CHAPTER 4

DESIGN ANALYSIS & RISK ASSESSMENT OF INDUSTRIAL GAMMA RADIOGRAPHY EXPOSURE DEVICES

CHAPTER OVERVIEW

This chapter describes the research work carried out for the design analysis and risk assessment for the industrial radiography practice. In-depth analysis of the existing designs of Industrial Gamma Radiography Exposure Devices (IGREDs) has been carried out. Existing procedures for the safety assessment of the IGREDs at the various levels by its stakeholders have been described. Each sub-unit of the IGREDs and importance of their functionality for the operation, has been described in this chapter. Analysis of all the components of IGRED has been carried out and the possible failures for each component have been identified. Failure Modes & Effect Analysis (FMEA) has been utilized for the design based risk assessment of the IGREDs. This chapter describes the FMEA methodology and steps involved in the study. Risk Priority Numbers (RPNs) have been calculated for each of the identified failures. Ranking of failures has been provided on the basis of the criticality of failure. FMEA results have been summarized in a table. RPNs greater than 100, where corrective actions are required, have been discussed in detail and recommendations have been made to reduce the RPN, and hence the associated risk.

4.1 INDUSTRIAL GAMMA RADIOGRAPHY EXPOSURE DEVICE

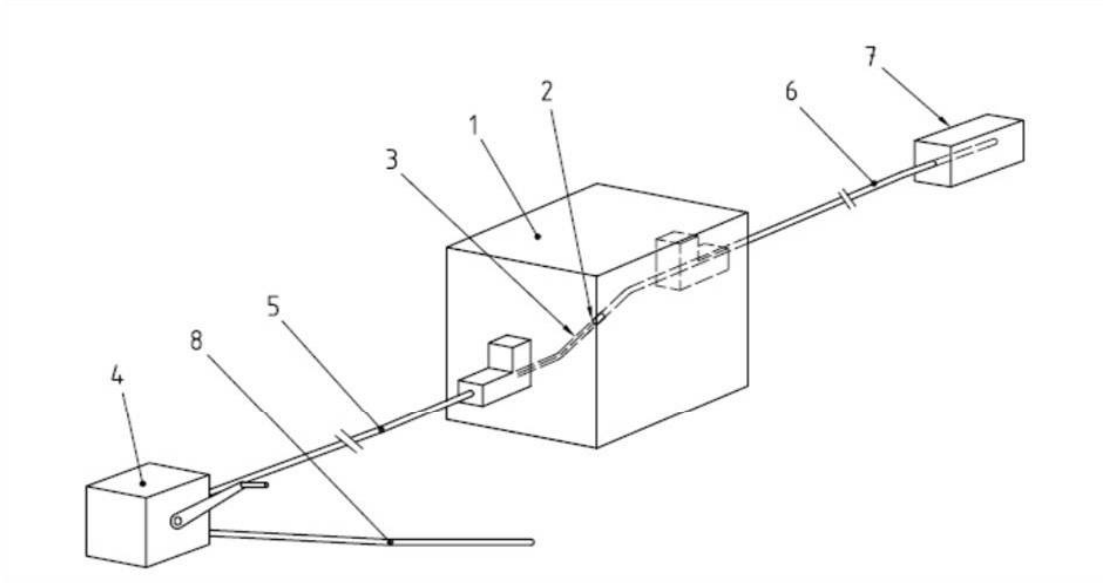
Industrial radiography operations are carried out using a suitable radioactive source. Since these sources continuously emit hazardous ionizing radiations, there is a need to provide shielding against radiation during non-working periods.

Radioactive sources used in industrial radiography are housed inside a shielded equipment called “Industrial Gamma Radiography Exposure Device” (IGRED) or simply, “radiography device”. The more conventional and common term used for these devices is "radiography camera”.

These IGREDs serve following two purposes

I. As a device for radiography operations, and
II. As a transport container for transporting the radioisotope contained in the device.

The shielding material required for gamma radiation should be a material of high atomic number, and therefore, depleted uranium, lead or tungsten are used as a shielding material in these devices. As the source capacity of these devices increases, the shielding material required also increases, which in turn increases the gross weight of the device. Figure 4.1 shows the schematic diagram of an IGRED [44].



Key

1	**Source Housing**	**5**	**Control Cable and Sheath**
2	**Radioactive Sealed Source**	**6**	**Projection Sheath**
3	**Source Holder**	**7**	**Exposure Head**
4	**Remote Control**	**8**	**Reserve Sheath**

Figure 4.1: Sketch of industrial gamma radiography exposure device (Image source: ISO-3999; 2004)

4.2 DESIGN ANALYSIS OF THE INDUSTRIAL GAMMA RADIOGRAPHY EXPOSURE DEVICES

The IGRED consists of four detachable sub-units namely, source housing, remote control unit, projection sheath and the source assembly. Following is the brief description about these sub-units. Each of these sub-units has been analysed for risk assessment in the present research work.

4.2.1 Source Housing

Source housing is the most important and largest part of the IGRED. The radioactive source is housed inside the source housing, which provides shielding from the ionizing radiations emitted from the source. The thickness of shielding material is chosen so that the radiation levels outside the IGREDs, are within permissible levels. Maximum permissible radiation levels around the gamma radiography devices are given in Table 4.1. As is evident in the table, the permissible radiation levels differ for the different class of devices [45].

Table 4.1 Maximum permissible ambient equivalent dose rate for IGREDs in mSv/h (mR/h)

Class	On external surface of source housing	At 5 cm from external surface of source housing	At 100 cm from external surface of source housing
Portable	2(200)	0.5(50)	0.02(2)
Mobile	2(200)	1(100)	0.05(5)
Fixed	2(200)	1(100)	0.1(10)

The basic design of source housing for all the models of radiography devices is the same, with slight variations in the source traveling conduit and safety interlocks. Some of the models have S-shape conduit and the others have straight conduit. S-conduit has the advantage that there is no direct streaming of the radiation outside the ‘shipping plug (end cap) hole’. Whereas in the straight conduit if ‘shipping plug’ is opened, there would be a direct streaming of

radiation through the hole. Figure 4.2 shows the source housing of the various models of IGREDs. Main parts of source housing are lifting attachments, shipping plug, storage cover, locking mechanism etc.

Figure 4.2 Source housing of various IGRED models used in India

4.2.2 Remote Control Unit

Remote control unit is the sub-assembly of the IGRED which controls and exposes the source out of the shielding. Remote control unit consists of a metallic wire with one of its end crimped with a male coupler. The metallic wire is a flexible wire having a diameter of about 5mm. Whenever source exposure is required, this male coupler is connected with the female coupler of the source assembly. Dimensions of the male and female couplers are very critical as worn-out male or female coupler dimensions may result in disconnection of the source

assembly from the control unit during operation, resulting in the source getting stuck, and hence leading to the possibility of accidental radiation exposure to the operating personnel. Figure 4.3 shows the picture of a remote control unit.

Figure 4.3 Picture of the remote control unit of IGRED

Another end of the control cable is connected to a handle through the driving unit gear assembly. Movement of the control cable is controlled by rotating the handle. The metallic cable of the control unit is protected by the PVC sheath, which covers the entire control cable. It restricts the dust and other particles to come in contact with the control cable. The typical length of the control cable is 25 ft. However, control units with cable lengths of 50 ft. are also available. Some of the models of the control unit come with an odometer to cross check the movement of the control cable, and hence the source assembly. The remote control unit of all the IGRED models has similar design and operational mechanism.

4.2.3 Guide Tube Assembly

Whenever the source is required to be exposed for operation, source assembly is pushed out of the shielding of the exposure device, in the projection sheath, generally referred to as the "guide tube". This projection sheath is steel braided flexible hose with outer diameter of about 13.5 mm. The end point of this guide tube is fitted with a metallic snout of stainless steel or aluminium. Another end

of projection sheath has provision to attach with the front side of the source housing. Projection sheath of the guide tube is made of a flexible material, since the loss of flexibility can cause the source getting stuck in the transit location. Figure 4.4 shows a picture of a guide tube assembly of IGRED.

Figure 4.4 Picture of the guide tube assembly of IGRED

The typical length of the projection sheath is 7 ft. Extension guide tubes are also available of the same length, which are used to increase the total length of the projection sheath. A maximum of two extension tubes along with main guide tube can be used for operations. For the operating an IGRED, it should be noted that the total length of the guide tubes used should be less than the control cable length present in the control unit.

Hazard analysis shows that use of guide tube of small length will decrease the distance of the operator from the source, hence, increasing the possible dose to the operator. On the other hand increasing too much the length of the guide tube will increase the source transit time, resulting in dose to the operator, as well as increase in the probability of the source getting stuck in the guide tube. Therefore, an optimum length of the guide tube is recommended.

4.2.4 Source Assembly

The source assembly is the most important and critical part of IGRED. It consists of a radioactive source, in the form of metallic pellets. These radioactive pellets are doubly encapsulated in a steel capsule. Source assembly of the radiography devices are broadly classified as, a) rigid source pencil and, b) flexible source pigtail.

Figure 4.5 shows the drawing and also the picture of some actual flexible source pigtails. In the case of a flexible source pigtail, the source capsule is crimped with the flexible metallic wire. Another end of the flexible wire is crimped with the female coupler. This female coupler is required to be connected with the male coupler of the control cable for source exposure. The length of the full source assembly is about 15-20 cm for various models. In a source pigtail, a steel ball is provided ahead of the female coupler, and this serves as an indicator for safe retrieval of the source inside the device. Unless this ball returns to its intended original position, the device cannot be locked.

