CHAPTER 2

LITERATURE REVIEW

CHAPTER OVERVIEW

This chapter presents a critical review of the past studies for risk assessment for various applications of radiation sources. Use of radiation sources involves health hazards to the operators. The risk assessment in the use of radiation sources will be helpful to manage the risk involved in the practice. Prospective risk assessment is thus, recommended for the existing and new practices. Several risk assessment studies have been carried out and published for nuclear power plants in India, and internationally. However, such risk assessment studies for non-nuclear radiation facilities are limited in number. This chapter outlines various risk assessment studies carried out for the non-nuclear radiation facilities in general. Most of those studies have been carried out for radiotherapy and industrial gamma irradiators, where radioactive sources of very high activity are used. The methodologies used for the published studies are also touched upon in the chapter. Very limited number of publications exist in the case of industrial radiography practice, which have been discussed in this chapter. And based on the literature review, the research gap in the industrial radiography practice has been outlined in this chapter. Various international guidelines for such studies have been published, and these are provided at the end of the chapter.

2.1 GENERAL

Industries handling hazardous materials or dangerous goods are highly concerned about the safety of the occupational workers from the associated hazards. These industries besides having to deal with industrial hazards like any other industry, have to deal with additional hazards associated with the handling of these hazardous materials. The risk associated with most of these hazardous materials is high and any accident can lead to permanent loss of body part, or may even cost the life of the worker. Similar is the case with the practice of use

of a radioactive source that emits hazardous ionizing radiations. These radioactive sources are used for various peaceful applications such as for power generation, medical applications for diagnosis and therapy, industrial applications for non-destructive testing, irradiation of food and allied products, gauging of physical parameters and for research applications. In spite of the associated hazards, these practices provide substantial benefits to the society which justify the use of radiation sources. However, if the overall risk associated with these applications is high as compared to the benefit accrued from them, then the practices cannot be justified and have to be stopped.

Health hazards associated with the ionizing radiations were noticed, as early as, immediately after the discovery of X-rays. In 1896, one of Thomas Edison's assistants reportedly developed a degenerative skin disease due to exposure to X-rays [2]. However, most of the evidences for serious radiation related hazards were noted from the epidemiologic data and the biological data generated from the people exposed to the atom bomb in 1945. Large data have been published till date for deterministic and stochastic health effects of radiations, including the incidence of cancer and genetic effects [2]. It is worth noting that while the exposures to the population of Hiroshima and Nagasaki w of the type of high dose exposure, the occupational exposures to radiation from the various industrial applications are of the type of low dose exposure. The hazard associated with the use of ionizing radiation indeed necessitates risk assessment in the use of radioactive sources.

2.2 PROSPECTIVE RISK ASSESSMENT IN THE USE OF RADIATION SOURCES

Prospective risk assessment of the practices involving hazardous material, like the radioactive source, is essential for continual safety enhancement of the operators and other auxiliary staff. Prospective risk management techniques are growing in the industries, which are aimed to provide quality management and safety in the operations. Assessment of prospective exposure, which is termed

as "potential exposure", is recommended in the case of applications of radiation sources. Risk assessment for such applications/practices is helpful for identification of area which requires interventions/modifications to enhance the radiation safety. Results of such risk assessment studies also provide important inputs for decision making to frame policies related to such practices. In fact, the International Commission on Radiological Protection (ICRP) and International Atomic Energy Agency (IAEA) recommend prospective risk assessment for the practices using radiation sources [3]. IAEA suggests the methodologies such as the Probabilistic Safety Assessment (PSA) and the Failure Modes and Effect Analysis (FMEA) for risk assessment of potential exposures from radiation sources.

ICRP and IAEA strongly recommended the use of probabilistic approach for risk assessment in the nuclear and radiation facilities. Safety of nuclear power plants has always been a concern. Accidents in Three Miles Island (1979), Chernobyl (1986) and Fukushima (2011) nuclear power plants created havoc in the public worldwide, and raised serious protests against nuclear energy. These accidents forced the concerned authorities for prospective risk assessment for the existing and newer power plants, to provide confidence to the operators as well as to the society.

Risk assessment using the PSA technique to a nuclear power plant (NPP) was first initiated in 1975 by the United States Nuclear Regulatory Commission's (USNRC) study for Reactor Safety [4]. Since that time risk assessment studies have been carried out by various nuclear power plants using the Probabilistic Safety Assessment (or Probabilistic Risk Assessment) and other relevant risk assessment methodologies. IAEA has published various documents for conducting PSA of nuclear facilities [5-11]. Several other risk assessment studies too have been published in the literature for nuclear facilities in the world, which are not elaborated here.

