NEAR-CONSUMER USE RISK ASSESSMENT METHODOLOGY

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Prepared by Safety Advisory Council AHG-S.5 Product Safety

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1 Introduction

This document has been developed in response to the emergence in recent years of more and more near-consumer uses of industrial gases products. Increasingly widespread use of such hazardous materials in such relatively low-skilled market segments can represent an unacceptable risk in many cases.

In order to encourage and facilitate a consistent approach to evaluation and mitigation of such risk a risk assessment methodology is been developed using well established process safety tools.

2 Scope and purpose

2.1 Scope

This guide is limited to assessing Near-Consumer Uses which involve only nitrogen (both liquid and gaseous) and carbon dioxide (all forms). In developing the risk assessment methodology documented here, two specific uses were assessed to validate the effectiveness of the methodology:

- use of carbon dioxide for fogging in nightclubs;
- use of liquid nitrogen in cryogenic food preparation (including cryo-cooking, instant ice-cream making, fogging of drink and frosting of drinks glasses).

2.2 Purpose

At a very high level, the key objectives are:

- to prevent incidents involving customers using EIGA member products in such near consumer uses; and
- to protect and enhance the reputation of the Industrial Gases industry.

In order to achieve these objectives a risk assessment methodology has been developed and is described in this document. The risk assessment methodology is suitable for product applications and may be applied to near consumer uses to allow a more quantifiable, more objective and more reproducible assessment of such uses.

By establishing such a risk assessment methodology, the objective is to create alignment and consistency in how EIGA member companies address risks associated with near consumer customer uses.

3 Terminology and definitions

3.1 Publication terminology

3.1.1 Shall

Indicates that the procedure is mandatory. It is used wherever the criterion for conformance to specific recommendations allows no deviation.

3.1.2 Should

Indicates that a procedure is recommended.

3.1.3 May and need not

Indicates that the procedure is optional.

3.1.4 Will

Used only to indicate the future, not a degree of requirement.

3.1.5 Can

Indicates a possibility or ability.

3.2 Definitions

3.2.1 Near-consumer use

Includes uses of industrial gases or speciality gases where a service is provided to a consumer, client or member of public and which also represents a potential exposure to the service provider or operative where such service provider can be considered professional, but low-skilled or lacking in knowledge and/or familiarity of hazards of the products and of typical industrial-type risk management measures e.g. following work instructions, use of engineering controls and use of PPE (personal protective equipment).

3.2.2 Safety professional

Someone trained, qualified and/or experienced in safety assessment techniques such as a full time employee in a safety function or a customer installation engineer.

4 Overall description of the risk assessment methodology

This risk assessment methodology has been developed to help EIGA member companies to determine whether a Near-Consumer use should be supported or prohibited. It is recommended that each EIGA member company maintains its own list of those Near-Consumer uses which are either supported or prohibited by their company and communicate this widely within their organisations. In cases where a use is supported it may be conditional on a set of defined risk management measures being in place.

The methodology will assess the effectiveness of existing risk management measures and, where needed, will recommend additional measures in order to ensure the overall risk is limited to a level considered tolerable.

The methodology can be used to assess both new and existing uses whether developed in-house by EIGA member companies or by their customers or their equipment suppliers.

Assessment of the use should be considered separately from assessment of the customer and their ability or reliability in implementing the recommended risk management measures in order to operate the process safely. In some cases where a use has been assessed as safe (i.e. tolerable level of risk) based on satisfactory implementation of defined risk management measures, it is still at the discretion of an EIGA member company as to whether they will supply.

Risk management measures can be categorised as either process design features (e.g. additional engineering controls) or administrative controls (e.g. work instructions, training, etc.). Ideally, the process should be designed with sufficient engineering controls to minimise or eliminate the reliance on administrative controls. Processes which rely heavily on administrative controls for safe operation will put much greater emphasis on the importance of the customer assessment.

