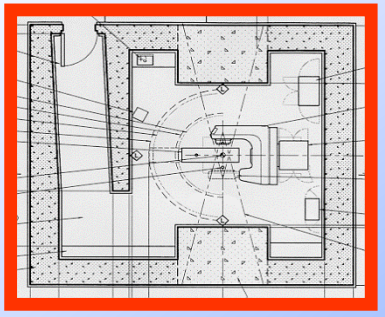
Presentation
RISK ESTIMATIONS. “RISK MATRIX METHOD” RADIOTHERAPY AND INDUSTRIAL GAMMAGRAPHY

International Atomic Energy Agency

OBJECTIVE

To show the theoretical elements that support the "Risk Matrix" method and explain the logical sequence of steps that must be followed in the practical application of this method.



SCOPE

- Logic sequence of occurrence of accidents and its relation with risk equations.
- Criteria to evaluate different variable’s levels of the risk equation.
- Steps for the practical application of the "Risk Matrix" method. First screening.
- Second screening procedure.

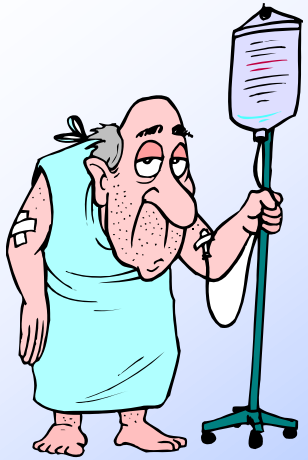
LOGIC SEQUENCE OF ACCIDENTS

Human error or equipment failure (f)

Defenses or security barriers (p)

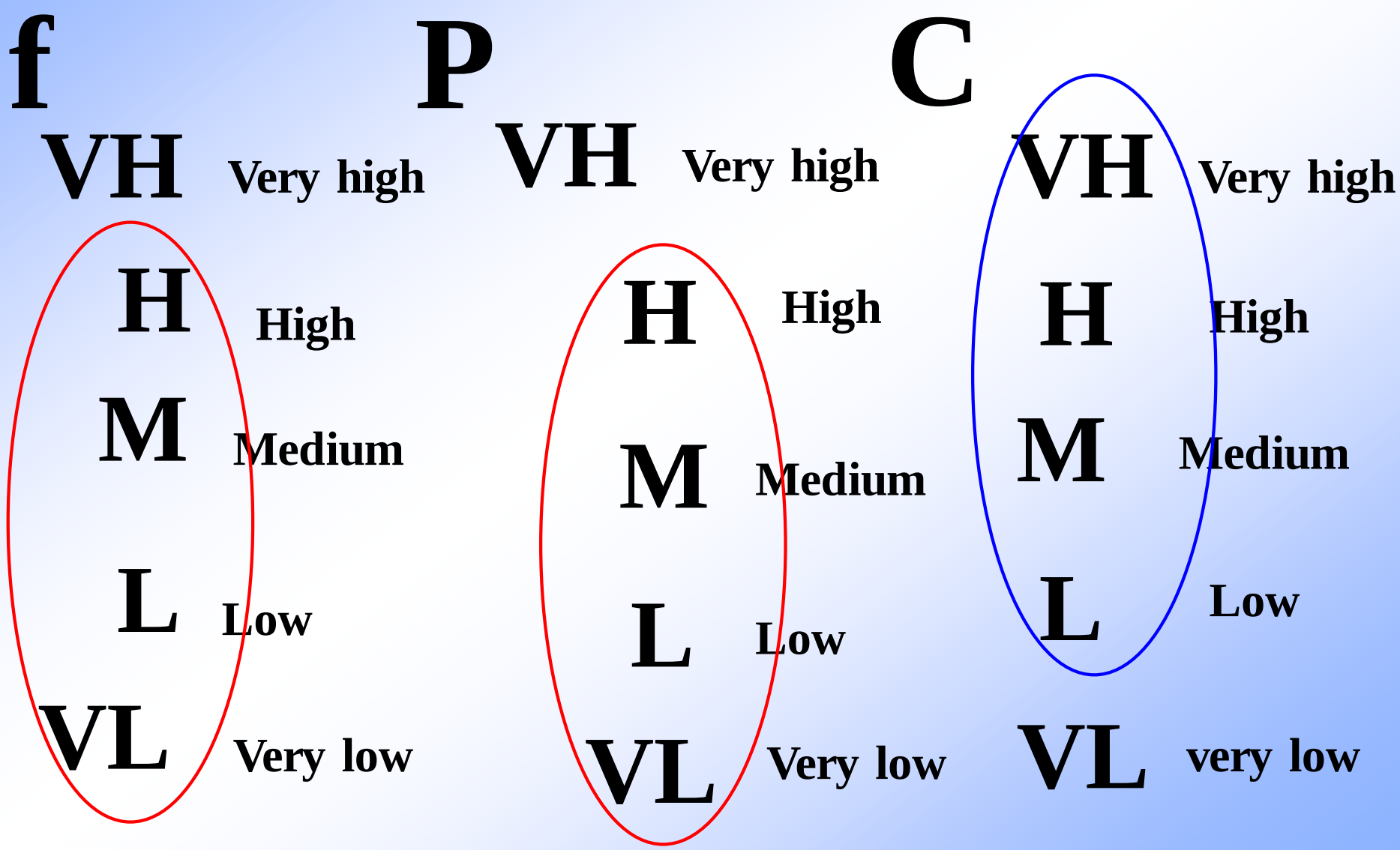
Accidental exposition

Consequences (C)



