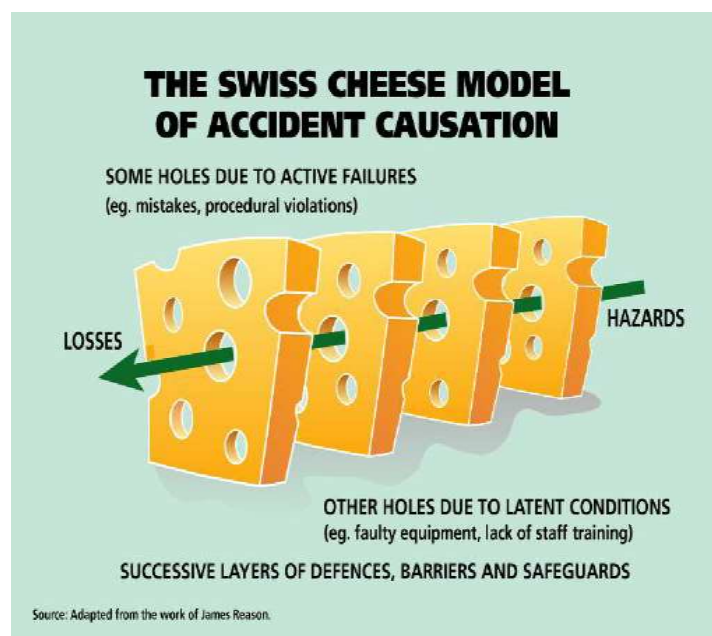


Figure 3.1. Graphical illustration of the Swiss Cheese Model, adopted from the works of James Reason (Reason, 1990; Reason, 2000).

### 3.3. Root cause analysis

The term 'root cause analysis' (RCA) originates from industry, where a group of tools are used to identify root causes from the investigation and analysis of incidents. RCA is a structured process for identifying the causal or contributing factors underlying adverse events or other critical incidents. The key advantage of RCA over traditional clinical case reviews is that it follows a pre-defined protocol for identifying specific contributing factors in various causal categories (eg, personnel, training, equipment, protocols, scheduling) rather than attributing the incident to the first error one finds or to preconceived notions investigators might have about the case. (Wald and Shojania, 2001; Bagian et al., 2002).

On the other hand, the term root cause analysis can be misleading in suggestion that there is a single root cause, or at least a small number of causes. Typically however, there is a chain of events and a wide variety of contributory factors leading up to the eventual incident. The difference between cause and contributing factors is not entirely a semantic distinction. As illustrated by the Swiss cheese model, multiple errors and system flaws must come together for a critical incident to reach the patient. Labelling one or even several of these factors as "causes" fosters undue emphasis on specific "holes in the cheese" rather than the overall relationships between different layers and other aspects of system design. Accordingly, some have suggested replacing the term "root cause analysis" with "systems analysis." (Taylor-Adams and Vincent, 2004). Specific resources that facilitate carrying out RCA or "systems analyses" can be found e.g. at the site of Veterans Affairs National Center for Patient Safety. (<http://www.patientsafety.gov/rca.html>).

### 3.4. System approach

One of the cardinal concepts in patient safety, borrowed from industry, is systems analysis. This is the concept that systems failures – not individual human failures – are to blame for many of the adverse events occurring in health care. Saying shortly, "Human beings make mistakes because the systems, tasks and processes they work in are poorly designed" (Lucian Leape).

An important part of moving beyond the blame and punishment often associated with medical errors is recognizing that the human factor is only one aspect of today's complicated medical systems. A systems approach to patient safety recognizes that health care providers work in a complex environment that can include many risk factors. All of these factors can come together to form a complicated chain of events that allows a medical error to occur. As outlined in the Institute of Medicine publication, *To Err is Human* (Kohn et al., 2000) "Preventing errors and improving safety for patients require a systems approach in order to modify the conditions that contribute to errors. People working in health care are among the most educated and dedicated work force in any industry. The problem is not bad people; the problem is that the system needs to be made safer."

The step further is Complexity Theory which emphasizes interactions between a local system and its environment (such as the larger system in which a given hospital or clinic operates). It is often tempting to ignore the larger environment as unchangeable and therefore outside the scope of quality improvement or patient safety activities. According to complexity theory, behaviour within a hospital or clinic (eg, non-compliance with a national practice guideline) can often be understood only by identifying interactions between local attributes and environmental factors (Rhydderch et al., 2004; Plsek and Wilson 2001).

### 3.5. Risk analysis tools adopted for health care system

The approach to health care quality considerably changed in the early 1990s. Prior to that decade, the prevailing paradigm was known as quality assurance. The International Organization for Standardization (ISO) defines quality assurance (QA) as "all those planned and systematic actions necessary to provide adequate confidence that a product or process will satisfy given requirements for quality" (IOS 1994). There are two major components to this definition of QA. The first is that there has to be some quantitative measure that determines whether a product or process has met the desired standard. Second, if the product does not comply with the standard, then there must be a defined process to bring the product in line with the standard. ISO also defines quality control (QC) as "the regulatory process through which the actual performance is measured, compared to existing standards and finally the actions necessary to keep or regain conformance to the standard" (IOS 1994). Thus, QA is the plan and definition of systematic actions and QC is the actual measurement and assessment process.

Quality assurance play a specially important role in radiology and radiotherapy. The increased complexity of the modern technology placed greater pressures on QA and quality control to ensure that patients are treated safely. There are two very major considerations. The first of these is that the treatment is carried out accurately and that all uncertainties are kept to acceptable levels. The second consideration relates to the avoidance of treatment errors or treatment misadministration.

Quality assurance programs are usually based on Plan-Do-Study-Act scheme, commonly referred to as PDSA (or PDCA, for Plan-Do-Check-Act). All the terms refer to the cycle of activities aimed at achieving a process or system improvement (Walley and Gowland, 2004). The components of the PDSA cycle can be briefly described as:

- Plan: Analyze the problem you intend to improve and devise a plan to correct the problem.
- Do: Carry out the plan (preferably as a pilot project to avoid major investments of time or money in unsuccessful efforts).
- Study: Did the planned action succeed in solving the problem? If not, what went wrong? If partial success was achieved, how could the plan be refined?
- Act: Adopt the change piloted above as is, abandon it as a complete failure, or modify it and run through the cycle again. Regardless of which action is taken, the PDSA cycle continues, either with the same problem or a new one.

In 1989, D.M. Berwick, in a seminal article published in the *New England Journal of Medicine* (Berwick, 1989) proposed a new paradigm for health care quality, borrowed from the manufacturing sector and embodied in the term total quality management (TQM). Applied to health and medical care, TQM is most familiarly known as continuous quality improvement (CQI) and suggests that all organizations, no matter how good or bad, have multiple opportunities to improve quality by adopting an approach rooted in customer satisfaction. The method is considered in more details in the chapter on safety assessment in X-ray diagnostics.

In order to address hazard and safety concerns, the attempt was made to adopt also some other models from industries to medical systems. Among them, the Failure Mode and Effect Analysis (FMEA), has been specifically redesigned for health care organizations and called Healthcare Failure Mode and Effect Analysis (HFMEA) (Mc Donough, 2002).

FMEA/HFMEA is a prospective risk analysis approach, which attempts to predict "error modes." The likelihood of a particular process failure is combined with an estimate of the relative impact of that error to produce a "criticality index." By combining the probability of failure with the consequences of failure, this index allows for the prioritization of specific processes as quality improvement targets. For instance, an FMEA analysis of the medication dispensing process on a general hospital ward might break down all steps from receipt of orders in the central pharmacy to filling automated dispensing machines by pharmacy technicians. Each step in this process would be assigned a probability of failure and an impact score, so that all steps could be ranked according to the product of these two numbers. Steps ranked at the top (ie, those with the highest "criticality indices") would be prioritized for error proofing.

Five key steps are involved in conducting an HFMEA analysis (Mc Donough, 2002):

1. Define the HFMEA topic. This should include a clear definition of the process to be studied.
2. Assemble the HFMEA team. The personnel should be multidisciplinary and include subject matter experts and an adviser.
3. Graphically describe the process. Develop a flow diagram; number each process step; identify the area of the process to focus on; identify all sub-processes; create a flow diagram of the sub-process.
4. Conduct a failure analysis. List all possible failure modes under the key sub-process; determine the severity and probability of each potential failure mode; use a Decision Tree to determine if the failure mode warrants further action; list all failure mode causes where the decision has been made to proceed.
5. Evaluate actions and outcome measures. Determine if you want to eliminate, control, or accept each failure mode cause; identify a description of action for each failure mode to be controlled or eliminated; identify outcome measures to test the redesigned process; identify an individual responsible for completing the action; indicate whether top management concurs with the recommended action.