As a first step in the risk assessment process, initial data gathering is undertaken by field personnel (e.g. sales, customer engineering) at the customer site using the Near-Consumer Field Data Collection Check-List (attached below) or some variant of this.

Personnel should collect as much detail as possible from the customer. This should include about the process itself and the safety culture of the company.

Based on the input from the Field Data Collection Checklist (see Appendix 3) a risk assessment is undertaken by a Safety Professional. This input allows a semi-quantitative evaluation of both the consequence and likelihood of an incident, which in turn determines its position on the Risk Assessment Matrix (see Appendix 4).

Where necessary, additional risk management measures may be required to achieve a tolerable level of risk. In this case, the assessment should be repeated to validate its new position on the Risk Assessment Matrix.

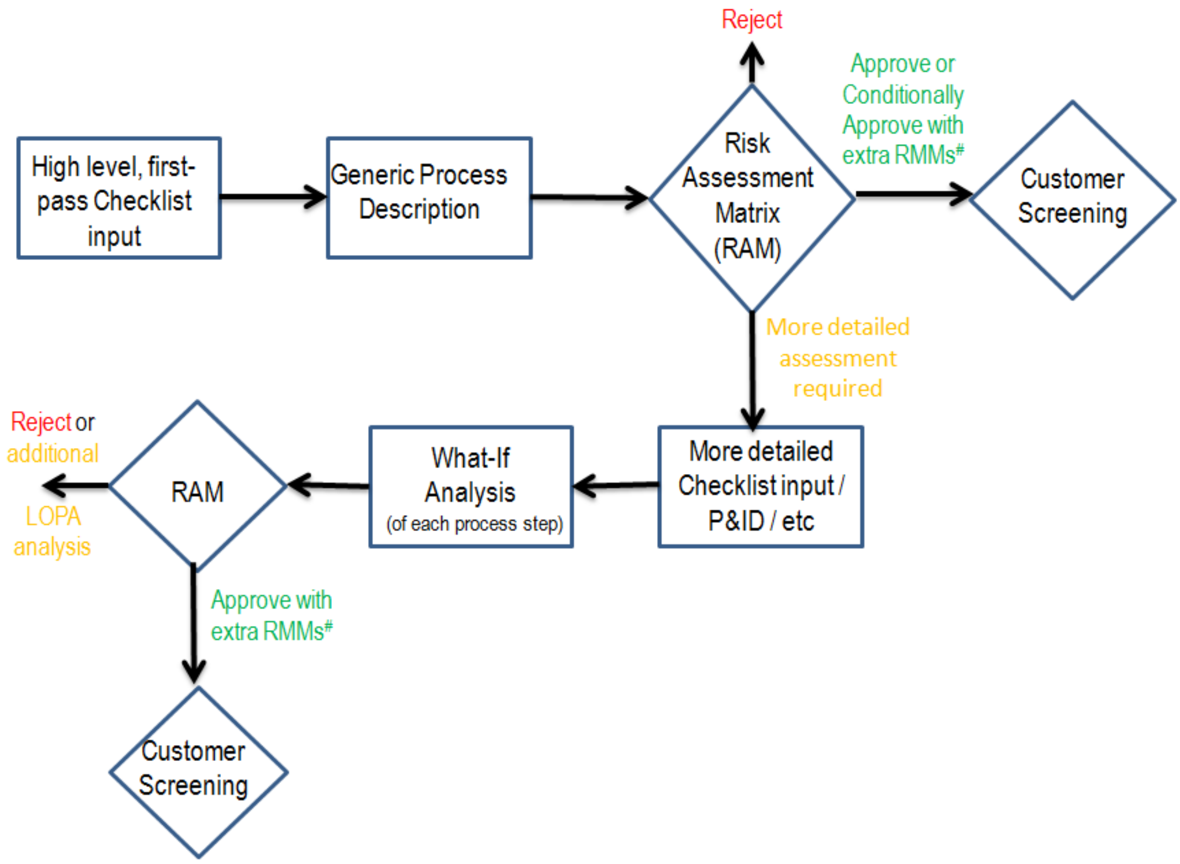

Figure 1: Risk assessment methodology process steps

If the risk is still considered as not tolerable or borderline, a site visit by a Safety Professional may be required to gather more information followed by a further in-depth review. Depending on complexity of the customer process and equipment additional assessment tools may be deployed such as:

- "What-If" analysis;
- LOPA (Layers of Protection Analysis).