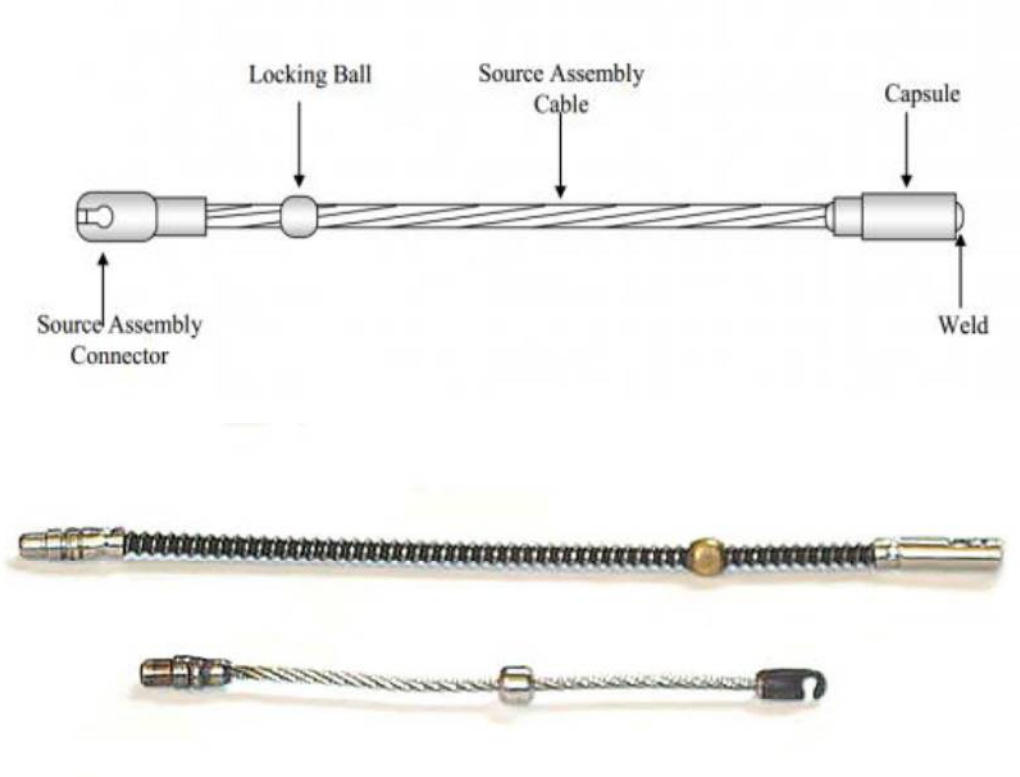


Figure 4.5 Drawing and picture of flexible source pigtail assembly

Another category of the source assembly is the rigid source pencil, in which small steel cylindrical structures combine together to form a train like assembly. The first hollow cylinder of the train can be opened to accommodate the sealed source capsule into it. The last cylinder of the train consists of a female coupler for connecting the remote control unit. Figure 4.6 shows a picture of some rigid source pencils.

Figure 4.6 Picture of rigid source pencil assembly

The rigid source pencil has the advantage that it is reusable, and the source capsule can be changed, once the source has decayed. The flexible source pigtail, however, cannot be reused as the wire of the pigtail would be required to be cut for removal of the decayed source, which would lead to reduction in the length of the wire.

The source capsule consists of small source pellets, which are the only active components of the source. The pellet dimensions are about 2.7 mm (diameter) X 0.3 mms (height). These pellets are irradiated in the nuclear power reactors, to build their activity. Activity in the pallets is built based on the factors like neutron flux, purity of pallet, time of irradiation etc. in the nuclear reactor. Each pellet has an activity of about 5-8 curries. These active pallets are transferred to the source capsule, and doubly encapsulated and welded by laser welding.

4.2.5 Operation of the IGRED

Whenever radiography exposure is required, all the three sub units, i.e. source housing, remote control unit and the guide tube are required to be connected together. The guide tube is connected with the 'threading' provided at the front end of the source housing. The male coupler of the control cable is connected to the female coupler of the source assembly in the source housing. After connecting the male and female couplers, the sheath of the control unit is threaded into the back side of the source housing. Once the connection is made, the source assembly, which is in the shielded position, for operation is driven out into the guide tube by rotating the handle provided in the control unit. After completion of the operation/exposure, the source is retracted back into the shielded position by rotating the handle in the reverse direction.

4.3 ANALYSIS OF SAFETY FEATURES AND INTERLOCKS IN THE IGREDs

In order to reduce the probability of any accident due to, malfunctioning of the equipment or operating errors, several safety features are provided in the exposure devices. These safety features are also aimed at restricting the operation of the exposure device by an unauthorized person. The following engineered safety features, provided in the radiography devices were analysed for their intended function and possible failures. It may be noted that some of these safety features are model specific.

Lock and key

All the radiography devices are provided with a mechanical lock-and-key arrangement. Prior to connecting the control cable and the source pigtail, the device should be unlocked with the help of the key. The lock-and-key feature also prevents unauthorized operation of the radiography device.

Selector ring/sliding ring

A Selector ring or slider ring is provided on the back side of the radiography device, around the back portion of the source pigtail. After connecting the male coupler of the control cable with the female coupler of the pigtail, the selector ring should be turned to a specific position, in absence of which the device cannot be operated. This safety mechanism also prevents unauthorised operation and accidental source exposure.

Pop-up button/source release knob

In addition to the lock-and-key, a pop-up button or source release knob is also provided in the IGRED. After unlocking the radiography device, the control cable is connected with the source assembly from the back end of the device. The control unit cannot be operated to expose the source out of the exposure device, unless this pop-up button or source release button is pressed. By pressing this button, source assembly is free to move and can be exposed outside the device. Once the exposure is finished and the source assembly is retracted in the shielded position in the device, this Pop-up button or source release knob pops up indicating that the source has returned to the safe position. However, in spite of this feature, use of radiation survey meter is strongly recommended to ensure safe location of the source.

Source assembly stop ball

The source pigtail is provided with a round ball (or cylindrical structure) around the pigtail cable, generally towards the female coupler, as shown in figure 4.5.This stop ball is designed to secure the source pigtail within the exposure device by a locking mechanism. The stop ball gets arrested in the lock of the device. Thus, the stop ball provides an indication about the safe retrieval of the source into the device.

Source stopper plug assembly

The ‘source stopper plug assembly’ (or the shipping plug) is connected to the front part of the radiography device. This ensures that the source cannot be

moved out of the device unless intended. The source stopper plug assembly also prevents the undue streaming of the radiation from the source tube of the device.

Odometer

The odometer is provided in the control unit of the exposure device. Reading of the odometer is in analog form. The Odometer reading reflects the movement of the control cable. This odometer indirectly provides gross idea about the source location.

Source (secured) position indicator

The Source position indicator is a colour indicator which is visible at least from the distance of 5m.Two colour indicators are used in the devices, green for the source in secured position, and red for the source in the exposed position.

4.4 SAFETY ASSESSMENT OF RADIOGRAPHY DEVICES

Radiation safety in radiography practice can be ensured by using radiography devices with the required safety features. These safety features ensure the safety of the radiography operators and also prevent unauthorized operation of the radiography devices. Failure of the IGRED or its some specific component may cause incident/accident resulting in excessive exposure to the radiography operator and in radiation injury in some cases. Hence, in order to ensure the in-built safety of the radiography device, engineering controls are applied in the design itself of the device.

4.4.1 History of the Radiography Devices in India

Radiography devices are in use in India since, as early as 1960. Those devices were then imported from outside. Design of the devices has improved drastically with time. Safety features provided in the earlier design were very limited and higher doses of radiation exposure were received by the operators at that time.

Till 1992, the manually operated industrial radiography devices were in use in India. These devices were first manufactured in India by the Bhabha Atomic Research Centre (BARC), and subsequently by the Board of Radiation & Isotope Technology (BRIT). Those devices were of the model IRC (2, 2A, 3 etc.), having a maximum source capacity of 10Ci of Ir-192. Those devices were of the shutter type, in which the shutter of the device had to be opened manually by the operator, while standing near the device. Another option available then was to use a manipulator rod to transfer the source to nearby area for radiography. Both of these options were seem to be providing high doses of exposure to the radiography personnel.

However, all these manually operated radiography devices were later withdrawn owing to, occurrences of several radiological accidents/incidents, higher doses of exposure to the operators, and because of the limited source capacity. And after 1992, an entirely new design of the radiography devices was introduced in India. Those devices were remotely operated, which increased the physical distance of the operator from the device, and hence significantly reduced the dose received by the operator. Those devices are of retractable source-type, and operated by rotating a handle on the control unit to extract or retract the source from a distance of 25-50 ft. Initially, imported models of those radiography devices viz. Techops 660, Gammarid, Teletron & SPEC-2T, were in use in India. Later on, BRIT, Mumbai developed an indigenous model of radiography device, i.e. model Roli-1.

