

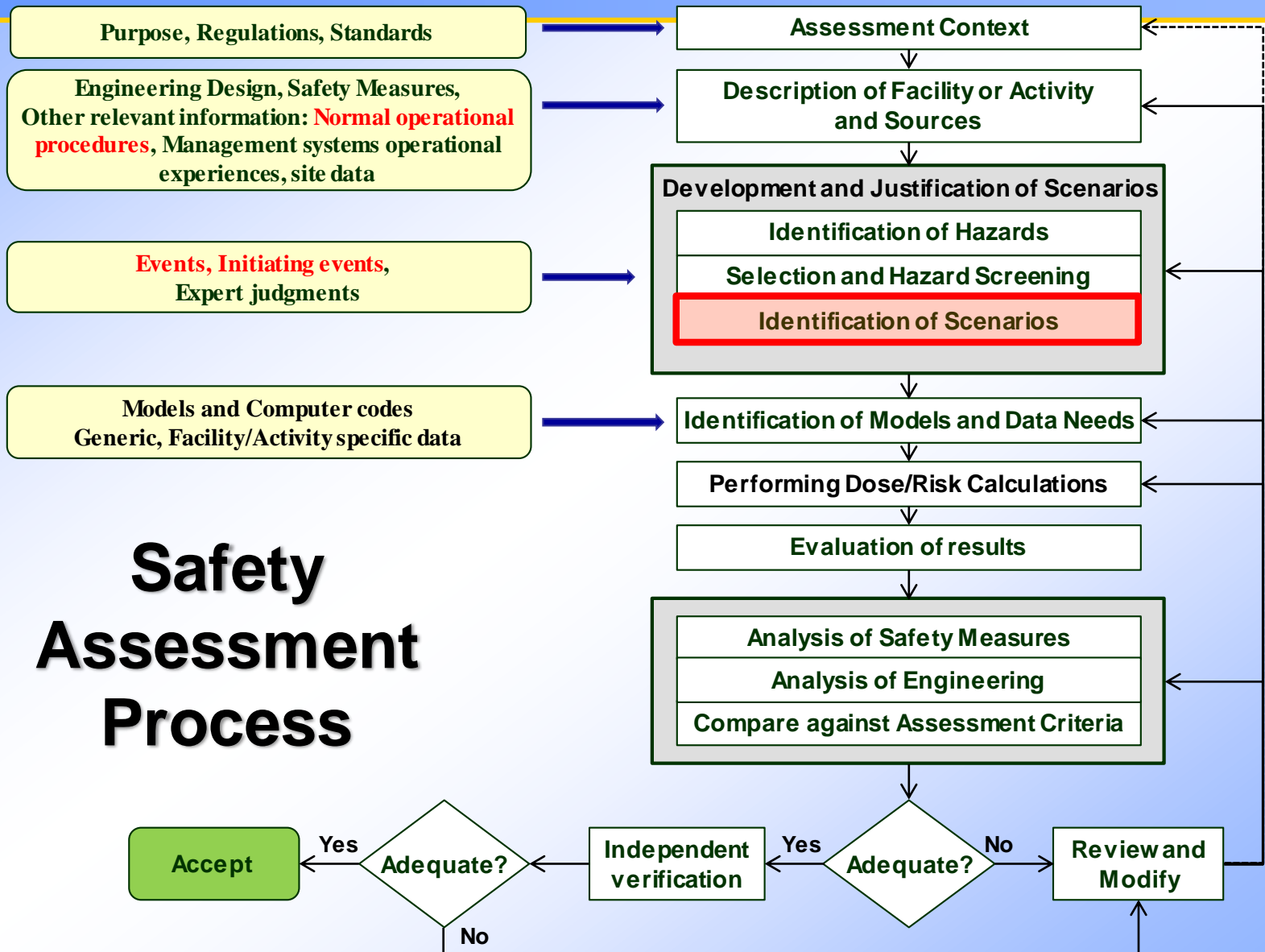


## ***L07. – Identification of scenarios***

***International Atomic Energy Agency***



# Focus of this lecture





# Outline of the lecture

- Identification of scenarios for normal operation
  - Specified operational procedures, limits and conditions
  - Example of scenarios (workers, members of public)
- Identification of scenarios for anticipated operational occurrences, and incidents and accidents
  - Initiating events, identification, grouping
  - Strategy for the selection of initiating events
  - Failure Modes and Effects Analysis (FMEA) and other methods of identifying initiating events
  - Example of scenarios (workers, members of public)



# Objectives

Highlight the importance in a safety assessment of

- 1) identifying and selecting scenarios for normal operation based on the range of conditions under which the facility may operate;
- 2) the identification of initiating events relevant for anticipated operational occurrences and accident conditions

Understand:

- *Scenarios for normal operation*
- *Definition of initiating events.*
- *Strategy for the selection of accident initiating events.*
- *Criteria for grouping and ungrouping the initiating events.*
- *Basic elements of the Failure Modes and Effects Analysis (FMEA) and HAZOP (Hazard and Operability study) methods for identifying initiating events.*



# Identification of scenarios for Normal operation



# Identification of scenarios for Normal operation

**Normal operation may be defined as:**

*'operating the facility, or conducting the activity, within specified operational limits and conditions'*

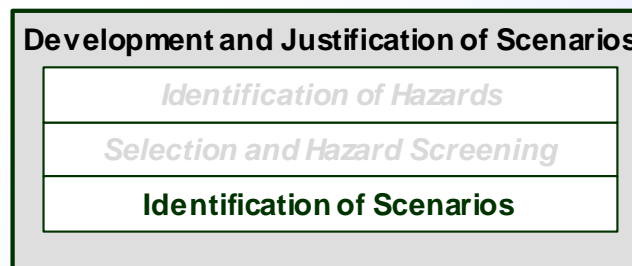
**Scenarios for normal operation should address:**

- All conditions under which the systems and equipment of the facility are being operated, or activity is conducted, as expected, with no internal or external challenges.
- Normal operation conditions includes all the phases of operation for which the facility is designed to operate (including start up and shutdown where appropriate) and maintenance over the considered time frame.
- The effects of variations in the input materials (feedstock, source material, receipts, etc.) on normal operations should be considered.
- If applicable, the planned and controlled release of radioactive material to the environment, as a legitimate practice, within limits authorized by the regulatory body



# Identification of scenarios for Normal operation

- Scenarios for normal operation should be defined with the goal to assess whether the activity can be carried out safely or the facility operated safely under normal operation.
- This includes assessment of whether radiation doses to workers and members of the public and planned discharges will be within prescribed limits and constraints and will be maintained as low as reasonably achievable.
- Identification, selection and screening of hazards do not explicitly need to be included. However, aspects such as considering the performance of each process during normal operation and considering all potential exposure pathways are common for the scenario identifications for both normal operation and for anticipated operational occurrences and accidents





# Example of scenarios for Normal operation

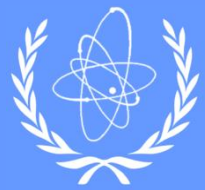
## Activity: radiotherapy treatment with sodium iodine-131

### Scenario 1 – Exposure to workers

- Dose to hospital personnel before, during and after treatment of a patient:
  - When preparing the radioiodine
  - When administrating the radioiodine to the patient
  - When having contact with the patient after the treatment





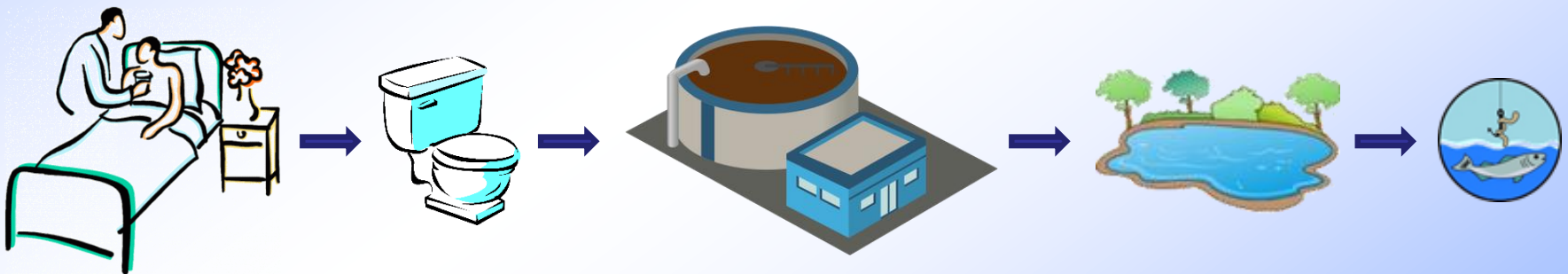


# Example of scenarios for Normal operation

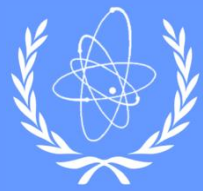
## Activity: radiotherapy treatment with sodium iodine-131

### Scenario 2 – Exposure to members of the public

- During the first 24 hours following treatment approximately 60 % of administered iodine activity is excreted, mostly via urine
- Example of exposure pathways for the scenario:
  - Excretion from patient via urine → public sewage system → effluent and sludge treatment at sewage plant → discharge of water to a lake



- Assessment endpoints for the scenario:
  - Doses to sewage plant workers, doses from ingestion of drinking water and fish



# Identification of scenarios for anticipated occurrences and accidents



## Definitions of Key Terms

### **Anticipated operational occurrence**

A deviation of an operational process from normal operation that is expected to occur at least once during the operating lifetime of a facility but which, in view of appropriate design provisions, does not cause any significant damage to items important to safety or lead to accident conditions.

### **Accident conditions**

Deviations from normal operation that are less frequent and more severe than anticipated operational occurrences.



## Definitions of Key Terms

### **Initiating event**

An identified event that leads to anticipated operational occurrences or accident conditions.

### **Postulated initiating event (PIE)**

A postulated event identified in design as capable of leading to anticipated operational occurrences or accident conditions.



# Initiating events

## Initiating events

- All human errors, equipment failures and external events that can lead (potentially cause) to operational incidents and accident conditions.
- The primary causes of initiating events may be credible equipment failures, operator errors (human errors) and external human induced or natural events.