$$R = f * p * C$$

RISK MATRIX


f
VH Very high
H High
M Medium
L Low
VL Very low
P
VH Very high
H High
M Medium
L Low
VL Very low
C
VH Very high
H High
M Medium
L Low
VL very low

CRITERIA FOR BUILDING A RISK MATRIX

General variable combinations logic:

1. The first two variables are multiplied. The result is multiplied by the third variable.
2. The multiplication of same level variables gives, as a result, the same level. Example: Low*Low=Low.
3. The multiplication of different contiguous level variables gives, as a result, the most conservative level. Example: Medium*Low= Medium.
4. The multiplication of different non contiguous level variables gives always two possible solutions, but the chosen variable is the one with the highest **p** variable. Example: Take f_L*P_L*C_{VH} combination. First result: f_L*P_L = L. When multiplying this result with C_{VH}, there are two intermediates, the M and the H. In this case, giving more importance to the probability level, the result would be $R_{M.}$

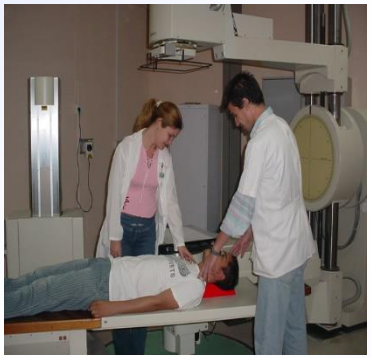
RISK MATRIX.

f_H	P_H	C_{VH}	R_{VH}	f_H	P_H	C_H	R_{VH}	f_H	P_H	C_M	R_H	f_H	P_H	C_L	R_M
f_M	P_H	C_{VH}	R_{VH}	f_M	P_H	C_H	R_H	f_M	P_H	C_M	R_H	f_M	P_H	C_L	R_M
f_L	P_H	C_{VH}	R_H	f_L	P_H	C_H	R_H	f_L	P_H	C_M	R_M	f_L	P_H	C_L	R_M
f_{VL}	P_H	C_{VH}	R_H	f_{VL}	P_H	C_H	R_H	f_{VL}	P_H	C_M	R_M	f_{VL}	P_H	C_L	R_M
f_H	P_M	C_{VH}	R_{VH}	f_H	P_M	C_H	R_H	f_H	P_M	C_M	R_H	f_H	P_M	C_L	R_M
f_M	P_M	C_{VH}	R_H	f_M	P_M	C_H	R_H	f_M	P_M	C_M	R_M	f_M	P_M	C_L	R_M
f_L	P_M	C_{VH}	R_H	f_L	P_M	C_H	R_H	f_L	P_M	C_M	R_M	f_L	P_M	C_L	R_L
f_{VL}	P_M	C_{VH}	R_H	f_{VL}	P_M	C_H	R_M	f_{VL}	P_M	C_M	R_M	f_{VL}	P_M	C_L	R_L
f_H	P_L	C_{VH}	R_H	f_H	P_L	C_H	R_H	f_H	P_L	C_M	R_M	f_H	P_L	C_L	R_L
f_M	P_L	C_{VH}	R_H	f_M	P_L	C_H	R_H	f_M	P_L	C_M	R_M	f_M	P_L	C_L	R_L
f_L	P_L	C_{VH}	R_M	f_L	P_L	C_H	R_M	f_L	P_L	C_M	R_M	f_L	P_L	C_L	R_L
f_{VL}	P_L	C_{VH}	R_M	f_{VL}	P_L	C_H	R_M	f_{VL}	P_L	C_M	R_M	f_{VL}	P_L	C_L	R_L
f_H	P_{VL}	C_{VH}	R_H	f_H	P_{VL}	C_H	R_M	f_H	P_{VL}	C_M	R_M	f_H	P_{VL}	C_L	R_L
f_M	P_{VL}	C_{VH}	R_M	f_M	P_{VL}	C_H	R_M	f_M	P_{VL}	C_M	R_M	f_M	P_{VL}	C_L	R_L
f_L	P_{VL}	C_{VH}	R_M	f_L	P_{VL}	C_H	R_L	f_L	P_{VL}	C_M	R_L	f_L	P_{VL}	C_L	R_L
f_{VL}	P_{VL}	C_{VH}	R_M	f_{VL}	P_{VL}	C_H	R_L	f_{VL}	P_{VL}	C_M	R_L	f_{VL}	P_{VL}	C_L	R_L