2.3 RISK ASSESSMENT IN THE NON-NUCLEAR APPLICATIONS OF RADIATION SOURCES

Non- nuclear applications of radiation sources such as industrial, medical and research activities also pose radiation hazards to the operators and others, and thus require practice specific risk assessment. The ICRP has recommended that PSA should be used for the assessment of potential exposures from radiation sources. The International Basic Safety Standard of IAEA suggests that the authorization process for radiation sources should include the assessment of all exposures including potential exposure [12]. In view of the ICRP recommendation of prospective risk assessment, IAEA supported various risk assessment studies for facilities using radiation sources. Table 2.1 shows the summary of the risk assessment studies carried out for various radiation facilities. These studies have been published in detailed by IAEA [13].

Table 2.1 Summary of risk assessment studies in radiation facilities, carried out with support of IAEA [13]

Title	**Radiation Application**	**Risk Assessment Methodology used**	**Country**
Probabilistic Risk Assessment Associated with the Operation of an Industrial Irradiator Installation	Industrial Irradiator	FMEA ET HRA	Mexico
Methods and Procedures To Apply Probabilistic Safety Assessment (PSA) Techniques to the Cobalt-Therapy Process. Cuban Experience.	Cobalt Teletherapy	FMEA ET FT	Cuba

ATHENA Application to Human Error Issues in Cobalt Therapy (Argentine Experience).	Cobalt Teletherapy	THERP ATHENA	Argentina
Investigation of Appropriate Methods and Procedures to Apply PSA Techniques in Safety of Radiotherapy and Industrial Irradiation Facilities	Cobalt Teletherapy & Industrial Irradiator	FMEA ET FT	China
Towards Probabilistic Risk Assessment in Brachytherapy	Brachytherapy	FMEA FT	USA

Extensive online and offline literature review was carried out to explore the past studies, and it was found that very limited work has been carried out till date in the field of risk assessment for non-nuclear applications (or radiation facilities). Following are the risk assessment studies of various types of radiation facilities, which were found to be published in the literature**.**

Radiation Processing Plants

Processing of food & allied products is carried out using gamma rays, for the purpose of increasing their shelf life, and sterilization of medical products. A Radiation processing plant uses radiation sources with highest source activities amongst all the industrial applications of radiation. Generally, the Co-60 sources of 1000 kCi are used in these plants. Due to such high activity of the sources, the hazard potential is very high in such plants. Hence, multiple safety barriers are provided in such facilities. However, the scenario of failures of all these barriers is possible, leading to a fatal dose to the exposed person. Solanki et al. carried out a Probabilistic Safety Assessment study to calculate the likelihood

of the over exposure and the risk of death due to such exposure [14]. That PSA study was carried out using Event Trees Analysis, and the total frequency of the fatal exposure was calculated as 4.76E-07/year. That included the scenario of accidental exposure to the operator when he is inside the radiation cell or makes an accidental entry into the radiation cell when the source is in exposed condition. Similarly, Keshk A. B. et al. carried out a risk assessment study using PSA aimed with the purpose of life extension of the Egyptian radiation processing plant IR-206 [15]. Those authors have eventually suggested various modifications in the electrical and mechanical systems of the plant for its longevity.

F. Castiglia et al. conducted a risk assessment study using PSA for a gamma radiation processing irradiator and calculated the frequency of potential exposure, and hence the risk coefficient. Four practical scenarios were considered in that study by which an operator could receive high radiation exposure. Fault trees were modeled, and component failure probabilities and human error were considered for the assessment. Fuzzy logic, using triangular fuzzy membership functions, was also utilized in that study to calculate the various probability values. Fuzzy doses were calculated for the scenario, when a person is inside the radiation cell and the operator exposes the source. Resulted fuzzy dose were found to be [0.4; 0.62; 7.7] Sv per event, which correspond to potential annual death of [3.7E-9; 4.2E-8; 1.24E-6] per year, considering the distance of 1m to 10 m for the time interval of 30 sec to 150 sec of exposure [16].

P. V. Varde et al. carried out a risk assessment of the Indian gamma irradiator "ISOMED" using the PSA and FMEA methods, to identify human actions and critical components, which could lead to excessive exposure or radiation accidents, both, outside and inside a radiation cell [17]. That study recommended eleven actions related to the system retrofitting, maintenance practices and changes in operation, for the life extension of the plant by 10 years.

