GUIDANCE ON THE PREPARATION OF A SAFETY REPORT TO MEET THE REQUIREMENTS OF DIRECTIVE 96/82/EC AS AMENDED BY DIRECTIVE 2003/105/EC (SEVESO II)

LEGAL NOTICE

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Preface

The Amendment of the Seveso II Directive adopted by the European Parliament and the Council on 16 December 2003, gave the Commission the mandate "to review by 31 December 2006 in close cooperation with the Member States, the existing Guidance on the Preparation of a safety Report (EUR 17690)."
The previous guidance document[1], published in 1997, was developed parallel to the legislative process leading to the Seveso II Directive (96/82/EC), which came into force in February 1997. This document was developed on the basis of experience gained in the implementation of the preceding Seveso Directive (82/501/EEC). As clearly stated in its introduction, the guidance was intended to specify the information to be contained in the report, but not intended to prescribe a particular format for its presentation.

Since the coming into force of the Seveso II Directive, considerable experience has been acquired in regard to preparation of safety Reports for establishments that fall under the requirements of this Directive. Thus the mandate from the European Parliament and the Council, included in the 2003 amendment to the Directive, enables this experience to be integrated into the existing guideline through the review process. The guidance also addresses requests to include general guidance on the principles and the purpose of safety reports in the guidance document.

[1] Papadakis & Amendola: (1997) "Guidance on the Preparation of a safety Report to meet the Requirements of Council Directive 96/82/EC (Seveso II)", EUR 17690 EN.

Any process of hazard identification and risk assessment is characterised by a certain subjective character and has degrees of uncertainty attached to it. The extent to which these uncertainties are recognised and understood by authorities and industry within Europe may vary considerably. In addition, the levels of tolerable risk, against which the risk decisions are taken, may also vary from Member State to Member State, not only in their magnitude but also in the extent to which they are legally binding. For example, values may be defined as advisory limits, target values or legal criteria. These aspects make the issue of comparability across the European Union very difficult to resolve.

The intention of this paper is therefore to produce a revised version of the current guidance in such a way as to maintain its high-level and overarching character, but also to improve the document through better definition of safety report principles and greater alignment with Annex II. As for the previous guidance, the purpose of this guidance is to assist all the involved stakeholders (i.e. operators of Seveso-type establishments, competent authorities, and consultants involved in the production of Safety reports) with the interpretation of the requirements on Safety reports contained in the Seveso II Directive and its amendment. This guidance reflects the Commission's opinion, shaped in close cooperation with the Member States, on the interpretation of the Directive's requirements. It is not a legally binding text.

Sections of the Directives Relevant to This Guideline

96/82/EC Directive (Seveso II): articles 5, 9 and Annex II as amended by 2003/1005/CE

I. Article 5: General obligations of the operator

This article is intended to impose a clear general requirement on the operator of a Seveso-type establishment. More specifically:

"...the operator is obliged to take all necessary measures to prevent major accidents and, in the case of such an accident, to limit its consequences for man and the environment"

"...the operator is required to prove, at any time, to the public authority responsible for carrying out the duties under the Directive (so-called Competent Authority) that he has taken all the necessary measures as specified in the Directive".

II. Article 9: Safety Reports

The present article of the Directive requires that an operator of an upper-tier Seveso type establishment produce a safety report. The original Seveso Directive (82/501/EEC) required the production of a similar type of document (a safety assessment of hazards). However, in the Seveso II Directive (96/82/EC) significant additional requirements (including the MAPP and SMS) were introduced as part of a more comprehensive "safety report". Some of the key features of safety reports can be described by means of the following questions:

WHY?
Safety reports are intended to demonstrate that:

• a major accident prevention policy (MAPP) and a safety management system (SMS) have been put into effect;

• major-accident hazards are identified and necessary measures have been taken to prevent such accidents and to limit their consequences for man and the environment;
• adequate safety & reliability have been incorporated into the design, construction, operation and maintenance of any installation;
• internal emergency plans have been drawn up, supplying information to enable the external emergency plan to be drawn up;
• information for land-use planning decisions has been given.

HOW?
The safety report must include the following minimum data and information that are specified in more detail in Annex II of the Seveso II Directive:

• Information on the MAPP and on the SMS
• Presentation of the environment of the establishment
• Description of the installation(s)
• Hazard identification, risk analysis and prevention methods
• Measures of protection and intervention to limit the consequences of an accident

The safety report may be combined with other reports produced in response to other legislation to form a single safety report in order to avoid unnecessary duplication or repetition of work.

WHO?
The safety report must be submitted to the authority by the operator.

It is up to the operator and within in its responsibility to decide on the sufficiency of competence of the people and organisations involved in the preparation of the safety report. Relevant organisations entrusted with such tasks must be named in the safety report.

WHEN?
The safety report must be submitted:

• in case of a new establishment a reasonable period of time prior to the start of construction or operation
• in case of existing establishments that come into the scope of the Directive by the Amendment Directive 2003/105/EC or later (e.g. due to a new

classification of substances of concern) without delay, but not later than within one year after the Directive applies
• without delay after a periodic or necessary review.

The safety report must be reviewed and, if necessary, updated:

• at least every five years, or
• at the initiative of the Operator or at the request of the Competent Authority, where justified by new facts, new technical knowledge about safety or about hazard assessment, or
• in case of a modification of a site which means modification of the establishment, the installation, the storage facility, the (chemical) process, the nature of dangerous substance(s) or the quantity of dangerous substance(s). The decision whether these modifications would have an impact on safety and, therefore, would require a review of the safety report should be taken by using a systematic analysis such as for instance a screening method or a rapid ranking tool.

III. Limits of the information required in safety reports (Art. 9.6 – dispensations)

• The applicability of this provision of the Directive requires in the first instance the development of so-called harmonized criteria for a decision by a Competent Authority that particular substances present at an establishment, or part thereof, are "in a state incapable of creating a majoraccident hazard".
• These harmonised criteria which have been elaborated by the Commission, in close co-operation with the Member States, were adopted by the Commission on 26 June 1998 in accordance with the Regulatory Committee procedure established under the Seveso I Directive (OJ No L 192 of 8 July 1998, p. 19).
• This provision allows the Competent Authorities, at the (justified) request of an Operator, to decide and communicate to the Operator that he may limit the information to be provided in his safety report. However, it is clear that

this cannot mean a total dispensation from the obligation to submit a safety report.

• The Member States are obliged to notify any dispensations granted to the Commission, including the reasons. The Commission shall forward the lists containing the notifications to the Committee established under the Directive on a yearly basis.

IV. Task of the Competent Authority in relation to safety reports

• The Competent Authority is required to examine the safety report and to communicate the conclusions of its examination to the Operator.

• Before finalising these conclusions, the Competent Authority may request further information from the Operator; in addition an inspection of the establishment, in accordance with Article 18, "Inspections" may be carried out to verify whether the information contained in the safety report corresponds with the situation as it is in reality. However, it is important to note that the inspection programme according to Article 18 is independent of whether a safety report has been received or a decision regarding the safety report been made.

• The conclusions should generally be in written form, and they should make reference to the date of the safety report in question and any other supplementary documentation reviewed for this purpose. A pro forma statement by the Competent Authority that the safety report has been received and seems complete will not be sufficient. Rather, the conclusions should make reference to general conclusions based on the safety report in general and to specific cases of accuracy where individual examples have been examined in detail. Deficiencies and inaccuracies must be described where identified, however it is not expected that the competent authority should identify every single inaccuracy. Moreover, a large number of deficiencies and inaccuracies may lead the competent authority to reject the safety report and require that a revised document is submitted.

