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Context

The *Guidelines* in this book characterize when and how to apply enabling conditions and conditional modifiers to Layer of Protection Analyses (LOPAs). A LOPA may have consequences and risk criteria expressed in final endpoint (impact) terms such as fatalities or environmental damage, and include *conditional modifiers* such as probability of fatality associated with a material or energy release. It may also take into account probabilities called *enabling conditions* that sometimes apply to scenario initiating events. One way to differentiate these two factors is that <u>enabling conditions</u> are associated with the part of an incident sequence <u>leading up to</u> a release of hazardous material or energy, whereas <u>conditional modifiers</u> are probabilities generally associated with the <u>post-release</u> part of an incident sequence.

As discussed in Chapter 4, these enabling conditions and conditional modifiers may be used with other scenario risk analysis methods such as Quantitative Risk Analyses and HAZOP/LOPA Studies. However, the main focus in this text will be their use in the context of LOPAs.

An overview of Layer of Protection Analysis is given in Section 1.1, followed by some pertinent variations in Section 1.2. Section 1.3 discusses the appropriate application of enabling conditions and conditional modifiers. These decisions on use of conditional modifiers are closely related to a company's risk criteria *endpoints* used when determining loss event impacts, as discussed in Section 1.4.

1.1 LOPA Overview

This section, taken in large part from Center for Chemical Process Safety's *Guidelines for Hazard Evaluation Procedures, Third Edition* (CCPS 2008)[1], provides a brief summary of the methodology for conducting Layer of Protection Analyses as described in the CCPS Concept Book *Layer of Protection Analysis: Simplified Process Risk Assessment* (CCPS 2001), with minor updates. Experienced LOPA practitioners and users may want to advance to Section 1.2, Pertinent LOPA Variations.

Layer of Protection Analysis is a simplified form of quantitative risk analysis that uses order-of-magnitude categories for initiating event frequency, consequence severity and probability of failure of independent protection layers (IPLs) to analyze and assess the risk of one or more incident scenarios. LOPA can

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[1] See References list at the end of this document for all cited references.

be useful in the process development, process design, operational, maintenance, modification and decommissioning life cycle phases.

Purpose of LOPA

LOPA was developed to help answer questions such as:

- What layers of protection are needed to meet our risk goals?
- How much risk reduction does each layer provide or need to provide?

LOPA can help answer these questions with less time and effort than a full quantitative risk analysis (QRA), although there are instances when use of a complete QRA may be warranted.

LOPA is an order-of-magnitude type of quantitative method (sometimes termed "semi-quantitative") that builds on qualitative hazard evaluations such as HAZOP Studies. By analyzing selected scenarios in detail, effective application of LOPA can determine whether the risk posed by each analyzed scenario has been reduced to meet a specified risk goal. However, if the analyst or team can make a reasonable risk decision using only qualitative methods, then LOPA may not be warranted. Qualitative hazard evaluation methods such as HAZOP Studies are intended to identify a comprehensive set of incident scenarios and qualitatively analyze those scenarios for the adequacy of safeguards. LOPA is generally used to analyze a subset of incident scenarios.

At times, simple order-of-magnitude LOPAs can be expanded with greater rigor by implementing aspects of a more complete QRA. The use of enabling conditions and conditional modifiers falls into this realm.

Description

LOPA is typically applied after, and builds upon, the information gathered in a qualitative hazard evaluation, but can be applied to scenarios gathered from any source, such as an audit or incident investigation. LOPA, in turn, can be used as a screening tool for scenarios prior to application of a full quantitative risk analysis. If desired, LOPA can also be implemented in conjunction with a qualitative scenario-based hazard evaluation method such as a HAZOP Study (see Section 4.2).

After the scope of the study is defined, LOPA consists of the six steps summarized below. The LOPA results can then be used to make risk-based decisions.

Step 1: Identify the scenario screening criteria. Since LOPA typically evaluates scenarios that have been developed in a prior study, a first step by the LOPA analyst or team is to screen these scenarios, and the most common screening method is based on consequence. Other screening criteria may also be

employed, such as based on "unmitigated risk" (consequence severity combined with initiating cause frequency estimates) or based on the judgment of the hazard review team as to which scenarios warrant closer examination.

LOPA consequence severity estimates and consequence screening thresholds may be defined in a number of ways, each having strengths and weaknesses and varying in the degree of conservatism incorporated into the analysis, with simpler methods generally being more conservative:

- Method 1 – Category approach without direct reference to human harm. Consequences are categorized in terms of the type and magnitude of a release or other consequence characteristic, rather than explicitly defining the final consequence in terms of the number and severity of injuries that may result from a particular release.

- Method 2 – Qualitative estimates of human harm. Human impacts are considered, usually allowing direct comparison with organizational guidelines, but estimates of impact magnitudes are arrived at using qualitative judgment. This method does not explicitly use conditional modifiers such as probability of personnel presence.

- Method 3 – Qualitative or order-of-magnitude estimates of human harm, with adjustments for post-release probabilities (conditional modifiers). This method extends the qualitative judgment in Method 2 using additional probabilities, giving a more quantitative (order-of-magnitude) estimate of the severity of human harm.

- Method 4 – Quantitative estimates of human harm. This method is similar to Method 3 but uses detailed analyses in determining the effects of a release and its effects upon individuals and equipment. Tools associated with full Chemical Process Quantitative Risk Analyses (CPQRAs) may be used here, including dispersion and blast effects analysis. The use of these tools adds complexity and time as well as a need for expertise and other resources such as computational tools. The level of sophistication required for these consequence analyses may be disproportionate to the order-of-magnitude frequency estimates employed within LOPA.