Another tool adopted for health care was Hazard Analysis and Critical Control Points (HACCP), which is now broadly used in medical-device manufacturing. This is a step-by-step approach to the identification and assessment of hazards and risks associated with the manufacture, distribution, and use of products. "Hazard" refers to any part of a production chain or a product that has the potential to cause a safety problem. Analysis is

the identification and assessment of the seriousness and likelihood of occurrence of a hazard. A Critical Control Point is a point, step, or procedure at which control can be exercised to prevent, eliminate, or minimize a hazard.

Seven steps form the core of the HACCP approach: (Mc Donough, 2002):

1. Conduct a hazard analysis, preparing a list of steps in a process where significant hazards occur and identifying preventive measures.
2. Identify critical control points—steps at which controls can be applied to prevent, eliminate, or reduce to acceptable levels a safety hazard.
3. Establish critical limits for preventive measures associated with each identified critical control point.
4. Establish monitoring requirements for each critical control point, and procedures to monitor results to adjust the process and maintain control.
5. Establish corrective actions to be taken when a critical limit deviation occurs.
6. Establish procedures to verify on an ongoing basis that the HACCP system is working correctly.
7. Establish record-keeping procedures to document the HACCP system.

While the similarities in FMEA, HFMEA, and HACCP are striking, a difference in emphasis is also apparent. With FMEA, the hazard is a failure mode in a process, and the principal goal is to redesign the process to reduce or eliminate the risk of the failure occurring. The goal of HACCP is detection and control of process failure to eliminate or reduce bad effects.

## 4. Human factors and patient safety

Post-accident investigations show that human factor is the cause of, or contributes to about 90% of all accidents. This is often the basis for the culture of blame with *à priori* statements like:

- If the device works, the problem must be the user.
- If something went wrong, it must be the user.
- If a mistake was made, let's find out who did it.

Such approach is very convenient for public opinion, lawyers and hospital managers but it is already clear that not the best for the patient safety, because the human mistakes are not prevented by punishing. Therefore, the individual accountability is not the right focus for improving systems. For this purpose, the question "What should we have done to prevent this from having occurred?" should be replaced by "How can we prevent this in the future?". Such an advanced analysis has to include elements of human factors engineering, which is "a discipline concerned with the design of tools, machines, and systems that take into account human capabilities, limitations, and characteristics." (Gosbee, 2002). Its fundamental goals in design are to: minimize or eliminate workplace injuries and hazards; minimize user and system-related errors; maximize worker and workplace efficiency and productivity. Human factors engineering studies are focused on learning how people function in accidents, on human errors (slips, mistakes, violations), performance deterioration due to stress, decision-making deficiencies and perceptual and attention variations (illusions, fatigue). The key factors are education and responsibility of the staff, proper organization of work, creation of a culture of patient safety and an adequate routine to analyse the causes of accidents, incidents and near miss cases.

The shortcomings in education of the staff contribute very often to the accidents, since the education does not follow the development of technology. The demands of the tasks that have to be carried out should match the competence of the individual who is going to carry out the particular task; otherwise there is a risk of an incident or accident. But, the staff must also realize their own responsibility in their work, provided that they have the qualification to do so, i.e. right education and training.

The acquisition of any new skill is associated with the potential for lower-than-expected success rates or higher-than-expected complication rates. This phenomenon is often known as a "learning curve." In some cases, this learning curve can be quantified in terms of the number of procedures that must be performed before an operator can replicate the outcomes of more experienced operators or centres.

While learning curves are almost inevitable when new procedures emerge or new providers are in training, minimizing their impact is a patient safety imperative. One option is to perform initial operations or procedures under the supervision of more experienced operators. Surgical and procedural simulators may play an increasingly important role in decreasing the impact of learning curves on patients, by allowing acquisition of relevant skills in laboratory settings.

Sometimes problems are caused by improper design of the hospital equipment. A perfectly designed device will be easy to use and (almost) no one will make mistakes with it. A poorly designed device will be difficult to use and be prone to mistakes. Why blame users for mistakes using poorly designed devices?

Some time ago, if an error is made with a device that is working like it was designed, the error has been called a "user" error, however, it might not be the fault of the user. Human factors engineering call now such cases as USE errors, which are not considered to be someone's fault, but the fault of the "system" (equipment, policies, communications, staffing, etc.

The most common of unsafe organization of work is uneven distribution of tasks among employees in the same department. This allows the burden of heavy workload to fall on a few hard-working employees. This type of set-up is common in laboratories, X-ray, nursing and pharmacy departments etc. When a few employees are carrying a larger workload, the quality of work is poor, operational cost is high and the danger of deadly errors is also very high.

The next point is an adequate routine to analyse the causes of the accident or incident. The analysis results are extremely important in prevention of similar cases in the future. The departments of biomedical and clinical engineering should have a central role to work together with the health care staff at the hospitals to fulfil these tasks.

Incident reporting is a part of the more general activity of surveillance for errors, adverse events, or other quality problems. From the perspective of those collecting the data, incident reporting is a passive form of surveillance. It relies on those involved in target incidents choosing to provide the desired information. More active methods of surveillance range from activities such as going to gatherings of frontline workers and asking if any recent incidents have occurred, to retrospective medical record review and to direct observation. In most hospitals the incident reporting captures only a fraction of incidents, compared with medical record review and direct observation (Weingar et al. 2000; Flynn, 2002 ).

Despite their low yield, spontaneous incident reporting systems have some advantages, including their relatively low cost and the involvement of frontline personnel in the process of identifying important problems for the organization. The involvement of frontline workers, however, also raises the issue of confidentiality. Because incident reports tend to come from personnel involved in the incidents, these personnel may have legitimate concerns about the effects reporting will have on their performance records. To encourage reporting, some organizations make incident reporting anonymous. In other words, personnel can report an incident without identifying themselves.

Taking all the above factors into account, the recommendations for the first steps in creation a culture of patient safety can be formulate as four following rules:

- Treat every adverse event, injury, accidental death as a precious learning opportunity.
- Seek to identify the active failures and latent conditions - within the system that contributed to the event.
- Do not just manage the last error.
- Eliminate the tendency to blame.

## **5. Safety culture**

### **5.1. The Safety Culture concept**

There are several theories about antecedents to accidents, but major schools of thought include Reason's belief that a number of latent factors embedded in organizational systems can align and result in accidents [Reason] and Rasmussen's approach to categorizing the different sources of error that interact with latent factors to produce accidents (Rasmussen, 1990; Rasmussen and Afterword, 1994). Another school of thought - Normal Accident Theory - developed by Charles Perrow (Perrow and Langton, 1994) and first publicized shortly after the Three Mile Island nuclear accident, emphasizes the ever-present possibility of accidents in organizations that exhibit complexity and "tight coupling" of processes and the inevitability of accidents. Regardless of the underlying theory, health care is vulnerable to error. The application of safety promotion theories used in other high hazard organizations, like in nuclear and aviation industries are being considered for health care.

The term “Safety Culture” was introduced by the INSAG Committee during the review of the Chernobyl accident (IAEA, 1986) and rapidly widespread. In 1991 and 2002 the INSAG issued two updated documents, where the scope and practical applications of Safety Culture were explained in more details (IAEA, 1991; INSAG, 2002).

The INSAG defined Safety culture as “a set of characteristics and attitudes of an organization and the individuals involved, establishing as first priority that the activities performed will deserve special attention in accordance with their importance concerning Nuclear Safety”. Later on, as a result of activities sponsored by International Atomic Energy Agency, the original Safety Culture concept was extended to include a large number of issues that are typical requirements of a Quality Assurance program and, thus, the understanding and application of the term became more difficult (Touzet, 2004).

