Training Course on Safety Assessment of Facilities and Activities

Using Radiation Sources



PRACTICAL EXERCISE MEDICAL PRACTICE (TEACHER's BOOK)

FOREWORD

These exercises are a complement to the presentations of the training course on "Safety Assessment of Facilities and Activities using Radiation Sources".

The objective of the exercises is to help develop the basic knowledge necessary to perform a safety assessment.

The contents of a safety assessment should include the following topics:

LIST OF CONTENTS OF A SAFETY ASSESSMENT

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Regulations and Standards.

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- 1.3.- Approach and scope of the Assessment
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- 2.1.- Identification of Hazards
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- 3.3.- Risk Calculations
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- 4.- ANALYSIS OF ASSESSMENT RESULTS
 - 4.1.- Comparison with assessment criteria
 - 4.2.- Analysis and revision (if it is needed) of safety measures and engineering

Exercises are proposed for each of the sections. To facilitate understanding of the exercises, each section of the content list corresponds to a block of the safety assessment process diagram used in the course presentations:



PART 1.- ASSESSMENT CONTEXT

1.1.- Introduction

The safety assessment shall be in accordance with the requirements of the current National Regulations based on the criteria of GSR part 3 and GSR part 4.

The 24 requirements from GSR part 4 used in performing safety assessments are:

Requirement 1: Graded approach

A graded approach shall be used in determining the scope and level of detail of the safety assessment carried out in a particular State for any particular facility or activity, consistent with the magnitude of the possible radiation risks arising from the facility or activity.

Requirement 2: Scope of the safety assessment

A safety assessment shall be carried out for all applications of technology that give rise to radiation risks; that is, for all types of facilities and activities.

Requirement 3: Responsibility for the safety assessment

The responsibility for carrying out the safety assessment shall rest with the responsible legal person; that is, the person or organization responsible for the facility or activity.

Requirement 4: Purpose of the safety assessment

The primary purposes of the safety assessment shall be to determine whether an adequate level of safety has been achieved for a facility or activity and whether the basic safety objectives and safety criteria established by the designer, the operating organization and the regulatory body, in compliance

with the requirements for protection and safety as established in the International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources, have been fulfilled.

Requirement 5: Preparation for the safety assessment

The first stage of carrying out the safety assessment shall be to ensure that the necessary resources, information, data, analytical tools as well as safety criteria are identified and are available.

Requirement 6: Assessment of the possible radiation risks

The possible radiation risks associated with the facility or activity shall be identified and assessed.

Requirement 7: Assessment of safety functions

All safety functions associated with a facility or activity shall be specified and assessed.

Requirement 8: Assessment of site characteristics

An assessment of the site characteristics relating to the safety of the facility or activity shall be carried out.

Requirement 9: Assessment of the provisions for radiation protection

It shall be determined in the safety assessment for a facility or activity whether adequate measures are in place to protect people and the environment from harmful effects of ionizing radiation.

Requirement 10: Assessment of engineering aspects

It shall be determined in the safety assessment whether a facility or activity uses, to the extent practicable, structures, systems and components of robust and proven design.

Requirement 11: Assessment of human factors

Human interactions with the facility or activity shall be addressed in the safety assessment, and it shall be determined whether the procedures and safety measures that are provided for all normal operational activities, in particular those that are necessary for implementation of the operational limits and conditions, and those that are required in response to anticipated operational occurrences and accidents, ensure an adequate level of safety.

Requirement 12: Assessment of safety over the lifetime of a facility or activity

The safety assessment shall cover all the stages in the lifetime of a facility or activity in which there are possible radiation risks.

Requirement 13: Assessment of defence in depth

It shall be determined in the assessment of defence in depth whether adequate provisions have been made at each of the levels of defence in depth.

Requirement 14: Scope of the safety analysis

The performance of a facility or activity in all operational states and, as necessary, in the post-operational phase shall be assessed in the safety analysis.

Requirement 15: Deterministic and probabilistic approaches

Both deterministic and probabilistic approaches shall be included in the safety analysis.

Requirement 16: Criteria for judging safety

Criteria for judging safety shall be defined for the safety analysis.

Requirement 17: Uncertainty and sensitivity analysis

Uncertainty and sensitivity analysis shall be performed and taken into account in the results of the safety analysis and the conclusions drawn from it.

Requirement 18: Use of computer codes

Any calculational methods and computer codes used in the safety analysis shall undergo verification and validation.

Requirement 19: Use of operating experience data

Data on operational safety performance shall be collected and assessed.

Requirement 20: Documentation of the safety assessment

The results and findings of the safety assessment shall be documented.

Requirement 21: Independent verification

The operating organization shall carry out an independent verification of the safety assessment before it is used by the operating organization or submitted to the regulatory body.

Requirement 22: Management of the safety assessment

The processes by which the safety assessment is produced shall be planned, organized, applied, audited and reviewed.

Requirement 23: Use of the safety assessment

The results of the safety assessment shall be used to specify the programme for maintenance, surveillance and inspection; to specify the procedures to be put in place for all operational activities significant to safety and for responding to anticipated operational occurrences and accidents; to specify the necessary competences for the staff involved in the facility or activity and to make decisions in an integrated, risk informed approach.

Requirement 24: Maintenance of the safety assessment

The safety assessment shall be periodically reviewed and updated.

In every step of the Safety Assessment Process, the requirements that are used are:



1.2.- Description of the facility or activity

Site characteristics

The radiotherapy service is located in the basement area of the Hospital. Figure #1 shows a layout of the different areas of this radiotherapy service.



- 1. Head of Service office
- 2. Consultation rooms.
- 3. Planning.
- 4. Medical physicist office.
- 5. Designation of volumes.
- 6. Reception counter
- 7. Patients waiting room.
- 8. Locker room.
- 9. CT room.
- 10. CT control panel.
- 11. Portal imaging developing room.
- 12. HDR room. (Out of order)
- 13. HDR control panel. (Out of order)
- 14. Co60 Unit room.
- 15. Co60 control panel
- 16. Mould room.
- 17. Archive, Medical records.
- 18. Toilets.