4.4.2 Safety Assessment of the IGRED at Various Stages

Safety assessment of the IGRED is carried out at various levels during its manufacturing and useful life. These safety assessments are aimed to reduce the probability of accidents due to design failure or equipment malfunctioning during its operational life. Thus, safety assessment starts at the manufacturing level itself. Before introducing a new model in the market, the manufacturer has the responsibility for obtaining design approval against safety assessment of the device. The tests conducted during safety assessment may be witnessed by the

regulatory body to ensure the compliance. During the use of the device the user institution is responsible for several checks, daily as well as periodic. The (radioactive) source supplying agencies too carryout assessment of these devices prior to each 'source loading'. Following is the brief description of the safety assessment at various levels by the different stakeholders of the device.

4.4.2.1 Design Assessment and Performance Testing of Radiography Devices by Manufacturer

Design assessment and performance testing of each model of radiography device is required to be carried out by the manufacturer or an appropriate recognised agency appointed by the manufacturer, as per the international standards [44]. Reports of these tests are evaluated by the regulatory agency for issuance of the design approval (or type approval) certificate. For indigenous devices, these tests are physically witnessed by the regulatory agency. Tests are carried out on the IGREDs, aimed to ensure that during normal operations and also during accidental conditions, including malfunctioning of the devices, the design of the device itself should prevent any radiation injury to the operators. These tests are carried out on prototype devices. Detailed test requirements for radiography devices are stipulated in the national [45] as well as international standards [44]. Summary of the tests, which are carried out to ensure the performance and design requirements as per the international requirements are provided in the table 4.2

Table 4.2 Summary of performance tests as per international design requirements for IGRED

Equipment	**Recommended Tests**
Entire apparatus	Endurance test
	Projection resistance test
Exposure Container (Source Housing)	Shielding efficiency test

	Lock breaking test
	Handle, attachment part or lifting mount test
	Vibration resistance test
	Shock test
	Accidental drops test
Source assembly and its connecting device	Tensile test
Remote control	Crushing and bending test
	Kinking test
	Tensile test
Projection sheaths	Crushing and bending test
	Kinking test
	Tensile test

4.4.2.2 Safety Assessment of Radiography Devices by End User

Even after the design and performance of the prototype devices have been tested by the manufacturer, periodic checks by the end users are recommended by the manufacturers. These tests are aimed to alert the end users for any malfunctioning of the device before an actual failure occurs.

Daily checks

Following are the examples of some of the recommended daily checks for radiography devices. These tests should be carried out by the operators [46].

i. A radiation survey of the outer surface of the exposure device. It should be ensured that the radiation levels are not more than 200 mR/h for a maximum capacity of the device. The radiation survey of the device also confirms the functional performance of the radiation survey meter

ii. Physical inspection of the source housing for the presence of the labels consisting of radiation symbol, cautions, and other important information.
iii. Inspection of the locking mechanism of the device
iv. Inspection of inlet and outlet ports of the device for its smooth operation.
v. Inspection of the guide tube swage fitting to verify that the threads do not have dirt, sludge or grease.
vi. Checking the dimensions of the male coupler of the control cable and female coupler of the pigtail using GO-NO GO gauge. This is to ensure that the dimensions of the mechanical parts have not reduced. Figure 4.7 shows the GO-NO GO gauge arrangements.

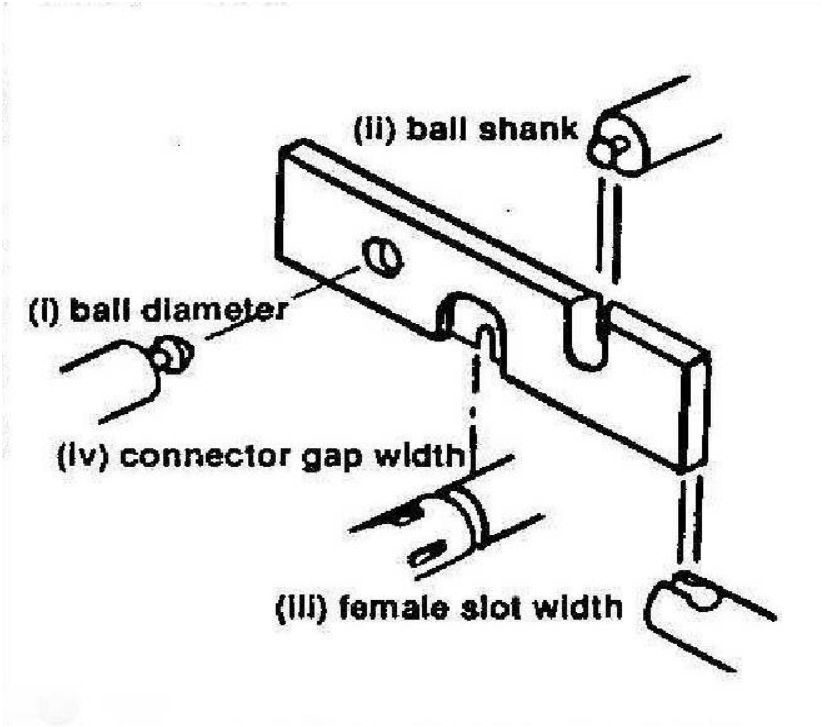


Figure 4.7 Verification of pigtail dimensions by Go- NOGO Gauge

Quarterly checks and maintenance

Various quarterly maintenance procedures are recommended by the manufacturers. Some of these procedures are disassembling the control cable,

the control conduits and the remote control crank, and cleaning and inspection of these parts. Any defecated system should be repaired. Similarly, the source guide tubes should be clean and inspected for any defects. Presence of dents in the guide tubes, and its flexibility should be noted down. Labelling of the source housing should be checked thoroughly for presence of steel tag plate consisting of information like model serial number etc. Survey should be carried out by measuring radiation levels on the surface and at 1 m from the external surface.

'Misconnect' tests are also recommended which should be carried out only by the experienced and trained personnel. In this test, equipment is tried to be operated as per procedure, except for not connecting the male and female couplers. If the device is still brought to operation during the misconduct test, then it implies that there might be severe damage to the locking mechanism.

Other than the daily and quarterly checks, several annual maintenances are also recommended, which should be strictly carried out only by the authorized servicing agency or the manufacturer. This requires disassembling of the exposure device, for which first the source is transferred to the source changer. The Annual maintenance also includes the 'leak' test of the radioactive source, as well as the 'leak' test for depleted uranium, the shielding material.

4.4.2.3 Safety Assessment of the Radiography Devices by Source Suppliers

Once the radioactive source has decayed and the residual activity is not useful for radiography, the source needs to be replaced by a new source of appropriate activity. Before loading a fresh source, a 'performance check' based safety assessment of the radiography device is recommended. The tests for this safety assessment ensure that the components of the IGRED are functioning as intended, and the device is safe to use. The agencies that supply the sources carry out these checks. The movement of the source assembly is also checked during the performance checks, which may also be carried out with a dummy source assembly. Therefore, these checks require transfer of the decayed source to the source changer, or these tests may be carried out after the decayed source

is removed for disposal. As some of the exposure device models have some unique safety features and designs, the inspection procedure for performance checks varies from model to model. Typical checklist for the IGRED model Roli-1 (SS) has been provided in the appendix 2. Similar checklists are available for the other models of exposure devices. The tests as mentioned in the table were carried out during this research work to generate field data of component failures.

4.4.3 Requirement for Design Based Risk Assessment

Performance tests as specified in table 4.2 are carried out on the prototype devices of new models of IGRED for their design approval. These checks are aimed to design and manufacture a device which is safe to use under normal and accidental operating conditions. However, these performance tests do not consider several practical aspects. For example, performance test considers that the guide tube should not fail under the accidental scenarios of kinking, cursing, bending, or during 50,000 normal exposure cycles. However, the testing of the guide tube is carried out under laboratory conditions, which may be different from actual operating conditions. Further, testing assumes that only one particular type of failure would occur at a time, but practically two or more different failure scenarios may appear simultaneously.

Similarly, various tests on the IGREDs by the source suppliers or the operators verify only the operational condition of the IGREDs at those moments of testing. Although, these checks can identify the failed components, but these are not much helpful to detect potential failures during future use.

The routine safety checks by various stakeholders are status checks, and cannot guarantee that the IGREDs will not fail. Further, these testing do not assess the consequences of failures in terms of hazards to the operator. And failure consequences for different components vary significantly. Therefore, consequences of each failure should be assessed independently. This

necessitates the risk assessment to identify the important failures of device/component considering their failure severity and its consequences.

All the performance checks or testing on IGREDs described in the section 4.4.2 are carried out to reduce the accident probabilities due to equipment failure. Accidents have been reported worldwide due to malfunctioning of the radiography equipment [1]. Following are some of the contributory factors for equipment failure:

(i) Operational environmental conditions, like working in dusty environment, where dust particles or other fine granules may enter the device. Prolonged exposure of the radiography device to such ambience may result in equipment failure.
(ii) Poor maintenance of the radiography devices during its useful life.
(iii) Ignoring the initial failure alerts like the requirement of abnormal force to expose or retract the source.
(iv) Exposure to beyond design basis conditions.
(v) Use of device/accessories beyond its designed/designated life.

Malfunctioning of the radiography devices has been identified as an initiating event for many accidents in the industrial radiography practice, which have resulted in deterministic health effects to the operator and the public [1].