General Principles and Definitions

I. Purpose of a Safety Report

According to the Directive, the purpose of a safety report is to demonstrate that:
• a major accident prevention policy (MAPP) and a safety management system (SMS) have been put into effect;
• major-accident hazards are identified and necessary measures have been taken to prevent such accidents and to limit their consequences for man and the environment;
• adequate safety & reliability for construction, operation, maintenance, etc. have been incorporated into the design;
• internal emergency plans have been drawn up, supplying information to enable the External emergency plan to be drawn up;
• information for land-use planning decisions has been given;
From this summary of the legal requirement the following *guiding principle* for a safety report may be established:
From the above definition it is clear the necessity of further developing the following terms or group of terms appearing in the guiding principle, namely:

A. "*demonstrate*"
B. "*necessary measures*"
C. "*prevent, control and limit*"
D. "*major accident*"

The safety report should demonstrate that necessary measures to prevent, control and limit the consequences of a possible major accident have been put in place and are fit for purpose.

A. "Demonstrate"

For this specific purpose, "*demonstrate*" is intended in its meaning of: "justify" or "argue the case" but not "provide an absolute proof". In reality, the hazard identification, its associated risk analysis and the sub-sequent decisions in regard to control measures are processes that are always characterised by a certain degree of uncertainty. As such, it is normally not possible to prove absolutely in the safety report that "all necessary measures" have been taken. In addition, it should always be assumed that the Competent Authorities will take the information and conclusions in the report largely as presented, using professional judgement more generally to assess the credibility and logic of the conclusions reached in the report. An extensive in-depth scrutiny or exhaustive examination is not envisaged in most cases.
Finally, the effective implementation of this principle is strictly dependent on the correct identification of all potential major-accident hazards and proper selection and application of the necessary control measures for each of them.
From these considerations the following guidance may be derived:
The considerations expressed in this section refer specifically to the general approach adopted when ela-borating a safety report. In particular "*to demonstrate*" is here intended to address the level of detail and the quality of the information in the safety report and not the list of information as described in Annex II of the Directive, which should be considered as exhaustive.

• *The operator shall expect professional judgment from the assessor of a safety report and should base its demonstration on this assumption.*

• *The demonstration must be "convincing". This means that the rationale for deciding the completeness of hazard identification and the adequacy of the measures employed should be supported and accompanied by all assumptions made and conclusions drawn.*

• *The demonstration should provide evidence that the process was systematic which means that it followed a fixed and pre-established scope.*

• *The extent to which the demonstration is performed should be proportional to the associated risk.*

B. *"Necessary Measures"*

"*Necessary measures*" shall be taken in order to prevent, control and limit the consequences of a possible major-accident. In the context of the assessment of a safety report it means that, in applying the identified measures, all risks of concern have been properly reduced according to current national practices.
A point to note is that, although the "*necessary measures*" are properly taken, some "residual risk" will always be present.
This decision as to whether the residual risk is acceptable depends very much on national approaches and practices. Nevertheless there are some widely accepted supporting principles for this decision:

• *The efficiency and effectiveness of the measures should be proportionate to the risk reduction target (i.e. higher risks require higher risk reduction and, in turn, more stringent measures).*

• *The current state of technical knowledge should be followed. Validated innovative technology might also be used. Relevant national safety requirements must be respected.*

• *There should be a clear link between the adopted measures and the accident scenarios for which they are designed).*

• *Inherent safety should be considered first, when feasible (i.e. hazards should always be removed or reduced at source).*

C. *"Prevent, Control and Limit"*

These terms are associated to the different type of measures required to meet the objective of Article 5 of the Seveso II Directive. More specifically they mean:

• *Prevent*: to reduce the likelihood of occurrence of the reference scenario (example: automated system to prevent overfilling; sometimes "avoid measures" are regarded to be a separate category as they refer to the total avoidance of a scenario, e.g. in case of the burying of a vessel);

• *Control*: to reduce the extent of the dangerous phenomenon (example: gas detection that reduces intervention time and may prevent major release);
• *Limit*: to reduce the extent of the consequences of a major accident (e.g. through emergency response arrangements, bunding or firewalls).

D. "Major Accidents"

The Seveso II Directive aims at the prevention of major accidents, which involve dangerous substances, and the limitation of their consequences to the man and the environment. As defined in Article 3 of the Directive, *"major accident"* means an "adverse occurrence such as a major emission, fire, or explosion resulting from un-controlled developments in the course of the operation of any establishment covered by this Directive, and leading to serious danger to human health and/or the environment, immediate or delayed, inside or outside the establishment, and involving one or more dangerous substances."

To qualify an accident as *"major accident"*, three criteria must be fulfilled:
• the accident must be initiated by an "uncontrolled development";
• "one or more dangerous substances" listed in Annex I of the Directive must be involved;
• the accident must lead to "serious danger" to human health, the environment, or the property.
Whereas the criteria "uncontrolled development" and "dangerous substance" are viewed as relatively unam-biguous, the interpretation of "serious danger" is more controversial. However, some direction in this regard can be found in Annex VI of the Directive, which provides criteria for identifying a major accident that should be notified to the Commission (notwithstanding the fact that the scope of a safety report may go further than the definition given in Annex VI). The criteria associate the definition of a major accident with a certain level of consequence, that is, endangerment. Therefore, from this annex it is possible to extract the key elements necessary to formulate the following generic description of "serious danger":
• potential life-threatening consequences to one human (on-site or off-site);
• potential health-threatening consequences and social disturbance involving a number of humans;

• potential harmful consequences to the environment at a certain (larger) extent;
• potential severe damage to property (on-site or off-site).
A major accident may therefore be considered as a specific event (or a group of specific events) that is characterised by certain potential consequences.
In applying the criteria listed above a major accident may include those events involving dangerous sub-stances that are often classified as "occupational accidents" (on-site) as well as those events that have effects outside the boundary of the establishment (off-site). The approaches adopted by the Member States for assessing the risks of major accidents may differ according to whether (i) the analyses of on-site and off-site effects are conducted separately or (ii) whether the analysis of off-site effects is conducted as the primary activity and on-site effects are covered within this analysis.

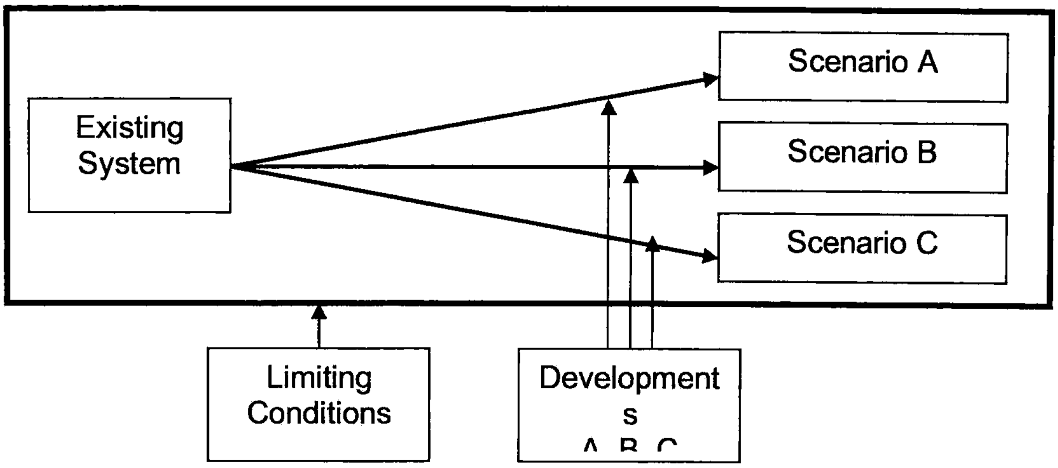
II. Practical Considerations

A comparison of the current state-of-the-art for safety reports and the common practices in the different Member States reveals a number of common principles. These are:
• The overall approach followed should be properly described and explained;
• The level of demonstration should be proportionate to the extent of potential consequences and the complexity of the installation/process/systems involved;
• Preparation is the sole responsibility of the operator. The Competent Authority has no responsibility for content;
• One of the main elements of the safety report is the definition of reference accident scenarios. These scenarios normally are the basis for demonstrating that the necessary measures are adequate. For this purpose, the scenario description should be structured and evidence provided to highlight the consistency between the scenario selected and the measures taken;
• The safety report should be of a summarising character, in which the information provided is limited to its relevance in regard to major-accident hazards, however the information should be sufficient to demonstrate that the requirements with regard to major accident hazards have been met and allow the competent authority to come to justified conclusions;

