ACCIDENTS IN RADIOTHERAPY: LACK OF QUALITY ASSURANCE?

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Abstract

About 150 radiological accidents, involving more than 3000 patients with adverse effects, 15 patient's fatalities and about 5000 staff and public exposures have been collected and analysed. Out of 67 analysed accidents in external beam therapy 22% has been caused by wrong calculation of the exposure time or monitor units, 13% by inadequate review of patient's chart, 12% by mistakes in the anatomical area to be treated. The remaining 35% can be attributed to 17 different causes. The most common mistakes in brachytherapy were wrong activities of sources used for treatment (20%), inadequate procedures fro placement of sources applicators (14%), mistakes in calculating the treatment time (12%), etc. The direct and contributing causes of radiological accidents have been deduced from each event, when it was possible and categorised into 9 categories: mistakes in procedures (30%), professional mistakes (17%), communication mistakes (15%), lack of training (8.5%), interpretation mistakes (7%), lack of supervision (6%), mistakes in judgement (6%), hardware failures (5%), software and other mistakes (5.5%). Three types of direct and contributing causes responsible for almost 62% of all accidents are directly connected to the quality assurance of treatment. The lessons learnt from the accidents are related to frequencies of direct and contributing factors and show that most of the accident are caused by lack, non-application of quality assurance (QA) procedures or by underestimating of QA procedures. The international system for collection of accidents and dissemination of lessons learnt from the different accidents, proposed by IAEA, can contribute to better practice in many radiotherapy departments. Most of the accidents could have been avoided, had a comprehensive QA programme been established and properly applied in all radiotherapy departments, whatever the size.

1. INTRODUCTION

The ultimate overall goal of radiotherapy is to deliver a specified radiation dose to the prescribed target volume with the least dose to healthy tissues. This means a sophisticated balance between the cure of the illness and the possibility of radiation induced complications. The demands for precision and accuracy are high, because very often a small increase in radiation dose will have crucial influence on the probability of a cure but simultaneously the probability of induction of irreversible damage to the patient will increase [1].

An "error" is any deviation between the given numerical value of a quantity, such as the dose at a point or the position of a point, and its "true" value [2]. In radiotherapy, errors may arise from at least four main sources: (i) human mistakes caused by inattention, misunderstanding or misjudgment; (ii) instrumental mistakes caused by mechanical or electrical failure; (iii) random errors due to unknown and/or uncontrolled experimental conditions in the process involved in the planning and delivery of radiation; and (iv) systematic errors, i.e. biases, in the same set of processes. In the following discussion, mistakes will be

considered separately from the random and systematic errors. In principle, mistakes can be eliminated completely by a proper system of cross-checks of both human and instrument performance (by quality assurance system), although, in practice this may prove very difficult and expensive. Random and systematic errors, on the other hand, cannot be eliminated but the magnitude of these uncertainties can be reduced by accumulation of better data and improved techniques of measurements and delivery of radiation
(by improved quality control of all steps of radiotherapy process).

Regarding radiation safety, errors or poor performance in diagnosis can lead to a higher collective dose than necessary, leading to undue radiation detriment to the population. Errors or poor performance in radiotherapy can lead to **severe** consequences to patients, hospital staff and general public which is different from radiological accidents in industrial irradiation facilities where only the last two groups of people can be involved. The full benefit of radiotherapy treatment of cancer can only be achieved if the radiation doses to patients are accurate and reproducible. There are two fundamentally different but equally vital requirements for achieving this.

Firstly, accuracy and precision can be achieved by **high quality** measurements of the treatment beams and careful calculation of doses to target volumes, supported by a good preventive maintenance programme for the equipment, i.e. well implemented quality assurance programme.

Secondly, it is necessary to prevent a wide range of simple **errors, which compromise safety.** This second requirement has not always been acknowledged but its importance may be demonstrated by accidents at busy radiotherapy centres. Failure to recognise and deal with it waste the effort devoted to accuracy and precision of doses.