Engineering design

A generic radiotherapy service was envisaged, with characteristics such as might be found in the region, although the service is not necessarily representative of the region but rather of the highest level of service that may be expected. The service would include the following equipment and elements:

Type of the Equipment	Model / Year of manufacture	Serial number		Type of	F	Manufactures
		Equip.	Source/ Activity	Radiation	Energy.	Manufacturer
Cobalt-60	THERATRO N 780C	150000		Foton	1.25 MeV	THERATRON

The following figure #2 shows a schematic of the bunker where the Teletherapy equipment with Co-60 is located and the uses of the surrounding areas are specified.

The main features of bunker construction are shown below:

- a) Distance from the isocentre to the control panel (Point 1): 7.6 m.
- b) Distance from the isocentre of the equipment to the place of the location of the person responsible for the medicine store, adjacent to the bunker (Point 2): 3,5 m.
- c) Distance source-isocentre: 0.8 m
- d) Thickness of the wall of the primary barrier (S): 1.50 meters.
- e) Use factor U= 0.25. Control panel is located on the primary barrier of the bunker
- f) Occupancy factor T= 1. In the Control panel.







Figure 1.- Bunker plane of the cobalt-60 equipment.

Safety measures

The installation has the following safety systems:

a) Stationary radiation detector inside the bunker with light and sound indication of the presence of high levels of radiation in case the source is exposed.

b) CCTV to visualize the patient and the head of the equipment during the treatment.

c) Interlock at the bunker entrance door, allowing the source to be stored in its shielded head when inadvertent entry of a person into the bunker occurs while the source is exposed.

d) Equipment is available for the daily control of the radiation beam (flatness and beam symmetry).

e) Emergency stop interlocks on the control panel and inside the team bunker

Operational procedures

The radiotherapy service has procedures for performing the different stages of the treatment process as shown below:

i.- Prescription of the treatment.

It includes medical review of the patient, the prescription of the total dose and the type of treatment that is intended to perform (equipment, technique, type of treatment planning, etc.).

ii.- Data acquisition for treatment planning.

It includes the process of acquisition of anatomical patient data (e.g. tomography images) and the processing of the data to be sent to the treatment planning system (TPS).

iii.- Treatment planning.

Includes the delimitation of volumes and the physical planning of the treatment in the "TPS". It also includes the preparation and data recording of the treatment plan.

iv.- Preparation of customized accessories.

This is the stage where the blocks for the conformation of the beams of treatment are prepared. These blocks are placed on trays that will be used during the treatment (in each section of the treatment).

v.- Initial treatment session.

In this stage the radiation oncologists, medical physicists and technologist jointly carried out the start of the treatment of the patient and verify that the treatment plan meets clinical prescription of treatment previously carried out.

vi.- Daily treatment.

In this stage, the patient is treated daily, replicating the parameters preset at the beginning of the treatment. To do this, the technologist must administer the daily

dose of treatment that has been planned, which means he/she will need to position the patient for each beam of radiation that has been planned and operate the equipment from the control panel, finalizing the process once the patient leaves the treatment room.

vii.- Weekly medical follow-up of the patient.

In this stage, the patient is attended by the radiotherapy doctor to perform a clinical control and to control the dose records of the patient. In case of finding anomalies, radiotherapy doctor can discontinue temporarily or permanently the treatment or, otherwise, give conformity to continue the treatment of the patient until all sessions of treatments that have been planned are administered.

Management Systems

The hypothetical service has enough radiation oncologists, medical physicists, and radiotherapy and mould technicians, and a safety and quality assurance programme, with written procedures and a committee to monitor compliance;

Equipment manuals are in the local language, in accordance with applicable IEC and ISO standards on accompanying documentation, the performance specifications and instructions for handling and maintenance, including translated instructions on protection and safety;

The calibration of beams and radiation sources used in radiotherapy are traceable to a standards dosimetry laboratory;

The quality assurance programme includes measuring physical parameters at commissioning and periodically thereafter, along with verifying relevant physical and clinical factors used in the diagnosis or treatment of patients, recording significant procedures and the results thereof in writing, and verifying that the calibration and operational state of dosimetry equipment are correct;

There are guidelines for training radiation oncologists, medical physicists, and radiotherapy and mould technicians and technologists. In addition to education in the professional specialty, clinical practice and experience are covered, along with specific training on the apparatus being used, including the treatment planning system (TPS), the correct interpretation of dosimetry equipment calibration certificates and lessons learned from accidental exposure;

There are procedures for the purchase and acceptance of equipment and accessories, and it is compulsory to validate changes to procedures that may have repercussions for dosage or dose distribution;

Procedures are in place to remove obsolete or disused files or make them inaccessible;

There are guidelines on keeping the workload moderate and creating conditions that facilitate conscious, careful work with no distractions.

It is assumed that full acceptance and commissioning tests are performed, along with periodic tests and tests following maintenance or repair. Periodic tests include the treatment geometry and radiation tests proposed in the revised version of IAEA-TECDOC-1040 ("Setting up a Radiotherapy Programme") and IAEA-TECDOC-1151 [20, 21]. Tests are grouped as follows:

 Acceptance tests for diagnosis and treatment equipment and accessories, whereby all the specifications and compliance with the requirements of safety standards, such as those of the International Electrotechnical Commission (IEC), are verified;

• Commissioning tests to verify all the conditions and parameters for treatment, both in the treatment unit and in the planning and simulation system, and for the accessories;

• Periodic quality control tests, including physical and clinical aspects, tests following maintenance or repair, and written records in the form of procedures and test results;

• Safety critical verification, performed redundantly;

• Determination of absorbed dose in water, using local procedures based on international protocols such as those of the IAEA (TRS 277 or 398) [22, 23]. Dosimetry equipment similar to that required by IAEA-TECDOC-1040 ("Setting up a Radiotherapy Programme") and IAEA-TECDOC-1151 [20, 21] is used. This determination is repeated by an independent person using a different measuring device;

• TLD postal dose audits and participation in intercomparisons. The initial postal audit and postal audits performed when sources are exchanged serve as a safety barrier if they are carried out and the results obtained before clinical use of the beam. Other audits serve to detect and lessen the consequences of any deviation;

• Determination of values for depth dose, symmetry and flatness tests, and field factors, and their comparison with the tables in BJR Supplement 25. Accessories, such as wedge and tray factors, are also measured, as is the effectiveness of immobilizers. The absorbed dose is also determined under reference conditions.