While an exact definition of a safety culture does not exist, a recurring theme in the literature is that organizations with effective safety cultures share a constant commitment to safety as a top-level priority, which permeates the entire organization. The noted components of the safety culture include: 1) acknowledgment of the high risk, error-prone nature of an organization's activities, 2) blame-free environment where individuals are able to report errors or close calls without punishment, 3) expectation of collaboration across ranks to seek solutions to vulnerabilities, and 4) willingness of the organization management to direct resources for safety concerns (Roberts, 1993; Cooper, 2000; Geller, 2000). Based on extensive field work in multiple organizations, Roberts et al have observed several common, cultural values in reliability enhancing organizations: "interpersonal responsibility; person centeredness; [co-workers] helpful and supportive of one another; friendly, open sensitive personal relations; creativity; achieving goals, strong feelings of credibility; strong feelings of interpersonal trust; and resiliency", (Roberts, 1993).

## 5.2. The role of Safety Culture within a Quality System

Safety Culture and Quality Assurance are often considered as being absolutely individual issues, however, Safety Culture should be considered as a part of the Quality System.

In the beginnings, Quality Systems were oriented almost exclusively to the technical issues of the organizations, mostly because the control and attention to technological issues is far simpler and less compromising than improving the social issues in the organization. On the other hand, even when all the technical issues are well under control and the training of the personnel is correct, a single inadequate attitude can bring along an error involving the failure of the prevention system. Therefore, increasing personnel training is not enough if simultaneously, no activities are performed to improve their attitude towards quality and safety (Touzet, 2004). The most dramatic example was the Chernobyl accident. In this case the statement of INSAG regarding the quality systems was as follows: “The mere existence of a Quality Assurance Programme is not an adequate guarantee in preventing accidents and even the compliance with all the procedures and good practices is not enough if they are performed mechanically and without conviction” and that “the main cause of the event was the lack of an appropriate Safety Culture”.

Safety Culture contributes towards improvement of safety, paying more attention to such human qualities like a sense of responsibility, being cautious or having a watchful attitude. Focused with this particular approach, Safety Culture is a valuable tool in making quality systems more effective and efficient.

There is a very important practical difference between the Safety Culture and Quality Assurance, because the first one was defined in terms of subjective nature, so the Safety Culture assessment cannot be made by means of conventional audit or regulatory inspection. The same situation arises when the Quality Assurance programs are compared with TQM. While the former include the requirements and standards, which can be audited and certified, the latter is described only by recommendations and the responsibility for compliance has to be judged by the users. Good examples (Touzet, 2004 ) of this statement are the “requirements” in the ISO 9001 Standards (Quality Assurance) and the “recommendations” in the ISO 9004 Standard (Total Quality).

Quality Assurance programmes are absolutely necessary for some medical practices e.g. those involving ionizing radiation. Nevertheless, it should be kept in mind that they originated from the needs of large-sized manufacturing industries and any attempt of extrapolation of the ISO-9001 Standard to health-care services has been always difficult and not always justified. Moreover, the requirements of the Standard generate a need for a large number of formal documents to be prepared in the organization. This is why such Standards lost some prestige and some health-care service managers state that “Quality Programmes are unnecessary when a job is well done” or “complying with the Regulatory Standards is good enough” (Touzet, 2004 ). For the same reason,

most health-care services do without a duly implemented quality system. A very small percentage of the services -below 5% in the most economically developed countries and even less in other countries – has a certified quality system. Most of the services have only few elements of the system, within “a natural quality system”, including some work procedures, registers of several processes, personnel training certificates and several quality practices that are performed systematically but not documented.

The new version of the ISO 9000 Standard, issued in 2000, represent a radical change in the philosophy and the methodology to be used, because the approach is primarily based on the analysis of the processes of the facility itself. Moreover, some criteria and rules contained in the Standard can be excluded at the user’s judgement when they are not applicable or when irrelevant. Consequently, the Standard becomes a customized tool, for different activities, hopefully including also the health care services.

### **5.3. Particular importance of the Safety Culture in the medical applications of radiation**

Two excellent examples of the safety culture importance are described in the work of Touzet (Touzet, 2004). First one refers to an accidents that occurred while the correct procedures were used and the equipment units were operating properly, but no adequate action was carried out. The accident occurred in US in 1992 with a High Dose Rate brachytherapy unit. The source was lost and remained the patient. After this, three attending technicians noticed the sound and light alarm generated by the radiation detector inside the treatment room, but they assumed that the instrument was malfunctioning and they did not perform any verification.

The second example also indirectly refers to the assumption of the false signal in the accident which occurred at the University Clinical Hospital of Zaragoza in Spain. between 10 and 20 December 1990. During that period, when 27 patients received radiation therapy for tumours of the head, neck, breast, or groin, the radiation intensity was far greater than intended. 18 patients eventually died as a result of radiation overexposures. The remaining patients all suffered major disabilities. The accident was caused by an error which occurred in the maintenance and calibration of a linear accelerator used for clinical radiotherapy, but the last barrier for the detection of the problem was the energy indicator in the unit’s command panel. The indicator was operating correctly, however, the abnormal value indicated was attributed to a malfunctioning of the monitor.

### **5.4. Red Rules**

Red Rules are the rules that must be followed to the letter. In other words, any deviation from a red rule should bring work until compliance is achieved. Red rules must relate to important and risky processes and they must be simple and easy to remember.

Unlike other standard rules, red rules are ones that will always be supported by the entire organization. In other words, when someone at the frontline calls to stop work on the basis of a red rule, top management must always support this decision. Thus, when properly implemented, red rules should foster a culture of safety, as frontline workers will know that they can stop the line when they notice potential hazards, even when doing so may result in considerable inconvenience or be time consuming and costly, for their immediate supervisors or the organization as a whole.

An example of a red rule in health care might be the following: “No hospitalized patient can undergo a test of any kind, receive a medication or blood product, or undergo a procedure if they are not wearing an identification bracelet.” The implication of designating this a red rule is that the moment a patient is identified as not meeting this condition, all activity must cease in order to verify the patient’s identity and supply an identification band (<http://psnet.ahrq.gov/glossary.aspx>).

## **6. Strategies to enhance the safety of patients**

Basic strategies to enhance the safety of patients were formulated in the World Health Organization Secretariat document (WHO, 2003) as follows:

„Safety is a fundamental principle of patient care and a critical component of quality management. Its improvement demands a complex system-wide effort, involving a wide range of actions in performance improvement, environmental safety and risk management, including infection control, safe use of medicines, equipment safety, safe clinical practice and safe environment of care. It embraces nearly all health care disciplines and actors, and thus requires a comprehensive multifaceted approach to identifying and managing

actual and potential risks to patient safety in individual services and finding broad long-term solutions for the system as a whole.

Thinking in terms of systems offers the greatest promise of definitive risk-reduction solutions, which place the appropriate emphasis on every component of patient safety, as opposed to solutions driven by narrower and more specific aspects of the problem, which tend to underestimate the importance of other perspectives.

Enhancing the safety of patients includes three complementary actions: preventing adverse events; making them visible; and mitigating their effects when they occur. This requires: (a) increased ability to learn from mistakes, through better reporting systems, skilful investigation of incidents and responsible sharing of data; (b) greater capacity to anticipate mistakes and probe systemic weaknesses that might lead to an adverse event; (c) identifying existing knowledge resources, within and outside the health sector; (d) improvements in the health care delivery system itself, so that structures are reconfigured, incentives are realigned, and quality is placed at the core of the system.”

Strategies for radiological protection of patients were formulated by International Atomic Energy Agency on the basis of the findings, conclusions and recommendations of the International Conference on Radiological Protection of Patients in Diagnostic and Interventional Radiology (IAEA, 2001). The Action Plan for future international work relating to the radiological protection of patients has been developed in consultation with the following organizations of the United Nations system: Pan American Health Organization, World Health Organization United Nations Scientific Committee on the Effect of Atomic Radiation. The Action Plan was approved by the IAEA Board of Governors and endorsed by the General Conference in September 2002 (<http://www-ns.iaea.org/downloads/rw/radiation-safety/PatientProtActionPlangov2002-36gc46-12.pdf>).

The recommendations of the “Action Plan” can be classified into three categories:

1. Generic recommendations applicable to all radiodiagnosis and radiotherapy practices. Among them, the most relevant deal with implementation of Quality Systems and with education and training of staff.
2. Specific recommendations related to technological issue in several applications.
3. Recommendations referred to the protection of special groups, such as children, pregnant women and caregivers.

According to the document, the implementation of a quality system is obviously an essential requirement in order to ensure radiological protection and safety. The key issues for the success in management and in improving the efficiency of the applied quality systems are team work, radiation protection in regular situations, preparedness for radiological emergencies, optimization network and reference levels, analysis of accidents, adaptation to technological innovation, implementation of sustainable quality system, regulatory integration, safety culture, qualification of the prescribing physicians and, finally, avoiding the risk of over-detailed regulations (Touzet, 2004).