Even if all recommendations for quality assurance, local rules and practical guidelines are followed the occurrence of misadministration and accidents in radiotherapy departments are still very common. Some recent accidents and errors in radiotherapy have been well reported, others have not been as widely discussed. Different international organisations (IAEA, EFOMP) tried to collect data about the radiological accidents in radiotherapy but with a limited success.

This document gives short analyses of several radiological accidents arising from radiotherapy, considers some lessons which can be learned and which can be introduced in new quality assurance programmes to minimize accidents. It is hopped that better understanding the nature and major causes of misadministration events, users will have better basis for evaluating their quality assurance programmes to determine their effectiveness in preventing various accidents.

2.MATERIALS AND METHODS

2.1 Definition of radiological accident in radiation therapy

The Basic Safety Standards [3] defines the radiological accident as:

ACCIDENT is any severe unintended event, including an operating error, equipment failure or other mishap, the consequences of which cannot be ignored from the protection or safety point of view, and which usually leads to potential overexposure or to abnormal exposure conditions for treated patient, staff or general public.

Any radiological accident in radiation therapy may lead to potential abnormal exposure to all three groups of people covered by the definition, i.e. to patients, staff and

general public. Different categories of people have separate dose limits from radiation protection point of view, and therefore it is difficult to apply this definition uniquely to the different individuals involved in radiological accidents. Patients, staff and general public belong to categories of medical, occupational or public exposures, respectively. Occupational and public exposures are in most countries regulated on the base of the ICRP recommendation [4] and therefore any exposure over well defined limits could be considered as an accident, but medical exposures desire a detail description.

2.2. Medical exposures

Medical exposures are usually intended to provide a direct benefit to the exposed individual. If the practice is justified and the protection and safety optimised, the dose in the patient will be as low as is compatible with medical purpose. Any further application of limits might be to the patient's detriment. The ICRU [4] therefore recommends that dose limits should not be applied to medical exposures.

Medical exposures are also confined to exposures incurred by individuals as a part of their own medical diagnosis or treatments and to exposures (other than occupational) incurred knowingly and willingly by individuals helping in the support and comfort of patients undergoing diagnosis or treatment.

Optimum treatment of the patient in radiation therapy does not mean avoiding exposure to radiation but rather the most judicious application of radiation. The risk for the patient is twofold: first and foremost is the failure to control the initial disease which, when it is malignant, is lethal to the patient; second is the risk to normal tissue from irradiation. While there is always some risk associated with radiation therapy, the risk becomes excessive if, taking into account the dose fractionation, either the cumulative radiation dose is too large or a large volume of normal tissues is irradiated. The acceptable level of normal tissue damage will depend upon the natural course of the disease if untreated, the availability of alternative therapeutic modalities, and upon how well normal structures can be excluded from the target volume. It also depends upon the intent of the treatment; a greater risk of damage may be justified when the intent is the cure of cancer rather than palliation of symptoms or treatment of non-malignant disease. Hence, the risk to patient is manifested in both cases: if the dose to treated volume is less than 10% than the risk of proper tumour control is increased; if the dose to treated volume is 10% high than it is causing complication of the treatment. The value of 10% differing from a prescribed dose is nowadays generally accepted limit for increased complication rate or decreased tumour control for most malignant tumours [2]. Doses applied incidentally outside the proposed treatment volume are always causing complication.

2.3. Criteria for selection of radiological accidents

In order to learn more about selected aspects of radiological accidents the data from reported misadministration and accidents were compiled and analysed. Four basic specific issues were addressed in this analysis. These issues are:

(i) direct causes of misadministrations;

(ii) contributing factors;

(iii) preventability of misadministration and accidents through proper implementation of user quality assurance programme;

(iv) classification of potential hazard.