All the above-mentioned factors demand detailed risk assessment of the existing design of the IGREDs. The results of risk assessment studies would provide important inputs for further improvement in the design of the IGRED, to reduce the accident probabilities.

4.5 FMEA METHODOLOGY FOR RISK ASSESSMENT

As mentioned above, several accidents associated with industrial radiography have been reported worldwide due to equipment malfunctioning. Even though the operation of these devices is simple, proper source transition requires

smooth functioning of various components of the exposure device, and consequences of device malfunctioning due to improper functioning of any component can be very severe. Safety interlocks and indicators provided in the device have an important role in preventing any incident/accident. Over the period of time, advancement in the design of the exposure devices has happened, due to which the incidents and the effective accidental dose to the operating personnel have reduced.

Lessons have been learned from the accidents reported in the industrial radiography practice in India and worldwide. However, in-depth analysis of the 'near-miss', and/or the interrelation of the past accidents with the common failures of the components of IGREDs has not been done. Out of the various risk assessment tools available, FMEA was found to be most suitable to perform the design based risk assessment of radiography devices. This technique is a proactive approach which is utilised to identify, analyse and prevent the design based failures in the equipment or a system, before a failure actually occurs. Further, FMEA has advantages over other techniques, like the end results of the FMEA analysis consider even the effects on the system and the people involved, which is not done in other techniques. In the present research work, the most important concern is to study and determine the effects of failure of the device components on the people, which in particular is the accidental radiation dose to the operators. Also, the results of FMEA are ordered and prioritized based on the probability of occurrence and severity of failures, and such failure prioritization is not possible in other techniques. For e.g. less frequent and more severe failure events are prioritized in the FMEA over more frequent and less severe failures, even though both have the same quantitative values. And even these qualitative gradations are automatically reflected in the FMEA results, but not in the other techniques.

Some of the important advantages of FMEA methodology are:

(a) This is team centric, which captures and utilizes the collective knowledge of a team.

(b) FMEA improves the reliability, quality & safety of the design or process.
(c) It is a structured and logical process to identify the concerned areas.
(d) It tracks the risk reduction activities for futuristic applications.
(e) It helps to recognize the critical-to-quality features.
(f) It delivers historical records and also useful for creating baseline.
(g) It helps to increase the safety.
(h) This method is simple and cost effective.

The FMEA for risk assessment in non-reactor radiation/nuclear facilities has been emphasized and encouraged by the International Commission on Radiological Protection [41] and by International Atomic Energy Agency [3, 38].

In view of its several advantages, risk assessment for the design of radiography devices, for component failure modes, was carried out using this method (FMEA).

4.5.1 Introduction and Objectives of FMEA Methodology

As mentioned above, the design based risk assessment of the industrial radiography devices, which is a big part of the present research work, has been carried out using FMEA methodology. FMEA is a well-established, highly structured and systematic technique for failure analysis of equipment/system design. FMEA is being used in the other areas, since 1950, for reliability testing of the different engineering systems. As mentioned earlier, the FMEA is a systematic method of identifying and preventing system and/or process problems before they actually occur. FMEAs are focused on preventing defects, enhancing safety, and increasing customer satisfaction in various engineering areas. Ideally, FMEAs are conducted in the product design or process development stages of the various industries. According to Robin MacDermott, conducting an FMEA on existing products and processes yields substantial benefits [47].

The objective of an FMEA is to look for all of the ways an equipment or system can fail. An equipment failure eventually occurs when the equipment does not function as intended or when it malfunctions in some way. Even the simplest design of an equipment may have multiple opportunities for failure. The FMEA methodology is a way to identify the failures, the effects, and the risks within an equipment. Based on the results of FMEA further actions may be recommended to reduce or eliminate the failures.

4.5.2 Steps for FMEA Study

FMEA has a systematic approach to identifying all the possible failures, and correlating the failures with their probabilities and the consequences. Principally, the following steps are involved in conducting a FMEA study:

Step 1: FMEA Team constitution:

Prerequisite to a FMEA study is to constitute a FMEA team. Members of the team should have experience of the operation of the system under consideration. In-depth knowledge about the design of the system is an essential requirement for the team members. The team should be large enough to avoid biased results and should have members from different working categories like operators, designers, personnel from the maintenance division, policy makers etc.

Step 2: Disassembling the system under consideration into its component level:

FMEA study focuses on the failure of the system at its basic component levels rather than considering only the overall failure of the full system. Therefore, it is required to theoretically disassemble the whole system into the basic component levels.

Step 3: Identifying failure modes of each component:

Each basic component is studied in detailed for failures. All the failures which are possible for a given component are identified and listed out.

Step 4: Assigning the failure occurrence ranking (O):

The failure probability of a given component can be determined by the previous experience of operating/using the system, or from other similar systems, by the failures reported by the users, by the inspection of the systems etc. For the purpose of FMEA, these failures are required to be ordered/converted to their respective occurrence ranking. Each failure mode is ranked between 1 to 10, by the FMEA team, where 1 represents the minimum and 10 represent the maximum occurrence probability. Standard values have been published for various failures, which help in providing the failure rankings which are based on the failure rates.

Step 5: Assigning the failure detection ranking (D):

A failure of the system can be avoided if the component failure can be detected before the actual failure occurs. Therefore, failure detection is an important parameter for risk assessment. For each failure mode identified in step 3, detection ranking is required to be assigned. Detection ranking is assigned from 1 to 10, where 1 represents the highest detection probability and 10 represents the least detection probability. Standard ranking tables have been published and adopted in the literature based on the detection probability percentage and the likelihood of detection scenarios.

Step 6: Assigning the failure severity ranking (S):

The severity of the failure on the system and the personnel are important factors to be analysed. For the purpose of the FMEA study, the severity of each failure mode, as identified in step 3, is assigned with a ranking of 1 to 10, where rank

1 is the least hazardous effect and rank 10 is the most hazardous effect of the failure.

Step 7: Calculation of Risk Priority Number (RPN):

The Risk Priority Number (RPN) is the final outcome of the FMEA study. The risk priority number for a component failure, is used to rank the failures according to the need for corrective actions to eliminate or reduce the potential failure modes. RPN is calculated as

$$RPN = O \times S \times D$$

Based on the O, S and D values, RPN may vary from 1 to 1000. Higher values of RPN represent more critical failures, which require urgent corrective actions. Priority for corrective actions should be given to failures with higher RPN, however, the failures with higher severity rankings should also be considered for decision making. Figure 4.8 shows a systematic process flow for FMEA study.

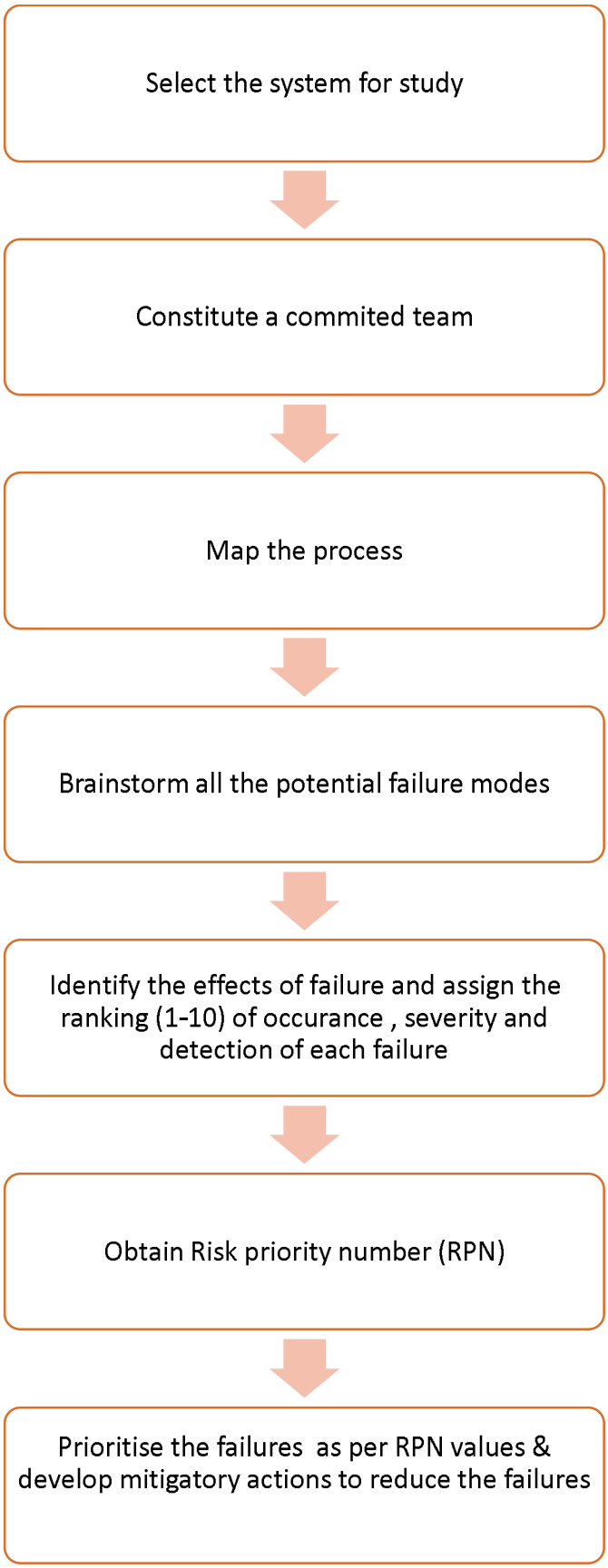


Figure 4.8 Process flow for FMEA study

4.6 RISK ASSESSMENT OF IGREDs USING FMEA

Risk assessment of the existing design of IGREDs has been carried out using Failure Modes and Effect Analysis (FMEA) methodology. The objectives of this study are;

i. Study the design of the industrial gamma radiography exposure devices.
ii. Identification of all the possible failures at the component level of the IGREDs.
iii. Assessment of failures and effects of these failures on the equipment and the operating personnel.
iv. Ranking the failures based on the criticality.
v. Recommendations to minimize the design based failures of IGREDs.
vi. And thus to verify the feasibility of using FMEA methodology for IGREDs.