## 7. Safety of medical devices

There are several essential elements of medical device safety. First of all, the absolute safety cannot be guaranteed and it is a risk management issue. The second point is that the safety of any medical device is closely associated with the device effectiveness/performance. The third issue is that the safety must be considered throughout the life span of the device and this requires shared responsibility among all the stakeholders.

Safety can only be considered in relative terms. The current approach to device safety is to estimate the potential that a device causes a hazard that could result in safety problems and harm. This estimate is often referred to as the risk assessment. Risk assessment is complex, as it can be influenced by personal perception and other factors such as cultural background, economic conditions, and political climates. In practice, risk assessment of medical devices is based on the experience of health care professionals and on safety design engineering.

Medical devices should be designed and manufactured in such a way that, when they are used under the conditions and for the purposes intended and, where applicable, by virtue of the technical knowledge, experience, education or training of intended users, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety (WHO, 2003). This statement highlights the risk/benefit nature of medical devices. The goal, therefore, is to maximize benefit and minimize risk.

In the case of medical devices manufacturing, the proper risk management requires an organized approach to provide a road map for assessing, assigning and reducing risk through the life of the device. The first step is the development of a risk plan that identifies the intended medical use of the device and addresses the risks at each phase of the life cycle of the product. Management needs to assign responsibilities to develop and carry out the risk to qualified personnel.

## **7.1. IEC Standards**

An effective risk management strategy is always evolving to meet global standards and requirements. The most general standard series concerning medical devices is IEC 60601-1 Medical Electrical Equipment—Part 1: General Requirements for Safety. The Standard has been adopted as a national standard in most major countries in the world for supporting regulatory registrations or approvals. It should be noted that in the United States, the numbering of the UL 2601-1 standard has been changed to UL 60601-1, titled Medical Electrical Equipment, Part 1: General Requirements for Safety. In fact, there were no changes to the requirements from UL 2601-1, only a change in the formatting of the standard. The common numbering scheme underlines that the main text of both standards is common with changes only in regard to country specific deviations.

The IEC 60601 standards series consists of four distinct parts. The IEC 60601-1 base standard is the core of the series. This document comprehensively addresses the general areas of risks, which are inherent in all electrical medical equipment, such as electric shock and mechanical hazards. The second layer are the Collateral Standards numbered IEC 60601-1-x. These standards are dealing with risks which are specific for certain groups of medical devices, such as ionising radiation, electromagnetic fields, coupling of many elements of the systems and human factors.

For the harmonisation of the safety requirements regarding ionising radiation, the Collateral Standard IEC-60601-1-3 “General requirements for radiation protection in diagnostic X-ray equipment” was developed in this second layer. The standard is applicable for all diagnostic X-ray equipment. All requirements given in this standard address the radiation protection of the patient.

The third layer is formed by Standards numbered IEC 60601-2-x, which lay out requirements for a specific type of medical device, e.g. IEC 60601-2-43 is the particular standard for the safety of X-ray equipment for interventional procedures. In this standard the specific requirements refer to the inherent safety of the equipment, to the safety preventions for the patient and to the safety for the user. In the case of interventional X-ray equipment the specific requirements concern filtration of the X-ray beam, collimation, dosimetric indications and zones of occupancy. Particular standards can amend, modify, and/or supersede part of the requirements specified in IEC 60601-1.

In order to verify the safety elements during the life cycle of the equipment, the fourth layer of standards was generated. This layer includes the performance testing standards (or acceptance testing) and the constancy testing standards.

IEC 60601-1 is based on the same concept as risk management. That is, to assess and control risks in the product design, manufacture, and intended use, by one or more of the risk-control measures. The standard forces inherent safety by design, it imposes protective measures in the medical device or its manufacturing process, or it requires instructions and/or labelling information for safety. The third edition of IEC 60601-1 from 2005, cites in this context the international risk management standard ISO 14971.

Generally, the IEC 60601-1 standards require that two levels of protection should be employed in various areas of the product to meet the requirements of the standard. If one level of protection fails, the product would then still have another level of protection to contain any electrical shock hazards and shield patients and operators from harm.

## **7.2. ISO Standard on risk assessment of medical devices**

From April 2004, ISO 14971 is the harmonized standard for risk assessment of medical devices under the medical devices directives. Its essential statements require manufacturers to define acceptable risks and to eliminate or reduce risks wherever possible and finally warn, by alarms or information, of any residual risks.

The manufacturer is required to include the results of the risk analysis within technical documentation. The risk analysis should address all hazards known or reasonably foreseeable for the particular product types and

technologies involved, together with the likelihood and consequences of occurrence and measures taken in order to reduce the resulting risks to acceptable levels. This should address all relevant risks. The results must demonstrate that an appropriate risk analysis has been performed and provide a conclusion, with appropriate evidence, that the remaining risks are acceptable when weighed against the intended benefits to the patient.

Due to the varied nature of medical devices the standard does not attempt to define acceptable risk levels. The manufacturer or developer is responsible for defining criteria for acceptable risk levels for its devices. Senior Management must approve the risk levels and define acceptable risk.

Hazard Assessment begins with the intended use of the product. The manufacturer must identify hazards for both normal operation and fault conditions, as well as "reasonable foreseeable misuse". Sources for identifying known or foreseeable hazards include published literature related to features of the device, compliant history of current products that are subject to similar hazards, public information on competitors' products and individuals knowledgeable in the field, including medical practitioners.

Risk analysis includes identifying the cause of the hazard and, if necessary, taking actions to reduce the risk. Risk Analysis should be compatible with the complexity and intended use of the device. Complex designs and high risk devices should be subject to formal risk assessment processes, such as Failure Mode Effects Analysis or Fault Tree Analysis.

Risk Control requires identification of the root cause of the hazard. It is at the root cause that the hazard can best be reduced or controlled. There are three basic ways to reduce risk. These are listed below in order of effectiveness and desirability.

- Inherent safety by design.
- Protective measures in the device or in the manufacturing process.
- Information on safety and hazards in the instructions for use.

Risk reduction and control must be part of the design inputs and design development. Identifying hazards early is the best way to ensure that safety is designed into the device and that warnings in the instructions are used as a last resort. This process involves making decisions on the acceptability of the risks identified, while taking into account the mitigations implemented in the design process.

As part of risk evaluation, the ISO 14971 standard requires to evaluate residual risk and to perform a risk/benefit analysis, which reviews the residual risks and weighs these risks against the benefits of the device.

ISO 14971 requires also that the manufacturer manages risk through the life of the product, by updating the risk analysis when new information affecting risk is acquired or when any new hazard is identified.

Harmonized standards are not mandatory but, Notified Bodies will expect to see manufacturers conducting risk analysis for devices under the Directives and risk management is required by the new quality assurance standard. ISO 14971 provides a model for risk management and the following Risk Analysis tools for conducting risk assessment:

- Failure Mode and Effect Analysis (FMEA).
- Fault Tree Analysis (FTA).
- Hazard and Operability Study (HAZOP).

It is for manufacturers to review the standard and determine how / whether to apply the standard in full or in part and justify decisions to deviate from what is recognized as the current EU harmonized standard.

### 7.3. European Directives

Compliance with IEC 60601-1 and/or a national standard does not equal medical device approval. Compliance is step one, approval step two, and marketing step three. The Global Harmonization Task Force (GHTF; [www.ghtf.org](http://www.ghtf.org)), established by the United States, Canada, Australia, Japan, and the European Union, gives credence to using the IEC 60601-1 standard as the model for compliance of electrical medical devices. There are three European that specifically apply to medical devices manufacturers:

- The Medical Devices Directive (MDD) applies to all general medical devices not covered by the Active Implantable Medical Devices Directive or the In Vitro Diagnostics Directive,
- The Active Implantable Medical Devices Directive (AIMDD) applies to all active devices and related accessories intended to be permanently implanted in humans.

- The In Vitro Diagnostics Directive (IVDD) applies to all devices and kits used away from the patient to make diagnosis of patient medical conditions.