R_{VH} R_H R_M R_L

CRITERIA TO EVALUATE FREQUENCY LEVELS

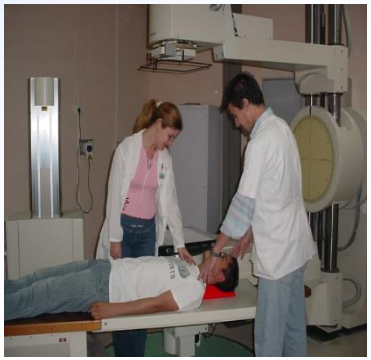
Every human error has its own probability (p_E).This probability is a function of the human behavior. The occurrence frequency of the initiating events motivated by human errors will be expressed in events/year. It depends of the human error probability and the number of times that the activity is performed in a given year (Nt), according to the following equation:



$$f = p_E * N_t$$

CRITERIA TO EVALUATE FREQUENCY LEVELS

Every equipment failure occurs with its own probability (n).This failure rate is a function of the characteristics of the failed component. The occurrence frequency of the initiating events motivated by equipment failure is expressed in events/ year. It depends on the failure rate and the component working time in a year (T) according the following equation:



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

CRITERIA TO EVALUATE FREQUENCY LEVELS

f

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

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

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

VL **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.

CRITERIA TO EVALUATE LEVELS OF CONSEQUENCES

Accidents can affect patients, workers and members of the public. Any human error or equipment failure can affect at the same time to one or more of those involved in the process.

Example: ***unplugging the source cable while it is inside the patient, at the end of the treatment with HDR Brachytherapy.***

Patient: It has consequences for the patient because causes overdose**.**

Worker: It has consequences for the worker because it receives anomalous exposure**.**

Public: It has consequences for the public because if the source is undetected at the patient's body , this patient goes freely home causing anomalous exposure to the members of the public.

CRITERIA TO EVALUATE LEVELS OF CONSEQUENCES

FOR PATIENTS

C

VH **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.

H **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.

M **Medium:** There is no risk to the patient's life. Only one of the patients treated is exposed during the session.

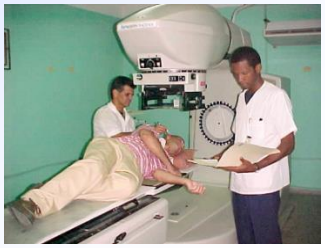
L **Low:** No effects whatsoever are produced on the patients. The level of defenses has decreased.

CRITERIA TO EVALUATE LEVELS OF CONSEQUENCES

WORKERS AND MEMBERS OF THE PUBLIC

VH **Very high:** Serious consequences producing very severe determinists effects that might become fatal or produce permanent disability.

C **H** **High:** Produce determinist effects, but do not represent danger to human life and do not produce permanent damage.

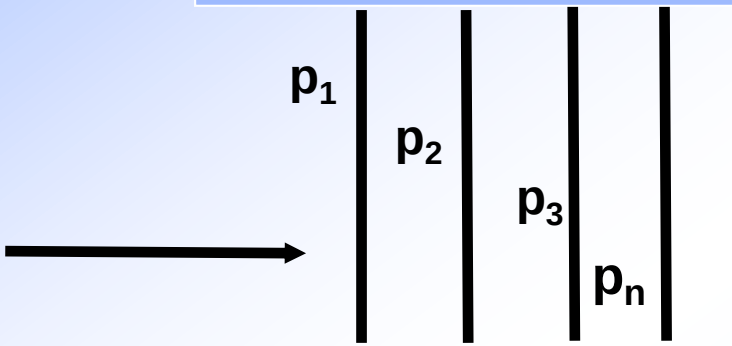


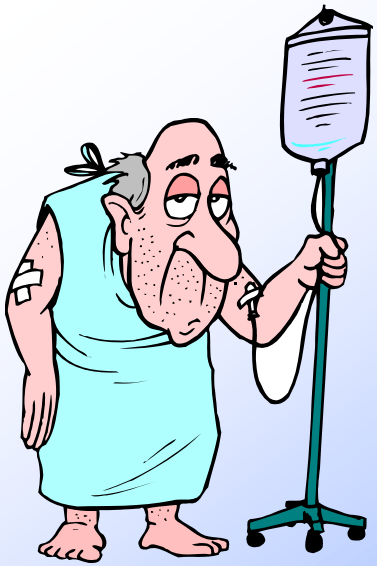
M **Medium:** Produce anomalous exposition below the determinist effects threshold. It is manifested as an increase of probability of the stochastic effects.

L **Low**: no effects are produced on the workers or public. The level of defenses has decreased..

CRITERIA TO EVALUATE THE PROBABILITY OF BARRIER FAILURE

Barrier group failure probability (p)



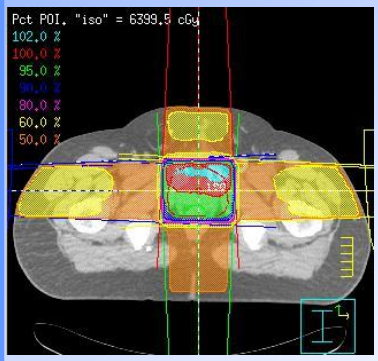


Simplified method.