4.6.1 FMEA Team Constitution

To carry out the study a dedicated FMEA team was constituted. While selecting the members of FMEA team, the following factors were considered.

(a) **Role in the industry**.

Inputs from the different stakeholders of IGREDs are useful to assess the failures throughout the lifecycle of the IGREDs. To give appropriate weight and to assess the failures from different angles, members from all the stakeholders were opted in the FMEA team. Thus, the team was consisting of operators, Radiological Safety Officers (RSO), suppliers of the devices & spare parts, maintenance and servicing personnel and officers from the national regulatory agency.

(b) Knowledge and experience.

While selecting the members of FMEA team, thorough knowledge about the design aspects and their experience with IGREDs of use were considered. An

experienced person with adequate knowledge can provide accurate inputs for the component failures of IGREDs, and their failure frequencies. Our FMEA team was constituted with ten members from different stakeholders of IGREDs having experiences of 10 to 35 years in their respective profession.

(c) Availability of the personnel.

FMEA study requires technical discussions, which in turn requires several meetings between the team members. Therefore, the availability of the members for multiple technical sessions was confirmed before adopting them in the FMEA team. All the meetings were conducted at Mumbai City.

Details of FMEA team members are given in Appendix 01. In the first technical session, induction training was given to all the team members about the FMEA method by providing few simple examples from daily life.

4.6.2 Component Failure Identification

FMEA study for IGRED was conducted at a servicing and maintenance site in Mumbai. Multiple technical sessions were conducted for this study. An IGRED with dummy source assembly was made available at the discussion site. Whenever required, a device with dummy source was operated to simulate the actual operation. Driven by international requirements [44], basic design and safety components of all the IGRED models are similar, and therefore the study was carried out considering a generic model of the radiography device. Thus, eventually, special safety provisions and interlocks provided in all the commercially available models of IGREDs were considered for the study.

For purpose of the study, the radiography device was divided into its four sub-units namely (i) source housing, (ii) guide tube (iii) remote control unit, and (iv) the source assembly. Each sub-unit was further divided till the component level. For the remote control/driving assembly, 07 failure modes were identified and assessed for its 04 components. For guide tube, 05 failure modes were identified for 03 components. For source assembly and source housing, 04 and 13 failure modes were identified, for 02 and 08 components respectively.

For each of the failure modes, a ranking for their occurrence (O), detection (D) and severity (S) is to be assigned. Determining the occurrence (O) values of the different component failures was the most crucial step in the FMEA study, which requires a quantum of field data.

4.6.3 Data Generation for Failure Occurrence (O), Severity (D) and Detection (D)

Data for a component failure was generated in this study by the following methodology:

a. The required field work was carried out, which involved inspection of several units of IGREDs at the Board of Radiation and Isotope Technology (BRIT), Navi Mumbai. Failures in each of the devices were noted. For this, all the commercially available models of the devices were inspected for failures.

b. Random inspections of radiography agencies were carried out and operation logbook of radiography agencies was checked, and failures were noted.

c. The servicing and maintenance personnel, who were FMEA team members provided inputs based on their servicing records. Demands and supply of spare parts of IGREDs were also considered while calculating the occurrence values.

d. Radiography operators and radiological safety officers, who were our FMEA team members, provided their inputs for occurrence of component failures, based on their operational experience.

The severity of a failure on the operating personnel depends on various factors. The Severity index was determined based on the simulation of practical scenarios considering the following factors.

(a) Source activity at the time of failure: An average value of 25 Ci Ir-192 was considered for calculation of severity.

(b) Time spent near the source for the specific scenario was considered.

(c) Proximity to the source: An appropriate distance from the source was considered for assessment for each of the failure. For example, in some failures the operator may touch the guide tube containing the source by his hand, whereas in some other type of failure operator can handle the situation by maintaining a minimum distance of 25ft. from the source, which is the typical distance of the source from the operating location.

(d) Mitigation actions: Each failure requires specific mitigation action. This aspect includes the knowledge/understanding of the RSO to handle the situation, availability of emergency handling accessories etc.

Detection (D) values for each of the failures can be assessed purely on the basis of experience, since these data are not recorded anywhere and cannot be collected by going to the field. Inputs from the RSO and the operators, who were FMEA team members, were very important for assigning the D values.

4.6.4 Occurrence, Detection and Severity Ranking

The failure occurrences of each component were analysed by the team based on the above field data. The FMEA requires the ranking of O, D and S values. Standard criteria for the O, S and D rankings have been published in the literature. Hence, a detailed literature review was carried out for the ranking methodology of O, S, and D. It was found that a harmonised criterion for ranking for a FMEA study are available in the literature, which have been accepted by the various industries, like those of automobile, aerospace and healthcare. Same criteria as for the above mentioned industries, also have been used in some other practices which use radioactive sources. The values from the latter mentioned practices, with minor modifications were utilised for translating the failure occurrences, severity and detection to their respective rankings in our study. The

failure occurrences were assigned rankings from 1 to 10 in our study. Table 4.3 to 4.5 shows the standards used for O, S and D ranking.

Thus, the rankings for occurrence (O) were derived from the field data collected for this research in the manner stated above. The Severity (S) rankings were assigned on the basis of the effect of the failures on the personnel, an aspect of main concern for our risk assessment study. Severity of a failure on the person is the severity of effect of exposure to ionizing radiation on person. Term 'Injury' in table 4.4, corresponds to the exposure to ionizing radiation from the radioactive source. For the purpose of ranking of detection (D) values, most of the components were used in demonstrative operations during various meetings between our FMEA members, and checked for their failures. Based on the demo exposures and consensus of the FMEA team members, the D rankings were assigned using table 4.5.

Table 4.3. FMEA ranking for Probability of Occurrence (O) for component failure [48-52]

Probability of Occurrence	**Ranking**	**Possible failure rate (No. of exposures)**
Remote	1	< 1:20,000
Low	2	1:20,000
	3	1:10,000
Moderate	4	1:2000
	5	1:1000
	6	1:200
High	7	1:100
	8	1:20
Very High	9	1:10
	10	1:2

Table 4.4. FMEA ranking for Severity (S) of component failure [48, 53-57]

Effect	**Rank**	**Severity of effect**
No effect	1	No reason to expect failure. Slight annoyance-no injury to worker or public.
Very Minor	2	Very minor effect on device performance. Slight danger- no injury to worker or public.
Minor	3	Minor effect on device performance. No injury to worker or people.
Very Low	4	Very low effect on device performance. Minor or no injury to the worker.
Low	5	A moderate effect on device performance. The device requires repair. Very moderate danger-minor injury to the worker.
Moderate	6	Device performance is degraded. Some safety functions may not operate. The device requires repair. Moderate danger- minor to moderate injury to the worker.
High	7	Device performance is severely affected but operational with a reduced level of safety performance. Dangerous-moderate to major injury to worker OR Minor injury to the public.
Very High	8	Primary safety function(s) of device is lost. Failure can involve hazardous outcomes. Dangerous-may result in major injury to worker OR moderate injury to the public.
Hazardous with warning	9	Failure involves hazardous outcomes. Very dangerous-may result in major injury or death of a worker or major injury to the public.
Hazardous without warning	10	Failure is hazardous and occurs without warning. It suspends the operation of the system. Extremely dangerous- may cause the death of worker or public.

Table 4.5 FMEA ranking for Detection (D) of component failure [48, 52, 53, 57, 58]

Detectability	**Rank**	**Probability of detection (%)**	**Likelihood of detection of failure or error**
Almost Certain	1	86-100	Design/operation control will almost certainly detect a potential failure mode.
Very High	2	76-85	
High	3	66-75	High chance that the design/operation control will almost certainly detect a potential failure mode.
Moderately High	4	56-65	
Moderate	5	46-55	Moderate chance that the Design/operation control will detect a potential failure mode (e.g. the defect will remain undetected until the device performance is affected).
Low	6	36-45	
Very low	7	26-35	Remote chance that the design/operation control will detect a potential failure mode (e.g. the defect will remain undetected until device inspection is carried out).
Remote	8	16-25	
Very Remote	9	6-15	Defect most likely remains undetected (e.g. the design/operation control cannot detect potential cause or the operation will be continued to be performed in the presence of the defect).
Absolute Uncertain (impossible to detect)	10	0-5	Device/component failures are not detected (e.g. there is no design/operation verification or the operation will certainly be continued to perform in the presence of the defect).