To facilitate analysis of the issues identified above, a simple database containing information about past misadministration events was developed. The criteria, used in this report, for choice of data to database where following:

a) All radiation therapy misadministration (defined in the Code of Federal Regulation (10 CFR Part 35)[5]):

1) A radiopharmaceutical or radiation from a sealed source other than the one intended;

2) A radiopharmaceutical or radiation to the wrong patient;

3) A radiopharmaceutical or radiation by a route of administration other than intended by the prescribing physician;

4) A therapy dosage of a radiopharmaceutical differing from the prescribed dosage by more than 10 percent;

5) A therapy radiation dose from sealed source such that error in source calibration, time of exposure, treatment geometry, machine failure, etc. results in a calculated total treatment dose differing from the final prescribed dose by more than 10 per cent.

Extending this definition to linear accelerators or other radiation therapy machines and treatment procedures it is possible to establish a basis for separating misadministration from random or systematic errors and uncertainties occurring during radiotherapy treatments.

b) All overexposures of radiation therapy facility staff exceeding annual limits defined by ICRP recommendation [4] originating from the use of radionuclide therapy sources, brachytherapy sources, unsealed sources and radiation therapy machines;

c) All overexposures of general public exceeding annual limits defined by ICRP recommendation [4] as a consequence of radiological accident in radiotherapy;

d) All abnormal occurrence events leading to increased risk to the patient, staff or general public which happened during radiation therapy procedures (mechanical, electrical hazards, etc.).

2.4. Sources of information

Basic source of data consists of Abnormal Occurrence Events reported in the National Regulatory Commission (NRC) [6] quarterly reports to Congress (NUEREG-9000 documents) issued from 1987 through 1992 as well as misadministration events contained in the NRC's Office of Analysis and Evaluation of Operating Data (AEOD) database. Some reports were obtained through different international organisations (IAEA, WHO), national medical physicists organisations (AAPM, HPA, SEFM, and others) and selected from published reports in different scientific journals or publications [7- 20].

A simple database was developed by interpreting and extracting information from the data sources regarding event causes, dose information, treatment modality and other parameters. The database contains up to date 147 records with reasonably described accidents and more than 100 with short records. A few typical accidents will be described elsewhere[21].

3. ANALYSIS OF RADIOLOGICAL ACCIDENTS

3.1 Direct causes and contributing factors

The analysis, based only on data interpretation and extraction from sources regarding event causes, dose information, treatment modality, and other parameters, depends on information provided by these reports. Some of them were reported sufficiently, but unfortunately in many of them the basic data, as a number of patients involved, were expressed by terms like "several patients", etc. Therefore, this analysis could not be regarded as completely exhausting. The main aim of this analysis was to show the extent of radiological accidents, their consequences and to point out a number of common threads that can be identified.

The principle product of analysis of each event should be an identification of the direct cause and the contributing factors that predisposed a direct cause. The ***direct cause*** is defined as a fundamental condition or error that directly results in the occurrence of an accident. A direct cause is absence, inadequacy, or improper implementation of a policy, action or decision that directly initiates or propagates the accident. ***Contributing factors*** are conditions, often environmental or contextual, which did not directly cause an accident. Rather, these conditions serve to increase the likelihood that direct cause will manifest itself, resulting in an accident.
In looking at the direct causes of most accidents analysed for this paper, it is interesting that most of the events involved more than one direct cause. This finding suggests that any steps taken to prevent accidents in future should be systematic in nature and should not address only specific direct causes.

Table 1 to 3 show the main causes of accidents in external beam therapy, brachytherapy and unsealed source therapy according to licensee's reports. In fact they did not express the very direct cause of accident but approximately only what had occurred.

Table 1: CAUSES OF RADIOLOGICAL ACCIDENTS IN EXTERNAL BEAM THERAPY.