# Initiating events

*Identification of postulated initiating events (PIEs) and their evolution should be carried out using appropriate techniques and information on the:*

- ✓ *Site;*
- ✓ *Design and operation of facility or*
- ✓ *Operational experience;*
- ✓ *Feedback from other facilities or activities.*

**Postulated Initiating Events (PIE's) :**

- *natural event (external),*
- *human induced outside the facility or the site*
- *human induced inside the facility or the site*





# Initiating events

## External initiating events.

- **Natural events:** adverse meteorological conditions (e.g. wind, snow, rain, ice, temperature, flood, lightning), earthquakes, biological intrusion;
- **Human induced events:** aircraft crashes (with or without subsequent fires), explosions, fires, loss of electrical power or other services, unauthorized access.



# Initiating events

## Internal initiating events at the facility or the site;

- ✓ *Fire, explosion, structural collapse, leakages or spillages, failures of ventilation, drop of heavy loads, failures of protective measures.*

## Human induced initiating events;

- ✓ *Operator errors and violations, misidentifications performing incompatible activities.*





# Identifying initiating events

**Two types of mutually exclusive events should be distinguished** when analyzing the effects or consequences associated with each failure mode or human error:

1. Events that trigger an incident and require a response from the defence in depth.
2. Events from faults of the defence in depth in response to breakdowns. **These do not create problems for themselves. If no initiators occur, they play no role.** Only if a previous event that demand its action occurs, the outcome of this event is noticeable.

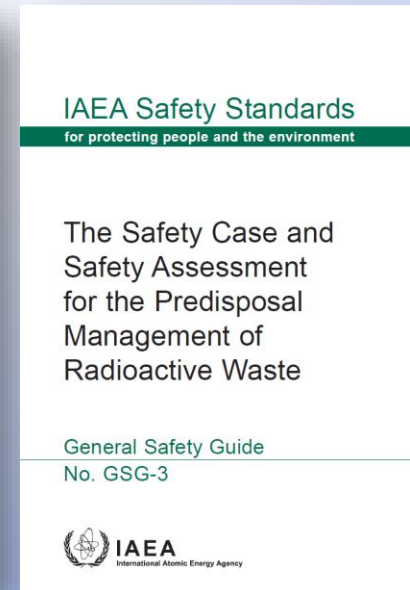
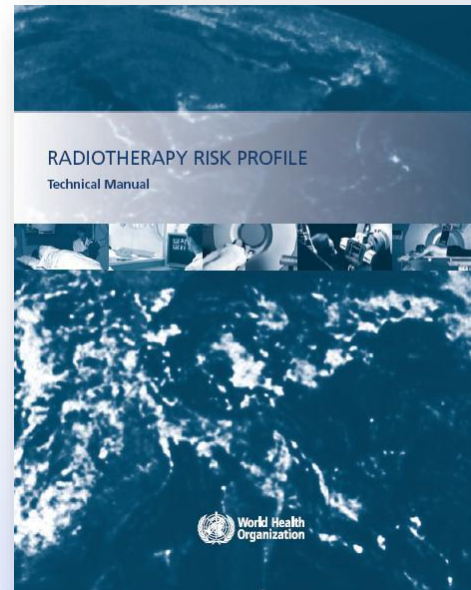


# Identifying initiating events

Only failure modes or human errors of the **first group of events** should be selected to define the list of **Initiating Events**.

The second group of events will form part of the accidental sequence. These events are considered as part of the likelihood of defence failures.

The use of some publications presenting generic lists of initiating events can be useful to properly formulate the selection.





# Frequency of initiating events

**The identification of initiating events should be complemented by an assessment of the frequency of each identified event.**

- If the identified incident is extremely rare (very rare), it can be excluded from the assessment since it hardly will occur.
- If the identified event is very frequent, it should be considered even if its consequences are not very serious.



# Grouping initiating events

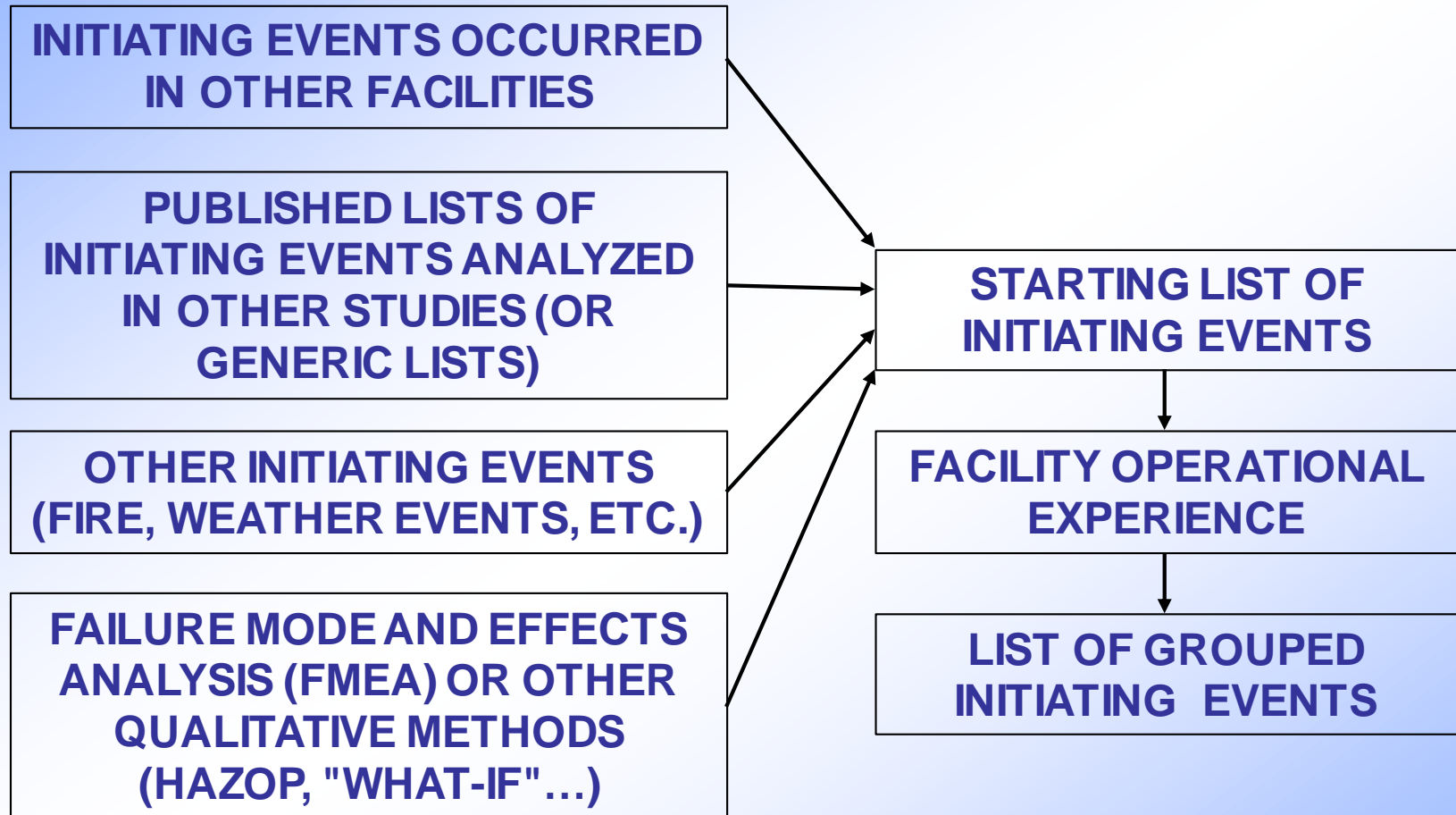
Although failure modes and human errors selected directly from FMEA are initiating events of the accident, the **number of events is often unmanageable.**

In these cases, **initiators could be grouped** according to the following criteria:

- Initiating events with the same safety layers;
- Initiating events that can lead to the same accidental exposure consequences;
- Initiating events that can be grouped under the same definition and have a similar frequency of occurrence.

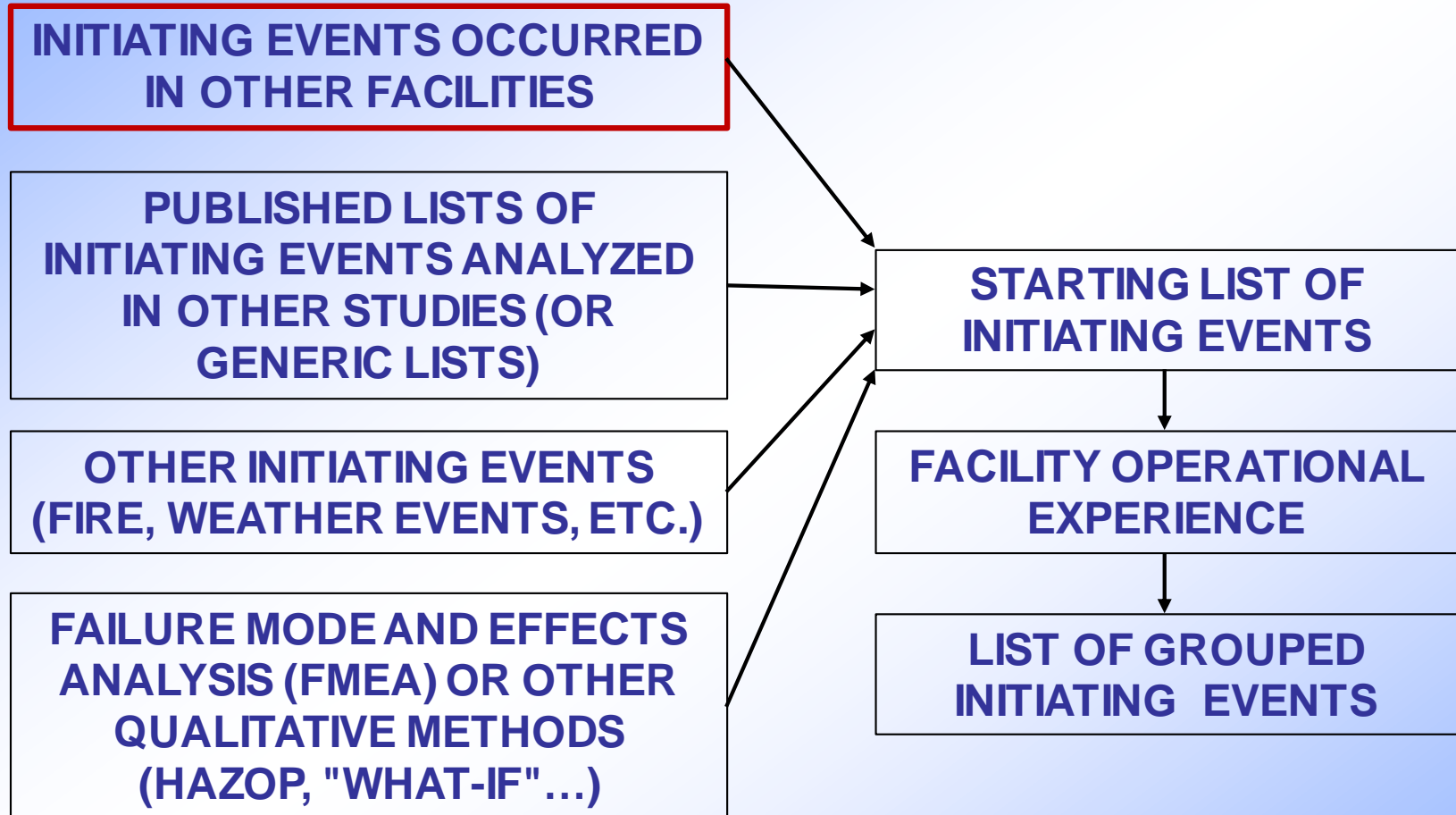


# Strategy for selecting the initiating events





# Strategy for selecting the initiating events





# Initiating events occurred in other facilities

Literature search for accident reports in similar facilities or activities performing the same practice