• The description of measures should be limited to the explanation of their specific objectives and functions. Specific technical details should be provided within the safety report when this is necessary to demonstrate that the measures are sufficient, ie. the measures have the required reliability and effectiveness, thus enabling the competent authority to come to appropriate con-clusions;
• Other areas of safety legislation may have an impact on the scope of assessment.

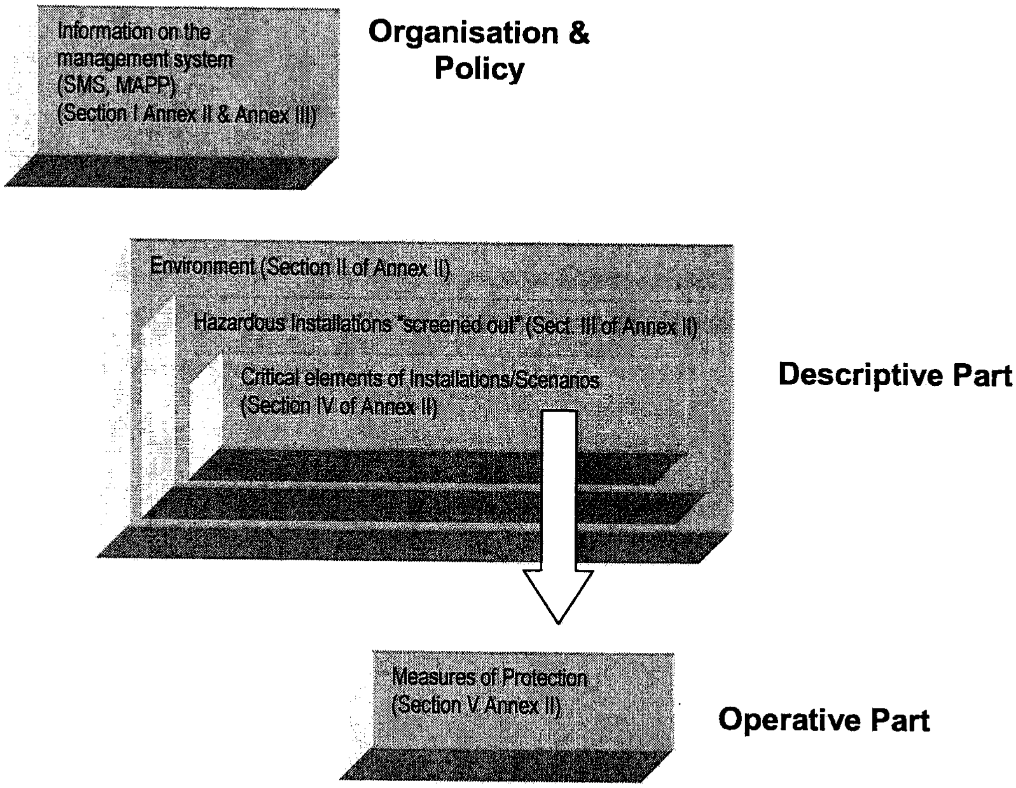
II. Definition of "Accident Scenario"

As mentioned above, one of the main elements of safety reports is the definition of reference accident scenarios. In practice, all scenario methodologies are modelling tools for planning and decision-making under uncertainty. As such, they are widely used for statistical, economic, environmental and technological purposes. In general, they are based on the following main elements:
The modelling process is roughly illustrated in the picture below:
For the specific purposes of safety reports in the context of Seveso II requirements, a scenario is always an undesirable event or a sequence of such events characterised by the loss of containment (LOC) or the loss of physical integrity and the immediate or delayed consequences of this occurrence.

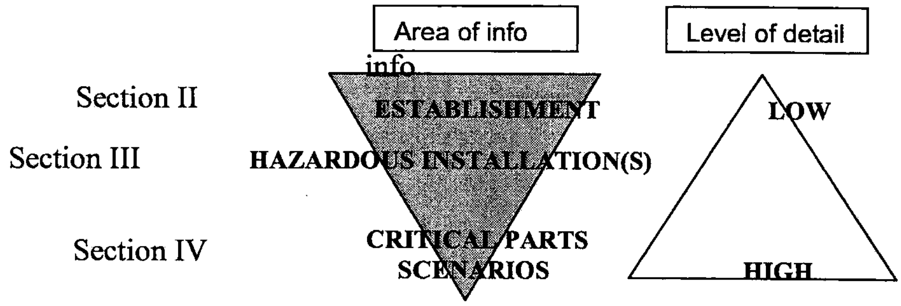


Essential Elements of a Safety Report

The following sections are structured according to the contents of Annex II of the Seveso II Directive, which describes the "Minimum Data and Information to be considered in the safety report specified in Article 9." It should be noted that, safety reports do not necessarily always follow this structure exactly. Nevertheless the explanations are given in order of the items as they appear in the annex, while acknowledging that this exact order may not be followed in many safety reports.
The different items described in Annex II are illustrated in the following diagram and logically grouped in three main parts:



An essential and extensive part of a safety reports is the central box, which refers to the description of the establishment, its surrounding, the hazardous installations and the critical scenarios which could lead to a major accident. In this case, the description of the different sections is expected to be characterised by a different level of detail depending on the relevance of the involved topic to the purpose of the safety report. A suggested general approach is illustrated in the diagram below. However, it should be emphasised that in some individual cases the hazard related to the various sections might be of particular relevance and it will then require a greater level of detail.



I. Information on the Management System and on the Organisation of the Establishment With a View to Major Accident Prevention2

The Seveso II Directive contains several management and organisational related requirements (Article 7, Article 9, Annexes II and III). In particular, Article 7 imposes the elaboration of a Major Accident Prevention Policy (MAPP), which is a "self-commitment" by the operator of a Seveso type establishment to meet the requirements of Article 5. A safety management

2 Specific Guidance given in: Mitchison/Porter: "Guidance on a Major Accident Prevention Policy and Safety Management System as required by Council Directive 96/82/EC", 1997, EUR 18123 EN

system (SMS) is instead a set of activities that ensures that hazards are effectively identified, understood and minimised to a tolerable level. In this sense, it may be regarded as the transposition of the general goals identified in the MAPP into specific objectives and procedures. As safety reports address major-accidents deriving from hazardous substances the safety management system is a subset of the overall management system.