Calculational error of the exposure time or dose	15
Inadequate review of the patient's chart	9
Error in the anatomical area to be treated	8
Error in identifying the correct patients	4
Error involving lack of/or misuse of a wedge	4
Error in calibration of Co-60 source	3
Transcription error of the prescribed dose	3
Decommissioning of teletherapy source error	2
Human error during simulation	2
Error in commissioning of TPS	2
Technologist misread the treatment time or MU	2
Malfunction of accelerator	1
Treatment unit mechanical failure	1
Accelerator control software error	1
Wrong repair followed by human error	1

Wrong position of the treatment marks on the body	1
Leakage radiation from accelerator	1
Wrong tattoo mark used to identify the treatment area	1
Miscommunication	1
Error in selecting treatment modality	1
Error in the computer programming entry	1
Human error during the treatment	1
Error in the formula for treatment planning computer	1
total	66

Table 2: CAUSES OF ACCIDENTS IN BRACHYTHERAPY

Wrong activities of brachytherapy sources were used	13
Inadequate procedures for placement of sources in applicator	9
Error in calculating the treatment dose	8
Error entered into the computer data	5
Lack of training of involved personnel	3
Brachytherapy source mishandling	3
Error in defining the treatment area	3
Failure to perform surveys and/or a week radiation safety	3
Lost of brachytherapy source	3
Equipment malfunction	2
Inadequate review of patient's chart	2
Unintended removal of sources by patient	2
Leaking I-125 source used in patient	1
Broken brachytherapy cable left source in patient	1
Incorrect number of brachytherapy sources	1
Inadequate patient restraint	1
Miscommunication among the licensee and staff	1
Misinterpretation of a computer error message	1
Wrong isotope entered into treatment planning system	1
total	63

Table 3: CAUSES OF ACCIDENTS IN UNSEALED SOURCE THERAPY

Error in identifying the correct patient	4
Error in verifying radiopharmaceutical labelling	4
Inadequate assay of the dosage in dose calibration	4
Lack of training of involved personnel	2
No verification of prescribed dose	1
Defective equipment	1
Error in calculation of dosage	1
Miscommunication	1
total	18

In effort to identify the relative impact of various direct causes of radiological accidents, the percentages of events in the database that involved each of the defined direct causes were also evaluated. Although this way of measuring the relative frequencies of specific direct causes of radiological accidents cannot be probably used to draw definite conclusions for true physical common cause. The measures provide valid insight into the degree to which specific causes are common to the sample of radiological accident included in the database. The next Table 4 shows frequencies of primary and secondary direct causes of radiological accidents.

Table 4: ABSOLUTE AND RELATIVE FREQUENCIES OF INITIATING AND CONTRIBUTING CAUSES.

Errors in judgement	***16***	5.7 %
Errors in procedures	***84***	29.8 %
Professional errors	***47***	16.7 %
Communication errors	***44***	15.7 %
Hardware and software errors	***13***	4.6 %
Training	***24***	8.5 %
Supervision	***17***	6.0 %
Error in interpretation	***20***	7.0 %
Other	***17***	6.0 %

The frequencies of direct causes of accidents, presented in Tab.4, reveal that the three most significant direct causes of accidents were inadequate procedures (29.8 %), professional errors (16.7 %) and communication problems (15.7%). These three direct causes were responsible for almost 2/3 (62.2%) of all accidents included in the database. The rest of other direct causes, which contributed to radiological accident, is approximately equally distributed.

Direct cause of inadequate procedures or failure to follow procedure represents procedures that are (a) erroneous, ambiguous, or incomplete; (b) unavailable in the proper place; (c) misunderstood; (d) not used at all. Examples include failures to verify dose information, failure to properly identify the patient or patient chart, failure to verify a treatment site, to verify number and activity of used sources, to verify labels, inadequate procedures to govern administration of radiopharmaceuticals, etc. The lack of procedures or errors in use of procedures for decommissioning of radionuclide sources, lost sources, decontamination actions might have impact on a number of staff and general public to be involved, not only on the patient. The majority of staff and general public involved in the studied events fall into this group.