## INVESTIGATION OF AN ACCIDENTAL EXPOSURE OF RADIOTHERAPY PATIENTS IN PANAMA

Report of a Team of Experts, 26 May–1 June 2001

 INTERNATIONAL ATOMIC ENERGY AGENCY

## Accidental Overexposure of Radiotherapy Patients in Białystok



 IAEA  
International Atomic Energy Agency

## Accidental Overexposure of Radiotherapy Patients in San José, Costa Rica



INTERNATIONAL ATOMIC ENERGY AGENCY

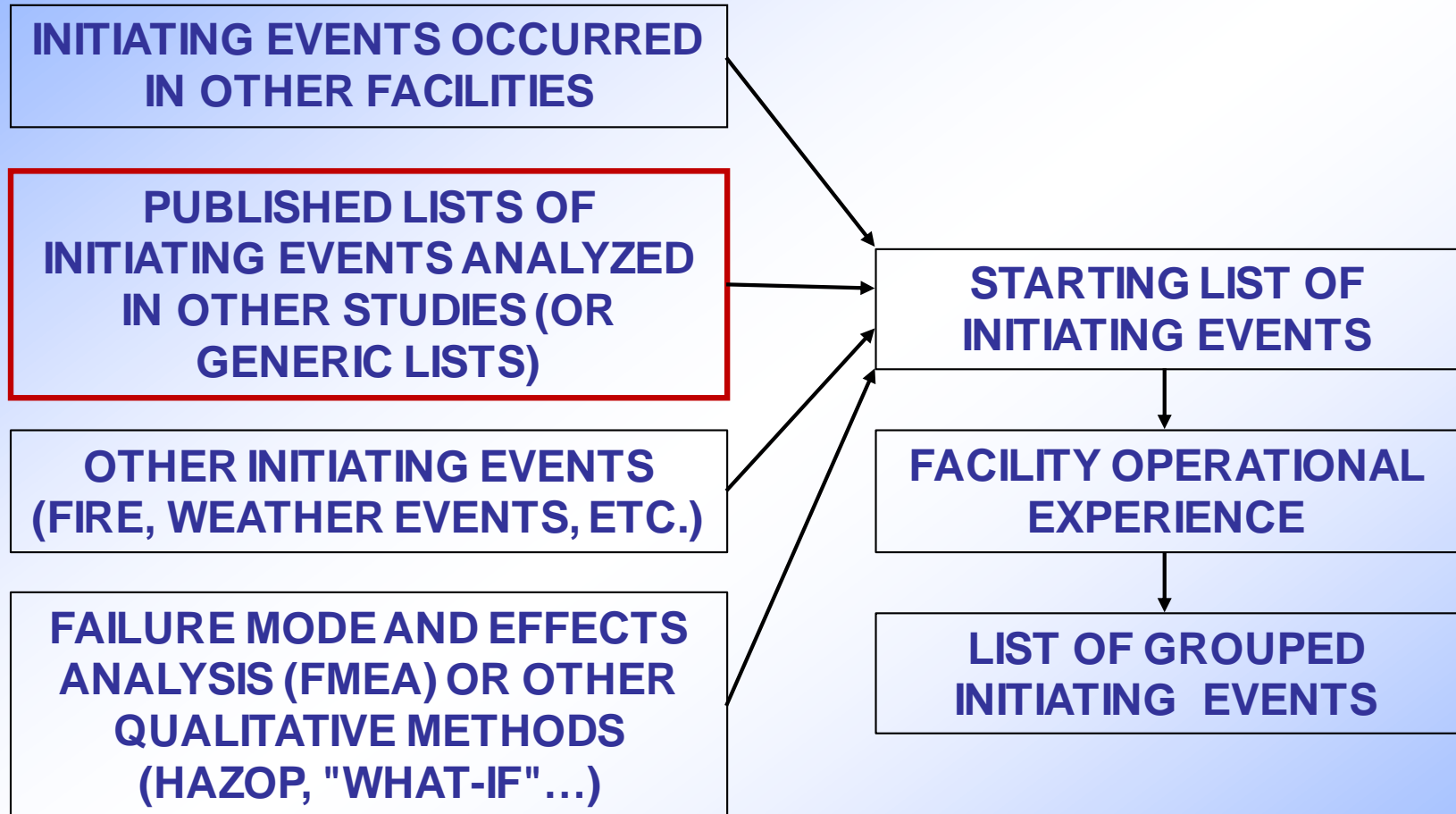
## Safety Reports Series No. 17



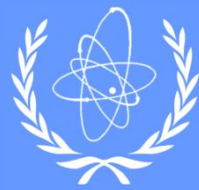
LESSONS LEARNED FROM ACCIDENTAL EXPOSURES IN RADIOTHERAPY



# Strategy for selecting the initiating events





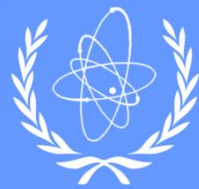


# Published lists of Initiating Events

## **Published lists of Initiating Events analyzed in other studies, generic lists**

Searching bibliographic information about safety assessments in similar facilities to find 'generic lists of initiating events' that may apply total or partially to our facility.

A generic list is one that has been developed on the basis of a structured, systematic and detailed analysis of the equipment and processes assessed.



# Published lists of Initiating Events

## Example of a list of Initiating Events

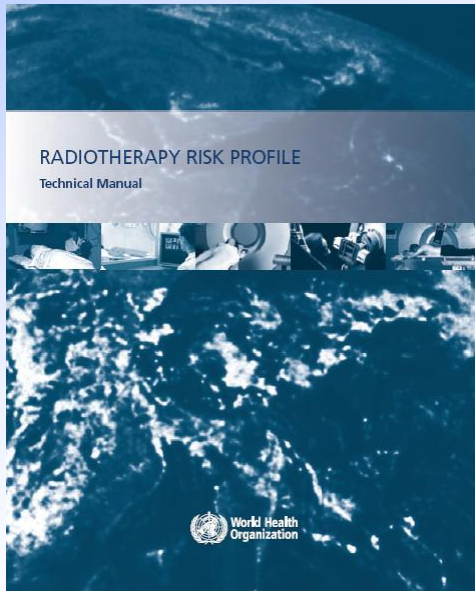
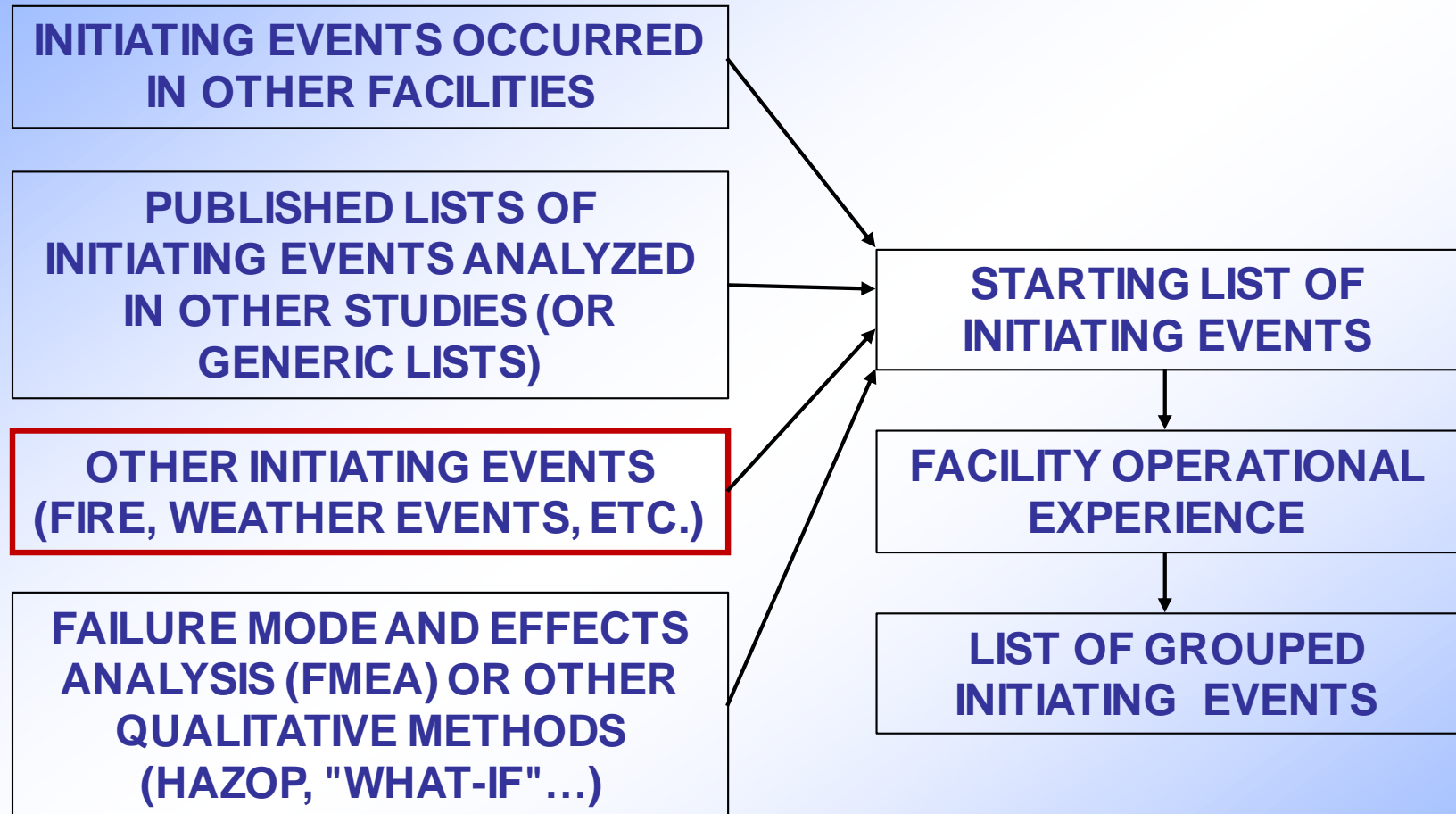