If subsequently additional customers need to be assessed for the same use, the list of risk management measures developed for the original assessment can be used as a checklist to define the minimum requirements for safe operation.

All the assessment tools incorporated into this Near-Consumer Use risk assessment methodology are well known and well established tools with which all Safety Professionals are likely to be familiar already.

5 Field Data Collection Checklist

(See Appendix 3 Near-Consumer Field Data Collection Checklist)

It is expected that a customer site visit will be made in order to complete the Checklist. The initial input to the Checklist can be completed by field personnel (e.g. sales), but if a more in-depth assessment is needed further input may need to be gathered by a Safety Professional.

This Checklist provides input to the risk assessment and specifically to determine the position on the Risk Assessment Matrix (RAM). The answers on the Checklist determine potential consequence and likelihood rating along each axis of the RAM.

For each predictive factor used to determine the likelihood rating, there is an equivalent question in the Checklist. Similarly, for each consequence type ("People", "Impact of Reputation" and "Asset Damage") there is an equivalent question in the Checklist.

The Checklist also prompts a consideration of any regulatory compliance obligations to which a particular near-consumer use may be subject e.g. Medical Device Directive, Food Additives Regulations etc.

In case of subsequent additional customer assessments for the same use when a list of risk management measures has already been developed from the original assessment, each EIGA company may wish to develop a separate Customer Assessment Checklist containing the list of risk management measures as well as questions on the customer's ability to reliably implement.

6 Risk Assessment Matrix

The Risk Assessment Matrix (RAM) (See Appendix 4) is a two-dimensional grid with "Likelihood of Occurrence" along one axis and "Potential Consequence" along the other. The position on the RAM grid is determined by the rating of both "Likelihood" and "Consequence".

The threshold for risk tolerance (i.e. what is/is not acceptable) is determined independently by each EIGA member based on their own corporate risk policy; this will determine which boxes on the grid represent an unacceptable risk.

RISK ASSESSMENT MATRIX (RAM)

Potential Consequences				Likelihood of occurrence				
	PEOPLE	REPUTATION	ASSETS	Very low *Rare*	Low *Unlikely*	Medium *Possible*	High *Likely*	Extremely High *Almost Certain*
0	*No injury / disease*	*No impact*	*No damage*	N	N	N	N	N
1	*Slight injury / disease*	*Slight impact*	*Slight damage*	VL	VL	L	L	M
2	*Minor injury / disease*	*Limited impact*	*Minor damage*	VL	L	L	M	H
3	*Major injury / disease*	*Considerable impact*	*Localised damage*	L	L	M	H	H
4	*Single fatality / permanent disability*	*Major national impact*	*Major damage*	L	M	H	H	EH
5	*Multiple fatalities / permanent disability*	*Major international impact*	*Extensive damage*	M	H	H	EH	EH

Figure 2: Risk assessment matrix

a. Likelihood

The Likelihood position is determined by completing the rating of Predictive Factors which will determine its overall rating and position on the axis of the RAM. The Predictive Factors include:

- Application method,
- Type of end use,
- Location,
- Exposure frequency,
- Exposure amount,
- Technical competencies of customer,

- Level of maturity of customer safety culture, and
- Safety level of the equipment used for application.