Step 2: Select an incident scenario. LOPA is applied to one scenario at a time. The scenario can come from other analyses, such as qualitative hazard evaluations and/or management-of-change reviews, but each scenario must describe a single initiating event – loss event ("cause-consequence") pair, except for an uncommon situation where a scenario requires two concurrent initiating events. (This situation, which may warrant using quantitative risk analysis, is discussed in Appendix A.)

When scenarios are selected from a qualitative hazard evaluation, such as from a HAZOP Study, they may need to be separated into multiple scenarios for evaluation. For example, where a scenario involves an emergency relief system, the LOPA could be applied both to the case in which the emergency relief device does not function properly (usually involving a greater severity but lesser

likelihood) and to the case in which it does function properly (usually involving a lesser severity but greater likelihood).

Step 3:   Identify the initiating event of the scenario and determine its frequency.   The scenario *initiating event* must lead to the loss event, given failure of all of the preventive safeguards.   (An initiating event is comprised of one or more aggregated initiating causes, such as from a HAZOP Study. Initiating causes can only be aggregated if they are protected by the same IPLs and lead to the same loss event.) Most companies provide guidance on estimating the frequency to achieve consistency in LOPA results; suggested frequencies are also given by CCPS (2001).   The team should determine whether the suggested value is appropriate, based on plant historical performance and/or experience with the initiating event occurring under similar plant conditions.   Other factors may also enter into the determination of the initiating event frequency, such as extraordinary design or maintenance or a keylock system to make a human error less likely.

Background aspects, such as the probability that the process is in a certain mode of operation at the time another failure occurs, are not initiating events but *enabling conditions*.   In LOPA, their probabilities modify the initiating event frequency. These aspects are the subject of Chapter 2 of these *Guidelines*.

Step 4: Identify the IPLs and estimate the PFD of each IPL.   The heart of the LOPA methodology is recognizing the existing preventive safeguards that meet the requirements of *independent protection layers* (IPLs) for a given scenario. (All IPLs are safeguards, but not every safeguard meets the requirements of being an IPL.)

An IPL is a device, system, or action that is capable of keeping a scenario from proceeding to the undesired loss event, independent of the initiating event or the action of any other layer of protection associated with the scenario.   A preventive safeguard meets the requirements of being an IPL when it is designed and managed to achieve the following seven core attributes:

- *Independent* – the performance of a protection layer not being affected by the initiating event or by the actions of other protection layers.
- *Functional* – capable of operating successfully in response to a specific abnormal condition.
- *Integrity* – the risk reduction that can reasonably be expected given the protection layer's design and management.
- *Reliable* – assurance that a protection layer will operate as intended under stated conditions for a specified time period.
- *Validated, maintained, and audited* – implementing, maintaining and verifying information, documents, and procedures that demonstrate the adequacy of and adherence to the design, inspection, maintenance, testing, and operation practices used to achieve the other core attributes.

- *Access security* – the use of administrative controls and physical means to reduce the potential for unintentional or unauthorized changes.
- *Management of change* – the formal process used to review, document, and approve modifications that are not replacements in kind, prior to implementation of the modifications.

IPLs can be viewed as "lines of defense" against potential incident scenarios. The independence of the IPL from the initiating event and from other IPLs is very important. The LOPA team must assess the independence of each IPL and estimate its probability of failure based on the IPL design and management. All IPL equipment should be included in the facility's mechanical integrity program and be subjected to inspection and proof tests as necessary to maintain the target probability of failure on demand (PFD). IPLs depending on operating personnel should have key steps explicitly described in written procedures, with identified personnel being trained and tested on the procedures to show they are capable of responding in time. Access to IPL equipment should be controlled, and proposed changes should undergo management of change review prior to implementation.

One type of IPL is the *safety instrumented system (SIS)*. CCPS has published guidelines covering the life cycle of safety instrumented systems and other instrumented protective systems (CCPS 2007).

The integrity of each IPL is quantified in terms of its probability of failure on demand, which is a dimensionless number between 0 and 1, inclusive. The PFD of an IPL is the probability that, when needed for the scenario in question, the IPL will not perform the required task. Most companies provide a predetermined set of PFD values for use by the LOPA analyst, so the analyst may pick the IPL that best fits the scenario being analyzed and the PFD that best fits the equipment configuration and the facility's integrity management plan.

Step 5: Calculate the scenario frequency. The overall predicted frequency of realizing the scenario consequence is estimated by mathematically combining the initiating event frequency and the IPL PFDs. Combining methods include arithmetic formulae and graphical approaches. Regardless of the method, most organizations provide a standard form for documenting LOPA intermediate and final results. The following mathematical approach is applicable for low-demand situations (F_i^I less than twice the test frequency for the first IPL; see CCPS 2001 Appendix F).

$$f_i^C = F_i^I \cdot \prod PFD_{ij}$$

$$= F_i^I \cdot PFD_{i1} \cdot PFD_{i2} \cdots PFD_{ij}$$

where

f_i^C is the scenario frequency for consequence C for initiating event i

F_i^I is the initiating event frequency for consequence C for initiating event i

PFD_{ij} is the probability of failure on demand (fail-dangerous failure mode) of the j th IPL that protects against consequence C for initiating event i.