#### 7.4. Incorporating human factors engineering into risk management

Human factors (HF) is the study of how people use technology. It involves the interaction of human abilities, expectations, and limitations, with work environments and system design. The term “human factors engineering” (HFE) refers to the application of human factors principles to the design of devices and systems. It is often interchanged with the terms “human engineering,” “usability engineering,” or “ergonomics.” The goal of HFE is to design devices that users accept willingly and operate safely in realistic conditions. In medical applications, HFE helps improve human performance and reduce the risks associated with use error.

Hazards arise in the use of medical devices due to the inherent risk of medical treatment, from device failures (or malfunctions), and from device use. Hazards associated with device use are a common and serious problem. The frequency and consequence of hazards resulting from medical device use might far exceed those arising from device failures. Use-related hazards occur for one or more of the following reasons (Kaye and Crowley, 2000):

- Devices are used in ways that were not anticipated.
- Devices are used in ways that were anticipated, but inadequately controlled.
- Device use requires physical, perceptual, or cognitive abilities that exceed those of the user.
- Device use is inconsistent with user’s expectations or intuition about device operation.
- The use environment effects device operation and this effect is not understood by the user, or
- The user’s physical, perceptual, or cognitive capacities are exceeded when using the device in a particular environment.

To understand use-related hazards, it is necessary to have an accurate and complete understanding of how a device will be used. Understanding and optimizing how people use and interact with technology is the subject of human factors engineering (HFE).

There are several general HFE concepts that should be considered in the context of risk management (Kaye and Crowley, 2000):

- a) User preference does not necessarily indicate safety and effectiveness. A focus solely on user preference in the development of a design does not assure that safety and effectiveness have been adequately considered. Users generally prefer devices that are easy and satisfying to use and are aesthetically pleasing. Although design features that assure safety and effectiveness could decrease user preference in some instances, they are necessary nevertheless.
- b) Scenarios with a low frequency of occurrence that result in hazards require careful consideration. Rare or unusual scenarios resulting in hazards with serious consequences often prove to be the greatest threat to safe and effective medical device use. Users are often not prepared for infrequent, unexpected use scenarios. Infrequent but dangerous use scenarios are often difficult to identify, which underscores the necessity for careful application of the analytic and empirical approaches early in, and throughout the design process.
- c) Direct inspection or paper-based analyses of a device might not identify all hazards. Use-related hazards involve interactions among aspects of the use environment, user, and the device. Many hazards involving unsafe or ineffective device use can be identified through careful inspection and analyses of existing information pertaining to the use of similar devices. Some use scenarios are rare. Some involve unusual or unexpected ways of interacting with a device, or involve use in unusual circumstances. Use scenarios of this kind are difficult to identify by using only analytic approaches. Therefore, it is important to obtain information from the intended user population and test devices under actual or simulated conditions.

Safe use of medical devices is determined by the major components of the device-user system, such as use environments, user characteristics, and device user interface characteristics.

Use environments for medical devices can vary widely and can have major impacts on device use and use-related hazards. The amount of thinking and concentration which a person exerts while using a device is called mental workload. The mental workload imposed on users by the device and disturbing factors from the environment in which they use the device can exceed the users’ abilities to use the device(s) properly.

The user characteristics also can be very different. A device that is easy for one person to use safely and effectively might present problems for another person. In order to assure that the devices are used safely and

effectively, it is necessary to understand abilities and limitations of the intended users. It is convenient to refer to the group of users who use a given device as its user population. It is then helpful to describe the user population with respect to the abilities and limitations of its members.

The user interface includes all components of a device with which users interact while using it, preparing it for use, or performing maintenance. HFE considerations relate directly to the device-user interface and to the responses of the device to user actions. A well-designed user interface will facilitate correct actions and will prevent or discourage actions that could result in hazards. An important concept pertaining to user interface is error tolerance, defined as the quality of a user interface that prevents or mitigates dangerous or disastrous consequences when an error occurs.

There are two approaches for identifying, understanding and evaluating use-related hazards for medical devices - analytic and empirical (Kaye and Crowley, 2000). Analytic approaches involve the description and systematic decomposition and analysis of device use. They are based on the expected use of new devices and on existing information about the use of similar devices. They should be used to identify use-related hazards early in development of the user interface and operating logic of a device. Empirical approaches derive information from actual or simulated use of devices. Because empirical approaches evaluate actual or simulated device use, they allow for previously unanticipated use scenarios resulting in identification of hazards in better understanding of the use-related hazards (<http://www.fda.gov/cdrh/HumanFactors.html>).

## 8. Safety assessment for the control of medical sources of ionizing radiation

Basic Safety Standards of the International Atomic Energy Agency (IAEA, 1996) defines safety assessment as: "A review of the aspects of design and operation of a source which are relevant to the protection of persons or the safety of the source, including the analysis of the provisions for safety and protection established in the design and operation of the source and the analysis of risks associated with normal conditions and accident situations." The assessment of the level of safety in the design and operation of a source is performed against criteria which are normally specified by the regulatory authority. The detail and the scope of this assessment depend very much upon the magnitude and likelihood of the exposures expected from the practice or source under consideration. In the case of medical sources, a full safety assessment is usually not required because the magnitude and likelihood of the exposure expected from the source do not justify it.

Safety assessment provides a formalized methodology for the judgment of the level of safety in the design and operation of a radiation source. Safety assessment conducted in terms of a practice at the design stage of a source will also provide a basis for the establishment of the operational programs. It can also aid as a technique to evaluate the safety of proposed modifications to already operational equipment or procedures.

The radiological safety assessment should be always focused on two targets. The first one concerns the conditions of normal operation and includes the measures to ensure that the external doses to the radiologists and members of public are kept below dose limits and follow the ALARA principle. The exposure of the patient has to be justified and optimized. This is achieved by a proper system of shielding, access control, proper prescription of the diagnostic investigation as well as by the quality assurance and radiation protection systems applied to the whole diagnostic or therapeutic process.

Another approach has to be applied to the assessment of potential exposure of the patient. In the case of medical exposures, the errors or unintended exposure may be of two types. First - the exposure may be either greater or lower than intended. It should be underlined that the lower dose does not mean safer. In radiotherapy it causes the risk of the tumour recurrence and in diagnostics there is a risk of improper diagnosis or the necessity to repeat the investigation. Second type of possible error is the exposure of a wrong part of the patient or even a different patient than intended. In this case, the risk is associated both with unwillingly delivered exposure and with lack of proper diagnosis or therapeutic effect.

The evaluation of potential overexposures should give an answer, whether the risk is below some acceptance criteria. The general criterion, adopted by the International Commission on Radiological Protection, ICRP, (ICRP Publication 60, 1991; ICRP Publication 64, 1993) says that the mortality risk from potential exposure should be of order of  $2 \cdot 10^{-4} \text{ y}^{-1}$ . In simplistic terms, risk is calculated as the product of the absorbed dose, the probability of death following exposure at the absorbed dose and the probability of the events which might lead to the absorbed dose. It is therefore, a central feature of risk assessment to estimate the probability of the events which lead to such exposures. It is important to note that both stochastic and deterministic effects could, in principle, contribute to the total mortality risk following exposure of an individual.

The risk of stochastic effects resulting from the exposure is evaluated as proportional to the effective dose. The scheme for the risk evaluation involves the construction of scenarios of events leading to the exposures, the assessment of the probability of each sequence, the assessment of the resulting dose, the evaluation of the detriment associated with that dose, the comparison with the acceptance criterion and optimization of the protection, if necessary.

Deterministic effects occur in organs that are irradiated to such an extent that organ function is impaired due to the of cells affected by the exposure. If the organ is vital and the dose is sufficiently high, the end result will be death. The probability of causing harm will be zero at doses up to about 1 Gy, depending upon the organ or tissue, and then, above some level of dose called the threshold for clinical effect, it will increase steeply to unity. Risk models are available to determine the mortality risk to an individual following irradiation of the lung, gastro-intestinal tract and the red bone marrow (Keenan, 2000).

### **8.1. Application of TQM in diagnostic radiology**

The most general definition of quality can be given as “conformance to requirements”. In the field of X-ray imaging, the sets of requirements were issued by different bodies at national or international level (e.g. European Commission) and the programs of quality control and quality assurance are widely introduced. According to the ISO definitions, the Quality Control (QC) comprises the qualitative or quantitative measurements or tests of performance of an instrument or program and the determination of adequacy and acceptability of performance. This includes the set of operations (programming, coordinating) intended to maintain or to improve quality. The Quality Assurance (QA) is the application of a service of quality control steps at multiple stages of the procedure to verify that all aspects of the procedure are of acceptable quality. In practice of X-ray imaging, the QA is usually restricted to testing of the performance of the radiological equipment. Therefore, it takes corrective actions on outlying values and is much less focused on the coverage of the whole process.