In commissioning the TPS, the protocols recommended by the IAEA, such as IAEA TRS 430 [24], are used, and a second, independent verification of the tables and basic parameters entered into the TPS during commissioning is carried out, along with manual verification of TPS calculations at specific points and measurements on phantom. Once the basic data have been introduced into the TPS, testing takes place, including:

• Manual calculation of absorbed dose at various points using the original basic data, compared with the results of TPS calculations made using the basic data entered into the system;

• Measurements on phantom to confirm the values calculated by the TPS for various configurations of beams and beam shapers.

When a computed tomography (CT) unit is used, whether within the radiotherapy service or in a diagnostic radiology service:

• There are procedures for calibrating the CT unit for radiotherapy, including geometric parameters such as density correction, using the Hounsfield scale, and use of CT images in the TPS.

In planning and preparing individual treatments:

• Standardized forms are used to collect and report treatment information.

• Independent verification (usually by the physicist) takes place for all treatment planning and manual calculations are made for one or two points;

• There are specific protocols for special treatment, such as emergencies or urgent cases treated with a single dose;

• Once planning is complete, a verification/simulation is carried out. Finally, the treatment is updated during the first session with the participation of the radiation oncologist, medical physicists, dosimetrist, radiotherapy technicians and mould technician, if relevant, including portal imaging. This update is repeated if changes are made to the treatment plan.

When treatment is given, use is made of the following:

• Redundant procedures for patient identification: identification carried by the patient and a photograph on the treatment chart;

• In vivo dosimetry, for accelerator treatment only (not for 60Co teletherapy);

• Portal imaging (whether with electronic devices or portal imaging) performed during the first treatment session and weekly throughout the treatment process;

- · Weekly verification of patient's treatment chart;
- Immobilizers and, if required, sedation for patients;

• Procedures to ensure that radiotherapy technicians observe the patient daily and that the radiation oncologist monitors patients weekly.

Elements that mitigate consequences, in the event that an initiating event results in accidental exposure:

- Daily observation of the patient by the operating technician;
- Weekly follow-up observation of the patient by the doctor;
- Weekly review of patient's treatment chart;

• Continuous observation of the patient through a lead glass window or via the viewing system TV monitor. Two technicians per piece of equipment on every shift. Use of intercom system for (two-way) communication with the patient. Emergency shutdown switch on the equipment.

In terms of maintenance and repair, the following measures are in place:

• A log of incidents involving the equipment. Requirement for control of the unit to be transferred between maintenance workers and radiotherapy staff, with a repair sheet, and for the medical physicists in charge to be notified so that the relevant parameters can be verified, depending on the repair carried out.

1.3.- Approach and scope of the Assessment

The safety assessment is focused on ensuring the radiological safety of patients, workers, and the public during oncological treatments using Co-60 source-based teletherapy equipment. It includes all stages and substages of the treatment process as well as the acceptance, commissioning, maintenance and quality controls that are performed on this equipment.

1.4.- Assessment criteria

The criteria are based on what is established in the current national regulation according to IAEA recommendations, and are as follows.

- a) Dose limits. According to GSR Part 3
 - i. For workers: 20 mSv / year on average in 5 years and no more than 50 mSv in a year.
 - ii. For public: 1mSv / year.
- b) Dose Restrictions. According to applicable National Regulation.

i. For workers: 10 mSv/year.

ii. For public: 0.5 mSv/year.

iii. For people who provide assistance to patients: 5 mSv for whole treatment

c) Acceptability of Risk. According IAEA-TECDOC 1685.

a. Accidental Sequences of "Very High Risk" (VHR). They are unacceptable, it is necessary to stop the treatments since they are an imminent risk.

b. Accidental Sequences of "High Risk" (HR). They are unacceptable, it is necessary to implement a plan of measures to reduce the risk within a reasonable time since they are not an imminent risk.

c. Accidental sequences of "Medium Risk" (MR). Are Tolerable, a plan of measures to reduce the risk according to criteria of Cost-Benefit must be implemented.

d. Accidental Sequences of "Low Risk" (LR). They are widely accepted, no risk reduction required.

EXERCISES PART 1.- ASSESSMENT CONTEXT



These exercises cover first block of presentations.

EXERCISE PART 1 #1

<u>GSR Part 3 Requirement 13: Safety assessment</u> states: "The regulatory body shall establish and enforce requirements for safety assessment, and the person or organization responsible for a facility or activity that gives rise to radiation risks shall conduct an appropriate safety assessment of this facility or activity.

3.29. The regulatory body shall establish requirements for persons or organizations responsible for facilities and activities that give rise to radiation risks to conduct an appropriate safety assessment. Prior to the granting of an authorization, the responsible person or organization shall be required to submit a safety assessment, which shall be reviewed and assessed by the regulatory body.

3.30. The person or organization, as required under para. 3.9(d), or registrants and licensees, as appropriate, shall conduct a safety assessment that is either generic or specific to the practice or source for which they are responsible.

3.31. Safety assessments shall be conducted at different stages, including the stages of siting, design, manufacture, construction, assembly, commissioning, operation, maintenance and decommissioning (or closure) of facilities or parts thereof, as appropriate, so as:

(a) To identify the ways in which exposures could be incurred, account being taken of the effects of external events as well as of events directly involving the sources and associated equipment;

(b) To determine the expected likelihood and magnitudes of exposures in normal operation and, to the extent reasonable and practicable, to make an assessment of potential exposures;

(c) To assess the adequacy of the provisions for protection and safety.

3.32. The safety assessment shall include, as appropriate, a systematic critical review of:

(a) The operational limits and conditions for the operation of the facility;

(b) The ways in which structures, systems and components, including software, and procedures relating to protection and safety might fail, singly or in combination, or might otherwise give rise to exposures, and the consequences of such events;

(c) The ways in which external factors could affect protection and safety;

(d) The ways in which operating procedures relating to protection and safety might be erroneous, and the consequences of such errors;

(e) The implications for protection and safety of any modifications;

(f) The implications for protection and safety of security measures or of any modifications to security measures;

(g) Any uncertainties or assumptions and their implications for protection and safety.

3.33. The registrant or licensee shall take into account in the safety assessment:

(a) Factors that could give rise to a substantial release of radioactive material, the measures available to prevent or to control such a release, and the maximum activity of radioactive material that, in the event of a major failure of the contain ment, could be released to the environment;

(b) Factors that could give rise to a smaller but continuing release of radioactive material, and the measures available to detect and to prevent or to control such a release;

(c) Factors that could give rise to unintended operation of any radiation generator or a loss of shielding, and the measures available to detect and to prevent or to control such occurrences;

(d) The extent to which the use of redundant and diverse safety features that are independent of each other, so that failure of one does not result in failure of any other, is appropriate to restrict the likelihood and magnitude of potential exposures.