For example, if the frequency for the first initiating event (i =1) is estimated to be once every ten years ($F_1^I = 10^{-1}$/year), and two IPLs each having a PFD of 0.01 ($PFD_{11} = 10^{-2}$ and $PFD_{12} = 10^{-2}$) are protecting against this particular initiating event and will prevent consequence C from being realized if either IPL works successfully in response to initiating event 1, then the calculated frequency for consequence C for initiating event 1 (f_1^C) is equal to 10^{-1}/year x 10^{-2} x 10^{-2} = 10^{-5}/year.

An *enabling condition* factor (as described in Chapter 2) may be included in the scenario frequency calculation if an organization chooses to use enabling conditions and if the factor is pertinent to the scenario being evaluated. The enabling conditional probability is combined into the frequency equation above in the same way PFDs are included.

Conditional modifier factors (as described in Chapter 3) may be included in the scenario frequency calculation, depending on the approach used for estimating consequence severity (if Method 3 or 4 is used, as discussed in Step 1 of this Section) and an organization chooses to use conditional modifiers. For example, when a company is estimating the frequency of direct human harm, the analysis may include additional modifying probabilities in the scenario frequency calculation, such as probability of ignition or presence of personnel near a release. Those probabilities are then included as additional factors in the frequency equation, as in

$$f_i^C = f_i^I * \prod PFD_{ij} * P^{ignition}$$

for the frequency of ignition, and

$$f_i^C = f_i^I * \prod PFD_{ij} * P^{ignition} * P^{person\_present}$$

for the frequency that a person might be present near the fire, and so on.

Step 6: Evaluate the risk to reach a decision concerning the scenario. The frequency of the outcome of interest is multiplied by a factor related to the magnitude of the consequences to obtain the scenario risk:

$$R_k^C = f_k^C * C_k$$

where

R_k^C is the risk of incident outcome of interest k, expressed as a magnitude of consequences per unit time, such as fatalities per year.

f_k^C is the frequency of the outcome of interest k, in inverse time units

C_k is a specific measurement of the severity of consequences (impact) of the incident outcome(s) of interest k (e.g., fatalities, serious injuries, public impacts, environmental impacts, economic loss).

The scenario risk or frequency may be calculated and compared to a specific target, or may be shown on a matrix of consequence versus frequency.

Step 7:   Using LOPA to make risk decisions.   Once LOPA has been applied to yield order-of-magnitude risk estimates for a scenario, a risk-based decision can be made. This evaluation is normally in relation to an organization's risk criteria related to scenario risks (CCPS 2009). If the calculated risk exceeds

the tolerable risk level, the proportion by which the calculated risk exceeds the tolerable risk level indicates by how much the risk must be reduced. Risk reduction can be achieved by various means, including eliminating scenarios by inherent safety approaches, reducing initiating event frequencies, increasing integrity of IPLs, adding more IPLs and/or reducing loss event impacts. Many other uses have been found for LOPA results, including adjusting mechanical integrity programs to emphasize oversight of particular equipment components.

Anticipated Work Product

Implementation of LOPA results in a set of order-of-magnitude risk estimates for the scenarios selected for evaluation. LOPA also includes an assessment of the adequacy of the independent protection layers for each scenario in the form of risk-based decisions and, if deemed necessary, recommendations and specifications for additional IPLs.

An example LOPA worksheet that illustrates these results for a single scenario is shown in Table 1.1. CCPS (2001) can be consulted to understand the details of this example. This example includes one enabling condition (Probability that reactor in condition where runaway reaction can occur on loss of cooling) and two conditional modifiers (Probability of personnel in affected area; Probability of fatal injury) although no risk-reduction credit was given for either of the conditional modifiers (i.e., probability = 1 for each).

Table 1.1 Example LOPA worksheet (adapted from CCPS 2001, Table B.2)

Scenario # 1	Scenario title: Cooling water failure results in runaway reaction with potential for reactor overpressure, leakage, rupture, injuries and fatalities. Agitation assumed.		
Date: mm/dd/yyyy	Description	Frequency (per year)	Probability
Consequence description and impact category	Runaway reaction and potential for reactor overpressure, leakage, rupture, injuries, and fatalities **Category 5**		
Risk tolerance criteria (for given Category)	Unacceptable (Greater than) Tolerable (Less than or equal to)	1×10^{-4} 1×10^{-6}	
Initiating event	Loss of cooling water	1×10^{-1}	
Enabling condition	Probability that reactor in condition where runaway reaction can occur on loss of cooling (annual basis)		0.5 (per reactor)
Conditional modifiers (if applicable)	Probability of ignition		N/A
	Probability of personnel in affected area		1
	Probability of fatal injury		1
	Others		N/A
Frequency of consequence without IPLs		5×10^{-2}	
Independent protection layers (IPLs)			
BPCS alarm and human action	Shortstop addition on BPCS loop high reactor temperature alarm; adequate time to respond		1×10^{-1}
Pressure relief valves	With required modifications to system (see Actions; PFD may be conservative if modifications added)		1×10^{-2}
Safety instrumented function (SIF)	SIF to open vent valves to be added (see Actions for design details)		1×10^{-2}
Safeguards (non-IPLs)	**Operator action.** Other operator actions not independent of the same operator already credited. **Emergency cooling system** (steam turbine). Not credited as an IPL as too many common elements (piping, valves, jacket, etc.) that could have initiated initial cooling water failure.		
Total PFD for all IPLs			1×10^{-5}
Frequency of consequence with IPLs		5×10^{-7}	
Risk tolerance criteria met? (Yes/No): Yes, after implementation of actions listed below.			
Actions required to meet risk tolerance criteria	Add SIS for all 3 reactors. Install SIF with minimum PFD = 1×10^{-2} for opening vent valves on high temperature. Separate nozzles and piping for each vent valve. Install separate nozzle and vent lines for each PSV to minimize blockage and common cause. Consider nitrogen purges under all vent valves / PSVs. **Responsible group / person / date:** Plant Technical / J. Doe / mm/yyyy		
Notes	1. Ensure operator response to high temperature meets requirements for IPL. 2. Ensure RV design, installation, maintenance meet requirements for PFD 1×10^{-2} as a minimum.		