Direct cause of professional error represents what can be thought of as human errors. Errors in which licensee personnel properly identified the patient, correctly understood the intended treatment procedure, knew how to properly administer the treatment, but still made some kind of mental or physical mistake fall into this category. Almost 17% of events involved professional errors as either primary or secondary direct cause. Typical examples of professional errors are arithmetic errors in calculating doses prior to administration, improper administration of dose, improper positioning of patient during simulation process, source calibration errors, etc. Although it could be argued that more stringent procedures, closer supervision, or more independent verification could have eliminated many of these errors, the events to which these primary direct causes were assigned appeared to be most directly caused by kind of slips and lapses that would likely have occurred regardless of the sophistication of procedures, the degree of training, or amount of oversight that might be present. Thus, they are attributed to simple professional errors. These errors might be easily prevented by incorporating effective human factors design principles into the treatment system. It is not likely, however, that any practical means will ever be found to eliminate all such professional errors.

Communication problems represent the third most common cause of radiological accidents. Communication problems include a lack of communication or the communication of incorrect information, either in written or vocal. More than half of studied events were caused by a lack of written directive, the rest by oral miscommunications, such as relying only on verbal means of identifying a patient, errors in transcribing information, errors in reading the information.

Of the remaining primary and secondary causes, hardware failures accounted only for 4.6%(the lowest value obtained), inadequate training accounted for 8.5 % which is comparatively high value that should be considered as serious problem and proper action must be advocated. An inadequate supervision accounted for 6%, errors for interpretation for 6% and other direct causes and unknown for 6% as well. Most of these direct causes are connected with radiation safety culture in the department.

The subjective nature of the event analysis and data development activities present a relatively large uncertainty in the percentage values presented here. We believe, however, that findings of this analysis provide a very valid indicator regarding the issues addressed. More detail analysis will require more exact data about radiological accidents which have occurred. The system might be useful for the future development of a proper reporting system and for data collection system on which more valuable detail analysis might be produced.

3.2. Observed consequences of accidents

The consequences of investigated radiological accidents range from almost no effect on the patient to the most probable contributing cause of death. The same can be applied to staff and general public involved also in some of the radiological accidents. The actual long-term consequences of accidents were not determined as a part of this study. The detail investigation of consequences is beyond this study.

It is very difficult to define the severity of radiological accidents. Several possible measures of severity can be considered. Perhaps the best measure of severity is reduced life expectancy resulting from the radiological accident. Of course, such measures were not available for most events and simple dedication from dependence of the measure from received absorbed dose is impossible. Likelihood of developing cancers due to the radiological accidents

make little sense for patients because many patients involved were already being treated for cancer. This gives some sense only for staff and general public involved in the radiological accidents. The real effect of radiological accidents represents a complex of different problems and therefore more detail studies will be necessary for finding a suitable measure of the severity of radiological accidents.

The following Tab.5 shows numbers of patients and staff and general public included in the database. As it was mentioned before, the numbers are only part of patients or staff and general public really affected by studied radiological accidents. For example in the famous and excellently reported 'Goiania' accident [7] more than 112 000 persons were monitored, of whom 249 were contaminated either internally or externally. Also, the environment was severely contaminated in this event pointing out another serious consequence of radiological accidents.

Table 5: NUMBER OF PATIENTS AND STAFF OR GENERAL PUBLIC INVOLVED IN RADIOLOGICAL ACCIDENTS.

Category	Involved	Fatal	Adverse effect
Patients	1616	15	around 1000
Staff and general public	4343	4	around 250

4. LESSONS LEARNED

Lessons have been learned from the reported accidents which occurred in radiotherapy departments. The general lesson learned from the analysis of radiological accidents is that licensees who have experienced radiological accidents often lack a comprehensive radiation safety culture, which shapes all aspects of daily operations and which regards patient, staff and public safety as the primary objective of all activities. Some specific lesson learned are briefly summarized as follows:

1. Radiation therapy can generally be performed with high precision and safety only if the equipment which affects the relationship between the prescribed dose and the dose delivered (such as treatment units, lasers, simulators, diagnostic equipment used for localisation and determination of tissue properties, treatment planning computers and devices for blocks and compensator fabrication) fulfill certain minimum requirements, which is done through acceptance tests and commissioning of equipment. Mistakes which happened during the commissioning of equipment and sources, such as:

- calibration of new beams or beams after source replacement,
- determination of beam output for Co-60 machine and dose per monitor units for accelerator,
- preparation of proper decay tables for radionuclide sources,
- proper commissioning of treatment planning systems,
- preparation of proper tables for output factors and wedge factors used for calculation of treatment plans,
- checking of activity of delivered closed and unsealed sources,

affected very large number of patients. When commissioning is complete, the whole system must be tested by comparing the dose planned for a given point in a suitable phantom with the dose measured at that point when the phantom is treated, like a patient, by the person who will routinely operate the machine. Commissioning mistakes can be prevented by:

- human redundancy,
- independent checks performed within institutes,
- independent external audits,
- by in vivo dosimetry performed at least for the first patient's treatment session,
- by well established quality control programme must be ensured that commissioning machine's standards are being maintained during the clinical life time of the equipment (quality control).

However, few events indicate that operators can force equipment to function under conditions which were not explored either by the manufacturer or by the commissioning process. Now therefore, it is also recommended that the equipment operators are given the opportunity to explore the limits to which they will push the equipment in routine use while confirming by measurement that the delivered doses are as expected.

Information for treatment planning, including data on depth doses and dose distributions, as supplied by the manufacturer, should not be used clinically without independent confirmation of the actual values. Back up copies of programmes and data files in use are essential.

2. Most of the radiological accidents analysed in this study involved a lack of procedures, inadequate procedures, or failure to follow procedures. Procedures that require:

- the positive identity of patient through the diagnosis and treatment,
- positive identity of treated tissues,
- clear and unambiguous procedure for tattoos,
- clear and consistent procedure in connection to images from different diagnostic techniques (nuclear medicine, ultrasound, CT, NMR) for simulations,
- radionuclide to be used for treatment,
- isotope source strength,
- location of the source,
- location of patient with radionuclide, etc.

should be carefully prepared and followed.

Although these mistakes affect usually only one patient each time, this type of mistake appears rather often. Failures in patient identification are very critical for all treatments performed only with one fraction (LDR, MDR brachytherapy, radiosurgery).

Prevention of these mistakes can be done by:

- clear identification of patient by photography attached on the patient's chart,
- double check of treatment chart,
- communication with the patient,
- clear assignment of functions,
- clearance by signatures,
- human redundancy, etc.

Effective procedures provide step-by-step instruction in a clear, concise manner for the completion of all tasks. They anticipate potential problems and provide means for detecting, avoiding, or correcting these problems. This means written procedures. Unwritten procedures are never clear and are frequently a feature of accidents. The procedures should not specify only how the work will be done but also when it will be done.

Note that merely developing procedures will not prove effective unless those procedures are fully carried out. Proper implementation means that staff members are aware of the procedures, understand them, have received training regarding the intent and provisions

of the procedures, and that the procedures are unfailingly used and followed. Even the best procedures are useless if they are not understood or used by the staff. A great deal of flexibility can be retained in using effective procedures with the proviso that this flexibility can be exercised or authorised only by staff members who have the knowledge, experience, training and responsibility (both legal and administrative) to deviate from the standard procedure.

3. Mistakes in patients chart:
- wrong dose per fraction or total accumulated dose recorded,
- wrong number of fraction,
- wrong calculation,
- wrong beam quality,
- wrong wedge identification,
- misreading of dose or dosage,
- misreading of the activity units,
- misreading of the patient full name, etc.,

are quite frequent mistakes which affect individual patients. These mistakes can be prevented by:
- two independent revisions per week (i.e. by two persons: physicist, radiotherapist),
- clear written procedures,
- clear definitions of functions and responsibilities,
- clearance by signatures,
- by verification systems.

The manual checking system serves two related distinct purposes: it is immediately effective and remains effective in eliminating most of the results of human fallibility under conditions applying in the centre, and provides a solid basis for the design of an automated system of treatment calculation and dose treatment verification. But even automated verification system has to be check before treatment of patient is started.