As it was already mentioned, some modern concepts of QA propose to implement the industrial concepts called Total Quality Management (TQM). The TQM systems are based on a principle assumption that the greatest efficiency in an organization is attained when all the personnel participates actively in attaining the established quality and productivity goals. The participation of the personnel is stimulated by the organization, where a working environment is generated considering that people constitute the fundamental value for the safety system.

The main difference between TQM and traditional QA is that the TQM is focused on a good system design and emphasizes the quality planning followed by the quality improvement (QI) and quality control. The QI means here the process of raising quality performance, mainly by improvement of the organization of the work of the whole team acting for a radiological department.

Management structures in radiology departments normally include medical, technical and nursing staff, with separate chains of goals. The target of the quality improvement is forming a steering group from the mentioned subgroups and then setting up the goals of the department in order to integrate the goals of all the members of the team. The application of the TQM techniques in health care is difficult and needs large effort to create a formal framework. In reward it may bring some considerable improvements. The reduction of over 35% in patient dose and nearly 40% reduction in poor quality film was reported by the team which succeeded in implementing the TQM system in a cancer hospital (Rehani et al. 1995).

It is rather clear that the optimization of the safety system in X-ray diagnostics causes some additional costs and man power, at least in the beginning of the implementation of the system. Without such funds, the quality assurance programs for radiological departments will be considered as bureaucratic tasks and real improvements will remain the wishful thinking.

### **8.2. Reference levels in X-ray imaging**

The idea to control the diagnostic exposure to a level commensurate with a medical imaging task was mentioned in several early publications of ICRP but until last years, all of them were rather general and no practical tool was created to help avoiding the unnecessary radiation exposure. In 1991, the ICRP provided the following recommendation, concerning optimization of protection in medical exposure: “Consideration should be given to the use of dose constraints, or investigation levels, selected by the appropriate professional or regulatory agency, for application in some common diagnostic procedures. They should be applied with flexibility to allow higher doses where indicated by sound clinical judgment”(ICRP Publication 60, 1991).

The concept was further developed by International Atomic Energy Agency (IAEA, 1996) and by ICRP in Publication 73 entitled “Radiological Protection and Safety in Medicine”(ICRP Publication 73, 1996). In both documents, the goal of achieving the adequate diagnostic information is considered as a primary clinical objective.

In Basic Safety Standards of the IAEA (IAEA, 1996), the term *reference level* is introduced as a common name for action level, intervention level, investigation level or recording level. Such levels may be established for any of the quantities determined in the practice of radiation protection. Then, *the guidance levels* for medical exposure are introduced and addressed to medical practitioners, in order that:

- a) “corrective actions be taken as necessary if doses fall substantially below the guidance levels and the exposures do not provide useful diagnostic information and do not yield the expected medical benefit to patients;
- b) reviews be considered if doses or activities exceed the guidance levels as an input to ensuring optimized protection of patients and maintaining appropriate levels of good practice”

IAEA recommends that the values of the guidance levels should be derived from the data from wide scale quality surveys for the most frequent examinations in diagnostic radiology and nuclear medicine. In the absence of such surveys, the values specified in the BSS should be used. As stated in BSS, these levels should not be regarded as a guide for ensuring optimum performance in all cases, as they are appropriate only for typical adult patients and, therefore, in applying the values in practice, account should be taken of body size and age of the patient.

In the concept of ICRP (ICRP Publication 73, 1996) the purpose of the reference levels is advisory. They serve as a kind of investigation levels to identify unusually high (or too low) exposures. They are not for regulatory or commercial purposes, not a dose constraint and not linked to limits or constraints. Their selection should be made by professional medical bodies using a percentile point on the observed distribution for patients, and specific to a country or region. It is recommended that a special review procedure should be started, if the typical exposures in a given department or clinic lay outside the range of reference levels.

The concept of a diagnostic reference levels permits flexibility in choice of quantities, numerical values and technical or clinical specifications. Therefore, a number of approaches was used by different sets of recommendations issued by national and international bodies (e.g. (ICRP Publication 73, 1996; European Commission, 1996; European Commission, 1999)). Some additional advice on the application of diagnostic reference levels can be also expected from the ICRP – the draft of the document is currently under discussion.

All the above mentioned documents consider the diagnostic reference levels as a quality assurance tool. Typically, they are used as investigation levels. The only exception is mammography used for screening, where some kinds of dose limits were introduced. Also the criteria for selecting the reference levels for X-ray procedures are rather consistent. The reference levels were selected for some clearly defined medical imaging tasks and expressed in terms of easily measured dosimetric quantities. Their numerical values were usually derived from distributions of dosimetric quantities for patients observed in practice in relevant region or country. Typically, only upper levels were specified and the lower levels have not been considered.

The attention should be paid to avoid the possible misunderstanding of the role of reference levels. They are intended to promote the optimum use of radiation exposure and are addressed primarily to the medical practitioners. Therefore, the reference levels should not be applied by external control authorities to assess the “conformance” of the practices in given radiological department with the stated values. In such form, the reference levels would be understood by medical staff as maximum permissible levels, especially if the exposures resulting from work of different persons would be averaged. It is hard to believe that such implementation of the reference levels would increase the effort paid for optimization of the exposures.

In principle, implementation of the reference levels should be associated with program of quality improvement, based on elements of total quality management. This would require some organizational changes in clinics – e.g. the role and responsibility of medical physicists and clinical engineers should be clearly defined and respected. On the other hand, the process of the monitoring of exposures and procedures of quality assurance cannot disturb the normal medical procedures.

### **8.3. Prevention of accidental exposures to patients undergoing radiation therapy**

From the point of view of safety, radiotherapy is a special application of radiation because:

- humans are deliberately placed in very intense radiation beams (external beam therapy), or sources are placed in direct contact with tissue (brachytherapy) with the intention of delivering very high localised doses (20-75 Gy),
- doses significantly below that prescribed can have severe consequences to the patient and may constitute an accident,
- a radiotherapy treatment, from prescription to delivery is a very complex process. It involves many professionals, a large number of steps and, in the case of external beam therapy 20 to 40 treatment sessions with many variable parameters. A radiotherapy technologist may be required to treat some 50 patients a day, for which the parameters are similar and yet different from one patient to the next, often with personalized ancillary devices (Ortiz et al., 2000).

Because of this complexity of equipment, techniques and procedures, there is considerable scope for errors and mistakes and it may not be possible to compensate for an error in under or over exposure.

The discussion of accidents in radiation therapy has become more public in recent years. In 2000, the International Atomic Energy Agency (IAEA) and the International Commission on Radiological Protection (ICRP) published reports on “lessons learned from accidental exposures” and “prevention of accidental exposures” in radiation therapy, respectively (IAEA, 2000; ICRP Publication 86, 2000). Also the 2001 European Society of Therapeutic Radiation Oncology (ESTRO) Gold Medal Lecture was entitled “Irradiation Accidents: Lessons for Oncology” (Cosset, 2002). More recently, individual institutions have published summaries of their own recorded/reported error rates (Yeung, 2005; Huang, 2005) and the last serious accident in Poland was extensively described in a special publication of the IAEA (IAEA, 2004).

The IAEA report (IAEA, 2000) describes 92 accidental exposures in radiation therapy and highlights some lessons that can be learned from the review of these accidental exposures., which provide some clear lessons that should be recognized by the professionals involved in prescribing, calculating, and delivering radiation treatments. summarizes the number of specific types of errors reviewed by IAEA. Similarly, the ICRP report (ICRP Publication 86, 2000) reviews a number of case histories of major accidental exposures of patients undergoing radiation treatment. From the data of IAEA, the causes of the reviewed accidents can be categorized as follows:

- Brachytherapy low dose rate sources/applicators (29 cases).
- External beam: treatment planning, patient setup, treatment (26 cases).
- Machine commissioning/calibration (15 cases).
- Unsealed sources (8cases).
- Failures associated with radiation measurement systems (5 cases).
- Mechanical/electrical malfunctions ( 4 cases + the Białystok accident).
- Brachytherapy high dose rate (3cases).
- Decommissioning of teletherapy equipment ( 2 cases).