The relative weighting of these Predictive Factors, as determined by their maximum scores, may need to be adjusted based on each EIGA members risk tolerance and also based on experience. For the purposes of developing this methodology they were calibrated against the use described in section 2.1 Scope.

b. Consequence

The Potential Consequences are considered for the categories “People", "Impact on Reputation" or "Asset Damage". Within the scope of this methodology, which considered only use of liquid nitrogen and carbon dioxide, impact on environment was not considered.

The highest rating for any one category ("People", "Impact on Reputation" or "Asset Damage") will determine the overall Potential Consequence rating e.g. If "People" rates as 5, but "Impact on Reputation" or "Asset Damage" both only rate as 2, the overall rating is 5.

7 What-If Analysis

Depending on complexity of the customer process and equipment additional, more in-depth assessment tools, such as a “What-If” Analysis, may be deployed.

The “What If” technique, in its simplest form, is really just brainstorming by a team, using a process flow-sheet of the use/process being assessed and a blank What-If work sheet which is filled in as the review proceeds.

The "What-If" technique provides a means to identify potential hazards of a facility, process, system or application, evaluate the significance of the hazards, evaluate the adequacy of existing safeguards and list preliminary recommendations to reduce or eliminate the likelihood or severity of the hazards.

The “What-If” technique is described in more detail in Appendix 1.

8 Layers-of-Protection Analysis

A Layers of Protection Analysis (LOPA) is a powerful analytical tool for assessing the adequacy of protection layers used to mitigate process risk. LOPA builds upon well-known process hazards analysis techniques, applying semi-quantitative measures to the evaluation of the frequency of potential incidents and the probability of failure of the protection layers.

A more detailed description of the analytical tool is provided in Appendix 2.

9 Hierarchy of Risk Management Measures

Listed here are examples of typical Risk Management Measures (RMMs) in order of increasing complexity and also increasing effort to implement. This list is of possible measures that can be implemented depending on the assessment of the level of risk and is not intended to be exhaustive.

A lower appetite for risk or a more proactive approach to Product Stewardship may drive some EIGA member companies to recommend more stringent RMMs.

a. Building customer risk awareness e.g. provide SDS, EIGA Info, etc.

b. Customer Training.

c. Customer Self-Assessment (provide checklist and ask for sign-off).

d. Individual Customer Assessment/Qualification by Gas Supplier.

e. Periodic (e.g. annual) customer audits.

f. Individual Equipment Supplier Safety Assessments.

g. Partner with Equipment Supplier to optimise design for safe operation.

h. EIGA member company implements (and possibly maintains) engineering control measures (essentially design features in the process e.g. oxygen monitors, automated shut-off valves, etc.).

i. Finally, in order to limit liability of EIGA member company, consider including clauses in supply contracts that clearly define risk ownership, ideally include an indemnity clause (customer indemnifies EIGA member company) and require a minimum level of insurance by customer (to cover their clients).

Appendix 1 – What-If Analysis

The "What-If" procedure involves experienced personnel brainstorming a series of questions that begin "What if?". Each question represents a potential failure in the facility, process, system or application or misoperation of the facility, process, system or application. The response of the process and/or operators is evaluated to determine if a potential hazard can occur. If so, the adequacy of any existing safeguards is weighed against the likelihood and severity of the potential scenario to determine whether modifications to the system should be recommended.

The "What-If" technique is one of the least structured hazard identification methods available. Its success is therefore highly dependent upon the experience of the analysts. However, it is a very flexible technique, and can be used in a wide range of circumstances. A "What-If" analysis can be conducted at any stage in the life cycle of a facility, process, system or application. It can be used in simple or complex situations and the level of detail treated in the study can be varied easily.

The technique is often effective for reviewing proposed changes to a facility, process, system or application since it can be used to focus attention on those aspects of the facility, process, system or application involved in the change without the need to evaluate other parts of the facility, process, system or application not affected by the change.

So typically someone or a team would do a "What-if" analysis on, say, a particular design of food freezing machine, and then make it generic by identifying the parts which could be applied to all food freezing machines and making this a checklist. But when applied to a different design of food freezing machine, the team would still need to brainstorm and identify any hazards specific to that design of machine.