M. Casamirra et al. carried out a Fuzzy Fault Tree analysis, considering various accidental scenarios in irradiation industrial plants [18]. The Human Error

Assessment & Reduction Technique (HEART) was used for the calculation of the probability of human error in that study. Those authors modified the HEART technique on the basis of the fuzzy set concept. The authors made recommendations based on that study on the operating procedures and the safety equipment to reduce the radiological risk.

Medical Applications of Radiation Source

Radiotherapy practice utilizes several sources of variable activities. Generally, a teletherapy equipment uses either a Co-60 source with a typical activity of 4.0E+3 Ci or a linear accelerator in the energy range 9 MV to 15 MV [19]. Similarly, brachytherapy equipment for cancer treatment utilizes several sources, most common of which are Co-60 and Ir-192 with typical source activity of 10 Ci. Assessment of radiotherapy practice for radiation safety is essential as this practice involves exposure to occupational workers as well as to the patients. In this regard, several risk analysis studies have been carried out and published for the radiotherapy practice. Julian et al. of the project **"**Guidelines on risk analysis of accidental and unintended exposures in radiotherapy**"** (ACCIRAD) have reported the then current status of implementation of European directives for risk management and for assessment of variability in risk management [20]. The study concluded that most European countries have taken steps for implementation of European directives designed to reduce the probability and magnitude of accidents in radiotherapy. However, there are differences in methodologies utilized for risk assessment by different countries to conduct a proactive risk assessment and reactive event analysis.

Several risk assessment studies concerning the radiotherapy staff and patients using the FMEA methodology have been reported in the literature, which aimed to risk assessment for the protection of radiotherapy staff and patients. N. Teixeira et al. carried out FMEA study at two different radiotherapy Centers in Lisbon City and provided recommendations for improvements in the practice [21].

P. Keall have carried out FMEA study for Quality Assurance of the dynamic MLC tracking system, and Juan López-Tarjuelo et al. have carried out procedure related FMEA study based on which interventions were recommended for an automated intraoperative electron radiotherapy (IOERT) procedures [22-23]. P. Keall, based on their study have recommended monthly testing of the components having failure modes of Risk Priority Numbers greater than 125. Juan López have similarly reported 57 potential failure modes and classified them into 'treatment cancellation' and 'delivering an unintended dose' events. Kelly Cooper et al. have utilized the FMEA method to improve the safety and efficiency of a new stereotactic radiosurgery program [24]. Shada Wadi-Ramahi et al. and D. Allan Wilkinson et al. have applied the FMEA method in the brachytherapy practice and identified the most likely and significant sources of error in the practice [25-26].

Castiglia F. et al. have utilized fuzzy logic to convert the FMEA values to crisp values for the analysis of the accidental exposure of medical staff during brachytherapy procedures [27]. Similarly, several other risk assessment studies based on FMEA for radiotherapy practices have been reported in the literature, which have not been referred here.

Similarly, the PSA methodology also has been used for various risk assessment studies in the radiotherapy practice. Ryu et al. have reported risk assessment for the workers in brachytherapy department using the PSA methodology [28]. In that study event tree was modeled for calculation of accidental and normal exposure probabilities. Gordon et al. have reported utilizing a combination of FMEA, PSA, and HRA for risk assessment in radiotherapy procedures [29]. That study identified 34 failure/error modes, which have the potential to affect the safe delivery of treatment. Liam Chadwick et al. have reported carrying out risk assessment using Human Error Assessment and Reduction Technique to analyze a critical nursing task within a modern radiotherapy system [30]. G. Sands et al. in their study have suggested integrated human error probability modeling, with components of FMEA and Fault Tree Assessment, and applied them in a clinical setting in radiotherapy [31].

Sara et al. have published a study on the application of FMEA to pretreatment phases in tomotherapy, an area of medical applications of radiation [32]. Those authors have assessed the risk to the patients going for radiotherapy using helical tomotherapy. 74 failure modes were identified in that study, out of which 38 were in the stage of volume determination and preplanning imaging, and 36 were in the planning stage of the therapy. The accepted benchmark value for RPN of 125 was found to be exceeded in four cases, where corrective actions were recommended.

Particle Accelerator Equipment/Facilities

Lekha M. Chowdhury and P.K. Sarkar have carried out risk assessment study for radiological risk from particle accelerators using a fault tree analysis [33]. That study concluded that main accident contributors in an accelerator facility are beam loss, due to beam line breaks or component failure, and target rupture. The scenario of a person trapped in the cell during an accelerator operation also has been analyzed in that study.