1.2 Pertinent LOPA Variations

Users have developed many variations on the basic LOPA methodology summarized in Section 1.1. The variations that are pertinent to the use of enabling conditions and conditional modifiers are discussed in this section. These particular variations are a function of three main factors:

- The resolution of the numerical values used in the LOPA calculations.
- The means by which these values are determined.
- The extent to which loss event consequences are evaluated.

Variations in LOPA Value Resolution

LOPAs most commonly employ frequency and probability estimates with only order-of-magnitude resolution. For example, initiating event frequencies are generally restricted to ten-fold differences from an annual frequency (10/yr, 1/yr, 0.1/yr, 0.01/yr, etc.), and probabilities to 1, 0.1, 0.01, 0.001, etc. Likewise, consequence estimates are typically made on roughly an order-of-magnitude basis.

One variation on this approach is to not limit values to order-of-magnitude categories. The preceding Table 1.1 shows an example of this variation, where an enabling condition probability of 0.5 is included in the analysis. Another variation is to use a resolution of half orders of magnitude. The use of LOPA values that are not necessarily on a full order-of-magnitude basis can facilitate the inclusion of factors such as enabling conditions and conditional modifiers, if the input data supports the use of such factors at greater than an order-of-magnitude resolution.

Significant figures. For most LOPA calculations employing the variation that does not restrict LOPA values to order-of-magnitude categories, it is appropriate to use only one significant figure in the presentation of the LOPA entries and the ensuing calculated values. This needs to be emphasized, since the use of computerized approaches for documenting LOPAs sometimes leads to values being presented with a misleading number of significant figures. By comparison, fully quantitative risk analyses often employ two significant figures in the presentation of calculated risk estimates, although this is often not warranted by the degree of uncertainty of many input values. In this document, the determination and use of enabling condition and conditional modifier probabilities will be discussed from both an order-of-magnitude perspective and from a more quantitative perspective that will allow for their understanding and usage both in LOPAs that do not restrict values to order-of-magnitude categories and in quantitative risk analyses.

Resolution and accuracy of enabling condition and conditional modifier values. The resolution of *enabling condition* and *conditional modifier* probability estimates (as defined and illustrated in Chapters 2 and 3, respectively) will vary

considerably, based on the specific factor being evaluated. Order-of-magnitude categories are appropriate for some factors such as probability of ignition that may have a relatively high degree of uncertainty.

Other factors will have historical data capable of supporting values with a much greater degree of resolution. For example, an enabling condition might be that the ambient temperature must be below freezing for a cooling water supply line to freeze upon failure of its heat tracing. Meteorological data for the location of interest is likely available that will give the fraction of the year with ambient temperature below freezing with a fairly high degree of resolution. Other examples of enabling condition and conditional modifier probabilities that may be able to be estimated with a resolution greater than an order-of-magnitude basis are the fraction of time a process unit is in a particular operating mode (such as full recycle or high-fire) and the fraction of time the wind is blowing towards a certain receptor location.

Nevertheless, error bands around some enabling condition and conditional modifier probabilities may be broader than those around typical initiating event frequencies and independent protection layer PFDs. The potential may exist for increasing the overall uncertainty of a LOPA or QRA by employing enabling conditions and/or conditional modifiers, versus not including them in the analysis, just by virtue of having a greater number of factors in the risk equation with each factor having an associated degree of uncertainty.

Where uncertainty does exist for a given factor, several possible approaches are available to those performing a LOPA study or a QRA. These include:

- Selecting a worst-case, most-conservative value
- Selecting a reasonable, conservative value
- Selecting a best-estimate value
- If the uncertainty is too high, not including the enabling condition or conditional modifier in the scenario analysis or QRA.

A suggested approach is to use best-estimate values where data, experience and/or standardization support them. Then, when a particular factor has some uncertainty associated with its frequency or probability, use a reasonable, conservative value for the factor. A check can be made on overall risk estimates that appear unexpectedly low or high by performing a sensitivity analysis on the factors with the greatest degree of uncertainty, and observing the effect of varying their values within their respective possible ranges. This approach avoids the pitfall of combining multiple factors each of which is skewed toward a conservative estimate (i.e., tending toward a higher overall scenario frequency), and ending up with a scenario frequency that is unrealistically high. The above discussion is especially pertinent when employing conditional modifiers, since a typical LOPA scenario evaluation considers only one enabling condition (if any), whereas three or more conditional modifiers might be included in the analysis, each with its own uncertainty.

In summary, one common pitfall in performing LOPAs is to document the individual factors and/or present the results with more significant figures than is warranted by the degree of resolution of the underlying data. Analyses using order-of-magnitude estimates for each factor should also present the final results as an order-of-magnitude value. Analyses using a greater degree of resolution should document individual factors and present the final results with only one significant figure (or as an order of magnitude, if any of the factors are only estimated on an order-of-magnitude basis). Using too many significant figures is misleading regarding the degree of resolution of the risk estimates.

