

Tolerable frequency of occurrence of major-hazard events: a deterministic approach for an effective and consistent risk reduction

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The allocation of a target Safety Integrity Level (SIL) to a Safety Instrumented Function (SIF) in compliance with the European Norm EN IEC 61511 “Functional Safety: Safety Instrumented Systems for the Process Industry Sector” does not state any selection requirement for qualitative, semi-quantitative and quantitative methodologies. The inconsistency of results of qualitative methodologies and the applicability limits of full quantitative methodologies meet halfway with the LOPA (Layer of Protection Analysis) semi-quantitative methodology.

LOPA methodology is based on the predetermination of the tolerable frequency of occurrence of hazardous event. Higher the tolerable frequency, lower the resulting SIL allocated to an SIF adopted as (independent) protection layer, and *vice versa*.

The paper introduces an evaluation methodology of the tolerable frequency of hazardous event based on the deterministic approach of Italian Ministerial Decree D.M. 9 May 2001 stating the safety minimum requirements on the subject of town and territorial planning relating to areas affected by major-accident hazard industries.

The major-accident probability classes stated on D.M. 9 May 2001 are turned into tolerable risk frequency classes to be adopted on a case-by-case approach to achieve an effective and consistent risk reduction.

The paper relates the limitations of applicability of D.M. 9 May 2001 to LOPA methodology and the required interpretations as well.

1. Introductory Notes to LOPA

According to EN IEC 61511-1 clause 9, the second activity of the Safety Instrumented System (SIS) Safety Life-cycle (SLC) to be carried out is the "Allocation of safety functions to protection layers".

The Layer of Protection Analysis (LOPA) is a semi-quantitative methodology suitable to cover in the most of application cases the EN IEC 61511-1 clause 9 requirements, supporting in the meanwhile the Seveso II Directive as far as technical, human and organizational protection and defense layers are concerned.

2. LOPA Main Objectives

The LOPA main objectives are the following:

- a) identify the passive and/or active independent protection layers (IPL);
- b) allocate the safety functions to the passive and/or active IPL;
- c) determine if one or more safety instrumented functions (SIF) are required to achieve the target risk reduction
- d) determine for each SIF, if required, the safety integrity level (SIL).

3. HSE Tolerable Risk Criteria

Before carrying out a LOPA analysis the Tolerable Risk Criteria for the impact on Health & Safety and Environment shall be stated. The tolerable risk on Health & Safety can refer to individual risk criteria, societal risk criteria or both combined. The tolerable risk criteria shall refer to the Environment consistently with the Seveso II Directive.

The economic risk associated to parameters such as loss of production, asset losses, insurance premiums penalization is often taken into consideration in addition to HSE risks. Specific tolerable risk criteria are set for economic losses in addition to HSE tolerable risk criteria based on the return of the additional capital expenditure required by a specific economic risk reduction.

Hereinafter the HSE tolerable risk only is considered.

4. HSE Tolerable Risk Criteria according to D.M. 9 May 2001

The Italian Ministerial Decree D.M. 9 May 2001 states the safety minimum requirements of town and territorial planning relating to areas affected by major-accident hazard (MAH) industries.

4.1 Objective of D.M. 9 May 2001

The objective of D.M. 9 May 2001 is the achievement of HSE compatibility of MAH industries with the surrounding territory.

The Health & Safety compatibility according to D.M. 9 May 2001 is deterministically stated as function of severity of consequences on Health & Safety of the hazardous events vs. the probability class set for that severity for each territorial category (A, B, C, D, E, F). For existing MAH industries in case of top events potentially causing the death of several persons, the D.M. 9 May 2001 excludes the territorial categories A, B, C. Consequently the risk reduction by reduction of the top event occurrence frequency is not allowed, remaining as only viable approach the reduction of the severity of consequences

(death to one person as worst consequence for C, permanent injury for B, reversible injury as worst consequence for A).

The Environmental compatibility according to D.M. 9 May 2001 is based on a "Consequences Only" approach. The categories of severity of consequences on Environment are limited to 'significant' and 'major', and in case major consequences are envisaged the environmental compatibility cannot be reached by decreasing the likelihood of the hazardous event by allocating active or functional protection layers.