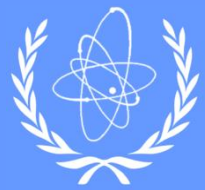
Table 6: The top three interventions

Solution	Stage	Risk
Planning protocol checklist	Positioning & immobilization	Incorrect patient positioning Different positioning for different imaging modalities Incorrect immobilization position Wrongly applied immobilization device Inaccurate transfer of prescription
	Simulation, imaging & volume determination	Incorrect imaging protocol Incorrect area imaged Wrong side/site imaged Altered patient position Incorrect orientation information
	Planning	Incorrect treatment modalities and beam positioning Incorrect beam energy Incorrect beam size Incorrect normalizations Lack of consistency on prescription point Incorrect inhomogeneity corrections Incorrect use of bolus in calculation Wrongly sited blocks Poorly constructed blocks Wrong depth dose chart for wrong machine
Independent checking	Treatment information transfer	Incorrect or inadequate data entry on record & verify system No independent check
	Patient setup	Wrong position Wrong immobilization devices Wrong side of body (left/right) Missing Bolus Incorrect isocentre Incorrect use or omission of accessories Incorrect treatment equipment accessories
	Treatment delivery	Incorrect field size and orientation Too many fractions or too few Inadequate checking of treatment parameters
Competency certification	Prescribing treatment protocol	Ad-hoc alterations of prescriptions
	Simulation, imaging & volume determination	Incorrect positioning of reference points and guides Defining wrong volume Incorrect margin applied around tumour volume Incorrect contouring of organs at risk Incorrect image fusion
	Planning	Misuse of planning software Erroneous monitor unit calculation
	Patient setup Treatment delivery	Failure to assess patient's current medical status Poor patient handling and care
	Treatment verification and monitoring	Misinterpretation of portal imaging



# Strategy for selecting the initiating events





# Other Initiating Events

## **Other external Initiating Events: Natural, meteorological or man-induced.**

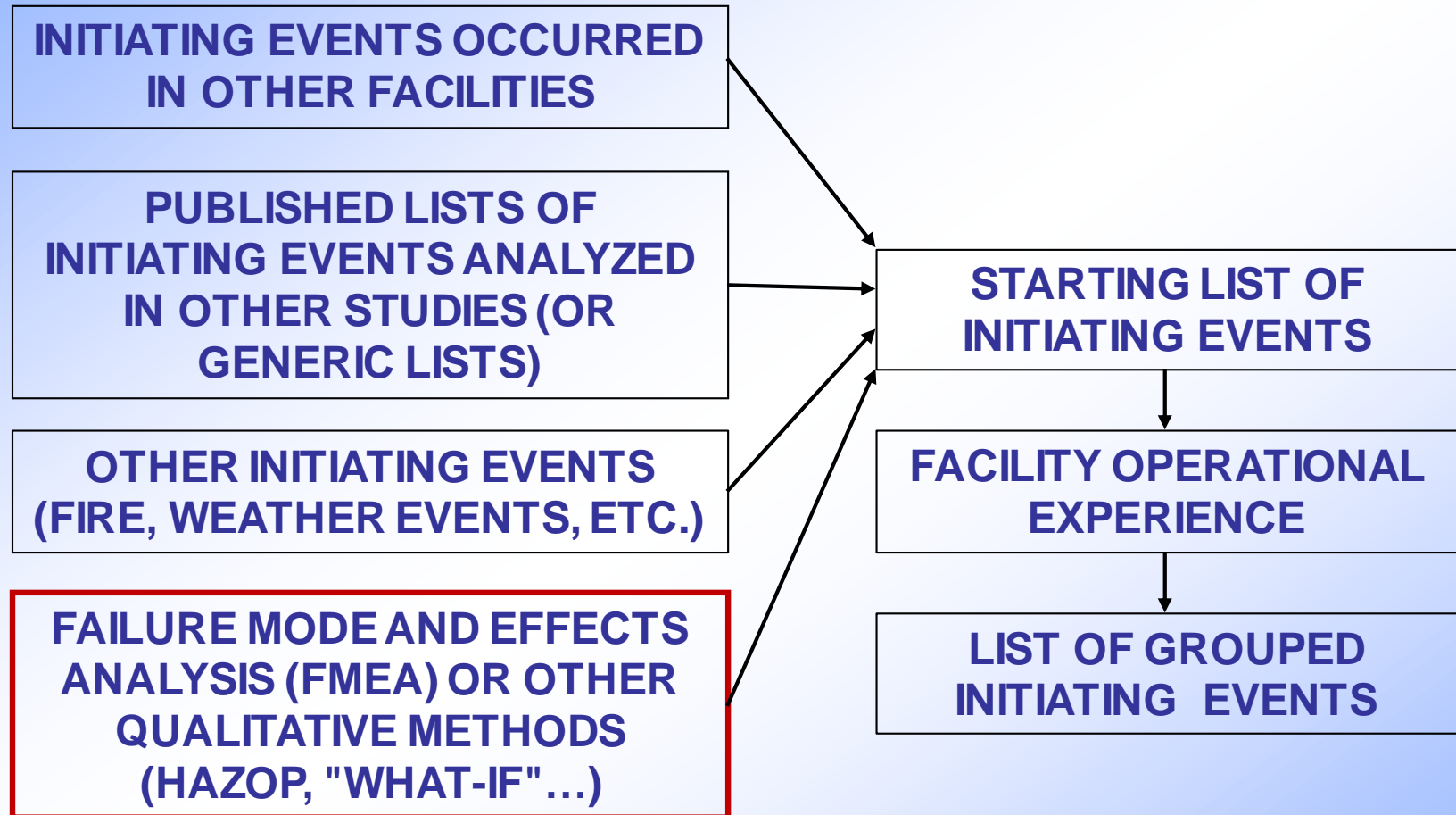
Looking for information about the feasibility of occurrence of natural, meteorological or man-induced events that may affect the safety of the equipment and processes operating in a facility.

In many facilities using radiation sources may be the case that these events will not affect the safety of the practice.





# Strategy for selecting the initiating events





# Strategy for selecting the initiating events

## Apply initiating events identification techniques

Using a technique of identification of initiating events to conform strictly to the particularities of the equipment and processes used in our facility.

This is the most important step in the strategy for selecting the initiating events.

FMEA (failure modes and effects analysis) and HAZOP (hazard and operability study) are examples of techniques that could be applied.





# Strategy for selecting the initiating events

## **FMEA (Failure Modes and Effects Analysis)**

FMEA is a step-by-step systematic approach for identifying and evaluating all potential failures in any design, manufacturing or assembly process, or a product or service.

*Failure modes* means the ways, or modes, in which something might fail.

*Effects analysis* refers to studying the consequences of those failures.

An FMEA is intended to recognize and evaluate the potential failures and its effects, and identify actions which could eliminate or reduce the chance of the potential failure occurring.

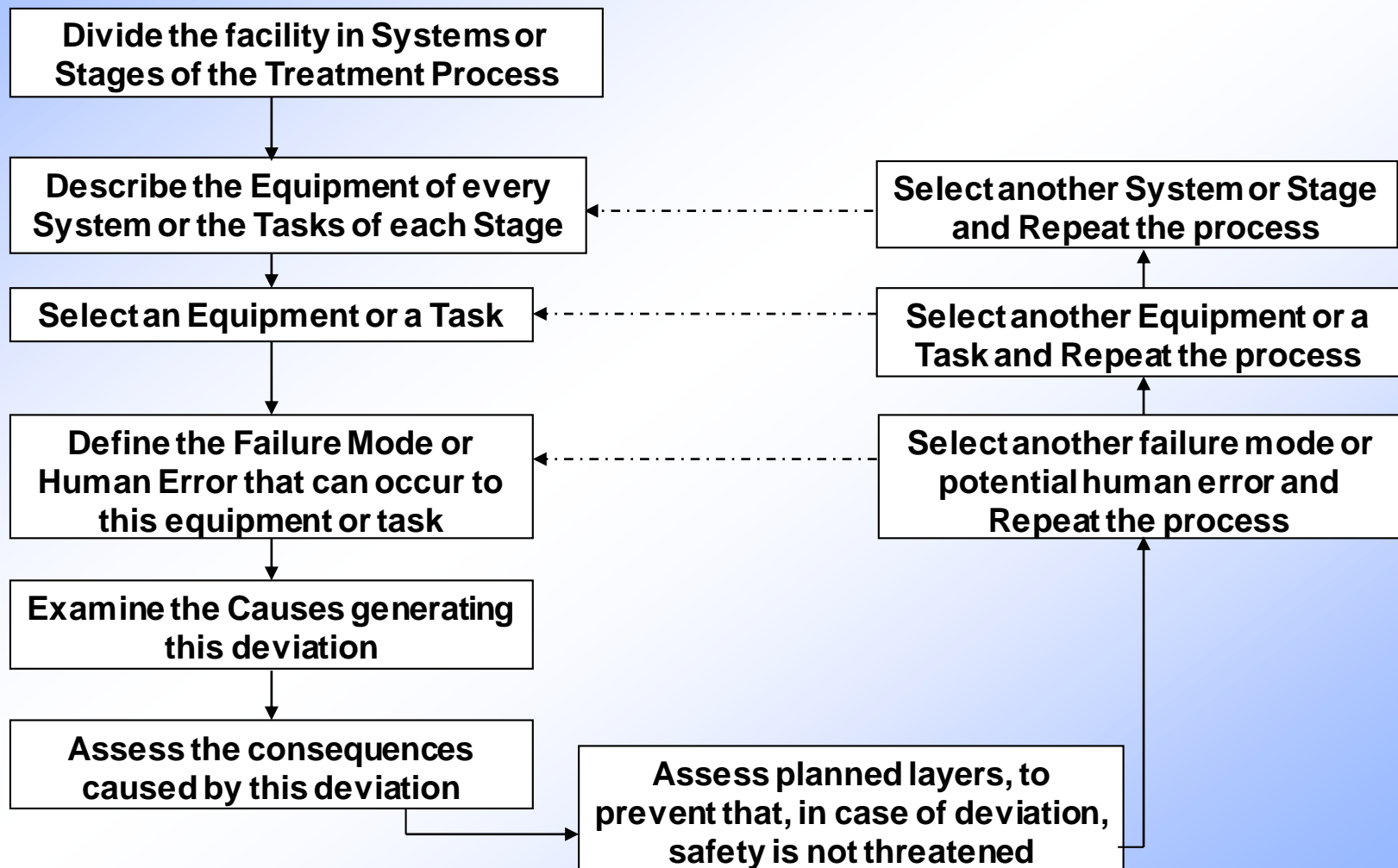
Failures are prioritized according to how serious their consequences are, how frequently they occur and how easily they can be detected.