Variations in LOPA Frequency and PFD Determinations

Companies or facilities employing LOPA often have standardized values that are used for various initiating event frequencies (e.g., maintained pump in standard service fails off 0.1/yr) and IPL failure probabilities (e.g., screening-value PFD = 0.01 for a relief valve failing to respond in non-plugging service). The same approach of picking from a standardized list can be used for enabling condition and conditional modifier probabilities. The standardized list should provide criteria for applicability of the factors to the actual scenario being evaluated.

However, it is possible to employ enabling condition and conditional modifier probabilities that are based on a more in-depth analysis of the specific scenario being evaluated. This becomes closer to a QRA approach, where some logic modeling or data analysis may be required to determine the best-estimate probability. The approach used is determined by what will best support the objectives of the LOPA study, consistent with the method and risk criteria established by the operating company.

Variations in LOPA Consequence Evaluations

The different approaches to making LOPA consequence severity estimates follow the consequence screening methods described in Section 1.1 (Step 1):

- Estimate severity using consequences categorized in terms of the type and magnitude of a hazardous material or process energy release or other consequence characteristic. This approach has the advantages of simplicity and avoidance of needing to estimate impacts such as on people, but still requires some estimate be made of the release magnitude. However, it will not distinguish between the same release event being in a remote area at one facility and in a highly populated area at another facility. For this reason, the category distinctions may need to be site-specific. The magnitude of a release implies anticipated impacts; hence, the probability of realizing loss and harm is often implicitly included when setting up the release magnitude categories.
- Qualitatively estimate severity using impact categories in terms of human harm, environmental impact and/or business impact. The example in the preceding Table 1.1 illustrates this approach, where the LOPA team has assessed the vessel rupture consequence severity to be "Category 5" (which is perhaps a "High Severity" impact with potential for injuries and

fatalities). Such an evaluation might use conservative assumptions such as flammable releases always igniting and/or personnel always being present when a release, fire or explosion occurs.

- Estimate severity using qualitative or order-of-magnitude impact categories in terms of human harm, environmental impact and/or business impact, with adjustments for post-release probabilities. This approach includes an explicit, documented consideration of conditional modifiers such as the probability of ignition and the probability of personnel presence in the effect area.

- Quantitatively estimate human harm, environmental impact and/or business impact using detailed analyses in determining the characteristics of a release and its effects. Tools associated with full QRAs may be used here, including dispersion and blast effects analysis. Enabling conditions (where pertinent) and conditional modifiers are likely to be employed in this type of consequence analysis, as are more detailed estimates of the factors contributing to loss event frequency.

It needs to be emphasized that **the approach selected must be consistent with the risk criteria used in the LOPA for determining the adequacy of risk control measures.** This is further discussed in Section 1.4 in relation to risk criteria endpoints.

1.3   When to Use Enabling Conditions and Conditional Modifiers

Enabling conditions and conditional modifiers are not used in every LOPA. They only warrant being used when they support the objectives of the LOPA and are consistent with the risk criteria employed.

Guidance on When to Use Enabling Conditions

The following are typical situations where enabling conditions might be used in LOPAs:

- The event sequence would only be realized if the unit was in a particular state of operation (e.g., in recycle mode or feeding directly from a transport container), where the unit being in that state is necessary to realize a consequence of concern but independent of the rest of the event sequence.

- The consequence would only be realized if the unit was using a particular raw material or catalyst or processing a particular formulation, where the situation was necessary to achieve the consequence of concern but independent of the rest of the event sequence.

- The event sequence would only be realized if other circumstances such as a low or high ambient temperature existed at the time an initiating event occurred.

In each case, the purpose of employing the enabling condition is to take into account conditions that are necessary for an abnormal situation to proceed to the consequence of concern. The capabilities of the LOPA analyst(s), the established company or facility LOPA methodology and the availability of relevant data would all need to support the use of enabling conditions.

A full description of LOPA enabling conditions, along with worked examples, is given in Chapter 2. Enabling conditions may be associated with short-duration situations with severe potential consequences. The elevated risk exposure during these brief situations, termed "peak risk," should be considered and managed appropriately. This topic is discussed in Appendix B.

Guidance on When NOT to Use Enabling Conditions

The following are typical situations where a LOPA team should avoid the use of enabling conditions:

- The LOPA analyst(s) have insufficient knowledge of enabling conditions to employ them correctly.
- Insufficient data or information is available to assess the probability to be assigned to an enabling condition.
- The company's or facility's established LOPA procedure specifically indicates that enabling conditions are not to be used in its LOPAs, for whatever reason.
- A potential enabling condition does not meet company criteria. For example, established procedures may specify that an enabling condition is valid only if it gives a full order of magnitude reduction in frequency, but the potential enabling condition does not meet this.
- The company or facility does not have the resources, capability or practices in place to properly assess and document the use of enabling conditions and maintain their ongoing validity. (See Section 2.6 for guidance on maintaining the validity of enabling conditions over time.)

In addition, situations where one particular type of enabling condition, namely a "time-at-risk" enabling condition, should not be used are listed in Section 2.3.

Guidance on When to Use Conditional Modifiers

A typical situation where conditional modifiers might be used in LOPAs is when a company's risk criteria are based on best-estimate risk values rather than conservative bounding estimates. In this case, not using conditional modifiers may result in risk estimates inconsistent with the company's risk criteria. For example, in a situation where the probability of igniting a given release is expected to be much less than 100%, then using a probability of ignition of 100% would give a conservative risk estimate but not a best-estimate value. Basing risk management decisions on an overly conservative risk estimate could result in a misallocation of risk-reduction resources. For scenarios where more than one conditional modifier is pertinent, this over-conservatism could be even further amplified.