A summary of major accidents which have occurred in external beam radiotherapy and brachytherapy is given in Table 8.1. Based on the analysis of the causes and main contributing factors, the most important deficiencies, common to the majority of accidents, have been identified.

Table 8.1. Major accidents in radiation therapy (data and description adopted from (ICRP Publication 86, 2000) and (Van Dyk, 1999)).

Country	Year	No of patients affected	Causes and main contributing factors
USA	1974-76	426	Co-60 dose calculations based on erroneous decay chart (varying overdoses). No independent verification of decay charts and dose calculations. More than two years without beam measurements. Physics manpower and attention shifted to other tasks, such as a new accelerator.
UK	1982-91	1045	Incomplete understanding and testing of a treatment planning system (up to 30% underdosage). No written procedures for commissioning and use. 492 patients developed local recurrence probably due to underexposure
USA and Canada	1985-87	6 (3 deaths)	Accelerator software problems. Software from an older accelerator design was used for a new, substantially different design.

Germany	1986-87	86	Co-60 dose calculations based on erroneous dose tables (varying overdoses). No independent determination of the dose rate
USA	1987-88	33	Re-use of outdated computer file for Co-60 treatments. No proper information available. No manual check for dose calculations.
UK	1988	207	Error in the calibration of a Co-60 therapy unit (25% overdose). No independent calibration of the beam.
UK	1988-89	22	Error in the identification of Cs-137 brachytherapy sources (-20 to +10% dosimetry errors). No independent determination of source strength.
Spain	1990	27 (18 deaths)	Error in the maintenance of a clinical linear accelerator. Procedures for transferring machine from and to maintenance (informing physicists) not followed. Conflicting signals and displays ignored. Procedures for periodic beam verifications (QA) not implemented. Overdosage ranging from 200% to 700%
USA	1992	1 (died)	Brachytherapy source (High Dose Rate) left inside the patient. Source dislodged from equipment. Conflicting monitor signals and displays ignored.
Costa Rica	1996	115 (at least 17 deaths)	Error in calculation during the calibration of Co-60 therapy unit. Lack of independent calibration and of QA. Recommendations from an external audit ignored. Overdosage about 60%.
Panama	2000	28 (at least 5 deaths)	Untested change of procedure for data entry into treatment planning system. No written procedure for the use of TPS. No check by manual calculations. Overdosage 100%.
Poland	2001	5	Fault on a linear accelerator. Description is given below.

The most recent accident happened on February 27th 2001 at the Bialystok Oncology Center in Poland. Five breast-cancer patients undergoing radiotherapy, received a single, high dose of 8 MeV electrons generated by a Neptun 10p linear accelerator. Neptun 10p is a Polish version of the Neptun accelerator manufactured by the now non-existing company CGR and was designed before the IEC safety standards for accelerators of this kind were published. It is capable of delivering electron beams of 6, 8 and 10 MeV, as well as a photon beam of 9 MV.

On the day of the accident the machine shut down due to a break in the mains power supply, while patient A1 was treated. After resuming operation the beam parameters appeared unchanged as judged by the readings of the console instruments. Following a warm up period the treatment was continued. The next four patients (A2-A5) reported itching and burning sensations during or shortly after treatment. Further treatments with the machine were stopped and dose output measurements of the beam were performed. They revealed that the doses were in the range of  $99 \pm 9$  Gy per the prescribed 150 MU (monitoring units).

The Neptun 10p accelerator is designed to operate both in electron and photon modes. Photons are generated when electrons are slowed down in an X-ray target and this process is associated with a considerable energy loss. Therefore, in order to obtain an appropriate dose rate of the photon beam a high current of electrons must be generated. This current is about 300 times higher than needed to produce a therapeutic electron beam of a similar dose rate. The dose rate of the electron beam is monitored by two transmission chambers which deliver control signals to the central processing unit. In case of a discrepancy between the readings, a safety interlock system should shut down the machine.

Upon examination of the accelerator after the accident a broken fuse was discovered in the circuit of the power supply to the dose monitoring chambers. In addition, a diode controlling the signal transfer from the dose monitoring chambers to the safety interlock system was broken. Finally, the limitation of the filament current of the electron gun was set to a high level so that the dose rate of the electron beam was practically unrestricted. The outdated construction of the Neptun 10p allowed to operate the machine under those conditions without any warning signals displayed on the control panel. Although it is presently impossible to reconstruct the exact sequence of events leading to the accident, a combination of the described factors led to the substantially higher doses to the patients (Wojcik et al., 2004).

The reported accidents with the most severe consequences were those related to the incorrect calibration of external beam equipment or brachytherapy sources. A single mistake in calibration will affect all the patients treated until the error is discovered, i.e., it may involve a very large number of patients. This type of accident is normally caused by poor education and training of radiotherapy medical physicists and by a lack of quality

assurance (and therefore reduced defence in depth) which allowed the error to remain undetected (Van Dyk, 1999).

In many cases, either a quality assurance programme was not in place or some verifications were omitted. The absence of written procedures and protocols for acceptance tests and the commissioning of new equipment has led to the use of incorrect values of basic parameters subsequently used for the treatment of patients. This problem applies not only to irradiation equipment but also, very importantly, to treatment planning systems.

A frequent cause of accidents was the ineffective procedures for communication and documentation leading to misunderstanding of a treatment plan. Change of personnel, without a formal transfer of information relevant to calibration and treatment planning, was also among the causes of reported accidents.

Insufficient training and lack of safety culture among medical physicists, medical doctors, radiotherapy technologists and brachytherapy nurses was often a contributory cause of accidents. Maintenance staff, not understanding the implication of misadjustments may also trigger severe accidents, such as the one in Spain.

One of major problems in radiotherapy area is maintenance, which often does not receive enough attention,. This problem tends to be more acute in developing countries where there may be a lack of national maintenance organizations and spare parts can be difficult to obtain, leading to the use of equipment in an unsafe condition in order to avoid disruption to the patient's treatment.

Looking at the factors contributing to the major accidents, it becomes clear that in many accidents, there was a combination of causes. The main lesson learned from the accidents is that, taking into account the complexity of radiotherapy and its sensitivity to errors and mistakes, nothing should be left to chance, but rather, a structured and systematic approach is needed. Once the strict quality programme is in place, the major challenge become to maintain the level of safety over time, which means looking at indicators of slow degradation. For this purpose, personnel and managers should not only look for formal compliance, but also for early warnings of potential problems.

## References

- Agency for Healthcare Research and Quality. Glossary. Available at: <http://psnet.ahrq.gov/glossary.aspx>
- Bagian JP, Gosbee J, Lee CZ, Williams L, McKnight SD, Mannos DM. The Veterans Affairs root cause analysis system in action. *Jt Comm J Qual Improv.* 2002;28:531-545.
- Berwick DM. Sounding board: continuous improvement as an ideal in health care. *New England Journal of Medicine*, 1989, 320:53–56.
- Committee on Quality of Health Care in America, Institute of Medicine, editor. "Crossing the Quality Chasm: A New Health System for the 21st Century. Washington, DC: National Academy Press; 2001.
- Cooper M.D. Towards a model of safety culture. *Safety Science.* 2000. 36:111-36.
- European Commission; European Guidelines of Quality Criteria for Diagnostic Radiographic Images. EUR 16267, 1996.
- European Commission; Guidance on Diagnostic Reference Levels (DRLs) for Medical Exposures, Radiation Protection 109, 1999.
- European Foundation for the Improvement of Living and Working Conditions "Working Conditions in Hospitals in the European Union", EF/95/27/EN, ISBN 92-827-5776-5.
- Flynn EA, Barker KN, Pepper GA, Bates DW, Mikeal RL. Comparison of methods for detecting medication errors in 36 hospitals and skilled-nursing facilities. *Am J Health Syst Pharm.* 2002;59:436-446.
- Geller ES. Ten Leadership qualities for a total safety culture. *Professional Safety.* 2000. 45:30-32.
- Gosbee J. Human factors engineering and patient safety, *Qual Safe Health Care*, 2002.  
<http://www.ahrq.gov/clinic/ptsafety/chap5.htm>
- <http://www.fda.gov/cdrh/HumanFactors.html>

IAEA International Atomic Energy Agency: "International Basic Safety Standards for Protection against Ionizing Radiation and for Safety of Radiation Sources" Safety Series No. 115, ISBN 92-0-104295, ISSN 0074-1892 (IAEA, Austria) (1996).