$p_1 = p_2 = p_n$

$$p = p_1 * p_2 * p_n$$

CRITERIA TO EVALUATE THE PROBABILITY OF BARRIER FAILURE.



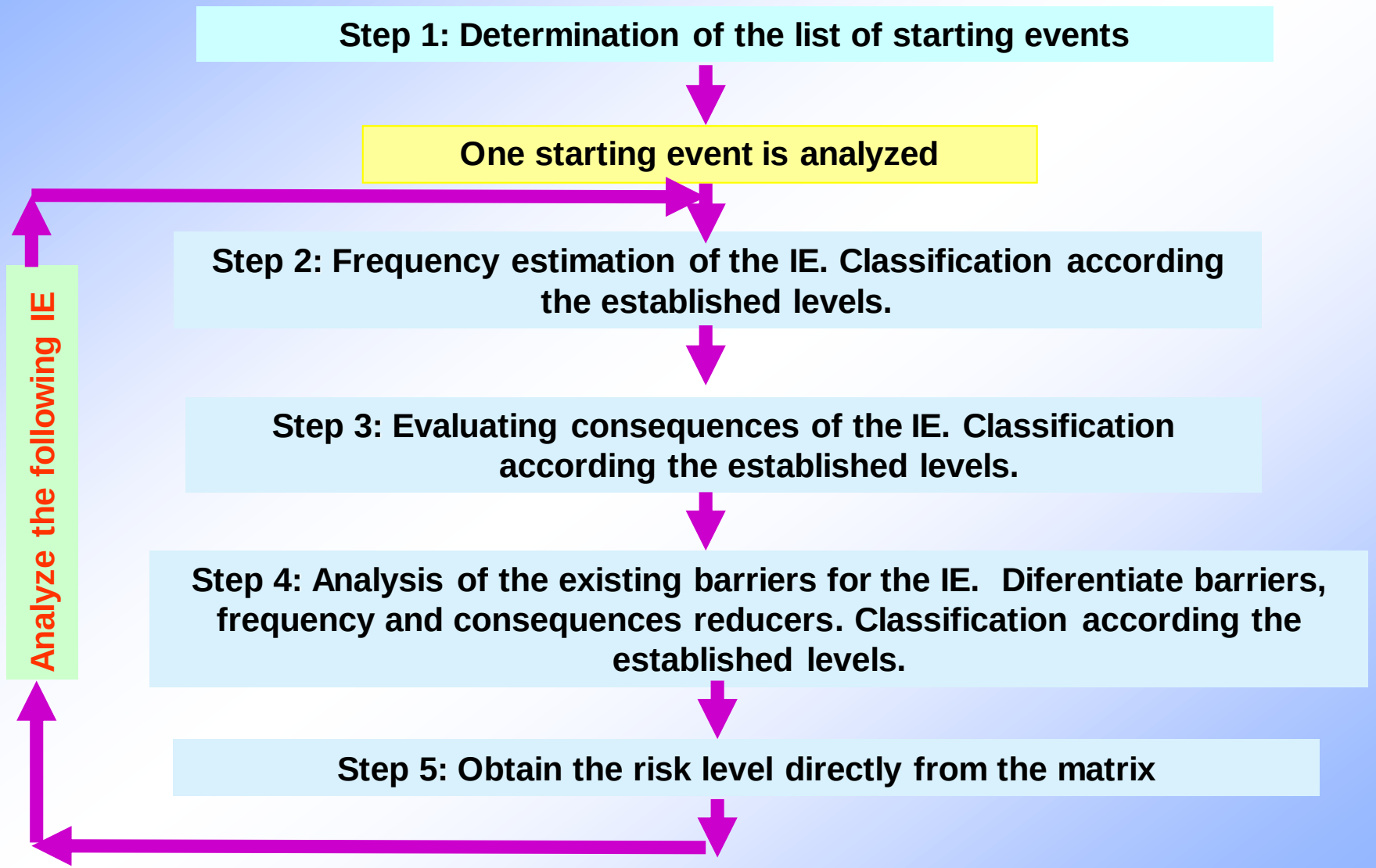
H **High:** most likely and expected accidental sequence (no safety barrier)

M **Medium:** failure of defenses is accepted if the barriers are not applied correctly.(one or two barriers)

P **L** **Low:** there are enough defenses but it is accepted the last failure case.(three barriers)

VL **Very low:** accidental sequences virtually impossible. There are enough deepest barriers (more than three barriers)