In this category, Luciano Burgazzi had utilized PSA methodology for risk assessment of an accelerator—Lithium target based experimental facility [34]. That study identified the accident sequences of the plant operation and quantified the accident frequencies. Their results showed that the accident frequency for all the sequences which could have led to potential undesired effects as a result of radioactive release to the outside at the International Fusion Materials Irradiation Facility (IFMIF), is well below the limit set for credible accident i.e. 1.0E−6/year.

Industrial Radiography Practice

Industrial radiography practice uses radioisotopes like Ir-192, Co-60, Se-75 etc. with a typical activity in the range of 10 Ci to 100 Ci. Potential hazard in the industrial radiography practice is high as compared to other applications of

radioactive sources. Several accidents have been reported worldwide in industrial radiography practice, resulting in permanent loss of body parts and fatalities in a few cases [1]. Prospective risk assessment is essential to understand the level of risk involved in this practice and for decision making for risk management in the practice. However, very limited risk assessment studies have been carried out for industrial radiography practice. Any safety assessment of industrial radiography practice should include the radiation risk from routine use and also the probability of potential exposures to radiography personnel [35].

João C. et al. have performed risk assessment study for industrial radiography practice carried out in Brazil [36]. That study utilized the PSA methodology to calculate the probability of potential exposure in the operation of an industrial gamma radiography exposure device. The event tree was modeled considering the steps involved in the operation of the device. The probability of emergency and accidental events was calculated to be 4.5E-01. However, in spite of the good results obtained, there are the following limitations of this study

I. Event tree sequencing in the study involves several headings which do not affect the quantity of radiation exposure received by the operator (example fixing the radiography films on the job, use of personnel dosimeter badges etc.). However, these event tree headings contributes to the results in terms of probability of potential exposure. For instance study considers if radiography films have not been fixed on the job, operator will receive abnormal radiation exposure, which is not true. Therefore, the probability of potential exposure to operators has been overestimated.

II. That study considers only for the open field radiography operations for risk assessment. Radiography work carried out inside the enclosed installation has not been addressed in the study.

III. That risk assessment study involved various data of human actions for the operation of radiography devices. Since, the human action data

considered in the above study is country specific, results may vary significantly with that for some other countries.

Another study in this category has been reported for risk assessment in industrial radiography practice in South Korea where PSA and Monte Carlo Analysis were used along with Bayesian inference [37]. The event tree in the study had only six headings, which did not consider several important factors, which may contribute to excessive exposure to operators. For example, that study presumes that for the entire duration of the operations the operator would have the radiation survey meter in the field, which he would use during the operations without fail, and that the operator would be maintaining a safe distance from the source during all the 'source exposures', since the failure of these factors have not been considered in the study. Further observation is that the study is valid for South Korean operators, and results from similar studies at other places/countries may vary due to variation in the operators' actions considered in the study. Also, that study is only for open field radiography operations and does not address the enclosed operations.

Other than the above two mentioned publications, no other work has been reported in the literature for operational risk assessment in industrial radiography practice. Similarly, no study is found in the literature for design based risk assessment of the existing or any new design of the industrial radiography devices.

2.4 IDENTIFICATION OF RESEARCH GAPS

Literature reveals that several prospective risk assessment studies have been carried out for practices involving radioactive sources and radiation generating equipment. Most of these studies are based on the FMEA, PSA and Human Reliability Assessment (HRA) techniques. For nuclear facilities, deterministic as well as probabilistic safety assessment studies have been carried out and published for the existing plants, as well as for the new plants. However, limited studies have been reported for prospective risk assessment of non-nuclear

radiation facilities. Most of the published studies are for radiotherapy practice. The radioactive sources used in the radiotherapy practice are of high activity and their safe use involves the safety of both, the patients as well as the operating staff. A large amount of data is recorded in this practice, which is helpful for conducting risk assessment studies. All these factors encourage risk assessment studies to be undertaken for radiotherapy practice.

In the case of industrial applications of ionizing radiations, few studies have been published for radiation food processing facilities, aimed to calculate the probability of inadvertent dose to the operator/another person.

Similarly, for prospective risk assessment in the industrial radiography practice, only two published studies were found in the literature. Both of these studies are related to the operational aspects of the practice, and results are country specific. No such study has been carried out for the Indian scenario. Further, these studies are only for the open field radiography operations. There are several limitations of these studies, as discussed in section 2.3. No study has been carried out for the radiography operations in enclosed installations.

Accidents may result due to operational errors or due to failure of the equipment. Several accidents have been reported in the literature for industrial radiography practice owing to the equipment failure. However, no study has been published till date for risk assessment for the existing or proposed design of the industrial radiography devices, in India or internationally.