3.34. Registrants and licensees shall ensure that the safety assessment is documented and, where appropriate, that it is independently reviewed under the relevant management system.

3.35. Registrants and licensees shall perform additional reviews of the safety assessment as necessary to ensure that the technical specifications or conditions of use continue to be met when:

(a) Significant modifications to the facility or to its operating procedures or maintenance procedures are envisaged;

(b) Significant changes occur on the site that could affect the safety of the facility or of activities on the site;

(c) Information on operating experience, or information about accidents and other incidents that could result in exposures, indicates that the current assessment might be invalid;

(d) Any significant changes in activities are envisaged;

(e) Any relevant changes in guidelines or standards have been made or are envisaged.

3.36. If as a result of a safety assessment, or for any other reason, opportunities to improve protection and safety appear to be available and improvement seems desirable, any consequential modifications shall be made cautiously and only after favorable assessment of all the implications for protection and safety.

The implementation of all improvements shall be prioritized so as to optimize protection and safety."

Question: Can you highlight the main recommendations of this requirement that would apply to the installation described in this exercise?

EXERCISE PART 1 #2

Split the students in 4 groups. Each group should identify the requirements that apply to the Safety Assessment parts:

- 1.- ASSESSMENT CONTEXT
- 2.- DEVELOPMENT AND JUSTIFICATION OF SCENARIOS
- **3.- SAFETY ANALYSIS**
- 4.- ANALYSIS OF ASSESSMENT RESULTS

EXERCISE PART 1 #3

Split the students in small groups. Each group should review the information given in #1.2. (Description of the facility or activity) and identify if it contains enough information to fulfil the safety assessment requirements.

PART 2.- DEVELOPMENT AND JUSTIFICATION OF SCENARIOS

2.1.- Identification of Hazards

The following are the hazards that have been identified for this safety assessment:

- Fire in the work area where the equipment is used.
- Physical damage due to blows to the patient during their placement in the equipment.
- Overdose caused to persons due to the operation of the equipment, including:
 - -Damages to the Worker.
 - -Damages to the patient
 - -Damages to the public.
- Uncontrolled use of sources.
- -Lack of training and/or experience of workers
- -Obsolete or faulty software
- Floods.
- Earthquakes.

2.2.- Selection and Hazard Screening

Considering the Approach and Scope of the Assessment, the following are the hazards that have been selected for consideration in this Safety Assessment:

- Overdose caused to persons due to the operation of the equipment, including:
 - -Damages to the Worker.
 - -Damages to the patient
 - -Damages to the public.
- Uncontrolled use of sources.
- -Lack of training and/or experience of workers
- -Obsolete or faulty software

2.3.- Identification and description of Scenarios

2.3.1 Scenario for normal operation. Stages.

During normal operation, the radiotherapy service operates a LINAC unit. 60 patients are treated every weekday and two medical technologists in each work shift operate the unit, with up to 30 patients in 8 hours of work shift. The treatment process includes the following stages:

Prescription of the treatment.

It includes medical review of the patient, the prescription of the total dose and the type of treatment that is intended to perform (equipment, technique, type of treatment planning, etc.).

Data acquisition for treatment planning.

It includes the process of acquisition of anatomical patient data (e.g. tomography images) and the processing of the data to be sent to the treatment planning system (TPS)

Treatment planning.

Includes the delimitation of volumes and the physical planning of the treatment in the "TPS". It also includes the preparation and data recording of the treatment plan.

Preparation of customized accessories.

This is the stage where the blocks for the formation of the beams of treatment are prepared. These blocks are placed on trays that will be used during the treatment (in each section of the treatment).

Initial treatment session.

In this stage the radiation oncologists, medical physicists and technologist jointly carried out the start of the treatment of the patient and verify that the treatment plan meets clinical prescription of treatment previously carried out.

Daily treatment.

In this stage, the patient is treated daily, replicating the parameters preset at the beginning of the treatment. To do this, the technologist must administer the daily dose of treatment that has been planned, which means he/she will need to position the patient for each beam of radiation that has been planned and operate the equipment from the control panel, finalizing the process once the patient leaves the treatment room.

Weekly medical follow-up of the patient.

In this stage, the patient is attended by the radiotherapy doctor to perform a clinical control and to control the dose records of the patient. In case of finding anomalies, radiotherapy doctor can discontinue temporarily or permanently the treatment or, otherwise, give conformity to continue the treatment of the patient until all sessions of treatments that have been planned are administered.

2.3.2.- Scenario for normal operation. Assumptions.

In normal operation, we will assume:

- a) The workload (W) is 450 Gy per week (30 patients/day, in 8 hours of work per day, 5 days per week and an average dose of 3 Gy in the isocentre per patient)).
- b) Working 5 days a week, 50 weeks a year.
- c) 2 technologists (Unit Operator) in each shift of work, each one of them assuming the positioning of 15 patients.
- d) During the positioning of the patient, the technologist remains 2 minutes at a distance of 1.5 meter from the head of the umit.

- e) The rate of leakage from the head of the unit, according to the manufacturer, is 0.02 mGy/h.
- f) The maximum dose rate in the isocentre Do is 2.35 Gy/min = 141 Gy/h.
- g) Distance source-isocentre: 0.8 m.
- h) Thickness of the tenth value layer for concrete of density 2.35 g / cm3 is TVL1 = 0.21 meters.
- i) Thickness of the equilibrium tenth value layer for concrete of 2.35 g/cm3 density is TVLe = 0.21 meters. (due to the Co-60 energy)

2.3.3 Scenario for an accident situation.

Several possible scenarios in accident situations have been analyzed and are shown below:

a) Clogging the source upon completion of a patient's treatment and preventing the source to return to the shielding position.

- b) Inadvertent entry of a member of the public into the treatment room.
- c) Human errors during prescription of treatment.
- d) Human errors during acquisition of anatomical patient data
- e) Human errors that cause the wrong treatment of a patient's treatment plan.
- f) Positioning errors of a patient in a treatment session.
- g) Human errors during the commissioning of the equipment.
- h) Maintenance errors that affect the physical parameters of the equipment.
- i) Human errors during the commissioning of the treatment planning system.
- j) Failures of the treatment team.
- k) Failure of the treatment planning (TPS).