4.7 FMEA RESULTS

All the component failures of IGREDs were identified and effects of these failures on the system and the operating personnel were discussed by the team. It was also considered that in some of the events, the failure may affect the member of the public also, besides the operating personnel. The potential causes of each failure were also identified and analysed. The eventuality of a failure may be anticipated (detected) prior to an actual occurrence of that failure with the help of appropriate means/mechanism. If it is possible to anticipate (detect) such eventuality of failure before it actually occurs, accidents can be prevented. The methods or mechanism available for such anticipations, were also outlined during our technical sessions. Finally occurrence (O), severity (S) and detection (D) rankings were assigned as per the procedure stated in the previous sections. Based on those rankings, a Risk Priority Number (RPN) is generated by taking the product of these 3 indices.

One of the salient features in the FMEA methodology, which is of utmost importance for any risk analysis and safety enhancement exercise, is that the final objective in it is to recommend the corrective actions to reduce the failure probability of the system. The FMEA team suggested actions in this exercise for each of the identified failure modes, which when undertaken appropriately would reduce the failure probabilities.

The table 4.6 given below, shows the compilation of the component-wise FMEA results for our study. In our results, the RPN values for each failure modes were calculated and the failures were then ranked as per the RPN values. In the case of same RPN value for two failure modes, priority has been given to the failure with higher severity index. A total of twenty-nine failure modes were studied in detail and the RPNs were ranked from 1 to 28 (rank one is the most critical failure and rank 28 is the least critical). Some of the failure modes which were not found to be significant from the point of view of radiation safety, were excluded from the assessment and do not reflect in the results. In our study, the

source housing contributed the maximum number of failures. Table 4.6 also summarizes the potential reasons for failures, the detection methods and the recommended measures to prevent the failures.

Table 4.6 FMEA Result

ID	Component	Potential failure mode	Potential failure effect on IGRED	Failure effect on person (Occupational worker/Public)	Potential cause(s) of failure	Detection method (if any)	O	S	D	RPN (O*S*D)	Recommended measures	Ranking
Remote Control/ Driving Assembly												
RC1	Control cable	Wire damaged/ broken	Source cannot be projected/retrieved	Potential exposure to occupational worker	Wear and tear	Inspection (partial wire length only)	3	8	8	192	Periodic QA testing	2
RC2		Male coupler dimensions worn out	Source detachment from control cable/source cannot be retrieved back in the device	Potential exposure to occupational worker/ public	Wear and tear	Inspection	2	9	3	54	Periodic QA testing using GO-NO GO gauge	11
RC3		Male coupler crimping with wire is damaged	Source detachment from control cable/ source cannot be retrieve back in the device	Potential exposure to occupational worker/ public	Excessive force at crimping/wear and tear	Inspection	1	9	3	27	Method alternate to crimping process should be applied e.g. e-beam welding	17
RC4	Rotating handle	Damaged	Source cannot be projected/ Source may be retracted with difficulty	Potential exposure to occupational worker (if source is in exposed position)	Accidental impact/fall	Physical verification before operation	2	5	3	30	Periodic QA testing. Care during operation & storage	16
RC5	Projection sheath/ conduit	Damaged (from inside)	Excessive resistance is required for source assembly movement	Potential exposure to occupational worker (if source is in exposed position)	Fall of heavy object/crushing/kinking/wear & tear	No method available	3	5	9	135	Method need to be developed for inspection	05
RC6	Odometer	Jammed/ damaged	Source location is not known	NAE	Wear and tear	Inspection/ during operation	4	3	4	48	Periodic QA testing	12

RC7		Malfunctioning	Misleading about source location	Potential exposure to occupational worker	Wear and tear/Fall of object on the remote control unit	Inspection	3	5	5	75	Periodic QA testing	08
Guide Tube												
GT1	Projection sheath	Damaged (from inside)	Source stuck inside guide tube	Potential exposure to occupational worker	Fall of heavy object/crushing/kinking/wear and tear	No method available	3	8	9	216	Method needs to be developed for inspection	01
GT2		Damaged (from outside)	No effect on the operation	NAE	Fall of heavy object/crushing/ Ageing	Physical verification before/during operation	4	3	2	24	Periodic QA testing	18
GT3		Flexibility lost	Source stuck inside guide tube	Potential exposure to occupational worker	Prolonged exposure to harsh environmental conditions/Ageing	Physical verification before operation	4	6	5	120	Coding of guide tubes	06
GT4	End tip of guide tube (exposure head)	Damaged/ decoupled from sheath	Source may move out of the projection sheath	Potential exposure to occupational worker/public	Fall of heavy object/crushing/ wear and tear	Inspection	2	9	2	36	Periodic QA testing	14
GT5	Connector	Threading damage	Difficulty in connecting the guide tube with source housing (operation not possible)	NAE	Wear and tear	Inspection/ during operation	4	3	1	12	Periodic QA testing	22
Source Assembly												
SA1	Female coupler	Crimping with wire is damaged	Female coupler part disconnected with wire. Source may be detached	Potential exposure to occupational worker	Poor crimping/wear & tear	Inspection	2	8	9	144	Method alternate to crimping process should be applied e.g. e-beam welding	04

SA2		Female coupler dimensions worn out	Source detachment from control cable/cannot be retrieved back in the device	Potential exposure to occupational worker/public	Wear and tear	Inspection	1	9	5	45	Periodic QA testing	13
SA3	Source capsule	Damaged	Source pellets dispersion	Potential exposure to occupational worker & public (if failure occurs during source exposed condition)	Compromised material quality/ Wear & tear	Leak test (not available with user)	1	9	10	90	Material control and stringent QC testing by manufacturer	07
SA4		Crimping with wire is damaged	Source capsule may disconnect with wire. Source detached from assembly	Potential exposure to occupational worker/public	Poor crimping /wear and tear	Cannot be detected with active source	2	9	10	180	Method alternate to crimping process should be applied e.g. e-beam welding	03
Source Housing												
SH1	Pop up button/switch / safety latch	Broken	Device Inoperable	NAE	Improper handling/fall from height/ impact with another heavy object	Inspection/ during operation	3	3	1	9	Training to operator	24
SH2		Blocked/Jammed	Device inoperable	NAE	No periodic maintenance	Inspection/ during operation	6	3	1	18	Periodic servicing & maintenance	20
SH3	Selector ring	Blocked/Jammed	Source cannot be driven out	NAE	No periodic maintenance	Inspection/ during operation	3	3	7	63	Periodic servicing & maintenance	10
SH4		Not rotating after control cable connection	Source cannot be driven out/device cannot be locked	NAE	Mishandling of the device/ impact with another heavy object	Inspection/ during operation	2	3	1	6	Training for operation/ carefully handling of the device	27
SH5	Source position indicator (colour indicator)	Broken/Jammed/ Damaged	Source location cannot be determined	Potential exposure to operator	Improper handling/fall from height/ impact with another heavy object	Inspection/ during operation	1	6	1	6	Training for operation/ carefully handling of the device	26

SH6		Colour(s) not visible	Source location cannot be determined	Potential exposure to operator	Wear & tear	Physical verification	3	6	1	18	Periodic servicing & maintenance	19
SH7	Device lock	Broken/Jammed/ Damaged	Device inoperable	NAE	Accidental fall of the device/impact with heavy object	Inspection/ during operation	2	3	3	18	Carefully handling during operation/ transport	20
SH8	Shipping plug	Threads worn out	Device cannot be plugged from front end	Undesired exposure to operator from streaming radiations	Wear & tear	Visual Inspection	3	4	1	12	Periodic QA testing	21
SH9		Cable damaged	Source positioning inside device may be marginally deviated	NAE	Wear & tear	Inspection/ during operation	1	1	7	7	Periodic QA testing	25
SH10	Safety Plug(storage cover)	Missing/Threads worn out/ damaged	Device cannot be plugged from rear end	NAE	Wear & tear/impact with other object	Inspection/ during operation	2	2	1	4	Periodic QA testing	28
SH11	Shielding structure	Damaged (visible)	Streaming of radiation	Potential exposure to occupational worker/public	Accidental fall/large impact with heavy object/crushing of the device	Visual inspection/ Radiation Survey of the device	1	9	1	9	Carefully handling during operation/transport	23
SH12		Damaged (invisible)	Streaming of radiation	Potential exposure to occupational worker/public	Accidental fall/large impact with heavy object/crushing of the device	Radiation Survey of the device	1	9	7	63	Carefully handling during operation/ transport	09
SH13	S-tube/source tube	Damaged	Unsmooth source movement in the device/Source stuck inside device	NAE	Wear and tear	No method available	1	4	9	36	Method need to be developed for inspection	15

NAE= no adverse effect

4.8 RESULT ANALYSIS AND DISCUSSION

Risk assessment for the industrial radiography exposure device was carried out by considering the whole device to be divided into its four sub-units namely, the remote control, the guide tube, the source housing and the source assembly. Each sub-unit was considered further divided up into its basic components, and failure modes of each component were discussed in detail during our study. The RPNs were calculated for all the identified failure modes of each of the sub-units of industrial radiography exposure device. Total twenty-nine unique failure modes were identified & analysed, and are provided in table 4.6. The rankings were then assigned based on the RPN values. Figure 4.9 below, shows the graphical representation of the distribution of component failures according to the RPN values. The figure shows that the maximum of the failures have RPN values less than 25.