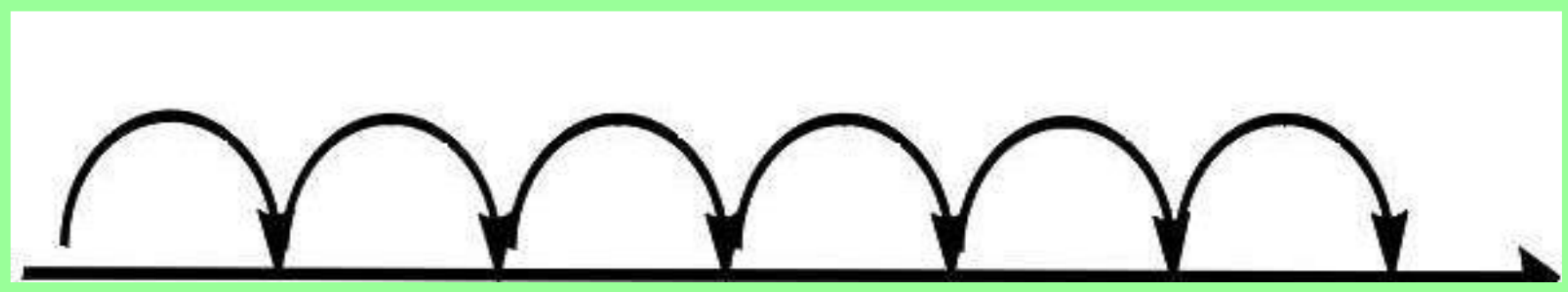
STEPS FOR PRACTICAL APPLICATION



STEPS FOR PRACTICAL APPLICATION

Step 1: Determination of the list of initiating events (IE)

- The list of *initiating events* ***(IE)*** can be realized by using risk analysis techniques, or
- Adapting the generic lists of IE elaborated for similar installations.



Diagnose type of Treat. Def. of Volum. Simulation Planning Treatment Next

STEPS FOR PRACTICAL APPLICATION

Step 2: Frequency estimation of the IE. Classification according the established levels.

Example of IE: Error in the determination of the absorbed dose in reference conditions (Telecobaltteharapy)

p_E → Human error , in a non-monotonous activity, technical complex activity that is realized following procedures, activity realized in pre operational conditions ,no influenced by the pressure to deliver the treatment. A human error probability of $8.0E^{-03}$ is accepted(8 errors per 1000 times the job is performed)

N_t → This task is performed during the initial assembly of the source and it is repeated every 5 years , when the source is changed. It is accepted a change rate of 1/5 times a year.

$f = p_E * N_t = 0{,}0016$ events /year (< 0,05 events/year)

→ f_{VL} → f_L

STEPS FOR PRACTICAL APPLICATION

Step 3: Evaluating consequences of the IE. Classification according the established levels.

Example of IE: Error in the determination of the absorbed dose in reference conditions (Telecobaltteharapy)

Question: What consequences can cause this IE supposing there is no barrier to avoid the accident occurrence?

Answer: It will affect multiply patients (systematic error)

The dose administrated to the patient differed more than 25% of the prescribed dose by the physician. Probably it might cause the patient death or disability damage to a lot of patients.

⟶ C_{VH}

ANALYSIS OF DEFENSES. DEFENCE IN DEEP

Frequency reducers

Direct barrier

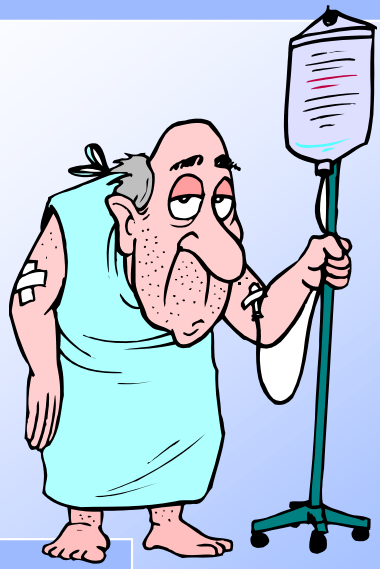
Consequences reducers

Human error or equipment failure (f)

Safety barriers or defenses (p)

Accidental exposure

Consequences (C)



$$R = f * p * C$$

STEPS FOR PRACTICAL APPLICATION

Step 4: Analysis of the existent barriers for the initiating events **(IE). Differentiate barriers ,frequency and consequences reducers. Classification according the established levels.**

Example of IE: Error in the determination of the absorbed dose in reference conditions (Telecobaltteharapy)

In this case the answer should be:

FREQUENCY REDUCERS

- Physicists capacitation through services test.
- International acknowledged protocols to do the tests.

STEPS FOR PRACTICAL APPLICATION

Step 4: Analysis of the existent barriers for the IE. Differentiate barriers ,frequency and consequences reducers. Classification according the established levels.

Example of IE : Error in the determination of the absorbed dose in reference conditions (Telecobaltteharapy)

In this case the answer should be:

DIRECT BARRIERS

- Redundant and independent verification of calibration results (by another Physicist and other dosimetry system).
- Commissioning of the TPS. Test Case planning and comparison of results with direct measurements.