MAPP and SMS should address the following issues:

1. organisation and personnel
2. identification and evaluation of major-accident hazards
3. operational control
4. management of change
5. planning for emergencies
6. monitoring performance
7. audit and review

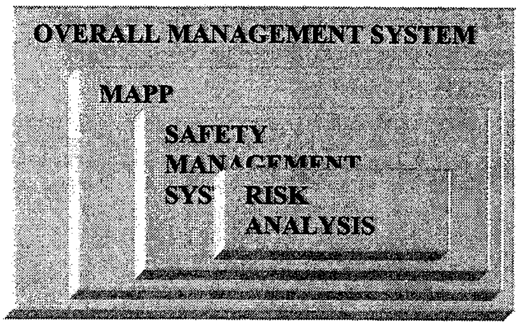
In practice a SMS consists of a compilation of written principles, plans, formal organisation charts, respon-sibility descriptions, procedural recommendations, instructions, data sets, etc. This does not mean that all of these documents do not have to be available in case of inspections but with respect to the safety report, most of them have the character of "underlying documents". Therefore for the purpose of a safety report, the description of the SMS is of a summarising character and should address all the above seven subsets. It shall at least consist of:

• the major accident prevention policy (MAPP)

• an explanation of the relationship of the MAPP to the site-specific aims and safety-related objectives

• explanations in generic terms concerning how these objectives are met, especially with respect to consistency between the approaches followed and the measures taken

The main relevance of the SMS is the setting of objectives for the concept of understanding the risk associated with the presence of dangerous substances and the selection of "lines of defence" – the risk analysis in a broad sense. This leads to a picture as shown below, where the MAPP is embedded in the overall management system of a company or site. The MAPP sets the general goals for the SMS, the latter serving as basis for the risk/hazard analysis (as far as it concerns major accident hazards).



II. Presentation of the Environment of the Establishment

A. description of the site and its environment including the geographical location, meteorological, geological, hydrographical conditions and, if necessary, its history;

B. identification of installations and other activities of the establishment which could present a major accident hazard;

C. description of areas where a major accident may occur.

A. Description of the site and its environment[3]

General

The safety report should contain an adequate description of the establishment to enable the authorities to have a clear picture of its purpose, location,

[3] With regards to the use of maps, it depends on the individual case if multiple information is given in the same document; in principle it is a matter of the required level of detail but it is probably unwise to use large scale maps (e.g. such for land use patterns) to contain information on installation details

activities, hazards, services and technical equipment. The extent of this description should be commensurate to the hazards of the establishments. The description should also aim at clarifying the interrelationship between the different installations and systems within the establishment, with respect to their technical parameters and management aspects.

An introductory section should contain general information on the establishment, i.e.:

• purpose of the establishment;
• main activities and production;
• history and development of the activities, including the status of authorisations for operations already agreed and/or granted, when applicable;
• the number of persons working at the establishments (i.e. internal and contractors' personnel, specifying working times, possibility of visitors, etc.);
• general statements characterising the establishment with respect to its main hazards as regards relevant substances and processes.

Location

The description of the location of the establishment should contain data on topography and accessibility to the site at a degree of detail commensurate with the extent of the hazards and the vulnerability of the sur-roundings. The description of the natural environment and the surroundings of the establishment should be detailed to an extent proportionate to the hazard. It should demonstrate that the natural environment and surrounding activities have been sufficiently analyzed by the operator to identify both the hazards that they pose to safe operation and the vulnerability of the area to the impact of major accidents.
The topographic maps submitted should be of an adequate scale and should include the establishment as well as all development in the surrounding area within the impact range of the accidents identified. (The scale of the maps must be indicated; different scale maps may be necessary when long distance effects are fore-seeable).
On such maps the land-use pattern (i.e. industry, agriculture, urban settlements, environmentally sensitive locations, etc.), the location of the

most important buildings, infrastructure elements (i.e. hospitals, schools, other industrial sites, motorway and railway networks, stations and marshalling yards, airports, harbours, etc.) and access routes to and from the establishment must be indicated.

The land-use pattern of the area surrounding the establishment may be presented according to the specification of the official land-use plan of the greater area.

In more detail, relevant information in this respect should be supplied on:

- inhabited (residential) areas (e.g. description of the areas including population densities);
- establishments frequented by the general public, meeting points (regular or occasional), and recreation areas (e.g. swimming beaches, outdoor life areas, etc.);
- sensitive public buildings (e.g. schools, hospitals, etc.);
- conservation areas or similar, ecologically vulnerable or sensitive areas (e.g. used for reproduction of specific species);
- public utilities possibly affected, (e.g. electricity, gas, telephone, water, sewers and treatment plants, groundwater supplies, etc.).
- industrial activities external to the establishment (e.g. relative distance, nature of their activity, limitations they may impose in terms of access in emergency cases or infrastructure, etc.);
- traffic routes and major transportation centres (e.g. roads, railways, waterways, ports, airports, marshalling yards, etc.).

As the natural environment of an establishment may present potential hazard sources and may influence the development and consequences of an accident, data will be needed for the description of these relevant environmental factors. In general, this type of data includes:
meteorological data, such as:

- average and maximum levels of precipitation (rain, snow, hail);
- thunderstorm severity;
- lightning probability;
- indices or values on humidity, fog, frost;
- winds (values for direction, speed);

• stability classes;
• maximum and minimum recorded temperatures,
geological, hydrological and hydrographical site data such as:
• general geological context;
• type and conditions of the ground/underground;
• seismic data;
• flooding (including run-off water due to flash flooding) and landslide likelihood;
and *other site specific natural factors* such as:
• surface and ground water location values;
• water quality and uses;
• shore and marine environment data;
• areas of special environmental interest, i.e. natural protected areas, protected fauna and flora species, sensitive ecosystems, areas of outstanding natural beauty, etc.

Lay out of the establishment

The lay-out of the establishment as a whole and of its relevant installations should be clearly presented on adequately scaled plans. Relevant diagrams and/or pictures of particular sections or equipment should be presented in an appropriately larger scale.

The lay-out should adequately identify installations and other activities of the establishment including:

• main storage facilities;
• process installations;
• location of relevant substances and their quantities;
• relevant equipment (including vessels and pipes);
• spacing of the installations and their main sections;
• utilities, services and internal infrastructure equipment;
• location of key abatement systems;
• location of occupied buildings (with an indication of the numbers of persons likely to be present);
• other units if relevant for the safety report conclusions.

B. Identification of installations and other activities of the establishment which could present a major accident hazard

The installations of an establishment to be submitted to risk analysis have to be possibly selected through a screening method. The selection may follow the use of index methods or threshold criteria for hazardous substances or other suitable methods. The SMS should provide the necessary objectives and approach basics.
Those installations which have not been selected through this preliminary analysis will not be considered as an essential element of the safety report. For this reason, this part of the analysis is particularly sensitive in terms of the following outcome of the safety report study (see also III/A).
The result of this screening process should be indicated in a separate form in the safety report, e.g. a list of the installations and activities of concern or a specific indication in the respective maps.

B. Description of areas where a major accident may occur

This issue is linked with II/A and IV/B and may be demonstrated together with these parts.

III. Description of the Installation

A. description of the main activities and products of the parts of the establishment which are important from the point of view of safety and sources of major-accident risks and conditions under which such a major accident could happen, together with a description of proposed preventive measures;

B. description of processes, in particular the operating methods;

C. description of dangerous substances:

1. inventory of dangerous substances, including:
— the identification of dangerous substances: chemical name, CAS number, name according to IUPAC nomenclature,
— the maximum quantity of dangerous substances present or likely to be present;
2. physical, chemical, toxicological characteristics and indication of the hazards, both immediate and delayed for man and the environment;
3. physical and chemical behaviour under normal conditions of use or under foreseeable accidental conditions.

A/B. Hazardous installations and activities and processes

Sufficient information should be provided in the safety report to permit the competent authority to assess the adequacy of the controls in place or foreseen in the hazardous installations[4] identified through the screening process. Reference can be made to other, more detailed documents available to the authority on request and/or on-site (the "underlying documents" already mentioned in the section about the SMS).