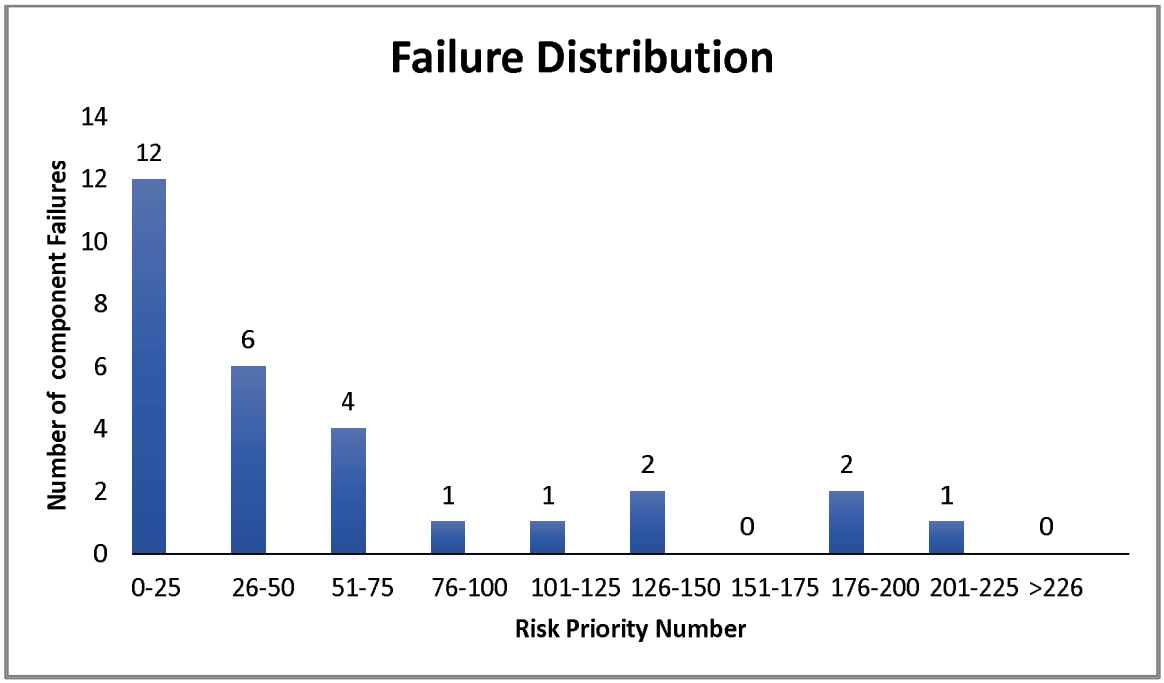


Figure 4.9 Graphical representation for distribution of component failures

Acceptance Criteria.

The highest RPN value obtained from our results, 216, is much smaller than the maximum possible value of 1000. However, instead of considering only the RPN values, it is essential to analyse the results considering some 'acceptance' criteria too. FMEA studies published in the literature recommends actions to reduce RPN values. However, no clear consensus on the acceptable values of RPN is available in the published literature. Lipol et al. consider RPN as acceptable if less than 200, undesirable if between 200 and 500 and unacceptable if more than 500 [59]. While, Serafini et al. consider RPN acceptable if less than 100, corrective action necessary if RPN between 100 and 150 and drastic and timely actions are necessary if RPN more than 150 [60]. For the present study, the following conservative acceptance criteria was set by our FMEA team, based on their experience and the available literature. On the basis of these acceptance criteria, results have been classified and presented in table 4.7

a. Acceptable if RPN $\leq$ 100
b. Corrective actions recommended for 500 $\geq$ RPN> 100
c. Urgent corrective actions are recommended if RPN >500

Table 4.7 Categorization of failure modes based on the acceptance criteria

Action	**Number of failure modes**
Acceptable	23
Corrective actions recommended	06
Urgent corrective actions are required	Nil

The following remarks and important observations are made from the analysis of our results:

1. Risk assessment for the design of industrial radiography devices was carried out using the FMEA methodology. This method has never been used before by anybody for industrial radiography application. The feasibility of FMEA methodology for risk assessment in the industrial radiography practice is also clearly established by this study.
2. Result analysis in the present research work shows that the RPN values for failure modes vary from 04 to 216. Thus, the highest RPN value obtained from the study is 216, which is much lower than the maximum possible value of RPN i.e. 1000. This reflects that very severe design based failures for the existing industrial radiography devices are not possible.
3. Our results show that the occurrence ranking of most of the component failures are on the lower side, which means the existing designs of IGREDs are robust.
4. Few failure modes have high RPN values, which is due to (a) the lower detectability of the component failure, before it actually occurs, and (b) if a failure occurs, the severity of the effect is considerably high. In case of an accident involving failure of IGRED, direct impact would be radiation exposure to the operating personnel.
5. No failure mode has RPN value more than 500, in which case urgent corrective actions would be required.
6. Six failure modes have been identified, where though not urgent, corrective actions are required.

One of the aims of the FMEA study is to reduce the RPN number for a failure. Our results show that the occurrence of most of the failures is relatively rare. Therefore, attention is required towards the remaining 2 parameters; severity and the detection probability. Since, the severity of a failure mode (which is the measure of exposure to the ionizing radiation of the personnel and public) can be reduced mainly by the human actions, therefore, the feasible and practical way to reduce the RPN of critical failures would be to increase the detection probability of failures.

Our FMEA team recommended actions to reduce RPN for each of the failure modes, and these are outlined in table 4.6. Most of these recommended actions focus on ways and means to increase the detection probability of failure before an actual failure occurs. The ranking of failures based on the RPN value is provided in the last column of the table 4.6. In the case of different failure modes having the same RPN values, the failure mode having higher severity ranking has been assigned higher final rank.

4.9 RECOMMENDATIONS

The results obtained from our present study provide important inputs for interventions required in the design of IGREDs with regards to risk management associated with design based failures in industrial radiography practice. Considering the acceptance criteria set in the study, the RPN values obtained for most of the component failure modes are well within the acceptable limits. None of the 'failure' was found with RPN value above 500, for which urgent corrective actions would have been required. RPNs of 23 component failure modes are found to be less than 100, which means that they fall in the acceptable category. RPN values of the remaining 6 component failure modes were found to fall in the range of 100 to 500, where corrective actions are required to be recommended. The discussion and recommendations for these critical failure modes is given in the following.

(i) Out of the 6 failure modes for which corrective actions are required, the most critical (rank 1) is the one in which the projection sheath of guide tube is damaged from inside. This may result in the source getting stuck in the projection sheath outside the shielded source housing and hence lead to excessive accidental exposure to the occupational worker. The high RPN value for this failure is attributed to the associated high severity (8) and lower detection probability values (9). It is pertinent to note that besides

this most critical one, the fifth most severe (rank 5) failure is also of same nature as the first one, i.e. related to the damage of projection sheath of the remote control unit.

Unfortunately it is not possible to detect any defect or deformation inside projection sheaths, unless any accident involving source stuck occurs. Techniques to examine the inner condition of projection sheaths are not available to the user, as well as to the servicing and maintenance agencies in India. Further, to complicate the matters, projection sheaths are interchangeable between different devices. It has been observed that these projection sheaths are generally continued in use beyond their useful design life, and until some difficulty is noticed by the operator in the smooth operation of the device. Also due to interchangeability of projection sheaths between devices, even the operators are mostly not aware about the age of a specific projection sheath.

To reduce the RPN value of this crucial failure, it is necessary to increase its (failure) detectability. It is recommended to develop technique(s) for periodic examination of the inner condition of the projection sheaths. The technique should then be made available to the user institution too.

Further, regulators may enforce a practice for coding of each projection sheath to ensure that these sheaths are not used beyond their useful life, especially when the probability of failure increases manifold beyond their 'design life time'. This may be achieved by various methods like coding by specific unique colours for the manufacturing years of the projection sheath or by engraving the manufacturing year on the metallic part of the projection sheath. These suggested actions will reduce the RPN values of not only this failure but all the 'failures' having severity rankings of 1, 5 & 6, as presented in table 4.6.

(ii) The second most critical 'failure' (Rank 2) is that of damage to control cable of the remote control unit, having S and D values, each of 8. The detection

of this failure is possible by visual inspection, but such inspection is limited only to the partial length of the wire, the one which can be projected outside the sheath. Almost half the length of the wire cannot be projected outside the sheath. Inspection of the entire length of wire is possible only by the servicing and maintenance agencies. Therefore, improving the detection of this failure, by performing periodic inspections of the control cable by the servicing and maintenance agency, will help in reducing its RPN value. An appropriate inspection frequency (e.g. once in quarter) can be set for this inspection.

Although occurrence of this 'failure' is relatively low, still methods may be explored to further reduce the failure occurrence. For this purpose an in-depth analysis of the design of the control cable was carried out by us. That analysis brought out the following variables in the control cable assembly for consideration.

a. Wire diameter
b. Number of strands in the wire
c. Type of loading on the wire
d. Angle of twisting of strands
e. Wire material composition
f. Friction with the inner surface of the projection sheath and source housing.

An analysis of the above parameters shows that the strength of the control cable can be increased by providing coatings, which reduce friction on the inner surface of projection sheath, which will reduce the frequency of strand breaks of the control cable. Such a coating will also reduce the failure of inner surface of the projection sheath due to reduced friction, thus also reducing the RPN of the failure of rank 1, considered above. In addition to this measure, the material used for wire strands should also be reconsidered. Presently, mostly carbon steel and stainless steel wire strands are being used. Some other options for choice of material like composite material

aluminium matrix with boron can be considered, which provide better wear resistance as compared to the carbon steel and stainless steel wire strands.