4.2 Category of Consequences on Health & Safety

The Table 2 of D.M. 9 May 2001 states deterministically the Category of Consequences on Health & Safety as function of hazardous event type and threshold limits of resulting effects to be exceeded to set the category of consequences:

Hazardous Event Type	Category of Consequences			
	Death to several persons	Death to one person	Permanent Injury	Reversible Injury
Fire (1)	12.5 kW/m ²	7 kW/m ²	5 kW/m ²	3 kW/m ²
BLEVE/Fireball (2)	fireball radius	359 kJ/m ²	200 kJ/m ²	125 kJ/m ²
Flash Fire (3)	LFL (4)	1/2 LFL (4)	-	-
VCE (5)	0,3 bar (6)	0,14 bar	0,07 bar	0,03 bar
Toxic release	LC50 (7)	-	IDLH (8)	-

NOTES:

- (1) steady thermal radiation
- (2) variable thermal radiation
- (3) instantaneous thermal radiation
- (4) Cloud Low Flammability Limit
- (5) Vapor Cloud Explosion peak overpressure
- (6) in confined spaces; 0,6 bar in open spaces
- (7) Lethal Concentration (30 min. exposure lethal for 50% of humans exposed)
- (8) Immediately Dangerous to Life & Health conc. (30 min. toxic inhalation does not cause permanent injury to humans exposed)

4.3 Category of Consequences on Environment

According to D.M. 9 May 2001 the hazard for the Environment is caused by an (occasional) loss of containment of noxious material potentially impacting on the following environmental matrices:

- landscapes and environmental resources
- natural protected areas
- ground water resources
- underground water resources
- soils.

The D.M. 9 May 2001 states two categories of severity of consequences on the Environment: 'significant' and 'major':

'Significant' Damages to Environment

Damages to the Environment following a top event, causing reclamation and environmental restoration actions to be accomplished within two years from the beginning of the intervention actions.

'Major' Damages to Environment

Damages to the Environment following a top event, causing reclamation and environmental restoration actions not accomplishable within two years from the beginning of the intervention actions.

According to D.M. 9 May 2001 the Environmental Compatibility can be claimed only in case 'Significant' Damages to Environment are potentially envisaged.

Even in case of potential 'Significant' Damages category the D.M. 9 May 2001 obliges to undertake construction and building prescriptions on the surrounding territory, as well as to undertake prevention and mitigation countermeasures, including territorial, infrastructural and management provisions to further reduce the severity of potential environmental damages. In this case the only viable approach to be able to comply with D.M. 9 May 2001 is to allocate one or more passive protection layers (e.g. explosion-proof design, closed drains, containment basins, dump areas, dikes, tank double-walls jackets, leak-proof pavements, bunkers, expansion tanks, etc.) to reduce the severity of potential consequences of the top event to *minor* environmental damages without the adoption active or functional protection layers.

As application reference the European Norm EN IEC 61511-3 categorizes in Table D.3 the *minor* environmental damages, as follows:

C_A release with *minor* environmental damage that is not very severe but is large enough to be reported to plant management
e.g. a moderate leak from a flange or valve, a small scale liquid spill, small scale soil pollution without affecting ground water.

4.4 Territorial Categories

According to D.M. 9 May 2001 the Territorial Categories are six, namely A, B, C, D, E, F. Each Territorial Category is duly and completely defined.

Here below we take into consideration the Territorial Categories D, E, F since the only ones allowed to be exposed to the worst category of consequences (see above) for existing plants. For the remaining categories reference is directly made to D.M. 9 May 2001.

Territorial Category F

1. Area within the Plant fence;
2. Area surrounding the Plant fence, wherein facilities or structures are not present where the ordinary presence of groups of persons is envisaged.

Territorial Category E

1. Areas with prevalently residential destination, for which the land building index is lower than 0.5 m³/m²;
2. Industrial, handicraft, agricultural, zootechnical installations, [*technical- production areas* (*)] .