FEMA also documents current knowledge and actions about the risks of failures, for use in continuous improvement.



# Strategy for selecting the initiating events

## Example of main steps for a FMEA for a facility







# Strategy for selecting the initiating events

## HAZOP (Hazard and Operability study)

The HAZOP study is a structured and systematic examination of a planned or existing process or operation in order to identify and evaluate problems that may represent risks to personnel or equipment, or prevent efficient operation.

The HAZOP study systematically questions every part of a process or operation to discover how deviations from normal operation can occur and whether further protective measures, altered operating procedures or design changes are required.

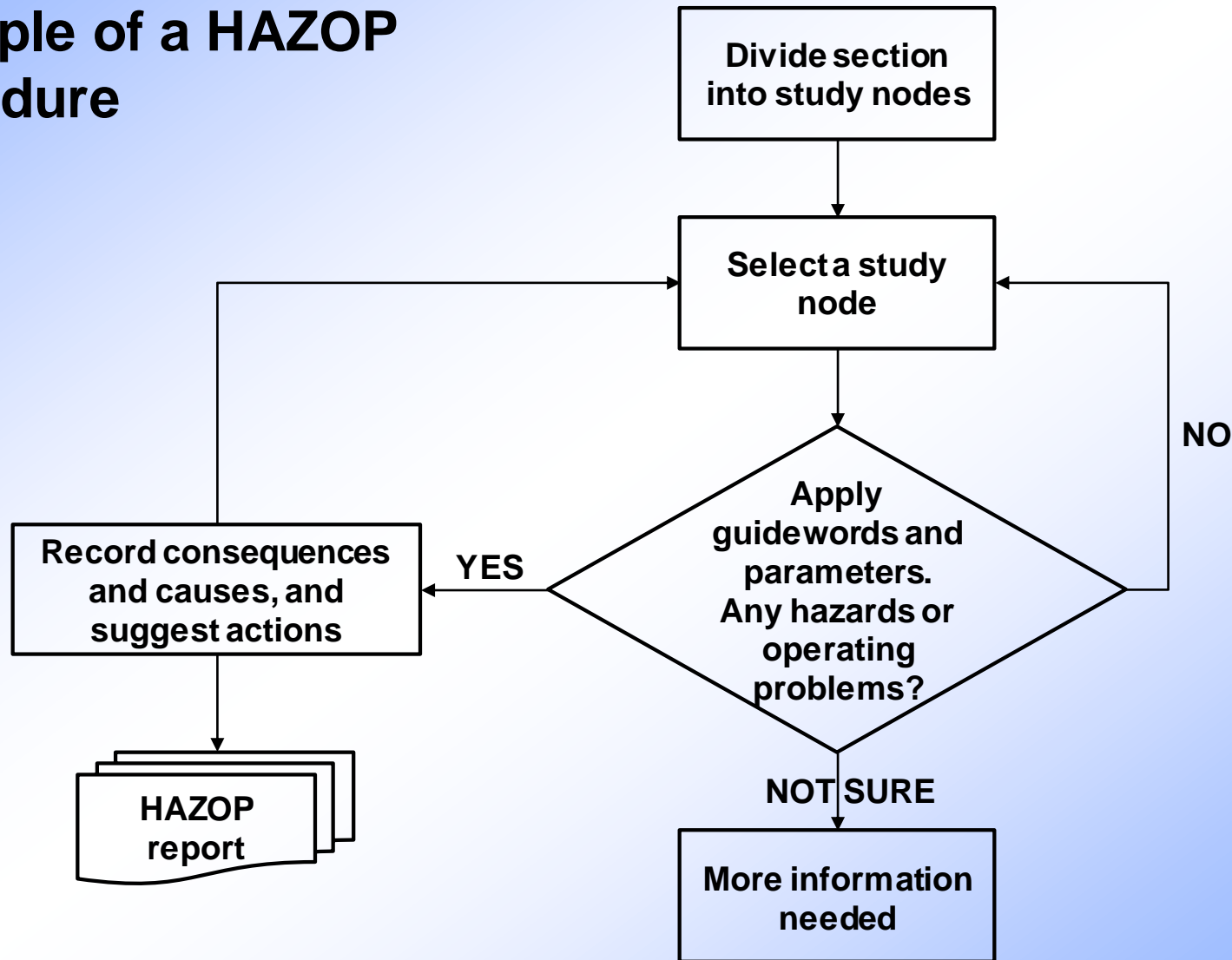
HAZOP is a qualitative technique based on guide-words and is carried out by a multi-disciplinary HAZOP team during a set of meetings.





# Strategy for selecting the initiating events

## Example of a HAZOP procedure





# Example of scenarios for anticipated occurrences and accidents

**Activity: well logging with Cs-137 – transport of well tools**

## **Scenario 1 – Exposure to workers**

- Initiating event:
  - Fire of the vehicle which contains radioactive sources inside
- Dose to workers:
  - External exposure when fighting the fire





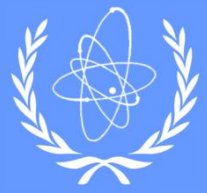
# Example of scenarios for anticipated occurrences and accidents

## Activity: well logging with Cs-137 – calibration of well tools

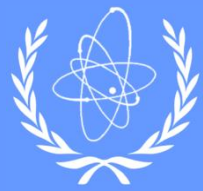
### Scenario 1 – Exposure to members of the public

- Initiating event:
  - Inadvertent entry of individuals to the controlled area during calibrations of well tools
- Dose to members of the public:
  - External exposure to the individuals entering the controlled area