All of these scenarios will be taken into account during the development of the safety assessment, particularly in the risk assessment. For the estimation of doses, in an accident situation, we have selected scenario (a), which was previously stated, considering that it is an extreme and representative scenario of the doses that can be received by workers, patients and the public in an accident.

2.3.3.1 Description of the scenario "Clogging the source upon completion of a patient's treatment and preventing the source to return to the shielding position"

During normal operation of a Co-60 teletherapy unit, at the end of a session of treatment of a patient, the source does not return to the shielded position, staying jammed in the treatment position. As a result of this event, derived of a failure in the return pneumatic system of the source, the unit keeps the signals light, that alert to the operator, "on" (at the control panel and at the head of the unit), and the sound and light alarm emitted by the stationary detector of radiation located inside of the bunker, is kept activated. All these signals alert the Unit Operator and immediately (by via of the intercom) gives guidelines to the patient to get off of the treatment bed and go out of the bunker as soon as possible. The patient finally gets off the treatment table and leaves the bunker. The patient remained on the stretcher at the end of treatment for 15 seconds, in which the patient did not receive a significant overdose of the total dose of planned treatment (70 Gy to the tumor).

Trying to quickly solve the event, one of the two operators of the unit take the bar "T" shaped and enters into the Bunker without noticing that the head of the unit was angled to 900. He stays during 1 min at a distance of 2 m within the primary radiation beam emitted by the head of the unit.

The second operator of the unit analyses the scenario and enters into the bunker avoiding the primary beam of radiation emitted by the unit. Takes the bar in "T" shape and, from a distance of 1 m from the head of the unit, in their front side, performs the procedure established by the manufacturer and in a time of 2.5 minute manages to introduce the source to the shield position.

2.3.4.- Scenario for an accident situation. Assumptions.

- a) 2 technologists (Unit Operator) in each shift of work.
- b) The maximum dose rate in the isocentre Do is 2.35 Gy/min = 141 Gy/h.
- c) Distance source-isocentre: 0.8 m.
- d) Patient stay time in the treatment bed after the source clogging occurs: 15 s = 0.25 min.

EXERCISES PART 2.- DEVELOPMENT AND JUSTIFICATION OF SCENARIOS

These exercises cover second block of presentations.



EXERCISE PART 2 #1. Analyze the list of hazards shown in #2.1 (Identification of Hazards) and select those that are present in a radiotherapy service using a Teletherapy equipment with Co-60 source.

EXERCISE PART 2 #2 Taking into account its radiological consequences, select the most important hazards that will be considered within the Safety Assessment.

EXERCISE PART 2 #3 Describe the most likely extreme scenarios that can trigger the hazards selected in question #2.

PART 3.- SAFETY ANALYSIS

3.1.- Identification of Models and Data Needs

For dose estimation under normal operating conditions, the following models a Estimation of doses in areas adjacent to the bunker. Methodology of the NCRP 151.nd methodologies have been considered:

- a) Estimation of doses in areas adjacent to the bunker. Methodology of the NCRP 151.
- b) Dose estimates within the bunker. Law of the Inverse of the square of the distance. Point source considerations.

For risk estimates, the "Risk Matrix" methodology has been considered. Publication IAEA-TECDOC 1685. The SEVRRA 3.0 software has been used. (Available on <u>WWW.foroiberam.org</u>)

3.2.- Dose Calculations

3.2.1 Dose estimates in Normal operation.

3.2.1.1 Occupationally exposed personnel.

Some of the service workers are exposed to radiation under normal operating conditions during radiotherapy treatments using the cobalt unit. The following table describes the job positions that are more exposed to ionizing radiation during the execution of their duties.

No.	Job position	Duties	Dose
1.	Radiotherapist	Prescription of treatments	No
		Obtaining CT images for planning	Yes
		Starting treatment	Yes
		Follow-up of the patient under	No
		treatment	
2.	Medical Physicist	Cobalt Unit calibration	Yes
		Quality control	Yes
		Treatment Planning	No
		Starting treatment	Yes
3.	Unit Operator	Starting treatment	Yes
		Positioning of patients	Yes
		Delivering the daily treatment	Yes
		from the Control Panel of the	
		Cobalt unit	

When analysing the conditions of work in each of the positions described in the above table and considering the functions they perform, it is considered that the position of Unit Operator of the Cobalt unit is exposed to higher radiation doses during normal operation. This is because the treatment is performed repetitively (between 25 and 30 sessions) for each patient and it includes receiving significant doses during the tasks of positioning the patient inside the treatment room and performing the treatment from the panel Control system.

Based on this analysis, we will perform the estimation of normal operating doses for the position of the Cobalt Unit Operator in order to demonstrate that this worker does not exceed the restrictions and dose limits established in this facility:

 a) Dosage received by the Unit Operator in the Control Panel of the Cobalt Unit (Point 1).

Since the control panel is located in the primary barrier, to estimate the dose received by the operator we must calculate the instantaneous dose rate (IDR) at the workplace using the following formula:

$$IDR = \frac{DR_0 \cdot B}{d^2}$$

Where:

 DR_0 – is the dose rate to the isocentre produced by the equipment

- d is the distance from the source to the Point to be protected outside the barrier in meters
- B is the barrier's transmission factor. To calculate B we must use the following formula:

$$B = 10^{-\left\{1 + \left[\frac{S - TVL_1}{TVL_e}\right]\right\}}$$

Where:

S - is the thickness of the barrier in meters.

The calculation of the transmission factor shows that:

Calculating the instantaneous dose rate in the control panel we have:

 $IDR = 1.76e^{-7} Sv/h = 1.76e^{-4} mSv/h.$

Based on the estimation of the instantaneous dose rate, the weekly dose can be estimated using the following formula:

$$R_{W} = IDR \times \frac{W U T}{DR_{0}}$$

Where:

IDR -is the instantaneous dose rate (Sv/h) when the unit operates at a dose rate of DR_0

W-is the weekly workload defined at 1 meter, in Gy/week, and

DR₀ - is the dose rate produced at 1 meter, in Gy/h,

U - is the use factor of the barrier, and

T - is the occupation factor at the point of calculation.