The safety report does not need to contain detailed information on structural characteristics and other design data of the storage or process installation handling the dangerous substances but only summarising descriptions, covering certain relevant topics, such as:

• choice of materials important to safety;
• foundations;
• design of equipment under high pressure or temperature and their supports;
• size;
• stability (static calculations, conditions and load-bearing capacity of the ground);
• design against external events.

[4] Annex II uses the term "proposed" which may be understood in the meaning of "present" or "planned".

Where equipment is built to a specific standard, this standard should be named, together with its date and an indication of the validity for the intended purpose made where this is not evident.

The descriptive part of the safety report with respect to the safety relevant sections of the establishment (the identified hazardous installations) should mainly provide an outline description of the procedures for safe operation in all process stages, which includes:

a) measures for operations (e.g. normal running, shut-down and start-up, exceptional operations, emergency and safety procedures);
b) specific precautions during storage, transport or handling because of specific characteristic of the substance (e.g. protection from vibration or from ambient humidity).

Identification:

A preliminary analysis should identify the safety relevant sections of the establishment. These sections (installations) are usually characterized by the quantity and the intrinsic properties of dangerous substances and/or the processes involved and hence constitute the parts of the establishment requiring more detailed hazard analysis. The analysis can be accomplished using a variety of hazard screening methods.

The safety report should in this respect contain a detailed description of the safety relevant sections and of the systems and components that are important for safety. The description should allow easy identification of:

• those parts of the process or installation containing dangerous substances and their location;
• those parts of the establishment involving hazardous processes;
• elements serving safety relevant functions, i.e. prevention, control and mitigation measures;
• elements capable of initiating a major accident;
• interrelationship between different installations/parts of installations.

Description:

The description of hazardous activities (processes/storage) and equipment parts shall indicate the purpose and the basic features of the related operations within the establishment which are important to safety and may be sources of major risks. This should cover:

a) basic operations;
b) chemical reactions, physical and biological conversions and transformations;
c) on-site interim storage;
d) other storage related activities i.e. loading-unloading, transport including pipe work, etc.;
e) discharge, retention, re-use and recycling or disposal of residues and wastes including discharge and treatment of waste gases;
f) other process stages, especially treatment and processing operations.

C. Dangerous Substances

The safety report should give information on types and quantities of dangerous substances to which the Directive applies at the establishment. The substances can fall into any of the following categories:

- raw materials;
- intermediate products;
- finished products;
- by-products, wastes and auxiliary products;
- products formed as a result of loss of control of chemical processes.

For the eligible dangerous substances, data to be provided should include:

a) *type and origin of the substance* (i.e. CAS Number, IUPAC Name, commercial name, empirical formula, chemical composition, degree of purity if relevant, the most important contamination, etc.);

b) *physical and chemical properties* (i.e. characteristic temperatures and pressures, concentration and phases at normal and at the onset of abnormal conditions, equilibrium data and operation curves if relevant, thermodynamic and transport properties, data on phase changes, flash points, ignition temperatures, combustibility of solids, spontaneousignition temperatures, explosion limits, thermal stability data, data on reactions and their rates, decomposition, etc.);

c) *toxicological, flammability and explosive characteristics* (i.e. toxicity, persistence, irritant effects, long-term effects, synergistic effects, warning symptoms, effects to the environment, ecotoxic data, etc.)

d) *substance characteristics under loss of control of process or storage conditions* (e.g. information on possible transformation into new substances with other properties of toxicity, degradability, etc.)

e) *others* (e.g. corrosion characteristics in particular relating to the containment material, etc.);

the latter two only when relevant for the safety report conclusions or specifically addressed there.

Some information may be found in safety data-sheets (including maximum permissible working concentrations, reference to guidelines for health at the work place, methods and means to detect their presence in the workplace and/or in the case of loss of containment, etc.). Data on accidental release threshold levels may be taken from literature, national recommendations or dedicated studies.

IV. Identification and Accidental Risks Analysis and Prevention Methods

A. detailed description of the possible major-accident scenarios and their probability or the conditions under which they occur, including a summary of the events that may play a role in triggering each of these scenarios, the causes being internal or external to the installation;
B. assessment of the extent and severity of the consequences of identified major accidents, including maps, images or, as appropriate, equivalent descriptions, showing areas that are liable to be affected by those accidents, subject to the provisions of Articles 13(4) and 20;
C. description of technical parameters and equipment used for the safety of installations.

Introduction

The main elements in any risk analysis process are as follows:

• hazard identification;

• accident scenario selection;
• scenarios' likelihood assessment;
• scenarios' consequence assessment;
• risk ranking;
• reliability and availability of safety systems

With regard to the hazard identification, a range of tools exists for systematic assessments, which are selected depending on the complexity of the individual case. Furthermore the level of detail required depends on the intended use of the safety report. Essential parts of the hazard identification are indications on the identification methods used, the scope of the analysis and related constraints. The identification of hazards is followed by designation of reference accidence scenarios which form the basis for determining whether the safety measures in place or foreseen are appropriate.
For the scenarios' likelihood and consequence assessment, which are essential steps in the risk analysis process, quite different approaches can be followed.

These assessments make use of methodologies that are generally subdivided into different categories, in particular:

• qualitative - (semi)quantitative and
• deterministic - probabilistic.

Qualitative/ (semi)Quantitative:

The likelihood of occurrence and the consequences of a major accident scenario could be assessed either:

• in qualitative terms using ranges , for example highly likely to extremely unlikely for likelihood, and very severe to negligible for consequences or
• in (semi) quantitative terms by providing numerical figures (e.g. occurrence per year, number of fatalities per year).

In general, the choice of either a *qualitative* or *quantitative* approach is strongly influenced by the specific safety culture philosophy within each individual Member State. Moreover, it is based on the level of detailed information and data available and the level of rigour and confidence required for regulatory acceptance. The depth and type of risk assessment is likely to be proportionate to the nature of the major accident hazards presented by the site, the extent of the possible damage, the complexity of the process and activities and the difficulty in deciding and justifying the adequacy of the risk control measures adopted. The nature of the simpler qualitative approach is that it can only act as an indicator of risk and does not constitute its numerical characterisation. The costs of undertaking a detailed quantitative analysis are, however, much higher and they need to be weighed against the potential benefits. In addition, for many situations, finding correct and reliable data to conduct a fully quantitative analysis can be very hard. In this circumstance, the adoption of a phased approach could be a reasonable strategy. Such an approach usually starts with a qualitative assessment at a system/installation level which is then used as the initial screening process. Once this assessment has been performed, the results should be analysed to decide whether or not a more thorough quantitative analysis would be beneficial.

In some circumstances, the process for selecting scenarios for a risk analysis implicitly takes into account the likelihood of occurrence of a certain scenario (with a general principle on consideration in the context of consequences; i.e. consideration of very unlikely but high consequential scenarios). For instance, when the initiating cause (event) is considered very unlikely, the scenario might be considered as not credible and therefore not contemplated for further analysis. This particular approach is also a type of *qualitative* approach.

For consequence assessment, normal practice suggests that, certain quantitative considerations are virtually indispensable (e.g. threshold limits, isorisk curves, etc.), especially in the case of high risk/consequence scenarios. This often is necessary for activities related to emergency planning and landuse planning.

Deterministic/Probabilistic:

The distinction in this respect is more difficult to define. Although the definitions are widely used in several engineering fields, these definitions depend a lot on the specific application and there is not always coherent understanding of them.

In the context of major-accident safety analysis, the meaning of probabilistic approach is relatively clear, and is associated with an evaluation that explicitly accounts for the likelihood and consequences of possible accident sequences in an integrated fashion.