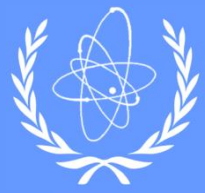


***Thank you!***



# **ADDITIONAL MATERIAL**

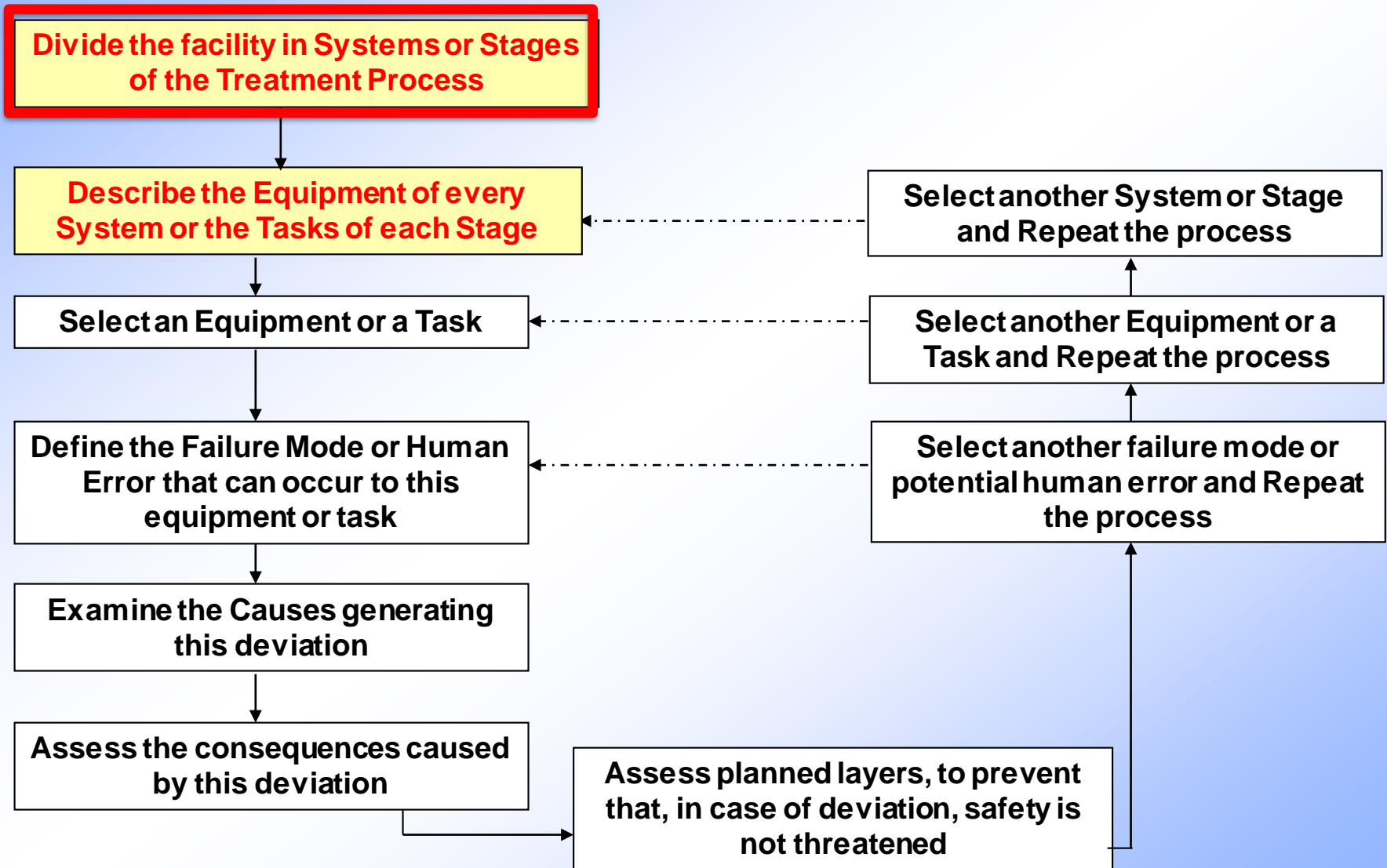
## **1. PERFORMING A FMEA 2 EXERCISE**



# 1. PERFORMING A FMEA



# Main stages for performing a FMEA





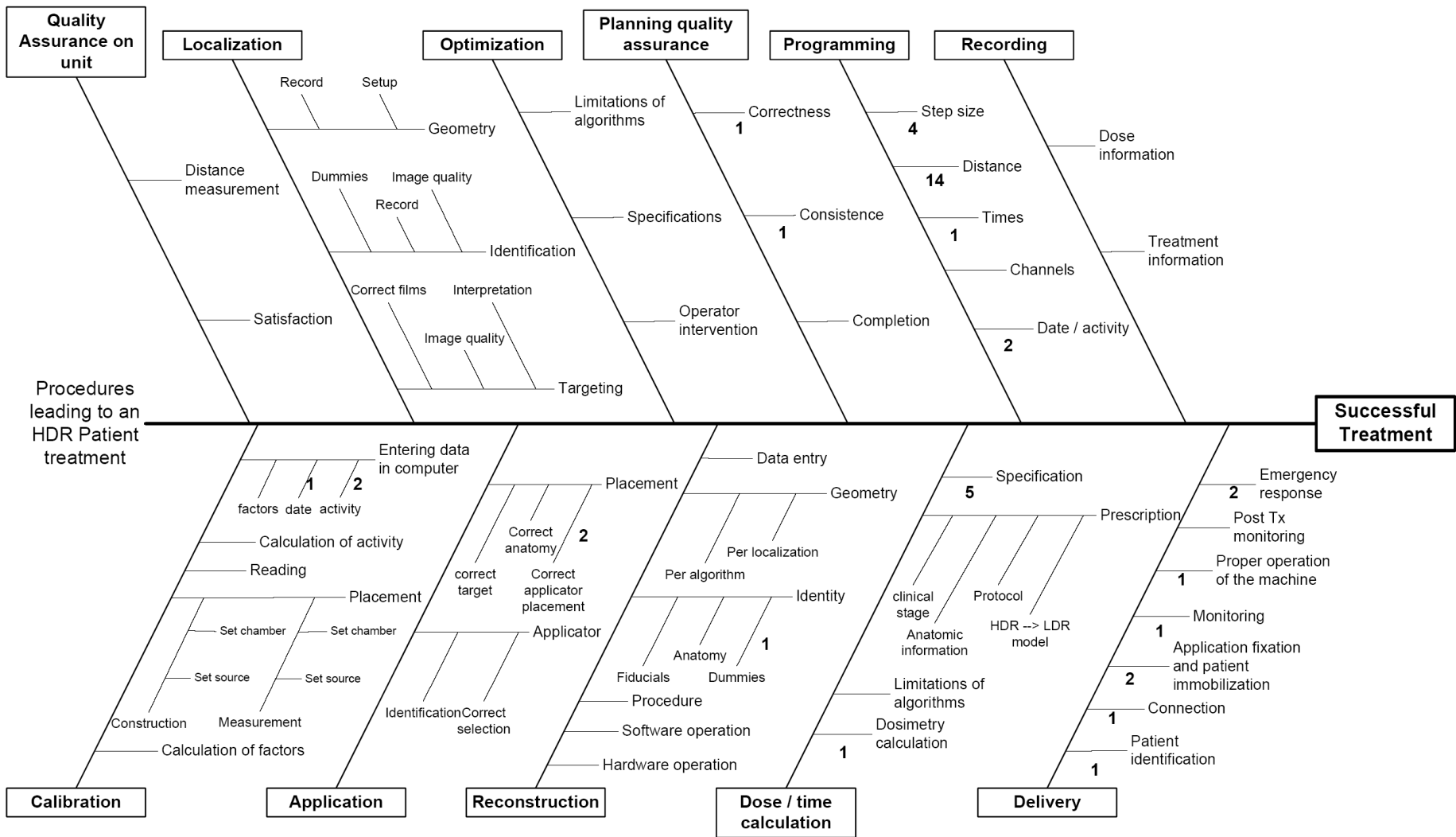


# Divide the facility in Systems or Stages of the Process

- **Objective: Discretize the process** in separate stages. Clearly identify the stages of the treatment process and the tasks associated with each stage, so that it facilitates the analysis of deviations associated with each step.
- It can be done through **Process Trees or Flow Diagrams**.
- Must **illustrate the task flow** and activities that take place within the Stage, **respecting**, wherever possible, **the logical sequence** in which tasks are performed and representing the **interactions between tasks** and other stages of the treatment process.
- Each stage must have a start point and an end point well discernible.