4. It is sometimes suggested that brachytherapy procedures involving implantation of sources are simple by comparison with teletherapy and do not need to be written down. However, this is a mistaken view because most of the operations are manual, providing great opportunity for human errors. Mistakes like:
- wrong radionuclide,
- wrong activity of sealed or unsealed sources,
- wrong application time,
- inadequate placement of sources in applicator,
- wrong calculation,
- wrong unit of activity,
- unintended removal of sources by patient,
- incomplete removal of the sources after application,
- wrong handling and storage of sources,
- damage or loss of sources,
- waste disposal,

are examples of mistakes which are as frequent as mistakes in external beam therapy. Most of these mistakes involve one patient, but they are dangerous because the treatment is usually performed in one fraction.

Prevention of these mistake can be achieved by:
- clear procedure for labelling and cross-checking of sources,
- clear allocation of functions for verifying sources,
- records keeping the movement of all sealed sources both inside and outside an establishment,

- checking of sources after application,
- measuring the patient before release,
- storage, use, issue and receipt of sources only by authorized person,
- clearance by signatures,
- quality control of sources and brachytherapy machines, etc.

5. Communication problems represent mistakes which were observed in many of radiological accidents. Communication problems include:

- lack of communication or the communication of incorrect information,
- verbal means of identifying a patient,
- language problems in multiliquinal countries or with large ethnic communities,
- errors in transcribing or reading information,
- oral miscommunications,
- vagaries of handwriting,
- use of unfamiliar, nonstandard or collegial terms,
- labelling of foreign made equipment not in mother language,
- telephone communication,
- interpersonal difficulties,
- use of part-time employees in key positions,
- messy work environment, etc.

Miscommunication mistakes can be reduced by:

- defining safety critical communication,
- preparing procedures for proper communication,
- defining responsibilities and functions for all member staff participating in communication process,
- insisting on written information,
- human redundancy,
- clearance by signatures,
- preparation of check list.

Due to the large number of steps and the number of persons involved in the treatment preparation, the transfer of information from one step to the next is very critical point. Indeed, errors due to inadequate transfer of information will be reflected in every next step and can seriously affect the final results of the treatment.

6. Unique conditions and changes in routine were identified as highly significant contributors to the radiological accidents. These changes or unique conditions might include:

- personnel changes,
- change of the supplier of equipment or radioactive materials,
- change of usual dosage,
- change of units for activity,
- performing a treatment in new location,
- treatment a patient with unusual position for the prescribed site, etc.

These changes or unique conditions serve to introduce unfamiliar and possibly difficult circumstances, which increase the likelihood of errors. The analysis of radiological accidents suggests that it would be beneficial for the licensee to:

- establish mechanism that help anticipates problems associated with changes and unique conditions,
- define formalism of clear, concise, disciplined procedures,
- perform additional training,
- define responsibility for treatments.

7. Based on analysis of the radiological accidents it would appear that the frequency of hardware failures resulting in accidents is low. The consequences of these hardware failures are, however, potentially very severe and have usually effect on many patients. Errors in hardware include such as:

- misinterpretation of displays and conflicting signals,
- safety interlocks failure,
- overriding of safety interlocks,
- improper maintenance,
- software errors having influence on the operation of a machine,
- hardware incompatibilities,
- treatment in non-clinical modes,
- abnormal operation, etc.

It seems likely that the evolution of a more rigorous safety philosophy through the application of disciplined procedures could result in the creation of fault tolerant system in which hardware failures, should they occur, could be quickly detected and, by carrying out systematic mechanisms to detect and mitigate hardware failures, the general impact of these failures might become negligible. Nevertheless, it is necessary to carry out:

- redundancy and independence of safety systems,
- testing of a machine under all possible clinical situations and operating mistakes,
- for treatment use only clinical mode,
- preventive effective maintenance,
- avoiding of bypasses in safety interlocks,
- training of operating staff also in abnormal situations of machine operation,
- redundant, diverse safety systems independent of operating systems.
- better contact with manufactures for obtaining information about all mishaps, accidents which happened with their machines.