Risk assessment in industrial radiography practice is still mostly unexplored. In India, while a few prospective risk assessment studies have been conducted and published for nuclear power plants, radiotherapy facilities, and industrial gamma irradiator facilities, no such studies have been carried out for the industrial radiography practice.

2.5 INTERNATIONAL GUIDELINES FOR RISK ASSESSMENT STUDIES OF RADIATION FACILITIES

International agencies like ICRP and IAEA recommend risk assessment studies for radiation facilities. For this purpose, various documents have been published which provide guidance for conducting such studies. These documents suggest the risk assessment methodology to be used for a specific practice, examples of accidental scenarios, and the initiating events for accidents. Table 2.2 provides few such guidelines for conducting risk assessment studies.

Table 2.2 Guidance documents for risk assessment studies for radiation facilities

Sr. No.	Publication [Ref.]	Description
1	Procedures for conducting a probabilistic safety assessment for non-reactor nuclear facilities [38]	International Atomic Energy Agency (IAEA) guidelines for conducting a risk assessment using PSA techniques for non- reactor facilities like fuel fabrication facilities, fuel reprocessing facilities, hot cell facilities, accelerators etc. This document also outlines the difference in the risk assessment methodologies for the reactor and non-reactor facilities.
2	Case studies in the application of probabilistic safety assessment techniques to radiation sources [39]	IAEA document provides details of a coordinated research project, which involves the case studies of risk assessment in industrial irradiator facility, telecobalt facility and brachytherapy facility, conducted in various countries using different risk assessment methodologies. This document also outlines the difficulties in the studies.

3	Protection from Potential Exposure: A Conceptual Framework, (Annals of the International Commission on Radiological Protection) [40]	ICRP document provides practical applications for protection from potential exposure, justification of practice, optimization of radiation safety, individual health risk estimation, risk assessment techniques (probabilistic and deterministic techniques) and application in complex and less complex practices.
4	Protection from Potential Exposures- Applications to Selected Radiation Source, (Annals of the International Commission on Radiological Protection) [41]	ICRP document provides description about radiation protection in case of potential exposures, reliability of systems, risk and consequences of potential exposures, risk assessment guidance with examples of industrial radiography and other applications of radiations
5	IAEA Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards, General Safety Requirements [12]	The objective of this IAEA publication is to establish the generally applicable requirements that need to be fulfilled in safety assessment for facilities and activities, with special attention paid to defense in depth, quantitative analyses and the application of the graded approach to the ranges of facilities, and of activities that are addressed. The concept of potential exposure has been considered there for safety assessment.
6	Comparing of Nuclear Accident Risks with those from other Energy Sources [42]	The document provides the comparison of risk in nuclear sector with that of other hazardous industries.
7	Protection from Public Exposure- A Conceptual Framework, (Annals of the International Commission on Radiological Protection) [43]	ICRP document suggests annual probability ranges for a sequence of events, which leads to normal exposure and for doses above normal exposure which leads to stochastic and deterministic effects.

2.6 CHAPTER SUMMARY

Radiation sources are being used for various applications. Use of these sources involves radiation-induced health hazards. Prospective risk assessment for the practices using these sources is helpful for the risk management, aimed to enhance the overall safety of the operator and the public. Various safety analysis and risk assessment studies have been carried out for the facilities that uses radiation sources. Risk assessment for the nuclear power plants by using various methods like PSA, FMEA, HEART, HRA etc. is well established and accepted worldwide. Several such studies have been published for nuclear power plants. However, limited risk assessment studies have been published for the non-nuclear radiation facilities. Very little literature is available for the risk assessment studies of radiotherapy practice, which uses sources of high activity and involves the risk of radiation exposure to the operator as well as the patients. Generally, data related to the radiotherapy operations are well maintained, a feature which helps in such studies. Similarly, few studies have been published for industrial irradiator facilities, which also utilize high activity sources, of the order of 10E+5 TBq of Co-60. These studies were aimed at calculating the probability of inadvertent dose to the operator or other persons, and for the life extension of the concerned plants. And in the case of industrial radiography, only two risk assessment studies have been published in the literature, which concern only with the operational aspects of the practice. Those studies too are limited to only the open field operations, and have some other limitations also. It is to be noted that no study has been published internationally or nationally for the design based risk assessment of industrial radiography devices. This research gap encourages for the risk assessment study to be conducted for the industrial radiography practice. Results of such studies will be helpful for identification of the areas which require modifications/interventions to enhance the overall radiation safety. And for these studies help may be obtained from the various international publications by ICRP and IAEA which provide guidance for conducting risk assessment studies for non-nuclear radiation facilities.