The capabilities of the LOPA analyst(s), the established company or facility LOPA methodology and the availability of relevant data would all need to support the use of conditional modifiers. A full description of LOPA conditional modifiers, along with worked examples, is given in Chapter 3.

Guidance on When NOT to Use Conditional Modifiers

Many organizations decide not to use conditional modifiers in LOPAs for various reasons that might include one or more of the following:

- If the organization's approach is used to implicitly include conditional modifier probabilities when selecting a consequence severity category, then their explicit use in a LOPA would be double-counting these factors.
- If the organization judges that the uncertainties or complexities involved in incorporating conditional modifier values in LOPAs are too great to warrant their use.
- If the organization considers that the difficulties inherent in validating conditional modifier values are considered to be too great, recognizing that conditional modifiers cannot generally be audited or functionally tested in the same way as for initiating events and independent protection layers.
- If the organization chooses to use a conservative approach that considers conditional modifier factors such as likelihood of ignition to always have a probability of 1.

In addition, the following are typical situations where conditional modifiers should be avoided or limited in LOPAs:

- The facility's risk criteria for evaluating LOPA scenarios uses severity categories based on the size of a material or energy release (for example, a 10,000 lb flammable liquid release may be one severity category) rather than the potential consequences of the release such as fire or vapor cloud explosion, fatalities or environmental impacts.
- The LOPA analyst(s) have insufficient knowledge of conditional modifiers to employ them correctly.
- Insufficient data or information is available to assess the probability to be assigned to a conditional modifier.
- The company's or facility's established LOPA procedure specifically indicates that conditional modifiers are not to be used in its LOPAs, for whatever reason.
- The company's or facility's established LOPA procedure is to not use conditional modifiers unless they provide a full order-of-magnitude effect on the risk calculation.
- The company or facility does not have the resources, capabilities or practices in place to properly document the use of conditional modifiers and maintain their ongoing validity. (See Section 3.8 for guidance on maintaining the validity of conditional modifiers over time.)

- Even when an organization's approach is to use conditional modifiers in LOPAs, situations exist where specific conditional modifiers should not be used when evaluating specific scenarios, as discussed in Chapter 3 for the various types of conditional modifiers.

It is hoped that the current *Guidelines* will aid in the decision process as to the appropriate use of enabling conditions and/or conditional modifiers in LOPAs and other risk evaluations, and to provide the understanding needed for their proper usage.

1.4   Risk Criteria Endpoints

As mentioned earlier, the consequence categories and risk criteria used in evaluating the adequacy of risk control measures must match the methodology used for estimating scenario risk. The basic difference between the categories and risk criteria used is the selection of *endpoints* for the determination of consequences.   These endpoints can range from release magnitude to injury/fatality, environmental damage and/or business impacts or impact categories.   This section will further discuss and illustrate different possible endpoints for various types of loss events (fires, explosions, toxic releases).

The following example will be used to illustrate different endpoints that may be used in a LOPA study. The hypothetical scenario for this example will be loss of containment of a toxic and flammable liquefied gas called "flamitox". The possible general outcomes of the loss-of-containment event are illustrated in the event tree of Figure 1.1. Table 1.2 shows the range of possible endpoints for addressing this event, following the same four consequence screening methods described in the LOPA overview in Section 1.1.

Note that this discussion of consequence endpoints is applicable to conditional modifiers but not to enabling conditions.   Even if a LOPA does not include conditional modifiers (i.e., uses endpoint type 1 or 2), it may include enabling conditions when evaluating the scenario frequency.

As can be seen in Table 1.2, conditional modifiers are normally applied to analyses when the risk criteria are based on ultimate consequences, often fatalities. The general principle is to develop endpoints in concert with the methodology and the risk criteria for those endpoints. Referring again to the example in Figure 1.1 and Table 1.2:

- A company that uses endpoint type 1 (release magnitude) might have a risk boundary of a specified frequency of having a 10 t flamitox release; i.e., if the likelihood is greater than that frequency, then risk reduction is required; if less than or equal to that frequency, safeguards are considered adequate and no further risk reduction is required.

- Another company, which uses endpoint type 2 (impact categories with no consideration of conditional modifiers), might have the same risk boundary but apply it to scenarios with any potential for severe injuries or fatalities. Companies using this approach need to recognize implicit assumptions that are made, such as probability of ignition of flammable vapor clouds assumed as 100%, and whether the risk boundary is based on worst-case impacts or on most likely impacts.
- Yet another company, which uses endpoint type 3 (impact categories with conditional modifiers considered), might have a different risk boundary for having an incident with an expected severe injury or fatality impact, since additional probabilities may be included in the scenario likelihood such as the probability of a person being present in the effect area at the time of the incident. Note that this same risk boundary might be used by companies performing quantitative risk analyses.