STEPS FOR PRACTICAL APPLICATION

Step 4: Analysis of the existent barriers for the IE. Differentiate barriers ,frequency and consequences reducers. Classification according the established levels.

Example of IE : Error in the determination of the absorbed dose in reference conditions (Telecobaltteharapy)

In this case the answer should be:

CONSEQUENCES REDUCERS

- QA of the Hospital. Monthly testing reference dose constant.
- QA of the Hospital. Annual testing reference dose constant . Intercomparing exercises (OIEA- OMS).
- Daily observation of the patient by the operator technician.
- Weekly follow up procedures of the patient by his physician.
- **Periodic external audit**. (Determination of the absorbed dose using reference conditions test).

APPLICATION EXAMPLE

Step 5: Obtain the risk level directly from the matrix

Example of IE: Error in the determination of the absorbed dose in reference conditions (Telecobaltteharapy)

$$R = f * P * C$$

Process stage : Acceptance and start of service

Frequency	web off	Consequences	Defences	Risk
f_L	Physicist capacitation	C_{VH}	P_M	?

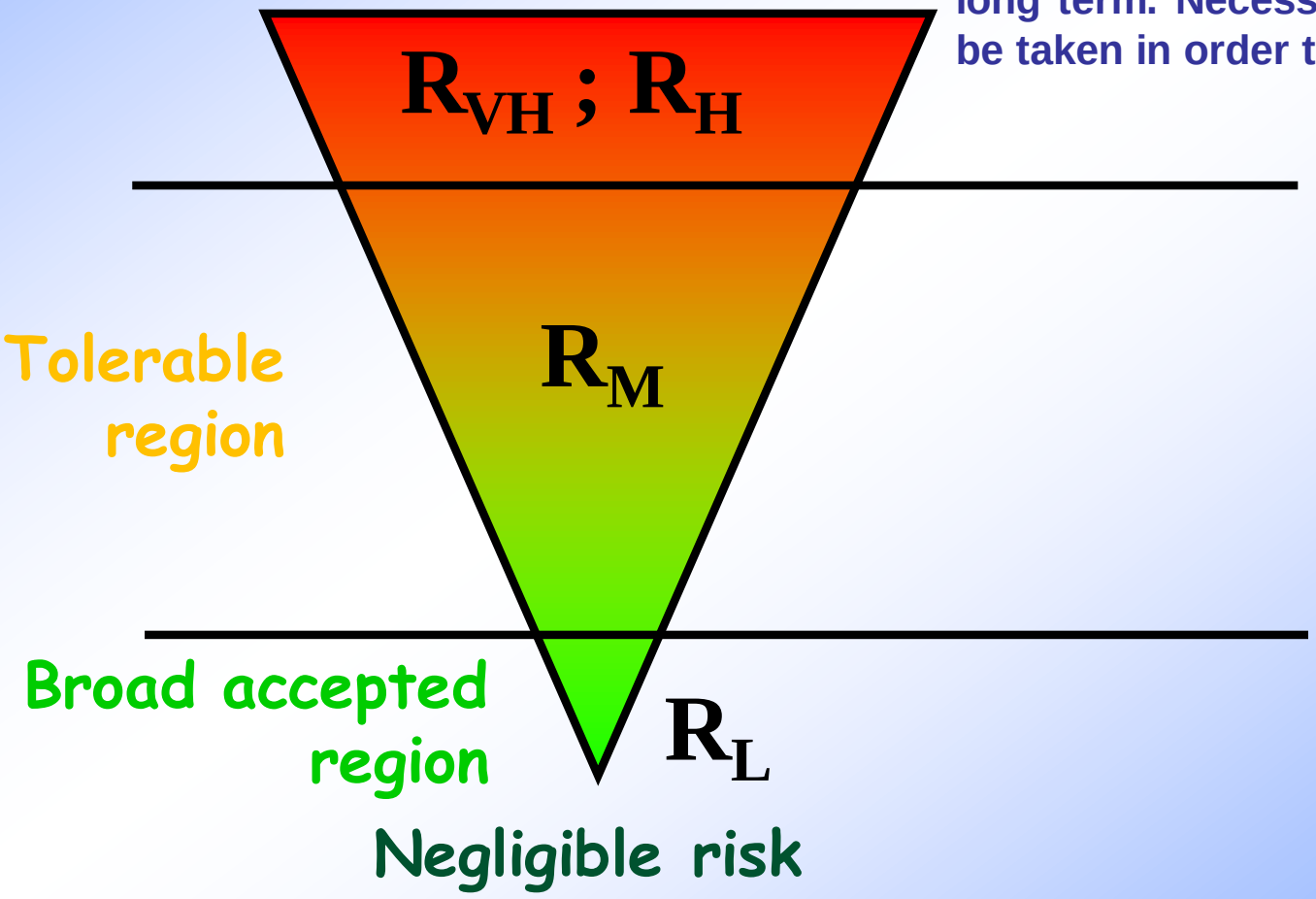
USING THE RISK MATRIX TO OBTAIN THE RESULTING RISK.