The facility, process, system or application being analysed is first broken down into smaller parts, called systems and subsystems, to simplify the study. In some cases for a small facility, process, system or application, the entire facility, process, system or application may be analysed without dividing it into smaller parts. For each part of the facility, process, system or application, the system drawings and operating procedures are studied and "What If" questions are developed. The study team addresses each question in turn, analysing the potential hazards, consequences and the response of the facility, process, system or application and/or operators (i.e., what safeguards exist). Each part of the facility, process, system or application, or step in the procedure, is systematically reviewed. Recommendations are identified, as appropriate, and assignments are made for their follow up.

Figure 3 shows the procedure followed in a typical "What-If" analysis:

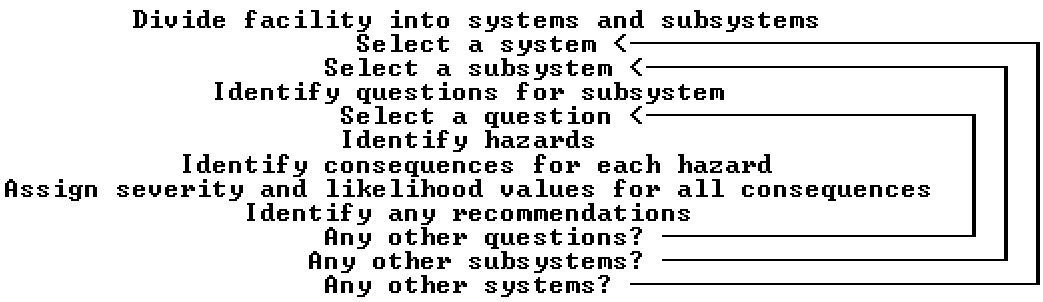

Figure 3: Typical "What-If" analysis procedure

The "What-If" process is dynamic and as one question is asked other questions will occur to the team. These questions should be documented as they occur for later consideration.

It is useful if some structure is used in developing and categorizing "What If" questions. For example, questions can be developed around the three basic causes of accidents: equipment failure, human error and external events. Questioning can also be focused on hazard categories such as personnel injury and equipment damage.

The results of the team review sessions are documented in a "What-If" worksheet.

The worksheet is usually a part of a final report prepared to document the study effort and findings. Attached in Appendix 5 is an example for fogging and cryo-cooking applications.

Appendix 2 – Layers-of-Protection Analysis

Paper:
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INTRODUCTION TO LAYER OF PROTECTION ANALYSIS

Angela E. Summers, Ph.D., P.E, President, SIS-TECH Solutions, LP

"Introduction to Layers of Protection Analysis," Mary Kay O'Conner Process Safety Center Symposium, Texas A&M University, College Station, Texas, October 2002.
"Introduction to Layers of Protection Analysis," Journal of Hazardous Materials, 104 (2003).
"Introduction to Layers of Protection Analysis," Angela Summers and Scott Sandler, ISA EXPO 2003, Research Triangle Park, NC: Instrumentation, Systems, and Automation Society, Houston, Texas, October 20-23, 2003.

Keywords

Layers of Protection Analysis, LOPA, hazard analysis, protection layers, IEC 61511, ANSI/ISA 84.01-1996, risk mitigation

Abstract

Layers of protection analysis (LOPA) is a powerful analytical tool for assessing the adequacy of protection layers used to mitigate process risk. LOPA builds upon well-known process hazards analysis techniques, applying semi-quantitative measures to the evaluation of the frequency of potential incidents and the probability of failure of the protection layers. This paper will provide an overview of the LOPA process, highlighting the key considerations.