In the case of the dose estimation for the Unit Operator in the control panel, U = 0.25 as recommended in publication NCRP 151 and T = 1 since we consider that the operator will always be present in the Control Panel when the unit is working.

 $R_w = 1.4e^{-7}$ Sv/week

The total dose received by the operator in the control panel (D_{op}) is estimated by multiplying the weekly dose by the number of weeks worked in the year (50 working weeks per year).

D_{op}= 0.000007 Sv/year = 0.007 mSv/year.

b) Dosage received by the Unit Operator at the Panel during the positioning of the patient in the Cobalt Unit.

During the positioning of the patients in the cobalt unit, the Unit Operator receives doses due to the radiation leakage from the head of the Cobalt unit. According to the documentation supplied by the manufacturer and as is recommended in the corresponding IEC standard, the head radiation leak rate is 0.02 mGy/h to one meter from the source.

Considering that, on average, the Unit Operator is located 1.5 meters from the head, the dose rate received is estimated, according to the law of the inverse square of the distance, in a value of:

$$T_{pos} = 0.02 \text{ mGy/h} * (1^2/1, 5^2) = 0.0089 \text{ mSv/h}$$

Considering typical treatments with an average of 3 fields per patient, that in the positioning of each field the operator is delayed 2 minutes and that each operator performs the positioning of 15 patients, we have.

$$D_{pos} = 15 \frac{pac}{d} 5 \frac{d}{sem} 50 \frac{sem}{a\tilde{n}o} 0.0089 \frac{mGy}{h} 6\min \frac{h}{60\min} = 3.34 \frac{mSv}{a\tilde{n}o}$$

c) Unit Technologist Operator during his work in the Cobalt Unit.
Based on the dose estimates made in points 5.1 and 5.2, the total dose received by a Unit Operator in a year will be:

 d) Conclusions on the estimate total dose received by the Unit Operator under Normal Operation.

•The dose estimation shows that most of the dose received by the operator is due to the patient positioning operation in the treatment table, so it is important to improve the procedures used for this activity and to train the operators to comply with them.

•The increase in the workload (number of patients treated daily) significantly increases the dose received by the operator since it influences the time and number of actions that the operator must perform inside the bunker during patient positioning.

•It is important that the work of the two operators be organized so that the workload (number of patients treated) related to the positioning of patients is equitably shared between the two operators.

3.2.1.2 Dose estimates in Normal operation. (For the public).

During the implementation of the Radiotherapy treatments using the Cobalt Unit, some members of the public and workers of the Hospital outside the Radiotherapy Service receive low doses due to the use of Telecobaltotherapy equipment. The following table describes the areas and members of the public exposed.

No.	Job position	Work Area Location	Dose
1.	Responsible for the	Office located at a	YES
	Hospital's Drug Store	distance of 0.3 meters	
		from the bunker wall	
		(Point 2).	
2.	Hospital personnel traveling	External corridor cloce to	YES
	at a distance of 0.5 meters	the radiotherapy service	
	from the wall, Through the	(Point 3)	
	corridor (Point 3)		
3.	Members of the public	Parking outside the	YES
	walking through the parking	Hospital (Point 4)	
	area, 3.5 meters from the		
	outer wall of the radiotherapy		
	service (Point 4)		

When analysing the exposure conditions in which the members of the public, mentioned in the above table, we consider that the Head of the hospital's Drug Store who works 8 hours a day at 30 centimetres of the wall, considered the Bunker's primary barrier, is the one that receives higher doses due to the operation of the equipment.

Next, we will estimate the dose received by this member of the public.

Parameters for the calculation of the dose:

a) Distance from the isocentre of the equipment to the place of the location of the person responsible for the medicine store, adjacent to the bunker (Point 2): 3,5 m.

- b) Distance source-isocentre: 0.8 m.
- c) Thickness of the wall of the primary barrier (S): 1.50 meters.
- d) Use factor U=0.25.
- e) Occupancy factor T= 1. In hospital's Drug Store.
- f) The Head of the hospital's Drug Store works at 30 centimetres of the wall.

g) Thickness of the tenth value layer for concrete of density 2.35 g / cm3 is TVL1 = 0.21 meters.

h) Thickness of the equilibrium tenth value layer for concrete of 2.35 g/cm3 density is TVLe = 0.21 meters. (due to the Co-60 energy)

$$IDR = \frac{DR_0 \cdot B}{d^2}$$

Where:

DR0 - is the dose rate to the isocenter produced by the equipment

d - is the distance from the source to the Point to be protected outside the barrier in meters

B - is the barrier's transmission factor. To calculate B we must use the following formula:

$$B = 10^{-\left\{1 + \left[\frac{S - TVL_1}{TVL_e}\right]\right\}}$$

Where:

S - is the thickness of the barrier in meters.

The calculation of the transmission factor shows that:

Calculating the instantaneous dose rate in the control panel we have:

$$IDR = 8,28e^{-7}Sv/h = 8,28e^{-4}mSv/h.$$

Based on the estimation of the Instant dose rate, the weekly dose can be estimated using the following formula:

$$R_{W} = IDR \times \frac{W U T}{DR_{0}}$$

Where:

IDR -is the instantaneous dose rate (Sv/h) when the unit operates at a dose rate of DR_0

W-is the weekly workload defined at isocentre, in Gy/week, and

DR0 - is the dose rate produced at 1 isocentre, in Gy/h,

U - is the use factor of the barrier, and

T - is the occupation factor at the point of calculation.

In the case of the dose estimation, U = 0.25 as recommended in publication NCRP 151 and T = 1.

 $R_w = 6,609e-7$ Sv/week = 6,609e-4 mSv/week.

The total dose received by the Head of the hospital's Drug Store, is estimated by multiplying the weekly dose by the number of weeks worked in the year (50 working weeks per year).

D_{pub}= 0,033 mSv/year.

Conclusions on the estimate total dose received by the Head of the hospital's Drug Store:

The Head of the hospital's Drug Store, is exposed to a dose rate higher than that received by the operator of the equipment in the control panel, which is explained by the fact that his job is located at a shorter distance from the source than the operator's work station, and both are located in the area covered by the primary barrier of the teletherapy equipment with Co-60 Source.

The fact that the dose rate received by this member of the public is higher than that received by the operator in the control panel does not mean that this is not acceptable since in order to assess this, acceptance criteria established in this safety assessment must be taken into account.