The determination of who might be impacted by a LOPA scenario goes beyond whether or not conditional modifiers are employed. The following paragraphs discuss various means of determining toxic release, fire and explosion impact boundaries.
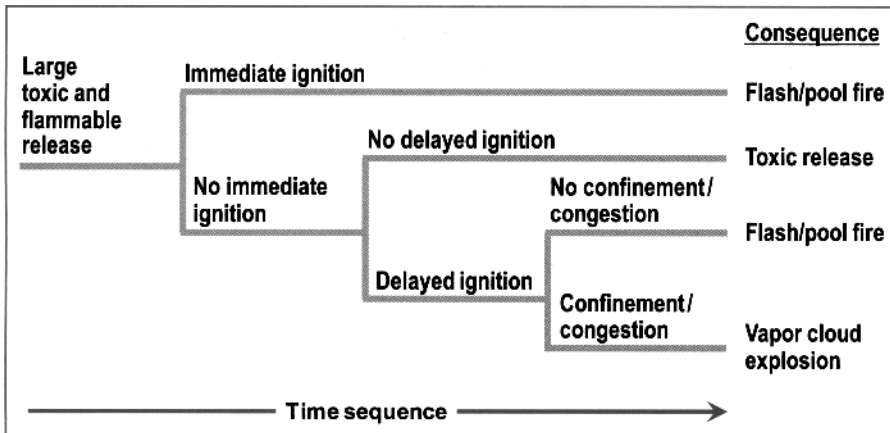

Figure 1.1 Event tree to illustrate different LOPA endpoints.

Table 1.2 Range of possible endpoints for example toxic/flammable release event

Endpoint type	Typical LOPA consequence description	Consideration of ignition probability	Consideration of other conditional modifiers	Number of scenarios evaluated
1 Release magnitude	10 t flamitox release	Not addressed	Not addressed	1
2 Qualitative categories of potential loss and harm impacts	10 t flamitox release, resulting in possible fire/explosion and potential for severe injury or fatality	Not explicitly considered; often assumed to be 100%	Reasonable worst-case consequences estimated, generally without explicitly considering, e.g., personnel presence or fatality probability	1
3 Qualitative or order-of-magnitude categories of potential loss and harm impacts, with conditional modifiers	10 t flamitox release generating a large toxic vapor cloud; severe injury/fatality from inhalation of toxic vapors	Probability of not igniting may be included in analysis	Conditional modifiers may be considered such as probability of fatality and either wind direction or personnel presence / time at risk	3
	10 t flamitox release resulting in flash fire and pool fire; severe injury/fatality from exposure to fire thermal radiation	Ignition probability may be included in analysis	Conditional modifiers may be considered such as fatality and personnel presence / time at risk probabilities	
	10 t flamitox release generating a large flammable vapor cloud migrating to confined/congested area(s); vapor cloud explosion with severe injury/fatality from exposure to thermal, blast effects	Probability of delayed ignition may be included in analysis	Conditional modifiers may be considered such as fatality and personnel presence / time at risk, as well as wind toward confined/congested area or probability of sufficient confinement and congestion	
4 Quantitative impacts, with conditional modifiers	Same as 3 above; may have delayed vs. immediate ignition scenarios for flash/pool fires	Ignition probability generally quantified	Conditional modifiers quantified, to the extent necessary to meet the analysis objectives	3 or 4

Toxic Release Impacts

Toxic release impact boundaries used in LOPAs range from exceeding a toxic threshold for sensitive individuals to exceeding the inhaled dose required to cause fatalities in a normal healthy worker population. The effect area and probability of exceeding the toxic threshold can be greatly different across this range of toxicity measures described in this section, so care should be taken that the risk criteria used by a company for toxic release effects are consistent with the toxic endpoint employed.

Duration of exposure is nearly as important of a consideration as vapor concentration. This is because the effect severity for most chemicals posing toxic inhalation hazards is based on the inhaled dose, which is a function of both concentration and time.

Toxic effect thresholds. Toxic release effects may be considered in a LOPA as resulting in human harm if a "serious health effect" concentration or dose threshold is exceeded. One set of toxic effect thresholds that can be used in determining impact boundaries where the general public could be affected are Acute Exposure Guideline Levels (AEGLs), established for over 100 substances at five exposure periods (10 and 30 minutes, 1 hour, 4 hours, and 8 hours). The second of the three AEGL levels, the AEGL-2, is defined as the airborne concentration of a substance above which it is predicted that the general population, including susceptible individuals, could experience irreversible or other serious, long-lasting adverse health effects or an impaired ability to escape.

Emergency Response Planning Guidelines (ERPGs) are defined similarly, but are based on a one-hour exposure duration. Counting any location at which the ERPG-2 is exceeded as being impacted by a given toxic release event is often quite conservative, especially with chemicals that have good warning properties. For example, the ERPG-2 for ammonia is 150 ppm, which is well above its odor threshold of 5 ppm. A person is very unlikely to be exposed to ammonia vapors for an entire hour without the vapors dissipating or exposed persons taking protective action. As a result, risk criteria based on the frequency at which one or more persons would be exposed to a vapor concentration above a toxic effect threshold such as the ERPG-2, regardless of the exposure duration, are likely to be different than risk criteria based on exceeding toxic effect thresholds for the actual expected duration of exposure.

Lethal thresholds. If a company's risk criteria are associated with human fatality potential, then a threshold lethal concentration or dose might be used. Typical thresholds include the AEGL-3, ERPG-3 and the LC_{LO} (lethal concentration threshold). The AEGL-3, for the same five exposure durations as the AEGL-2 (10 and 30 minutes, 1 hour, 4 hours, and 8 hours), is defined as the airborne concentration of a substance above which it is predicted that the general population, including susceptible individuals, could experience life-threatening health effects or death. By comparison, the ERPG-3 would be a conservative threshold for most scenarios, in that it is defined as the maximum airborne

concentration for exposures up to an hour in duration without experiencing or developing life-threatening health effects. The LC_{LO} may likewise be conservative, in that it does not explicitly consider duration of exposure.