Introduction

The process industry is obligated to provide and maintain a safe, working environment for their employees. Safety is provided through inherently safe design and various safeguards, such as instrumented systems, procedures, and training. During a HAZOP, the team is responsible for assessing the process risk from various process deviations and determining the consequence of potential incidents. The team identifies the safeguards used to mitigate the hazardous event. If the team determines that the safeguards are inadequate, the team will make recommendations for further risk reduction.

The team is instructed to list all safeguards. The team often lists safeguards that only partially mitigate the process risk. The team also does not address whether the safeguards are independent from one another. This often results in the team assuming more risk reduction from the safeguards than is possible based on the integrity of the individual components. Furthermore, a team's perception of the integrity of a specific safeguard impacts the assumed risk reduction for that safeguard, resulting in inconsistency in the number of required safeguards for successful mitigation of the process risk. Unfortunately, the inconsistency can result in over- and under-protected process risk, depending on the team composition. Consequently, there must be an independent engineering assessment of the safeguards to ensure that adequate risk reduction is being provided.

What is LOPA?

Layers of protection analysis (LOPA) is a semi-quantitative methodology that can be used to identify safeguards that meet the independent protection layer (IPL) criteria established by CCPS[1] in 1993. While IPLs are extrinsic safety systems, they can be active or passive systems, as long as the following criteria are met:

Specificity: The IPL is capable of detecting and preventing or mitigating the consequences of specified, potentially hazardous event(s), such as a runaway reaction, loss of containment, or an explosion.

Independence: An IPL is independent of all the other protection layers associated with the identified potentially hazardous event. Independence requires that the performance is not affected by the failure of another protection layer or by the conditions that caused another protection layer to fail. Most importantly, the protection layer is independent of the initiating cause.

Dependability: The protection provided by the IPL reduces the identified risk by a known and specified amount.

Auditability: The IPL is designed to permit regular periodic validation of the protective function.

Examples of IPLs are as follows:

- Standard operating procedures,
- Basic process control systems,
- Alarms with defined operator response,
- Safety instrumented systems (SIS),
- Pressure relief devices,
- Blast walls and dikes,
- Fire and gas systems, and
- Deluge systems.

LOPA is not just another hazard assessment or risk assessment tool. It is an engineering tool used to ensure that process risk is successfully mitigated to an acceptable level. LOPA is a rational, defensible methodology that allows a rapid, cost effective means for identifying the IPLs that lower the frequency and/or the consequence of specific hazardous incidents. LOPA provides specific criteria and restrictions for the evaluation of IPLs, eliminating the subjectivity of qualitative methods at substantially less cost than fully quantitative techniques (1).

When is LOPA Used?

LOPA can be used at any point in the lifecycle of a project or process, but it is most cost effective when implemented during front-end loading when process flow diagrams are complete and the P&IDs are under

[1] CCPS/AIChE, Guidelines for Safe Automation of Chemical Processes, 1993, pp. 7-16.

development. For existing processes, LOPA should be used during or after the HAZOP review or revalidation. LOPA is typically applied after a qualitative hazards analysis has been completed, which provides the LOPA team with a listing of hazard scenarios with associated consequence description and potential safeguards for consideration.

A LOPA program is most successful when a procedure is developed that sets the criteria for when LOPA is used and who is qualified to use it. A well-written procedure will also incorporate criteria for evaluation of initiating cause frequency and IPL probability to fail on demand (PFD). The development of these criteria takes time, but this cost is rapidly offset by the increased speed at which LOPA can be implemented on specific projects.

What is the LOPA process?

The overall LOPA process is illustrated in Figure 1. Depending on the project stage, the process may be initiated differently from what is represented. This should be considered a general overview of LOPA and not a limitation on its applicability.

The six major steps to the LOPA process are as follows:

1) Record all reference documentation, including hazards analysis documentation, pressure relief valve design and inspection reports, protection layer design documents, etc.

2) Document the process deviation and hazard scenario under consideration by the team. It is important to focus the team on a specific hazard scenario, such as high pressure resulting in pipeline rupture.