f_H	P_H	C_{VH}	R_{VH}	f_H	P_H	C_H	R_{VH}	f_H	P_H	C_M	R_H	f_H	P_H	C_L	R_M
f_M	P_H	C_{VH}	R_{VH}	f_M	P_H	C_H	R_H	f_M	P_H	C_M	R_H	f_M	P_H	C_L	R_M
f_L	P_H	C_{VH}	R_H	f_L	P_H	C_H	R_H	f_L	P_H	C_M	R_M	f_L	P_H	C_L	R_M
f_{VL}	P_H	C_{VH}	R_H	f_{VL}	P_H	C_H	R_H	f_{VL}	P_H	C_M	R_M	f_{VL}	P_H	C_L	R_M
f_H	P_M	C_{VH}	R_{VH}	f_H	P_M	C_H	R_H	f_H	P_M	C_M	R_H	f_H	P_M	C_L	R_M
f_M	P_M	C_{VH}	R_H	f_M	P_M	C_H	R_H	f_M	P_M	C_M	R_M	f_M	P_M	C_L	R_M
f_L	P_M	C_{VH}	R_H	f_L	P_M	C_H	R_H	f_L	P_M	C_M	R_M	f_L	P_M	C_L	R_L
f_{VL}	P_M	C_{VH}	R_H	f_{VL}	P_M	C_H	R_M	f_{VL}	P_M	C_M	R_M	f_{VL}	P_M	C_L	R_L
f_H	P_L	C_{VH}	R_H	f_H	P_L	C_H	R_H	f_H	P_L	C_M	R_M	f_H	P_L	C_L	R_L
f_M	P_L	C_{VH}	R_H	f_M	P_L	C_H	R_H	f_M	P_L	C_M	R_M	f_M	P_L	C_L	R_L
f_L	P_L	C_{VH}	R_M	f_L	P_L	C_H	R_M	f_L	P_L	C_M	R_M	f_L	P_L	C_L	R_L
f_{VL}	P_L	C_{VH}	R_M	f_{VL}	P_L	C_H	R_M	f_{VL}	P_L	C_M	R_M	f_{VL}	P_L	C_L	R_L
f_H	P_{VL}	C_{VH}	R_H	f_H	P_{VL}	C_H	R_M	f_H	P_{VL}	C_M	R_M	f_H	P_{VL}	C_L	R_L
f_M	P_{VL}	C_{VH}	R_M	f_M	P_{VL}	C_H	R_M	f_M	P_{VL}	C_M	R_M	f_M	P_{VL}	C_L	R_L
f_L	P_{VL}	C_{VH}	R_M	f_L	P_{VL}	C_H	R_L	f_L	P_{VL}	C_M	R_L	f_L	P_{VL}	C_L	R_L
f_{VL}	P_{VL}	C_{VH}	R_M	f_{VL}	P_{VL}	C_H	R_L	f_{VL}	P_{VL}	C_M	R_L	f_{VL}	P_{VL}	C_L	R_L

Analyzing all the initiating events, a first screening can be estimated in order to establish priority according to the risk criteria.

RISK MANAGMENT CRITERIA

R_{VH}, is considered unacceptable in medical practice (Eminent risk).
R_H is considered unacceptable in the long term. Necessary measures must be taken in order to reduce the risk.



RISK MANAGEMENT CRITERIA

The risk matrix method is a conservative method because in its application one assumes several conservative hypothesis, which are:

- All the direct barriers have the same probability of failure and the barriers robustness is not taken into account.
- The influence of the frequency reducers diminishing the IE frequency and the resulting risk has not being considered .
- The influence of consequences reducers diminishing the consequences and the resulting risk has not being considered .

A second screening is justified in order to show more realistic results.

SECOND SCREENING PROCEDURE

A_1- Are sufficiently robust the existing barriers to assign a lower failure probability that could allow to classify risk to a lower level?

A_2- Are sufficiently robust the frequency reducers or the existing consequences reducers?

A_3- Is it possible to introduce new barriers, or frequency or consequences reducers?

A_4- Conclusion. What additional measures can be proposed to diminish global risk?

SECOND SCREENING

A1- Are sufficiently robust the existing barriers to assign a lower failure probability that could allow to classify risk to a lower level?

No	Type of Barrier	Robustness expressed in points
1	Type 1 barriers : Interlocks	32
2	Type 2 barriers: Alarms	16
3	Type 3 barriers: work procedure performed by different persons.	8
4	Type 4 barriers: work procedure performed by the same person but in different stages or moments.	4

SECOND SCREENING

A1- Are sufficiently robust the existing barriers to assign a lower failure probability that allow us to classify risk to a lower level?

1. To failure probability p_M: (2 Barriers)

A group of barriers is considerate robust if: $p1*p2 \geq 32$ points. This allows to reclassify the probability from p_M to p_L.

A group of barriers is considerate very robust if : $p1*p2 > 64$ points. This allows to reclassify the probability from p_M to p_L.