# Example of a Process Tree

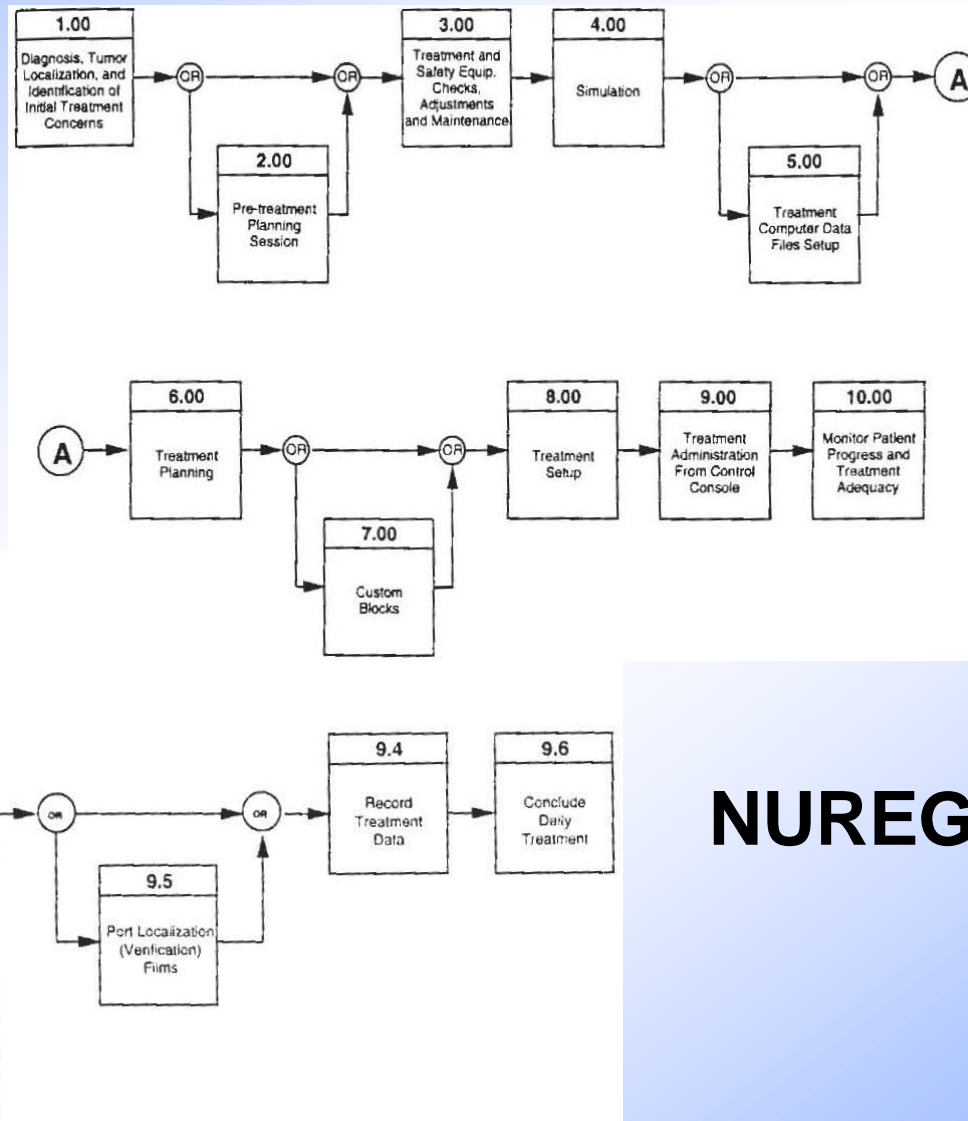


Process tree for brachytherapy

IAEA-TECDOC-1494



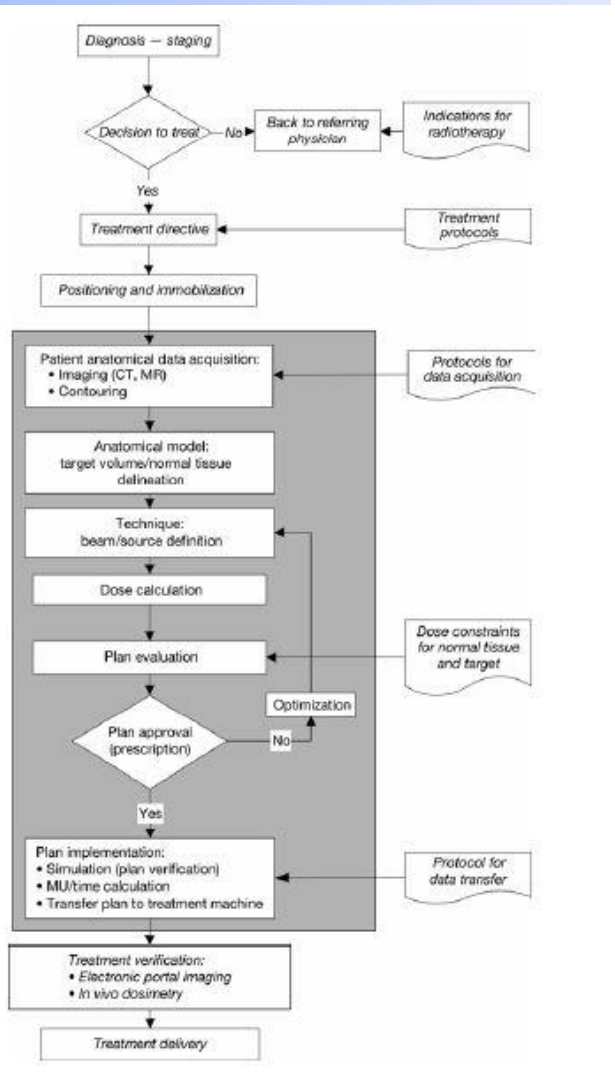
# Example of a Flow Diagram



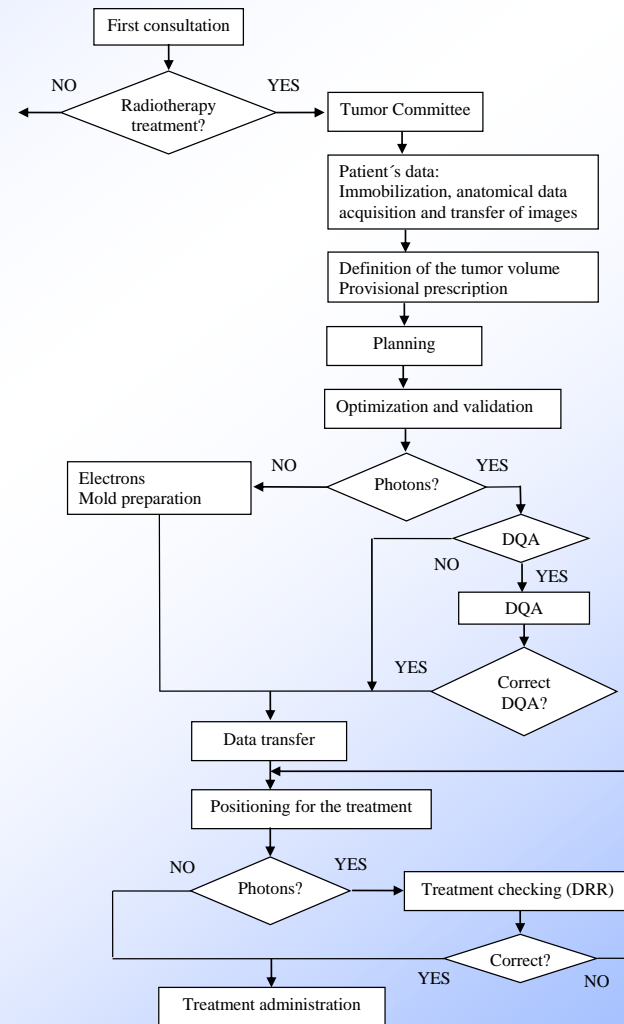
**NUREG/CR 6277**



# Example of Flow Diagrams



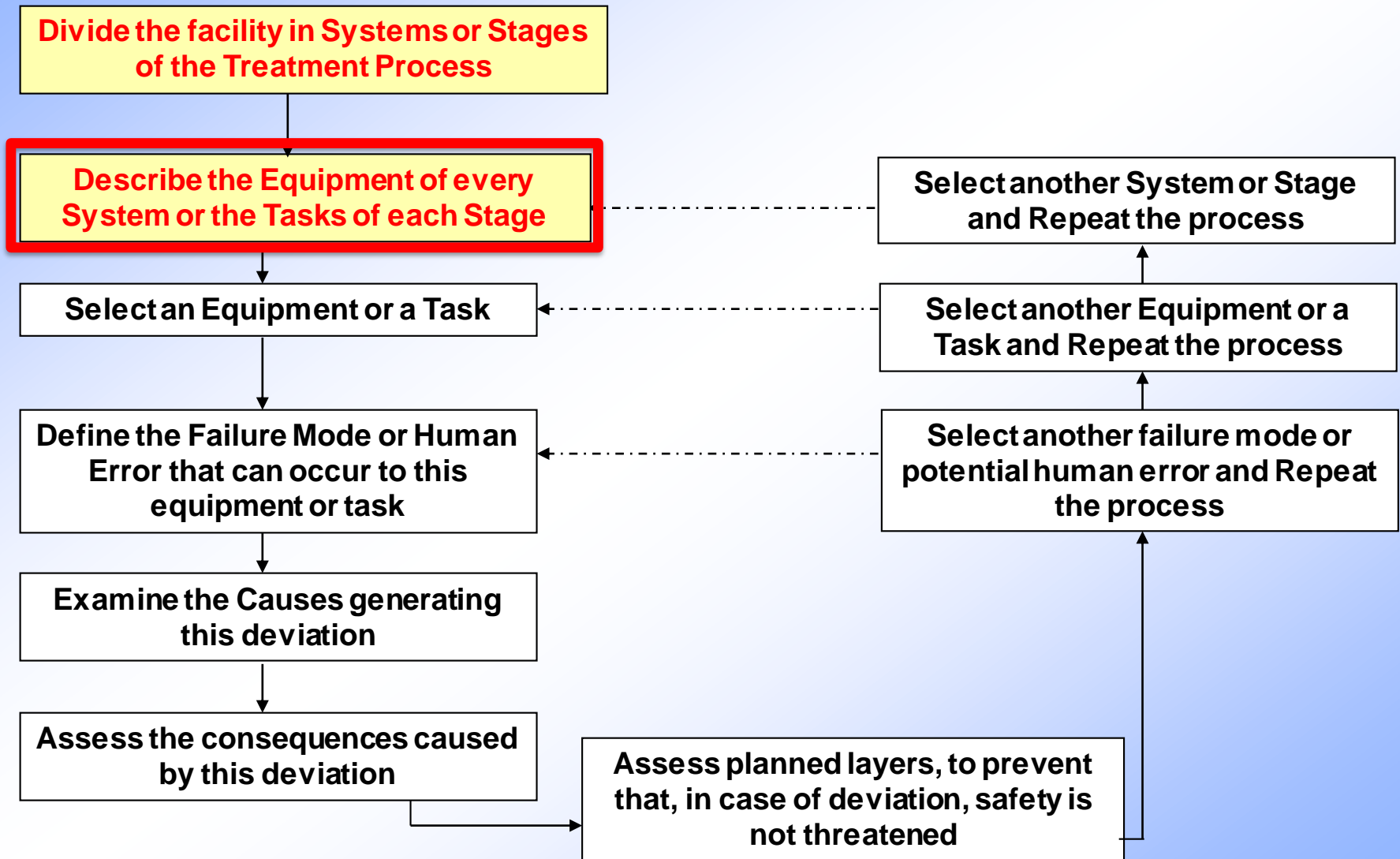
Steps in the radiation therapy planning process  
IAEA TECDOC- 1494



Partial flow diagram for the external beam therapy process  
IAEA TECDOC- 1670S



# Main stages for performing a FMEA





# Describe the Equipment of every System or the Tasks of each Stage

## For each stage

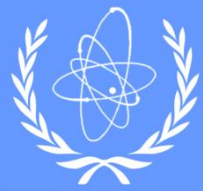
**Designation:** *Indicates the name of the stage, understood as a discrete unit of the treatment process, with start point, duration and end point well discernible .*

**Definition and Objectives:** *Indicates a brief definition and the final objective which is pursued in the stage .*

**Short description:** *The tasks that should be executed at this stage are briefly described.*

**Outcome achieved:** *Indicates the outcome or output achieved at the end of the stage both from the point of view of the treatment and documentation, materials and/or attachments that are generated.*

**Responsibilities and personnel involved:** *Indicates who is primarily responsible for the stage and the personnel from other specialties involved .*

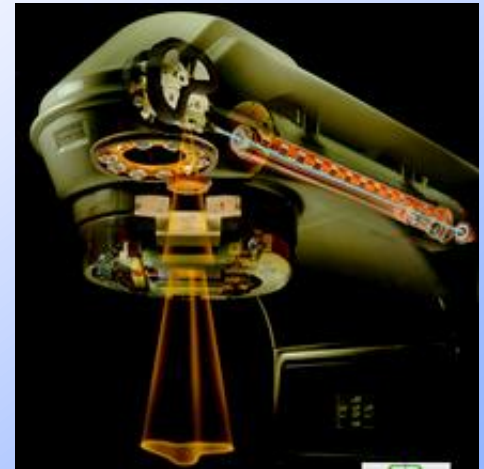


# Describe the Equipment of every System or the Tasks of each Stage

## For the equipment used in the practice

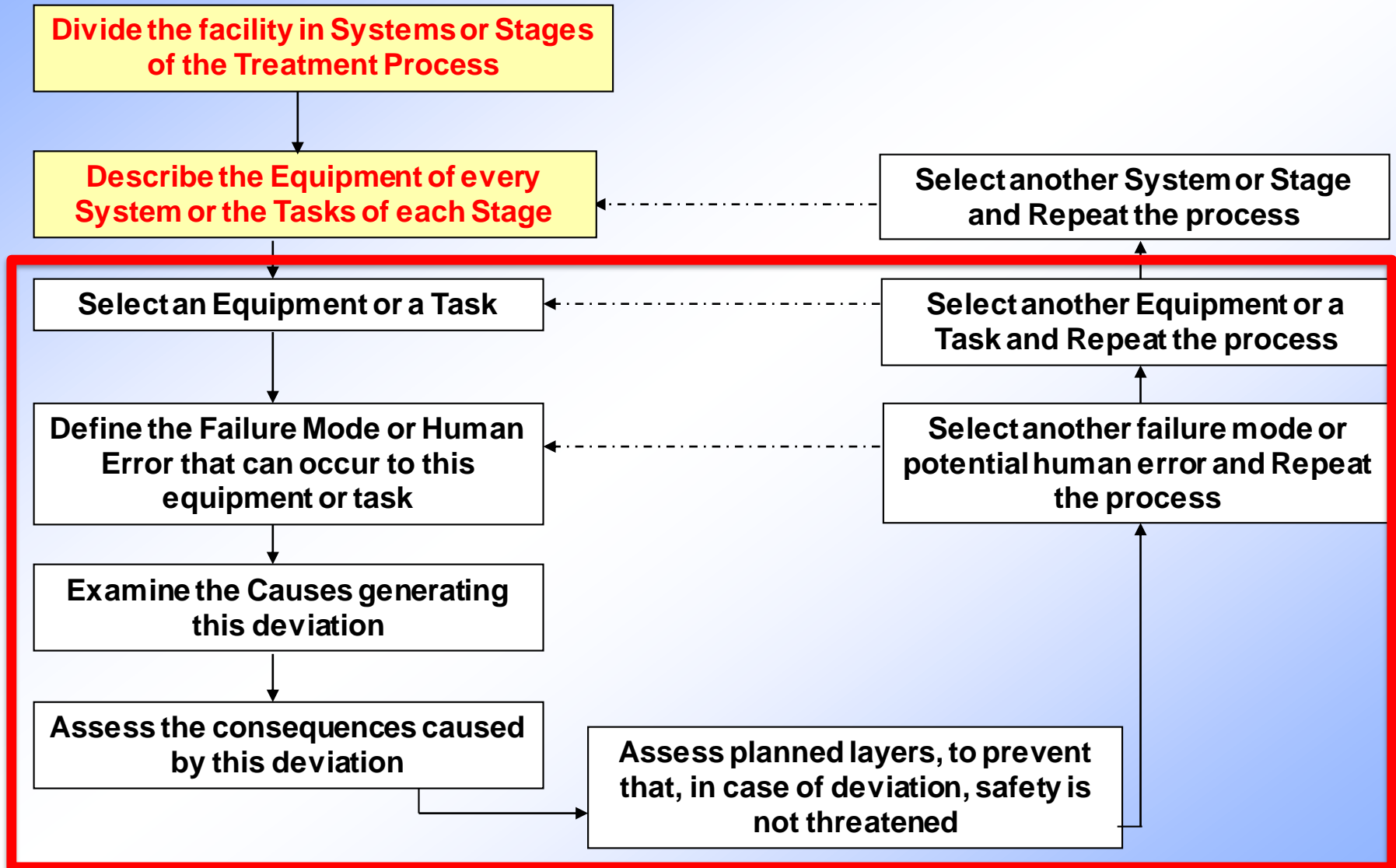
Description should have the following scope for each equipment:

- ✓ Designation of main systems.
- ✓ Description of the operation principle.
- ✓ System diagrams, drawings and/or schemes .
- ✓ Control and operation.
- ✓ System components.
- ✓ Interfaces with other systems.