3.2.2. Dose estimates in accident situation.

- 3.2.2.1. Dose received by the Occupationally Exposed Personal involved in the accident.
 - Unit Operator "A".
 - a) This operator is exposed first to the primary beam, stays during 1 min at a distance of 2 m, so the dose received is estimated as follows:

$$DHp = DTTo (d_0^2/d^2),$$

D_{Hp}: dose rate received from the primary beam.

D_{TTo}: dose rate at the isocentre of the unit.

*d*_o: distance from the source to the isocentre of the unit.

d: distance from the source to the exposed person.

Substituting the data into the previous equation we obtain:

DHp=22.56 Gy/h

Dpri = 752 mSv.

- Unit Operator "B"
 - b) This operator is then exposed to the leakage radiation as it is outside the primary beam and when the patient is not in the equipment we may neglect their exposure to the dispersed radiation, stays during 2,5 min at a distance of 1 m. Therefore the dose received is estimated as follows:

$$D_{f} = \frac{10^{-3} D}{d_{f}^{2}}$$

D: dose rate at the isocentre of the unit.

dr: distance from the source to the exposed person.

Substituting the data into the previous equation we obtain:

 $D_{\rm f} = 0.141 \; Gy/h$

Dsec = 5.875 mSv.

- *c)* Conclusions on the estimation of total dose received by technologists in accident situations.
 - The dose received by Unit Operator "A", when exposed to the primary beam is high and is comparable with the doses that cause deterministic effects. For the first technologist, the dose received will be determined by the dose of the treatment session, 2 Gy, on average, to the region to be irradiated. Of course, these absorbed dose values can produce tissue reactions (see Table 6 taken from ICRP 103) and should be considered separately from the stochastic effects.

Tissue and effect	Total Dose Threshold received in a single brief exposure (Gy)	
Testicles		
Temporary sterility	0.15	
Permanent sterility	3.5-6	
Ovaries		
Sterility	2.5-6	
Lenses		
Detectable Opacity	0.5-2	
Visual impairment (Cataracts)	5	
Bone marrow		
Hematopoiesis depression	0.5	

Table No 6. Dose thresholds for certain effects.

• The dose received by Unit Operator "B" is relatively low and demonstrates the importance of using these results in the development of emergency procedures.

3.3.- Risk Calculations

- 3.3.1. The selection of the accident initiating events list has been made by adapting the Event List Recommended initiators for the practice of Telecobalttherapy in IAEA's TECDOC 1685 by using the SEVRRA3.0 software (See Annex 1). The list of events analyzed included 132 events distributed along the different stages of the treatment process.
- 3.3.2. All selected events have been evaluated to estimate the applicable frequency level considering the following levels:

High: The initiating event occurs frequently, more than 50 events /year.

Medium: The initiating event occurs occasionally, greater or equal than 1 and equal or less than 50 events/year.

Low: Unusual or rare occurrence of the initiating event, less than 1 event/year and greater or equal than 5 events per 100 years.

Very Low: It is very rare that the initiating event occurs, less than 5 events per

100 years. There is no information the event ever occurred

3.3.3. Each event analyzed has been evaluated to accept the level of consequences proposed in SEVRRA 3.0. Consequences have been classified with the following levels:

Very high: Death or disability damage to various patients (systematic exposure). It is assumed that the magnitude of error in the dose is higher than 25%, regardless the prescribed dose.

High: Death or disability damage to one patient affected by the whole or a great part of the treatment (programmatic exposure) (the magnitude of error in the dose is higher than the prescribed dose). It also includes those expositions that affect multiple patients with dose errors between 10% and 25%, regardless the prescribed dose.

Medium: There is no health risk for the patient. Only one of the patients treated is exposed during the session.

Low: No effects whatsoever are produced on the patients. The level of defenses has decreased.

- 3.3.4. Each initiating event considered has been analyzed to identify the applicable defenses according to the principle of defense in depth. In each event, the Barriers and Reducers (Frequency and Consequences) were identified. Each of the initiating Events considered has been analyzed to identify the applicable defenses according to the principle of defense in depth. In each event, the Barriers and Reducers (Frequency and Consequences) were identified. Based on the quantity and quality of the existing defenses, SEVRRA evaluates the variables of the risk equation and assigns the Risk Level corresponding to each accidental sequence.
- 3.3.5. Risk Analysis Conclusions.

Annex 1 shows the risk profile of this radiotherapy service.

- None of the total 132 Initiating Events analyzed was evaluated with the Very High Risk (RMA) level. It was found that 42 initiating events were evaluated with High Risk (RA) level. The rest of the initiating events were evaluated with levels of Medium Risk and Low Risk.
- Annex 1 (Table 3.4) shows the events evaluated with "High Risk" and the barriers and reducers that could be implemented to reduce their level of risk.
- Stage 5 "Development of treatment plan" is where we can see the highest

number of initiating events with "High Risk" for which it will be necessary to review and upgrade the existing working procedures for this stage.

 Annex 1 (Table 3.5) shows the defenses that do not exist in the radiotherapy service with higher impact on the reduction of the risk profile since the same defense applies for several of the initiator events analyzed. Taking this result into account, we must first implement those that have higher impact in the reduction of this risk profile. As shown below:

Code	Barrier or Reducer	Robustness	Percentage
			of
			Impacted
			Initiating
			Events
B-243	Participation of the radiation oncologist, medical	Normal	50.0%
	physicist and radiotherapy technologists, in patient		
	positioning and immobilization for initial treatment		
	session		
B-229	Portal image taken during initial treatment session for	Normal	47.6%
	evaluation by the radiation oncologist and the medical		
	physicist, by which geometric treatment errors can be		
	detected.		
B-227	Joint treatment plan evaluation by the radiation	Normal	33.3%
	oncologist, the medical physicist and the radiotherapy		
	technologists		
FR-	Moderate workload	Normal	81.0%
304			
B-277	Redundant verification of the records by another	Normal	4.8%
	medical physicist		
CR-	At the weekly medical evaluation of the patient, errors	Normal	95.2%
377	in treatment delivery can be detected		
CR-	Weekly portal image wherewith geometric errors can	Normal	42.9%
350	be detected		

3.4.- Evaluation of results (uncertainty analysis).