The *deterministic* approach is generally associated with the safety assessment of the establishment in terms of the consequences of a pre-determined bounding subset of accident sequences. In this respect, the *deterministic approach assumes that* a scenario has been selected and all necessary facts about the scenario are already known. As with certain qualitative approaches, the uncertainty associated with the likelihood of the occurrence is implicitly considered in the scenario selection process. However, it is not taken into account in the assessment procedure itself. For the most part, the uncertainty is taken into account by the introduction of safety factors.
Normally, the decision procedures based on the deterministic approach are less time consuming and adequate for many cases. This approach could be definitely considered acceptable for all systems/installation, which are not characterised by a high degree of complexity.

The deterministic approach is normally associated with consequence-based decision criteria and it is also mostly related to the use of qualitative terms, whereas the probabilistic approach relates more to quantitative elements and is seen as a "risk-based" methodology.

The following table provides a general idea of the main differences between the two approach categories, without pretending to give a unique and complete definition of the elements involved:

	Deterministic ("consequence - based") approach	Probabilistic ("risk - based") approach
Decision criteria	Consequences (harm, damage etc. in absolute figures)	Risk of harm, damage etc.
Initiating Events	Pre-selected events; Events beyond this closed list are not considered	Seeks to consider all potentially relevant events within the procedure
Failure Description	Single failure postulated	Multiple failures considered
Operator behaviour	Qualitative case-by-case consideration	Diagnosis/execution errors considered numerically
Analysis characterization	"Conservative" (precautionary principle)	Seeks to be as realistic as possible
Account of uncertainty	Fixed "Safety Factor"(discrete value)	Numerical evaluation of risk (Distribution of values)

The methodologies currently in use in the different Member States do not always fall under one of these two general categories, but might belong to a combination of the two depending on which single analysis step is involved. For instance, for some methodologies, a deterministic approach can be used for the selection of significant scenarios ("worst case" approach) whilst a probabilistic approach could be used for the assessment of safety measures' efficiency and for the definition of a risk reduction strategy. Especially some considerations concerning rare initiating events (e.g. intentional attacks) or specific forms of consequence (e.g. environmental) may be subject to qualitative description only.

Other possible distinctions amongst existing methodologies may also be made and that differ from the strict dichotomy qualitative/quantitative or deterministic/probabilistic. For instance, in some methodologies, the risk from different sources/causes is typically aggregated in order to evaluate the overall risk (cumulative risk approach, e.g. QRA). In this case, the effectiveness of the measures is assessed as a whole and risk reduction is attained through a sensitivity study. In other methodologies, the analysis is conducted by considering each possible initiating event at a time together with the resulting accident scenario (single risk approach). In this case the estimated upperbound risk is the one resulting from the highest single risk. This approach allows the determination of what the effect of each single measure is that has been put in place in order to prevent the occurrence of a major-accident and limit its consequences.

A. Description of major-accident scenarios, initiating causes and the conditions under which they occur

As defined in the introductory chapter and explicitly expressed by the text of Annex II, part IV/A, the safety report shall demonstrate the adequateness of the measures taken by the systematic identification of possible major-accident scenarios and their initiating events (causes). The scenarios are normally based on the assumption of loss of the safe containment (LOC). However, not all scenarios are necessarily of the LOC-type, e.g. self-decomposition, and the subsequent start of fire or explosion may also be of relevance in such cases. A structured approach to scenario selection is a crucial step in the overall analysis. The safety report should, therefore, outline the principles and procedures followed (SMS) to determine the scenarios. In doing so, events which are documented in accident databases, near-miss recording, safety alerts and similar literature must be reviewed when drawing up the list of scenarios and appropriate lessons learnt incorporateds.

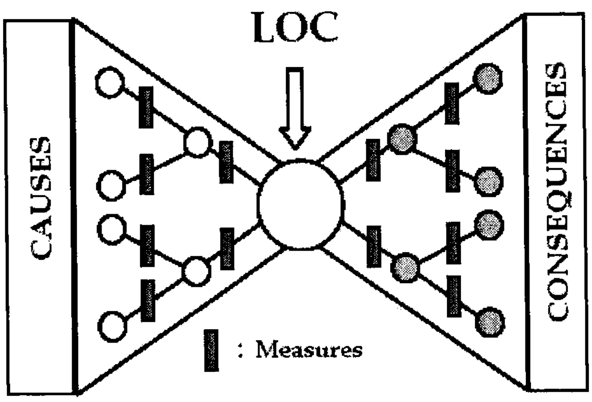
A major-accident scenario for the purposes of the safety report usually describes the form of the loss of containment specified by its technical type e.g.:

- vessel rupture
- pipe rupture
- vessel leak, etc.

and the triggered event, namely:

- fire
- explosion
- release of hazardous substance(s)

The "bow-tie" diagram is can be used to describe major-accident scenarios to include underlying causes:



The centre of the diagram is the loss of containment event i.e. the "top event". The bow-tie left depicts the overall possible causes, which could lead to the

5 As required by Annex III of the Seveso II Directive.

occurrence of the top event. The vertical bars refer to the measures that are put in place to prevent the release of dangerous substances by including also measures to control escalation factors. The bow-tie right side describes the development of possible outcomes resulting from the top event. The vertical bars in the bow-tie right side refer to the measures to prevent that the top event could cause harm too the men, the environment and the installations. Thus they are put in place to control the releases and the possible escalation factors, and to limit their consequences (e.g. bunds, explosion proof equipment, fire protection systems, etc.).

The following non-exhaustive list provides the most relevant event types that describe the consequences of the top event development (outcome):

• pool fire
• flash fire
• tank fire
• jet fire
• VCE (vapour cloud explosion)
• toxic cloud
• BLEVE (boiling liquid expanding vapour explosion)
• soil/air/water pollution

A point to note is that these events may occur in

• process units
• storage units
• pipe work
• loading/unloading facilities
• on-site transport of hazardous substances.

The hazardous substances may be present under various physical conditions (temperature, pressure, aggregate form). The safety report must demonstrate that, of these possible scenario elements, the relevant scenarios were chosen.

The selection may follow strategies such as:

• event likelihood
• consequences
• how comprehensive or representative the scenario is.

Major accident scenarios may serve different purposes, for example:

1. to demonstrate that, in practice, a particular scenario no longer presents a major-accident hazard due to the measures in place;
2. to demonstrate that the extent of the effects of a particular scenario have been limited due to the protective measures in place;
3. to demonstrate the efficiency and the effectiveness of mitigation measures put in place;
4. to establish whether the activity should be considered as unacceptable;
5. to establish whether further mitigating measures, which are specifically relevant within the safety report's scope, are necessary.

For the purposes of 1 or 2 it is necessary to consider the causes of the potential accident; the most relevant of these are listed below:

Operational causes are determined according to the methodology chosen; at least the following should be considered:

- physical and chemical process parameters limits;
- hazards during specific operation modes (i.e. start up/shut down);
- failure of containment;
- malfunctions and technical failures of equipment and systems;
- knock-on effects from other equipment;
- faults of utilities supply;
- human factors involving operation, testing and maintenance;
- chemical incompatibility and contamination;
- ignition sources (electrostatic charge, etc.)

Internal causes may be related to fires, explosions or releases of dangerous substances at installations within the establishment which the safety report covers and affecting other installations leading to a disruption of normal operation (e.g. the fracture of a water pipe in a cooling tower, thus leading to a disruption in the cooling capacity on site).