ICRP; Protection from Potential Exposure: A Conceptual Framework. Publication 64, Annals of the ICRP 23 No. 1, Pergamon Press, Oxford, 1993

ICRP; Radiological Protection and Safety in Medicine. Publication 73, Annals of the ICRP 26, No. 2, Pergamon Press, Oxford, 1996

International Atomic Energy Agency, International Action Plan for the Radiological Protection of Patients, GOV/2002/36-GC(46)/12.

<http://www-ns.iaea.org/downloads/rw/radiation-safety/PatientProtActionPlangov2002-36gc46-12.pdf>

International Atomic Energy Agency, Post Accident Review Meeting on the Chernobyl, Safety Series No 75-INSAG-1/1986.

International Atomic Energy Agency, Safety Culture, Safety Series No 75-INSAG-4/1991.

International Commission on Radiological Protection. Recommendations of the ICRP. Publication 60. Annals of the ICRP. 1991; 21(1-3).

International Nuclear Safety Advisory Group, "Key practical issues in strengthening safety culture", Report INSAG-15, IAEA, Vienna, Austria, 2002.

International Organization for Standardization. "Quality Management and Quality Assurance Standards. Part 1. Guidelines for Selection and Use." ISO 9000. (Geneva: ISO), 1994.

Kaye R., Crowley J. "Medical device use-safety: Incorporating human factors engineering into risk management" Guidance for Industry and FDA Premarket and Design Control Reviewers. U.S. Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health. Document issued on July 18, 2000.

Keenan N., Safety Assessment for the Control of Medical and Industrial Sources. In. Proc. 10<sup>th</sup> International Congress of the International Radiation Protection Association. Hiroshima, May 14-19, 2000. Eye opener E015. Available at: [www.irpa.net/irpa10/pdf/E15.pdf](http://www.irpa.net/irpa10/pdf/E15.pdf).

Kohn L.T., Corrigan J.M., Donaldson M.S. (Eds.). "To Err Is Human: Building a Safer Health System." (Washington, DC: National Academy Press), 2000.

Dr Lucian Leape, testifying to the Presidents Commission on Consumer Protection and Quality in Health.

Mc Donough J.E. "Proactive hazard analysis and health care policy" ISBN 1-88774851-2, Millbank Memorial Fund, 2002.

NRPB, National Radiological Protection Board, UK; Guidelines on Patient Dose to Promote Optimisation of Protection for Diagnostic Medical Exposures. Documents of the NRPB, Vol. 10, No. 1, 1999.

Perrow C, Langton J. The limits of safety: the enhancement of a theory of accidents. Journal of Contingency Management. 1994. 2:212-20.

Plsek PE, Wilson T. Complexity, leadership, and management in healthcare organisations. BMJ. 2001;323:746-749.

Radiological Protection of Patients in Diagnostic and Interventional Radiology, Nuclear Medicine and Radiotherapy. By the International Atomic Energy Agency, pp. 587, 2001 (International Atomic Energy Agency, Vienna, Austria), 128.63 ISBN 92-0-101401-5.

Rasmussen J. Afterword. In: Bogner MS, editor. Human error in medicine. Hillsdale, N.J.: L. Erlbaum Associates; 1994: 385-93.

Rasmussen J. Human error and the problem of causality in analysis of accidents. Philos Trans R Soc Lond B Biol Sci. 1990. 327:449-60.

Reason J. "Human error: models and management" BMJ. 2000;320:768-770.

Reason JT. "Human Error" New York, NY: Cambridge University Press; 1990.

Rehani M. M., Kaul R., Kumar, P. Berry, M.; Doses bridging the gap between knowledge and practice. Example of patient dose reduction in diagnostic radiology. J. Med. Phys., 20(2), 1995, p.18-22

Rhydderch M, Elwyn G, Marshall M, Grol R. "Organisational change theory and the use of indicators in general practice". *Qual Saf Health Care*. 2004;13:213-217.

Roberts KH. Cultural characteristics of reliability enhancing organizations. *Journal of Managerial Issues*. 1993. 165-81

Root Cause Analysis (RCA). Veterans Affairs National Center for Patient Safety Web site. Available at: <http://www.patientsafety.gov/rca.html>

Shojania KG, Duncan BW, McDonald KM, et al., eds. *Making Health Care Safer: A Critical Analysis of Patient Safety Practices*. Evidence Report/Technology Assessment No. 43, AHRQ Publication No. 01-E058, Rockville, MD: Agency for Healthcare Research and Quality. July 2001.

Taylor-Adams S, Vincent C. *Systems analysis of critical incidents: the London Protocol*. London, UK: Clinical Safety Research Unit, Imperial College London; 2004. Available at: <http://www.csru.org.uk/downloads/SACI.pdf>.

Touzet R.E., Strategies for patient protection, In Proc. 11th International IRPA Congress, Madrid, Spain, 23-28 May 2004, CD 4a6.pdf. Available from [www.irpa11.com/new/pdfs/4a6.pdf](http://www.irpa11.com/new/pdfs/4a6.pdf)

Touzet R.E., The practical implementation of Safety Culture, In Proc. 11th International IRPA Congress, Madrid, Spain, 23-28 May 2004, CD 5a16.pdf. Available from [www.irpa11.com/new/pdfs/5a16.pdf](http://www.irpa11.com/new/pdfs/5a16.pdf)

Wald H, Shojania KG. Root cause analysis. In *Making Health Care Safer: A Critical Analysis of Patient Safety Practices*. Evidence Report/Technology Assessment No. 43 from the Agency for Healthcare Research and Quality: AHRQ Publication No. 01-E058; 2001 Available at:

Walley P, Gowland B. Completing the circle: from PD to PDSA. *Int J Health Care Qual Assur Inc Leadersh Health Serv*. 2004;17:349-358.

Weingart SN, Ship AN, Aronson MD. Confidential clinician-reported surveillance of adverse events among medical inpatients. *J Gen Intern Med*. 2000;15:470-477.

World Health Organization, "Medical device regulations: global overview and guiding principles" ISBN 92 4 154618 2, 2003.

World Health Organization, Quality of care: patient safety. Report by the Secretariat. Fifty-fifth World Health Assembly, 23 March 2002, A55/13.

Ortiz P., Oresgun M., Wheatley J, Lessons from Major Radiation Accidents In. Proc. 10<sup>th</sup> International Congress of the International Radiation Protection Association. Hiroshima, May 14-19, 2000. T-21-1. Available at: [www.irpa.net/irpa10/cdrom/00140.pdf](http://www.irpa.net/irpa10/cdrom/00140.pdf).

International Atomic Energy Agency. "Lessons Learned from Accidental Exposures in Radiotherapy." IAEA SRS-17. (Vienna: IAEA), 2000.

International Commission on Radiological Protection. "Prevention of Accidental Exposures to Patients Undergoing Radiation Therapy." ICRP Publication 86. (New York: Pergamon), 2000.

Cosset J.M. "ESTRO Breur Gold Medal Award Lecture 2001. Irradiation accidents: Lessons for oncology?" *Radiother. Oncol*. 63:1-10 (2002).

Yeung, T.K., Bortolotto K., Cosby S., Hoar M., Lederer E. "Quality assurance in radiotherapy: Evaluation of errors and incidents recorded over a 10 year period." *Radiother. Oncol*. 74:283-291 (2005).

Huang, G., Medlam G., Lee J., Billingsley S., Bissonnette J.P., Ringash J., Kane G., Hodgson D. C.. "Error in the delivery of radiation therapy: Results of a quality assurance review." *Int. J. Radiat. Oncol. Biol. Phys*. 61:1590-1595 (2005).

International Atomic Energy Agency, *Accidental Overexposure of Radiotherapy Patients in Bialystok*, Vienna, Austria, 2004.

Van Dyk J. (editor) "The Modern Technology of Radiation Oncology: A Compendium for Medical Physicists and Radiation Oncologists" (Madison, WI: Medical Physics Publishing) 1999, 1072pp.

Wojcik A., Cosset J.M., Clough K., Gourmelon P et al. The radiological accident at the Bialystok Oncology Centre: cause, dose estimation and patient treatment, In Proc. 11th International IRPA Congress, Madrid, Spain, 23-28 May 2004, CD 7g3.pdf. Available from [www.irpa11.com/new/pdfs/7g3.pdf](http://www.irpa11.com/new/pdfs/7g3.pdf).