50% effect level. Rather than using a threshold concentration, if a company's risk criteria pertain to average or best-estimate health effects for a given population, then the LC_{50} (lethal concentration to 50% of a population for a given inhalation exposure time) might be used for the toxic release endpoint. The frequency of having a release large enough to exceed a 50% effect level would be generally lower than to exceed a threshold effect level. This again demonstrates the close connection between the LOPA method and risk criteria used.

Other toxic endpoints. Probit equations may be used in a quantitative risk analysis to calculate a probability of fatality as a function of inhaled concentration and duration for many volatile toxic materials. An approach that is intermediate between a concentration-based approach and a probit analysis has been developed and published by the U.K. Health and Safety Executive (HSE 2011). This approach calculates a Dangerous Toxic Load (DTL) value by multiplying the exposure duration times the vapor concentration to the nth power, with $n = 1$ for most materials but higher for some chemicals. The DTL is compared to either a Specified Level of Toxicity (SLOT) or a Significant Likelihood of Death (SLOD) threshold to determine expected effects to the general population, such as for providing land use planning advice. Values of n, SLOT and SLOD are given in HSE 2011 for over 200 toxics, along with explanatory information and information for the derivation of SLOT and SLOD values for chemicals which are not listed.

Escape from a toxic cloud. As described above, the effects of toxic inhalation exposures are based on the exposure time as well as the inhaled concentration. The use of AEGLs, a probit equation or the DTL may allow the user to establish an endpoint concentration for an expected exposure time, taking into account the ability of persons to escape from a toxic cloud or to otherwise limit their inhalation exposure time, based on their risk target severity (e.g., threshold or 50% level).

Because duration of toxic exposure is such an important factor in determining the outcome of a toxic release event, assumptions made regarding whether persons will escape from a toxic cloud will have a significant bearing on the appropriate risk boundary to use. Options include:

- Assume no credit for escape from a toxic cloud; persons in a given location would be exposed the entire time required for the toxic cloud to pass, unless perhaps they are only passing through a relatively small area such as on operator rounds or driving in a vehicle. This approach may be most appropriate for toxic vapors that do not have good warning properties, or that can readily disable a person (e.g., interfere with vision), or situations where the potentially affected population has no training or means of receiving communication of the situation or means of escape.

- Use an expected-average exposure duration based on an assumption that persons would take protective action if possible and escape from the toxic cloud. This assumption may be pertinent for toxic vapors that have good warning properties and where persons are not likely to be trapped in a location such as an elevated platform where escape is impaired.
- Take the probability of successfully escaping from a toxic cloud into account by including it in the LOPA as a conditional modifier. (Note that taking credit for a risk reduction factor of this nature would warrant an evaluation of all the steps involved in detecting, deciding and acting to successfully escape, as well as ensuring their ongoing validity such as through equipment integrity maintenance and personnel training and drills. This conditional modifier is further discussed in Section 3.6.)

Other considerations when evaluating escape from a toxic cloud and likely exposure duration include sheltering in place, vapor detectors, area alarms and the use of personal protective equipment such as escape respirators.

Indoor versus outdoor concentration. As a related consideration, when establishing toxic release endpoints and associated risk boundaries, a company may consider how to treat persons inside an occupied structure that could be affected by an external toxic vapor cloud. Again, multiple options are possible:

- Assume no credit for being indoors; persons inside the structure are assumed to be exposed to the same vapor concentration as the outdoor air. This approach may be most appropriate for toxic vapors that do not have good warning properties and for releases of relatively long duration, or that can disable persons quickly at low concentrations.
- Calculate the expected indoor concentration based on pertinent factors such as the building air exchange rate, then compare the calculated indoor concentration to the threshold or other toxic effect level used. This approach recognizes that the indoor concentration is often considerably less than outside the building, particularly for short-duration releases. Some dispersion modeling software packages such as ALOHA® (EPA 2012) include routines for evaluating indoor concentrations of toxic materials that are exposed to an external toxic cloud.
- Assume all persons inside the occupied structure are adequately protected against the toxic release and are not counted as being potentially affected by the release event. This assumption may be pertinent for short-duration releases and for protective designs such as a structure that has a system to ensure positive air pressure inside the building relative to the outside air, designed for the specific toxic hazard and included in the facility's asset integrity management program to ensure the system is properly tested and maintained on an on-going basis.

Fire and Explosion Endpoints

Much of the above discussion also pertains to fire and explosion endpoints. Exposure duration in particular is an important factor when determining burn injury severity. The effects of personal exposure to thermal radiation from fires or flares are well-established, with typical thresholds being second-degree or third-degree burn boundaries. Assumptions range from no credit for protective action such as seeking shielding or shelter, to use of a conditional modifier for probability of shielding or escape, to assuming protective action would always be taken within a given amount of time such as 40 seconds. Persons inside buildings are generally considered to be shielded from external flash fire or pool fire effects. Protection is sometimes credited against flash fire events when proper flame-resistant clothing is worn (but note that even persons protected by flame-resistant clothing could be injured by inhaling hot product-of-combustion gases).

Endpoints for explosion events can be more complex, since multiple mechanisms for causing injury or fatality are possible, including blast wave direct impingement, missiles or flying debris, being thrown against a hard surface or sharp object, being knocked or startled off of an elevated work location, or being inside a building that is damaged or collapses. Thresholds used for explosion events are sometimes greatly simplified, such as using a 1 psi overpressure as an endpoint, with an implied threshold of serious injury potential for persons inside buildings not blast-resistant. (A somewhat higher threshold such as 3 psi may be warranted for persons not inside buildings.) Conditional modifiers that pertain to these kinds of explosion effects are discussed in Section 3.6.