8. Lack of responsibility, supervision and training were also observed in most radiological accidents. These include:

- inadequate education and training,
- overestimating responsibility,
- ignorance of written "bureaucratic" procedures,
- unawareness of Local Rules,
- lack of safety culture,
- lack of environmental and personnel monitoring system,
- lack of duties of radiation protection supervisors,
- lack of emergency planning and preparedness, etc.

Protection of the patient can only be assured by :

- specifying entry qualification and training of all staff,
- specifying safety-critical function for each member of staff,
- drawing up a training programme for all staff,
- integration of radiation protection and safety into education and training programme,
- maintenance of a training schedule,
- indication of foreseeable accidents or occurrences and preparedness,
- recommended action for abnormal machine operation,
- provision for adequate communication in an emergency,
- keeping ongoing monitoring the programme.

9. Safe decommissioning of facilities is very important, as it can be documented by two most disastrous radiological accidents [7,8], where hundreds of persons were affected, happened due to the lack of decommissioning procedures. Decommissioning procedures involve:

- removal of sealed sources from a radiotherapy machine,
- disconnection of accelerators from power supply,
- disposal of sealed radionuclides when they are leaking or damaged,
- waste disposal from brachytherapy and nuclear medicine departments, etc.

. Radiation and contamination check must be made of the equipment from which the source(s) has been removed, followed by:

- if necessary, decontamination procedures,
- clear unambiguous labelling of 'empty' and 'clean' containers.

Arrangement must be made for the containment and packing of the sealed source(s) and contaminated items/waste, in preparation for reuse, safe temporary storage or proper disposal, as appropriate.

10. Based on the lesson learned from many radiological accidents apparently human errors are major contributors. Typical examples of human errors are following:

- arithmetic errors in calculation of dose or dosage,
- improper administration of dose or dosage,
- improper positioning of patient during simulation or treatment,
- source calibration errors,
- human-machine interfaces,
- misreading of information,
- misinterpretation of signals, alarms or warnings,
- decision or judgment errors, etc.

When designing a system for protection of the patient, it must be considered what the system requires from a human worker and what the worker can reasonably be expecting to do. This requires:

- proper design of equipment considering human limitations,
- space and time for training activities,
- concentration on work and not to attempt to do more than one thing at a time,
- proper workload of workers,
- proper housekeeping,
- function allocation,
- well-written equipment manuals and procedures,
- professionalism of all staff,
- allocation of additional resources (money, space, personnel support etc.).

Many of other factors which may contribute directly or indirectly to human errors leading to occurrence of incidents or accidents can be identified, like shift practices at facilities which operate twenty-four hours a day, overtime and on-call status, working hours etc. Research aimed at identifying common features in causes of human errors is required in this field [22].

From lessons learned it is oblivious that most of the accidents could have been avoided, had a comprehensive quality assurance programme been established and properly applied in all radiotherapy departments.

5. CONCLUSION

Safety is not to be considered in isolation or as a separate chapter of the radiotherapy syllabus for education of professionals. Rather, safety should be incorporated in all steps of management of radiotherapy, so that an *integrated quality management* system involves both quality and safety [23-25].

In fact, most of the control measures to monitor quality serve to detect any deviation concerning safety as well, since the parameters to be controlled are often the same. The quality control programmes and frequency of the constancy checked can be designed to combine both objectives (quality and safety). Test tools exist nowadays to make more frequent relative measurements as constancy checks, which monitor quality and safety at the same time.

To meet the very high requirements, many of the world's leading radiotherapy centres have implemented or are implementing techniques used in other disciplines, where the prevention of errors and mistakes in order to produce a high quality product over a large number of pieces of product is an everyday issue, and therefore this techniques are very developed. This permeability among different fields (with due care of the differences between industry and medicine) can only render mutual benefits. Elements of this technique (known as *quality management system* and fully defined by ISO standard 9,000/2) can be incorporated as a central framework for planning and delivery of radiotherapy services.

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