3) Identify all of the initiating causes for the process deviation and determine the frequency of each initiating cause. The team should list all initiating causes of the hazard scenario, such as loss of flow control, loss of pressure control, excess reaction, etc. The initiating cause frequencies should be based on industry-accepted and standards-compliant failure rate data for each device, system, or human. For rapid execution of the LOPA methodology, the initiating cause frequency for common systems should be provided in the procedure.

4) Determine the consequence of the hazard scenario. This evaluation should include an examination of safety, environmental, and economic losses. Safety and environmental impacts must be mitigated for United States OSHA PSM (4) and EPA RMP (5) compliance. In other countries, federal or local regulatory authorities (e.g. HSE, TUV) establish requirements for safety and environmental protection. In contrast, economic loss prevention is strictly a company decision and is not covered under any regulatory mandate. The economic risk should be assessed to ensure that loss prevention goals are met, but the risk should be clearly delineated to allow flexibility in the IPL selection and design.

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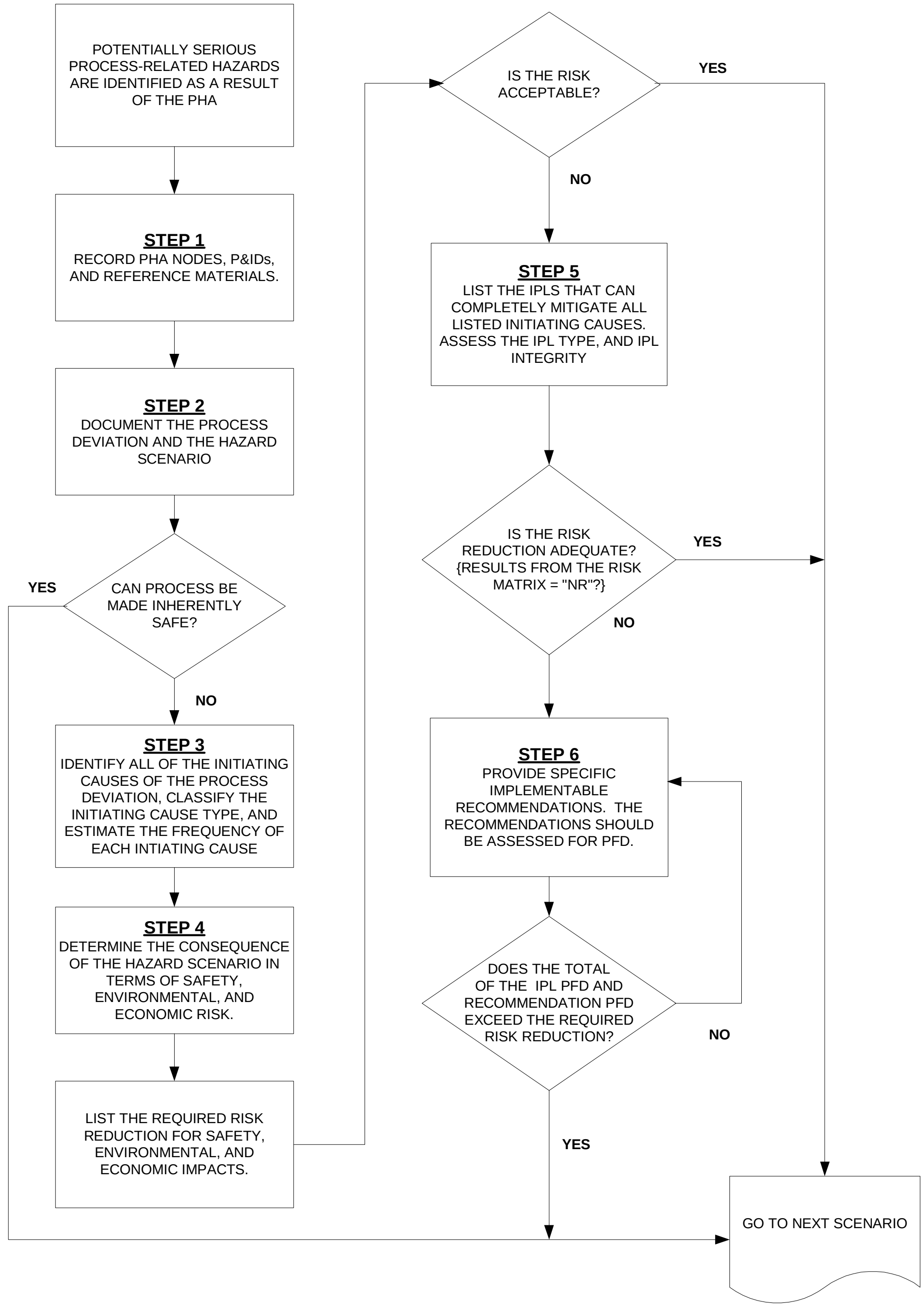
POTENTIALLY SERIOUS PROCESS-RELATED HAZARDS ARE IDENTIFIED AS A RESULT OF THE PHA
STEP 1
RECORD PHA NODES, P&IDs, AND REFERENCE MATERIALS.
STEP 2
DOCUMENT THE PROCESS DEVIATION AND THE HAZARD SCENARIO
CAN PROCESS BE MADE INHERENTLY SAFE?
YES
NO
STEP 3
IDENTIFY ALL OF THE INITIATING CAUSES OF THE PROCESS DEVIATION, CLASSIFY THE INITIATING CAUSE TYPE, AND ESTIMATE THE FREQUENCY OF EACH INTIATING CAUSE
STEP 4
DETERMINE THE CONSEQUENCE OF THE HAZARD SCENARIO IN TERMS OF SAFETY, ENVIRONMENTAL, AND ECONOMIC RISK.
LIST THE REQUIRED RISK REDUCTION FOR SAFETY, ENVIRONMENTAL, AND ECONOMIC IMPACTS.