External causes to be considered are mainly:

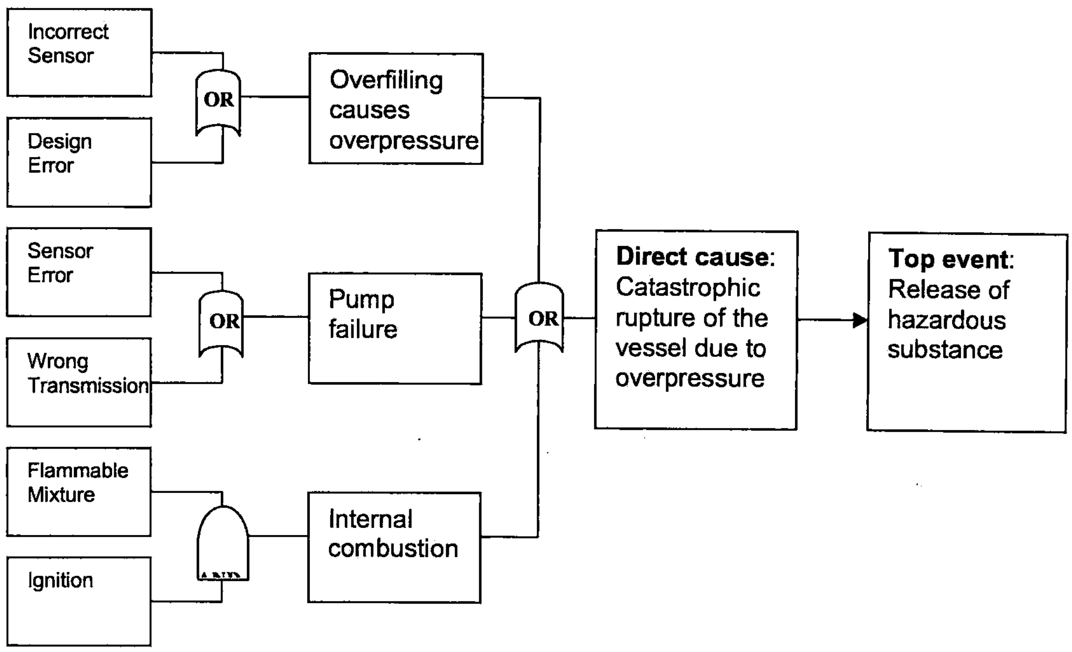
- Impact of accidents (e.g. fire, explosions, toxic release) in neighbouring establishments (Domino effects) and other third party activities and transportation networks

• Transportation of dangerous substances off site (e.g. roads, railways, pipelines, shipping, oil or gas ports, air, etc.).
• Functional interdependence with the installations of neighbouring activities;
• pipelines or other common utilities;
• Transport networks and centres (e.g. public roads, railway lines or airports close to the installation and/or establishment;
• Natural hazard sources e.g. precipitation (extreme), wind, thunderstorms, lightning, floods, landslide, seismic activity, etc. (Natural Hazard Triggering Technological Disasters - NATECH);

Plant security

The effect of possible intentional acts that could affect plant safety should also be taken in the proper consideration.
Other accident causes may be related to design, construction and safety management; these causes may concern also plant life cycle management, commissioning, decommissioning, equipment or process modifications, work permit system, maintenance, etc.

The "top event" and the related causes constitute what is often called the "fault tree" or left-hand side of the "bow-tie". In the picture below this is shown in a schematic form:



The example shows a hypothetical "unrestricted" event. To decide on the scenario likelihood usually the efficiency of technical measures and human intervention "measures" is taken into account.

An overall typology of measures could distinguish between those being (functioning) permanent, independent of the state of the process (all passive measures are permanent), and those being activated by the state of the process. The latter measures can either disable actions (interlock systems, preventing certain actions from being performed, e.g. safe operating envelopes for processes) or initiate one or more actions (e.g. opening of a relief valve or emergency shut down).

Activated measures always require a sequence of detection – diagnosis – action. Using hardware, software and human action as building blocks alone or in combination can perform this sequence.

A more detailed classification can be specified as follows:

A. Passive hardware measures (no actuation mechanism required to fulfil its safety function; e.g. a retention bund round a tank, enclosure designed for total containment or with elevated stack); passive hardware measures have a relatively high level of availability.

B. Active hardware measures (require external source of energy to fulfil the safety function but operating without human intervention, e.g. automatic shutdowns, emergency cooling systems).

C. Passive behavioural measures (behaviour consisting of staying away from defined areas, refraining from touching or modifying parts of the plant, and this behaviour alone constitutes the measure without any hardware being involved e.g. safety distances, exclusion areas, no smoking area).

D. Active behavioural measures (behaviour consists of acting in defined ways whilst interacting with the dangerous part of the plant, and this behaviour alone constitutes the measure without any hardware being involved, e.g. evacuation in case of toxic or fire alarm, safe working methods when handling chemicals).

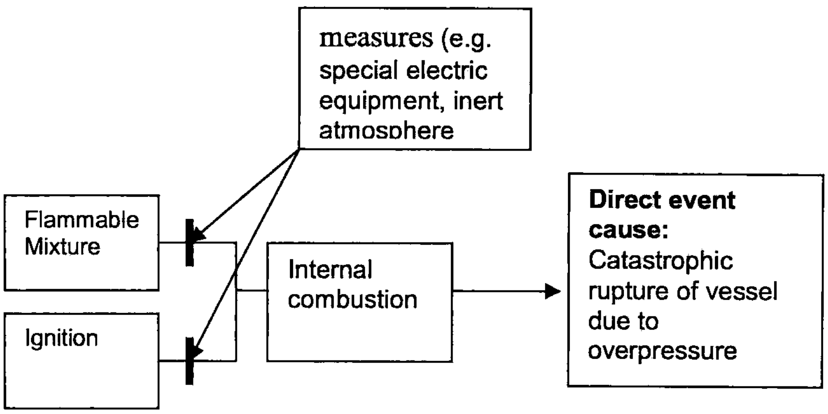
E. Mixed measures, where both hardware and behaviour are involved, and where, in theory, any combination of A and/or B with C and/or D are possible, but where the combination of B with D are the most important, since they interact (e.g. shutdown routines triggered by warnings).

The following picture shows the schematic role of measures in the fault tree: There is no common approach concerning which type of measures should be taken into account for the selection of scenarios and passive measures are almost always considered to be effective. In principle, active hardware or mixed measures may be taken into account as well, when demonstration is made through the safety report of good effectiveness and reliability. The decision may also relate to a legal framework that mandates the presence of certain measures. Human intervention (= behavioural measures) as the only means of protection usually is not given credit in this respect.

B. Assessment of the extent and severity of the consequences of identified major accidents

The assessment of accident consequences to people and the environment is essential in several steps of the overall risk assessment process and the safety report should summarise and document the conclusions of this assessment step. Within a safety report, the consequence assessment will be used for two different types of decision processes:

1. Consequence assessment constitutes an indispensable part of the systematic risk assessment aimed at the identification and establishment of technical/organisational safeguards to prevent major-accident hazards and to mitigate accident consequences, or to evaluate the efficiency and adequacy of the protective measures taken.



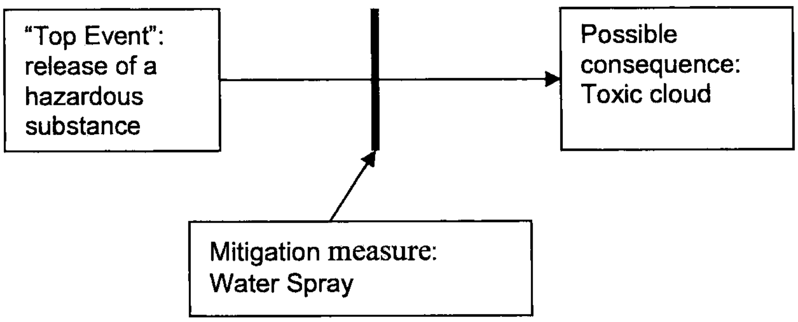
2. Consequence assessment also describes the outcomes of specific accident scenarios selected in order to provide information especially for external emergency planning and land use planning around establishments. The results of this assessment should be presented in the form of "maps, images and descriptions".