# Main stages for performing a FMEA







# HUMAN ERRORS

## 1. HUMAN ERROR : Examples of classification:

### ✓ *BY ITS EXTERNAL FORM*

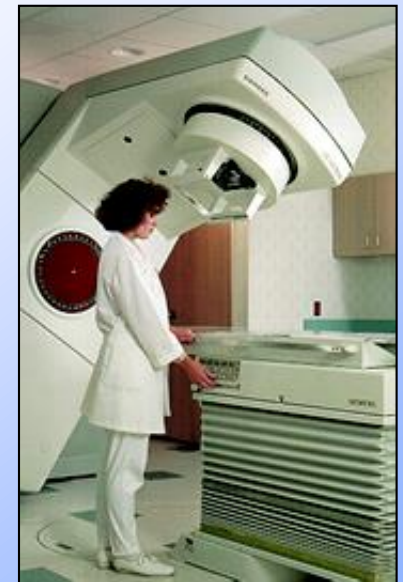
- Error of Omission
- Error of Commission

### ✓ *BY HUMAN PROCESSES ENGAGED*

- Cognitive error
- Manual error

### ✓ *BY THE MECHANISM OF THE ERROR*

- Unintentional
- Violations





# Human Errors of Omission and Commission

- ✓ ***ERROR OF OMISSION: An action or task required not performed. Errors can be:***
  - ❖ **Omission of a complete task**
  - ❖ **Omission of a step of the task**
- ✓ ***ERROR OF COMMISSION: Improper completion of a task, or performing a task that is not required and may cause an unintended consequence. Errors can be:***
  - ❖ **Selection errors: Issuance of wrong information or command , oral or written; Wrong control selection; Wrong control positioning .**
  - ❖ **Qualitative errors: by default, by excess.**
  - ❖ **Sequence error: Orders for a given sequence of operations are changed.**
  - ❖ **Time errors: too late, too early**



# Cognitive and Manual human errors

- ✓ ***COGNITIVE ERROR: Occur when human beings receive a signal that requires a response during the diagnosis and decision process.***
  
- ✓ ***MANUAL ERROR : Occur in the post-diagnosis stage, during the response implementation:***
  - ❖ **Selection errors: Issuance of wrong information or command , oral or written; Wrong control selection; Wrong control positioning .**
  - ❖ **Qualitative errors: by default, by excess.**
  - ❖ **Sequence error: Orders for a given sequence of operations are changed.**
  - ❖ **Time errors: too late, too early**



## ✓ **UNINTENTIONAL ERROR:**

- ❖ **Slips.** *Errors that occur when even knowing what to do, unintentionally, an action is performed incorrectly.* They are often caused by lack of attention.
- ❖ **Mistakes:** Errors that occur when a wrong action is performed (an action that is appropriate for another different situation).

## ✓ **VIOLATIONS:** *Intended decisions (for any reason) ignoring the rules and the established safety codes*



# Identifying Initiating Events. Frequency

## Human error probabilities

Error type	Type of behavior	Task Features	Human Error Probability
1	Extraordinary errors: of the type difficult to convince how they could occur: stress free, powerful cues initiating for success.		$10^{-5}$ (1 in 100 000)
2	Error in regularly performed, commonplace simple tasks with minimum stress		$10^{-4}$ (1 in 10 000)
3	Errors of commission: such as operating wrong button or reading wrong display. More complex task, less time available, some cues necessary.	Easy, under stress	$10^{-3}$ (1 in 1000)
		Complex, no stress	$3 \times 10^{-3}$ (3 in 1000)
		Complex, under stress	$6 \times 10^{-3}$ (6 in 1000)
		Monotonous	$9 \times 10^{-3}$ (9 in 1000)
4	Errors of omission: where dependence is placed on situation cues and memory. Complex, unfamiliar task with little feedback and some distractions	Easy, under stress	$10^{-2}$ (1 in 100)
		Complex, no stress	$3 \times 10^{-2}$ (3 in 100)
		Complex, under stress	$6 \times 10^{-2}$ (6 in 100)
		Monotonous	$9 \times 10^{-2}$ (9 in 100)
5	Highly complex task, considerable stress, Little time to perform it.		$10^{-1}$ (1 in 10)
6	Process involving creative thinking; unfamiliar complex operation where time is short, stress is high.		$10^{-1}$ to 1 (1 in 10 – 1 in 1)

Data from "2008 National Conference on Major Hazard Facilities, Adelaide, Australia"



# Example of a FMEA-H Table

Process: Radiation therapy treatment with Linear accelerator for Medical Practices (LINAC).						Stage: Treatment dosimetry planning (TDP-LINAC)		
Date: July, 2006								
No	Task	Human Error	Causes	Effects			Safety layers	Comments
				Pac.	TOE	Púb.		
1	Patient selection in the TPS	Omit patient selection in the TPS	-	-	-	-	-	• No credit is given to the error.
		Select a wrong patient in the TPS (different from the planned one according to Treatment Sheet)	<ul style="list-style-type: none"> <li>• Lapsus</li> <li>• Similarity of patient names</li> <li>• RO job interruptions</li> </ul>	x	-	-	Isocenter positioning at the beginning of treatment  MP and the RO Portal image review  Patient medical check during treatment	• Low probability error because the name of the patient and the same pathology should match



# Equipment Failure Modes

## Examples of classification: **SWITCHES AND VALVES**

Failure Mode	Description
<b>Failure to remain in the position</b>	Component failure to remain in the desired position. This failure means the component moves toward opposite positions.
<b>Failure to close</b>	Component failure when moving to a new position (closed).
<b>Failure to open</b>	Represents the failure of a component to move to a new position (open). Opposite of "Failure to close".
<b>Undesired operation (false)</b>	Represents the failure of components to keep its status (eg: 1 - change of State without being ordered, 2 - a component that must be disconnected but is connected and operating without been required).



# Equipment Failure Modes

## Examples of classification: **ROTATING EQUIPMENT** **(ENGINES, PUMPS, COMPRESSORS)**

Failure Mode	Description
<b>Start Failure</b>	Represents the failure of components to start when they are demanded. Applies to all components that execute its function starting and moving continuously (rotating).
<b>Operational failure</b>	Represents the failure of a component to continue to operate (usually rotary motion), during the required time . Applies to any component that performs its function through a continuous movement.





# Equipment Failure Modes

## Examples of classification: **TRANSPORT AND STORAGE OF FLUIDS**

Failure Mode	Description
<b>External leakage</b>	Represents the failure of the component in charge of retaining the fluid
<b>Break</b>	Represents a great break on the border retaining the fluid. It is a catastrophic failure
<b>Obstruction</b>	Represents any failure that prevents the flow not flowing in a required direction , and not caused by the normal operation of the component



# Equipment Failure Modes

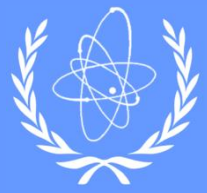
## Examples of classification: *OTHER*

Failure Mode	Description
<b>Software failure</b>	A software programming error. Subset of failure when running
<b>Out of calibration</b>	Represents the failure of a component when its output parameters are mis-adjusted with respect to the original calibration
<b>Overheating</b>	Represents the failure of a component that raises its temperature above the design parameters



# Example of an Equipment FMEA Table

Item: Linear accelerator for Medical Practices (LINAC).										System: Target positioning, and beam filtering and collimation system. (CCH)	
Date: March, 23th 2006											
No	Equipment	Failure mode	Causes	Effects				Safety layers		Comments	
				Disp.	Púb.	TOE	Pac.	Type	Description		
<b>Target change subsystem</b>											
1	Target position change motor	Malfunction	- False signal - Motor failure				Z31 C	V	Position switches	<ul style="list-style-type: none"> <li>Position switches determine target position. The system includes a protection by software that inhibits the operation of the LINAC until correct positioning is achieved.</li> </ul>	
								V	Check position potentiometer	<ul style="list-style-type: none"> <li>Potentiometer allows to monitor target position.</li> </ul>	
								T	Hardware interlock	<ul style="list-style-type: none"> <li>LINAC is blocked if the target position is not the expected one.</li> </ul>	
								T	Dosimetry interlock	<ul style="list-style-type: none"> <li>Dosimetry control system should detect that it is receiving a different from the prescribed dose and should stop treatment by means of the dosimetry interlock</li> </ul>	



## 2. EXERCISE



# Exercise

**For the practice of Diagnostic Nuclear Medicine:**

- 1. Develop a flow diagram of the stages on which this practice can be divided.**
- 2. Select 3 tasks and analyze possible human errors using a FMEA table.**
- 3. Consider as human errors:**
  - Skip a step**
  - Perform a task incorrectly (by excess, by default, by changing the order of a sequence, etc.)**





# Identifying Initiating Events. Frequency

The frequency of an initiating event depends on its type. "Human Errors" and "Equipment Failure" are assessed in a different way.

- Human errors are more frequent and are a function of the probability of error and the number of times the task is performed.



$$f = p_E * N_t$$

$f$  → The event frequency evaluated as events/year

$p_E$  → Probability of human error (bibliography)

$N_t$  → Number of times the task is performed



# Identifying Initiating Events. Frequency

The frequency of initiating events derived from "Equipment failure".

- Equipment Failures  $f$  teams are less frequent events since the development of technology demands it.



$$f = \frac{2n + 1}{2T}$$

$f$   $\longrightarrow$  The event frequency evaluated as events/year

$n$   $\longrightarrow$  Component failure rate (bibliography)

$T$   $\longrightarrow$  Component working time in a year