(iii) The next most critical 'failures', with RPN ranks of 3 & 4, are those associated with the damage of the crimping part of the source capsule and the female coupler of source assembly respectively. The detection probability of these 'failures' is very low, since it is not possible to inspect the crimping part during the operational life of the source assembly, as it has an active source in it.

The source capsule and the female coupler are joined with a metallic wire by the process of crimping, as shown in the figure 4.10. Crimping, as is normally understood, is done by applying a force, and in the present context too, the metallic part of the male/female coupler or the source capsule is pressed hard onto the wire.

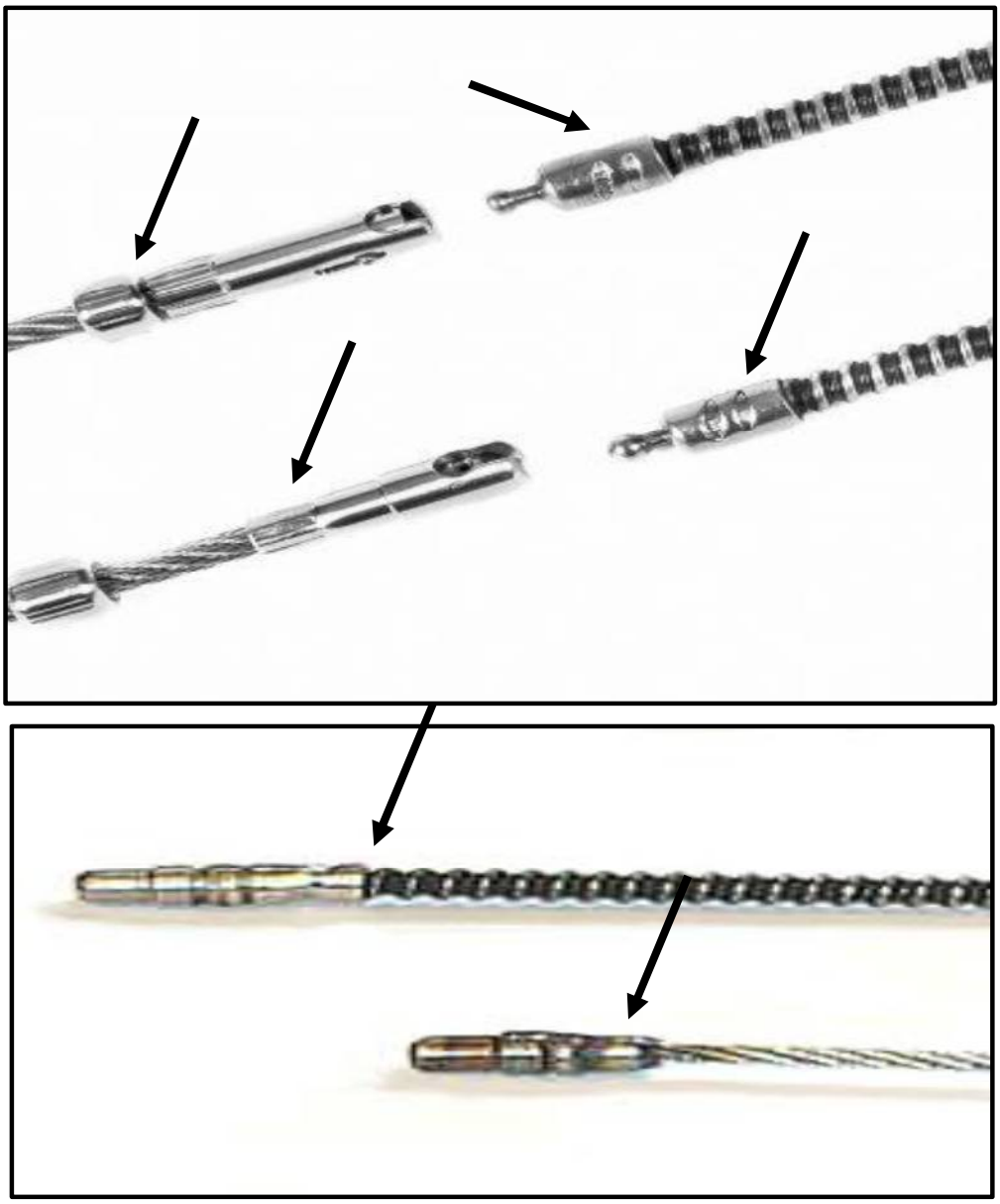


Figure 4.10: Crimping part (indicated by arrows) of the control cable and source assembly

The metallic cable of the source assembly is actually made up of multiple strands of thin wire bonded together. With prolonged use, these wire strands may gradually come out of the crimped part during operation, and lead to detachment of the source capsule or the female coupler. Sometimes the process of crimping itself may not be good to hold the source capsule or female coupler effectively.

It is hereby recommended, vide our present study, to modify the existing design of the source assembly and the control cable. In place of crimping of metallic parts on the wire, alternate methods of laser welding or electron beam welding should be used to fix the female coupler and the source capsule with the metallic cable. Laser or e-beam welding are more efficient than the crimping process. The welded source capsule will have more ruggedness than the crimped source capsule, which will definitely reduce the occurrence probability of their detachment from the cable.

It is also recommended here to frame and implement a policy to test the 'joint' (welded or crimped) part of each inactive source assembly using appropriate testing procedures before the actual source loading. This measure can be adopted as part a of quality control procedure at the manufacturer site, or by the agency involved in source loading.

(iv) Most of the other less severe failures can be addressed by insisting the operating institutions to adopt the stringent and mandatory periodic Quality Assurance (QA) test procedures. Training to the operators about proper handling and operation of devices will also reduce several failures. QA tests as prescribed by the device-manufacturing agency should be made to be followed strictly by the operating institutions as per the prescribed frequency (monthly, annually or before source loading). An example of QA test has been provided in the section 4.4.2.

4.10 SCOPE OF THE TECHNIQUE AND THE RESEARCH WORK

Traditional FMEA technique has a few drawbacks, like, missing the unknown failures, ranking values not being crisp values etc. However, the FMEA is a simple and economical method of assessment, and a useful tool to identify the

areas for improvement in design. FMEA is helpful to improve the reliability, quality & safety of a design. No other study, similar to ours, has been reported till date for industrial radiography devices. The results of our study provide a broad picture of risk assessment for the design of industrial gamma radiography exposure devices.

4.11 CHAPTER SUMMARY

Industrial radiography has its own very important and inimitable role in non-destructive examinations. Industrial radiography using gamma ray sources is carried out using the industrial gamma radiography exposure device (IGRED) or the "radiography camera". This device houses a radioactive source of significantly high activity of gamma radiation (Co-60, Ir-192, Se-75 etc.). These devices are operated manually through a control unit. In some occasions the malfunctioning of the device can be dangerous and may cause severe radiation exposure to the operator and the nearby public, and thus, should be practiced under a systematic risk control. Historically, incidents have been reported in India and internationally, of equipment failure. To ensure radiation safety, proactive risk assessment must be implemented in the practice. The industry and the policy makers have felt this need to carry out design based risk assessment of the IGREDs, to identify the areas which require attention for improvement. We have carried out a very thorough, design based, risk assessment of the radiography device in this study, using the Failure Modes & Effects Analysis (FMEA) methodology. For this purpose a FMEA team with ten members from different stakeholders of the IGREDs was constituted.

The IGRED consists of four detachable sub-units namely, the source housing, the remote control unit, the projection sheath and the source assembly. For the purpose of FMEA study, each of these four sub units were further divided into their basic components. As per the standard FMEA procedure, all possible failure modes of each component were identified in our study. The Failure occurrence data in our study was generated by carrying out field inspection of

IGREDs at the source loading site, and through inspection at the radiography operating sites. The severity rankings were established by simulating the different practical scenarios corresponding to identified failures. Each failure mode was assigned a ranking for its Occurrence (O), Severity (S) and Detection (D), and a Risk Priority Number (RPN) was then calculated for it from the product of the O, S & D rankings.

Our rigorous and detailed study of risk assessment using the FMEA technique shows that none of the failure for IGRED had RPN value above 500, a threshold value for RPN which require urgent corrective actions. The RPNs of 23 of the total 29 component failure modes were found to be less than 100, which make them fall in the 'acceptable' category. The RPN values of the remaining 6 component failure modes were in the range of 100 to 500, where corrective actions need to be recommended. Our results are significantly helpful in learning about the necessary interventions required for risk management associated with design based failures in industrial radiography.

Based on our thorough and detailed study, we have made recommendations for some design interventions in the IGREDs. Implementations of these recommendations are expected to reduce the RPN values for the respective failures. Our present results reveal that increasing the failure (predictability) detectability is a practical and feasible approach to reduce the risk in most of the failures of IGREDs. Our FMEA team also suggested actions for reducing RPN values for each of the identified failure. This is the first reported risk assessment study for industrial gamma radiography exposure devices using the FMEA methodology. Also, significantly, our present study clearly establishes the feasibility of use of the FMEA technique for risk assessment in industrial radiography practice.