For the first type of process, the assessment may be carried out in a qualitative way only and without any calculation (in the strict sense, not in the meaning of "estimation") of effects. Such an approach is often adopted for assessing the adequacy of existing or proposed measures or safeguards; for this type of approach only in exceptional situations (e.g. if the measure is very expensive) would a more comprehensive consequence assessment be considered.

If the consequence assessment has the character of a more complete calculation it requires a procedure that is some form of detailed modelling. In general, modelling the consequences of major accidents is based on several inputs such as for instance:

• the physical and hazardous properties of the substances in question (flammability, toxicology, etc.)
• emission potential (thermal radiation, overpressure)
• release characteristics (amount, phases, conditions, etc.) and
• weather conditions.

The foundation of modelling of this type is again a specific set of reference scenarios. In this case it is the right side of the "bow-tie" that serves as the starting point. For this assessment measures to limit the consequences (=mitigation measures) are taken into account (and mitigation measures may also be identified as a result of the assessment).
The following picture shows this part of the bow-tie, usually called the "event tree":



Results of this modelling exercise are expressed in terms of severity of (potential) impact. For safety reports, potential impact is commonly defined in terms of human health, although relative property or environmental damage may also be presented.

Two main approaches are used to measure severity of impact:

- the damage probit curve
- fixed damage thresholds.

The probit curve approach considers the impact on a vulnerable receptor (e.g. a human being) over time and relates this impact to a probability that certain damage (physiological or material) will occur, given a specific level and time of exposure. In contrast, the fixed threshold approach links specific impacts, such as the onset of death or serious injury, to specific level and time of exposure. The thresholds are usually established, using probabilistic methods, as levels at which or above which particular effects are expected to occur. Threshold levels for accidental airborne releases of toxic substances, static or dynamic thermal radiation, and overpressure have been calculated by various expert groups, including national authorities and industry/professional associations. These levels are generally available in technical publications or publications (including websites) of the originating organisations.

C. Description of technical parameters and equipment used for the safety of installations

In connection with the risk assessment the technical parameters, the equipment used for safety and their fitness for purpose need to be justified. This activity is usually performed together with the identification of scenarios and the initiating events.
The safety report should discuss general criteria assumed (i.e. best available technology, good engineering practice, quantitative risk criteria), should give the reason why a method of presentation has been selected over and above other possible options, and in particular should describe:
- the criteria used to decide the degree of redundancy, diversity and separation required for the prevention, control and mitigation measures;

• the reliability of components and systems and the efficiency of organizational measures;
• the functional calculations needed to confirm the capability of the measures to cope with the design-basis accidents (design criteria and load assumptions according to the relevant good engineering practice; time and order in which the measures become effective in relation to the process/accident evolution and the man-machine interface, etc.);
• feedback from measures to the system as a whole;
• declaration of compliance with relevant national regulations and relevant codes of practice.

Prevention, control and mitigation measures of a hazardous installation may include:
• process control system including back ups;
• fire and explosion protection systems;
• devices for limiting the size of accidental releases, e.g. scrubbing systems, water spray;
• vapour screens, emergency catch pots or collection vessels, and emergency shut-of valves;
• alarm systems including gas detection;
• automatic shut down systems;
• inerting systems;
• fail-safe instrumentation;
• emergency venting including explosion panels;
• fast shut-down and other emergency procedures;
• special precautions against unauthorized actions related to the plant security

Further details may be required of the safety relevant sections in accordance with the actual risk assessment. This description should thus include a substantial amount of data significant from the process engineering and technical safety standpoint; and cover the safety systems as well. This may include:

a) flow charts and Piping and Instrumentation (P&I) diagrams[6];

[6] Please give regard to the generic character of this term; there are various levels of information provided by P&I-diagrams of which not all may be suitable for safety report purposes.

b) flow patterns and machinery/equipment needed in the processes; inventories and key dimensions of the containers and pipes shall be available if relevant;

c) process conditions, i.e. pressure, temperature, concentration (their safe operation ranges)and any relevant thermodynamic and transport properties at the successive steps of the process such as:

– normal and maximum flows, consumption of reactants, production of intermediate/end-by-products (e.g. overall and substance mass balances);
– average or typical quantities normally or accidentally possible to be present, stored or in process;
– formation conditions of by-products and unplanned accident products;
– conditioning of the final products;

d) instrumentation, control/alarm and other safety systems;

e) relevant qualitative and quantitative information on energy and mass transport in the processes, i.e. material and energy balances:
– in normal running;
– in start-up or shut-down periods;
– during abnormal operations;

f) characteristic process conditions and substance state parameters (i.e. temperature, pressure, concentration, boil-off fluctuation, etc.).

V. Measures of Protection and Intervention to Limit the Consequences of an Accident

A. description of the equipment installed in the plant to limit the consequences of major accidents;
B. organization of alert and intervention;
C. description of resources that can be mobilised, internal or external;
D. summary of elements described in a, B, and C above necessary for drawing up the internal emergency plan prepared in compliance with Article 11.

The safety report should also clearly include information which identifies any key mitigation measures resulting from the analysis that are necessary to limit the consequences of major accidents, as referred to in Annex II, part V of the Directive, namely:

• description of the equipment installed in the plant to limit the consequences of major accidents;
• organisation of alert and intervention;
• description of resources that can be mobilised, internal or external;
• summary of elements described above necessary for drawing up the internal emergency plan.

It is very important that there is a clear link between the consequences of scenarios identified in section IV and the measures of protection and intervention to limit the consequences of an accident.

A. Description of equipment

A description of equipment installed in the plant to limit the consequences of major accidents should be provided. This list should include an adequate description of the circumstances under which the equipment is intended for use.

B. Organisation of alert and intervention

The organisation for alert and intervention should be adequately described. This description should include:
• organisation, responsibilities, and procedures for emergency response;
• training and information for personnel and emergency response crews;
• activation of warnings and alarms for site personnel, external authorities, neighbouring installations, and where necessary for the public;
• identification of installations which need protection or rescue interventions;
• identification of rescue & escape routes, emergency refuges, sheltered buildings, and control centres;
• provision for shut-off of processes, utilities and plants with the potential to aggravate the consequences.

D. Description of resources that can be mobilized

The report should contain an adequate description of all relevant resources which will need to be mobilised in the event of a major accident. This report should include:

- activation of external emergency response and co-ordination with internal response;
- mutual aid agreements with neighbouring operators and mobilisation of external resources;
- resources available on-site or by agreement (i.e. technical, organizational, informational, first aid, specialized medical services, etc.).

E. Summary of elements for the internal emergency plan

The report should include a summary of elements described above that are necessary for the preparation of the internal emergency plan to deal with major accidents, or for foreseeable conditions or events that could be significant in bringing about a major accident. It may be useful to include or refer to the internal emergency plan which has been drawn up to comply with Article 11 of the Directive.

Presentation of the Overall Result

The safety report should present the results and arguments of the hazard analysis and risk assessment. The safety report may refer to documents available on the hazards analysis and risk assessment performed. In particular, documents which contain information on the assumptions made, and the judgment criteria adopted should be clearly referenced.
The identified accident scenarios, their consequences and likelihood and the identified initiating events should be clearly documented so they might be used for preparing the basis for further decisional processes (e.g. external emergency planning and land use planning).

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This guidance reflects the Commission's opinion on the interpretation of the Directive's requirements. It is not a legally binding text

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