Territorial Category D

1. Areas with prevalently residential destination, for which the land building index is in between 1 and $0.5 \text{ m}^3/\text{m}^2$;
2. Locations subject to considerable crowding with maximum monthly frequentation, such as for instance fairs, curbs or other periodic events, cemeteries, etc.;
3. *Highways and expressways, provided with public alarm and traffic detouring systems in case of accident; (*)*
4. *High vehicular traffic state routes. (*)*

(*) according to Lombardy Region DGR N. 7/19794

4.5 Health & Safety Compatibility

With reference to D.M. 9 May 2001 here below the Health & Safety Compatibility of Territorial Category F, E, D for existing Plants is summarized in association to the probability class allowed by D.M. 9 May 2001:

Territorial Category F

Category of Effects on Health & Safety	Probability Class of Top Events D.M. 9 May 2001
Reversible Injury	$> 10^{-3}$
Permanent Injury	$> 10^{-3}$
Death to one person	$> 10^{-3}$
Death to several persons	$> 10^{-3}$

Territorial Category E

Category of Effects on Health & Safety	Probability Class of Top Events
Reversible Injury	$> 10^{-3}$
Permanent Injury	$> 10^{-3}$
Death to one person	$10^{-3} - 10^{-4}$
Death to several persons	$10^{-4} - 10^{-6}$

Territorial Category D

Category of Effects on Health & Safety	Probability Class of Top Events
Reversible Injury	$> 10^{-3}$
Permanent Injury	$10^{-3} - 10^{-4}$
Death to one person	$10^{-4} - 10^{-6}$
Death to several persons	$< 10^{-6}$

5. Assessment Methodology of Top Events Target Frequencies for LOPA Analysis

The assessment methodology of Target Frequency of Top Events is required for SIL allocation to SIF by LOPA Analysis. Whenever the Top Event impacts on Health & Safety the mandatory H&S territorial compatibility requirements of D.M. 9 May 2001 shall be satisfied.

The assessment methodology of Target Frequency of Top Events outlined here below fully matches the mandatory H&S territorial compatibility requirements of D.M. 9 May 2001.

1st. Step

Identification of top events (type, category of effects on H&S, territorial category involved inside and outside the Plant fence).

2nd. Step

Evaluation of number of top events impacting on each territorial category per each category of effects on H&S.

3rd. Step

Calculation of Top Events Target Frequency based on:

- PC, probability class [adim.] of top event per territorial category and per each category of effects (see above)
- N, nos. of independent top events [occ.] per each territorial category and per each category of effects on H&S; and
- T, operation time [years] of the Plant (or Unit or Section taken into consideration within the Plant fence); and

$$\text{Top Event Target Frequency} = PC / N / T$$

The calculation result is the Top Event Target Frequency [occ./year] to be used for the LOPA analysis to identify any necessary protection layer, such as in particular an SIF and to allocate to each protection layer a suitable probability of failure on demand.

In case the Top Event Target Frequency were not reached, one or more independent Safety Instrumented Functions (SIF) can be added to mitigate the risk and a suitable SIL allocated to each SIF to eventually satisfy the Top Event Target Frequency.

A risk reduction safety factor can be introduced to further reduce the Top Event Target Frequency - with specific reference to Territorial Category F - to take into due consideration any Plant future modification or new installation or the uncertainty level of risk assessment and last, but first for importance, the value set for Probability Class for Territorial Category F on D.M. 9 May 2001 not conservative in case of severe consequences on Health & Safety..

6. Conclusions

Based on Top Events Target Frequency set as above outlined for each territorial category and per each category of effects on Health & Safety the LOPA analysis allows to allocate the SIL to SIF and the PFD to any additional independent active safety function in full compliance with D.M. 9 May 2001 suitably considering the overall Fatal Risk.

It's Author's strong opinion the tolerable risk to be accepted by the current society for an individual person living in the surrounding of a process industry shall in any case not higher than the individual risk of death due to natural hazardous events such as earthquakes, flooding, lightning, insects & animals (in Italy in the last 25 years an overall of $3.3\text{E-}06$ occ./year).

Last but not least the Legislators shall revise the D.M. 9 May 2001 since:

- a) the Consequences Only approach for the Environment is not consistent with the deterministic approach for Health & Safety and excludes the contribute to risk reduction of active protection layers;
- b) the environmental matrices are not well and completely defined;
- c) the severity of consequences on Environment is susceptible to "interpretation";
- d) the Probability Class $> 10^{-3}$ for the Territorial Category F is misleading and not in line with *de minimus* international requirements for individual worker risk .

7. Disclaimer

Although the Author believes the information contained in this paper is factual, no warranty or representation, expressed or implied, is made with respect to any or all of the content thereof, and no legal responsibility is assumed therefore. The worked example reported in this paper is simply for illustration, and such does not intend to represent a guideline. The readers shall use data, methodologies, criteria, and information exclusively appropriate for their own situations.

8. References

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