The results of the safety analysis performed in point 3 have associated the uncertainties inherent to the methodologies and data used. These uncertainties are widely known because they are widely recognized internationally.

Uncertainties have been applied under conservative precepts and considering the worst scenarios in such a way that if the results are accepted when comparing them with the evaluation criteria it indicates that these uncertainties do not negatively influence the safety of the practice.

EXERCISES PART 3.- SAFETY ANALYSIS

These exercises cover the third block of presentations



DOSE CALCULATIONS

Using the information provided in part 3 and with the support of the presentations about dose calculations, solve the following exercises:

EXERCISE PART 3 #1 Fill the following table taking into account the job positions that are more exposed to ionizing radiation during the execution of their duties:

No.	Job position	Duties	Dose
1.	Radiotherapist	Prescription of treatments	NO
		Obtaining CT images for planning	
		Starting treatment	
		Follow-up of the patient under	
		treatment	
2.	Medical Physicist	Cobalt Unit calibration	
		Quality control	
		Treatment Planning	
		Starting treatment	
3.	Unit Operator	Starting treatment	
		Positioning of patients	
		Delivering the daily treatment	
		from the Control Panel of the	
		Cobalt unit	

EXERCISE PART 3 #2 Estimate the dose received, in normal operating conditions, for the position of the Cobalt Unit Operator in order to demonstrate that this worker does not exceed the restrictions and dose limits established:

- a) in the Control Panel
- b) during the positioning of the patient
- c) total dose

EXERCISE PART 3 #3 Fill the following table for the members of the public potentially exposed.

No.	Job position	Work Area Location	Dose
1.	Responsible for the	Office located at a	
	Hospital's Drug Store	distance of 0.3 meters	
		from the bunker wall	
		(Point 2).	
2.	Hospital personnel traveling	External corridor cloce to	
	at a distance of 0.5 meters	the radiotherapy service	
	from the wall, Through the	(Point 3)	
	corridor (Point 3)		
3.	Members of the public	Parking outside the	
	walking through the parking	Hospital (Point 4)	
	area, 3.5 meters from the		
	outer wall of the radiotherapy		
	service (Point 4)		

EXERCISE PART 3 #4 Estimate the dose received by the Head of the hospital's Drug Store in normal operating conditions.

RISK CALCULATIONS

Using the information provided in part 3 and with the support of the presentations about risk analysis and SEVRRA software, practice with the following exercises:

EXERCISE PART 3 #5: Using SEVRRA software, analyze the events on the following stages:

- a) Commissioning of the Co-60 Unit
- b) Treatment planning

EXERCISE PART 3 #6: Analyze the results generated by SEVRRA after the assessment of the reference installation (Annex 1)

PART 4.- ANALYSIS OF ASSESSMENT RESULTS

4.1.- Comparison with assessment criteria.

- The total annual dose received by the Unit Operator from the Cobalt Unit is well below the dose limit (20 mSv / year as an average) established in the current national regulations and recommended in the GSR part 3. This annual dose is, in turn, also lower than the dose restriction established at the Hospital (10 mSv / year).
- The total annual dose received by the member of the public in the worst conditions (from the point of view of radiation protection) is less than the dose limit (1 mSv / year) established in the current national regulations and recommended in the GSR part 3. This annual dose is, in turn, also lower than the dose restriction established at the Hospital (0.5 mSv / year).
- There are 42 accidental sequences evaluated with the "High Risk" level, risk unacceptable in the long term in accordance with the criteria established in the IAEA-TECDOC 1685. It will be necessary to implement a plan of measures to reduce the risk (at least until "Medium Risk" level) for these 42 accidental sequences.

4.2.- Analysis and revision (if it is needed) of safety measures and engineering.

To reduce the risk of accidental "High Risk" sequences, considered unacceptable, it is proposed to implement the following safety measures.

Code	Barrier or Reducer	Robustness	Percentage of Impacted Initiating Events
B-221	Weekly patient evaluation by the radiation oncologist	Soft	2.4%
B-222	When performing commissioning tests, the air kerma rate is measured at 1m distance and compared with the value reported by the source manufacturer on the certificate. The measurement can be made in terms of absorbed dose to water and this value can be correlated with the air kerma values reported on the certificate	Normal	2.4%
B-227	Joint treatment plan evaluation by the radiation oncologist, the medical physicist and the radiotherapy technologists	Normal	33.3%
B-228	Joint treatment plan evaluation by the radiation oncologist, the medical physicist and the radiotherapy technologists. This includes the new plan upon prescribing a modification	Normal	2.4%
B-229	Portal image taken during initial treatment session for evaluation by the radiation oncologist and the medical physicist, by which geometric treatment errors can be detected	Normal	47.6%
B-243	Participation of the radiation oncologist, medical physicist and radiotherapy technologists, in patient positioning and immobilization for initial treatment session	Normal	50.0%
B-244	Participation of the radiation oncologist, medical physicist and radiotherapy technologists in patient positioning and immobilization for initial treatment session	Normal	2.4%
B-277	Redundant verification of the records by another medical physicist	Normal	4.8%
FR-284	Training of the dosimetrist and the medical physicist	Soft	2.4%
FR-304	Moderate workload	Normal	81.0%
CR-332	Annual external audit	Soft	2.4%
CR-336	Annual external audit. Auditing procedure. Test for dose rate measurement at points around the irradiation head	Soft	2.4%
CR-339	Annual external audit. Review of the generated tables based on commissioning tests	Soft	2.4%
CR-345	Verification of congruence of light fields against patient skin marks	Normal	2.4%
CR-350	Weekly portal image wherewith geometric errors can be detected	Normal	42.9%
CR-357	Daily patient setup wherein the radiotherapy technologists can detect errors of geometry or dose by observing visual signs on the patient (skin reddening, etc.)	Normal	2.4%
CR-377	At the weekly medical evaluation of the patient, errors in treatment delivery can be detected	Normal	95.2%

EXERCISES PART 4.- ANALYSIS OF ASSESSMENT RESULTS

These exercises cover last block of presentations



EXERCISE PART 4 #1: Use the result of dose calculations in exercises "part3 #1 and #2" and compare these results with the assessment criteria defined in paragraph 1.4 "Assessment criteria".

EXERCISE PART 4 #2: Use the results of risk calculations with SEVRRA software (Annex1), assess these results and propose measures to reduce the risk of accidental "High Risk" sequences.