2. To failure probability p_L: (3 Barriers)

A group of barriers is considerate robust if : $p1*p2*p3 > 64$ points. This allows to reduce the probability from p_L to p_{VL}.

SECOND SCREENING

A1- Are sufficiently robust the existing barriers to assign a lower failure probability that could allow to classify risk to a lower level?

Example: How to evaluate the robustness of the existing barriers?

No	Type of barrier	Robustness expressed in points
1	"Redundant and independent verification of calibration results (by another Physicist and other dosimetry system)" Type 3 Barriers	8
2	"Commissioning of the TPS. Tests Case planning and comparison of results with direct measurements" Type 4 Barriers	4

$(p_1 * p_2) = 32$. Meets the criteria of two robust barrier (*p1*p2* ≥ 32 points).

$P_M \Longrightarrow P_L$

SECOND SCREENING

A2- Are sufficiently robust the frequency reducers or the existing consequences reducers?

Robustness of Frequency Reducers

CRITERIA FOR ASSESSING THE ROBUSTNESS OF THE FREQUENCY REDUCER ASSEMBLY. METHODOLOGY OF THE RISK MATRIX.

Overview of Frequency Reducers	Robustness	Weight
Interlocks and Technological Improvements	Very robust	32
Signals and Alarms	Robust	16
Protocols, procedures and moderate workload	Normal	8
Training	Soft	4

SECOND SCREENING

A_2- Are sufficiently robust the frequency reducers or the existing consequences reducers?

For frequency reducers

1. **If the multiplication of the robustness of the Frequency reducers is greater than or equal to 32 Points (RF1*RF2*RF3*…*RFn ≥ 32), It is possible to reduce a level of Frequency, ie: for example, from F_H to F_M.**
2. **If the multiplication of the robustness of the Frequency reducers is greater than 64 Points (RF1*RF2*RF3*…*RFn > 64), It is possible to reduce two Frequency levels, ie: for example, from F_H to F_L.**

Note: In both cases it is not allowed to reach the very low frequency (F_{VL}) level, in the case of events derived from human errors.

SECOND SCREENING

A_2- Are sufficiently robust the frequency reducers or the existing consequences reducers?

Example: how is the robustness of the frequency reducers evaluated?

No	Type of Barrier	Robustness expressed in points
1	Internationally acknowledged protocols to do the tests. Frequency Reducer Type 3	8
2	Physicists capacitation. Frequency Reducer type 4	4

There are only 2 frequency reducers. The robustness of the Frequency reducers is greater than or equal to 32 Points (RF1 * RF2 = 32), it is possible to reduce a Frequency level. **It is not possible to reduce the frequency from the F_L level to the F_{VL} level if an initiating event derived from Human Errors is treated.**

SECOND SCREENING

A_2- Are sufficiently robust the frequency reducers or the existing consequences reducers?

Consequences reducers

1. **If the multiplication of the consequences reducers robustness is greater or equal to 64 Points (RC1*RC2*RC3*…*RCn > 64) it is possible to reduce consequence level, given example from C_{VH} goes to C_H.**

Note: Regarding the consequences reducers, no case can be reduce medium consequences to low consequences because by definition never low consequences can be reached from medium consequences sequences.

SECOND SCREENING

A_2- Are sufficiently robust the frequency reducers or the existing consequences reducers?

Robustness of the consequences reducers

TABLE 6. CRITERIA TO EVALUATE ROBUSTNESS OF THE CONSEQUENCES reducer GROUP .RISK MATRIX METHODOLOGY-

GENERAL DESCRIPTION OF THE CONSEQUENCES REDUCERS	Robustness	Weight
interlocks	very Robust	32
Alarms	Robust	16
Protocols and procedures	Normal	8
Emergency plans	Soft	4
Quality controls (annual and monthly)	Theoric	1

SECOND SCREENING

A2- Are sufficiently robust the frequency reducers or the existing consequences reducers?

Example: How to evaluate the reducers robustness of consequences?

No	Type of barrier	Robustness Expressed in pointsn
1	"weekly medical revision of the patient" consequence reducer type 3	8
2	"annual and monthly quality controls" consequence reducer type 5	1

(RC_1* RC_2 = 8) The robustness of the consequences reducers is not greater than 64 points, therefore it is not possible to reduce the consequence level.

SECOND SCREENING

A3- Is it possible to introduce new barriers, or frequency or consequences reducers?

This objective of the analysis is to propose new safety measures in order to reduce the accidental sequence risk.
The introduction of new barriers and reducers influences in the independent variables of the risk equation. To propose each one of this measures, the risk matrix reevaluates the robustness of the barriers and reducers group with the criteria exposed in questions A1 and A2

SECOND SCREENING

A4- Conclusion. What additional measures can be proposed to diminish global risk?

The main objective is to propose a strategy to reduce risk in each accidental sequence .

The answer to these questions allows to define, about to which variable of the risk equation we must act, to reduce the risks to an acceptable level of safety, with the lowest cost.