IS THE RISK ACCEPTABLE?
YES
NO
STEP 5
LIST THE IPLS THAT CAN COMPLETELY MITIGATE ALL LISTED INITIATING CAUSES. ASSESS THE IPL TYPE, AND IPL INTEGRITY
IS THE RISK REDUCTION ADEQUATE? {RESULTS FROM THE RISK MATRIX = "NR"?}
YES
NO
STEP 6
PROVIDE SPECIFIC IMPLEMENTABLE RECOMMENDATIONS. THE RECOMMENDATIONS SHOULD BE ASSESSED FOR PFD.
DOES THE TOTAL OF THE IPL PFD AND RECOMMENDATION PFD EXCEED THE REQUIRED RISK REDUCTION?
NO
YES
GO TO NEXT SCENARIO

Figure 1

For instance, a hazard scenario may describe damage to furnace tubes, causing substantial downtime, but no safety impact. An instrumented system may be used to prevent this economic impact, but the IPL selection, design, operation, testing, and maintenance is not driven by the need to comply with the safety instrumented system (SIS) standards (2,3). Cost/benefit analysis can be used to determine what the actual design should be.

Once the team has an understanding of the frequency and consequence of the potential hazardous event, a risk matrix is used to determine whether the risk is acceptable or whether IPLs are required for further risk reduction. The risk matrix is developed, as part of the LOPA procedure, using Corporate risk criteria and provides consistency to the assessment of acceptable risk. Quantitative targets can also be used to assess whether additional risk reduction is required. However, this does require more specific assessment of the consequence and the declaration of a specific numerical risk tolerance, e.g. tolerable fatality rate. Whether a risk matrix or specific numerical risk tolerance is used, if it is determined that additional risk reduction is necessary, the team is required to identify IPLs (Step 5) or list recommendations (Step 6).

5) List the IPLs that can completely mitigate all listed initiating causes. The IPLs must meet the independence, specificity, dependability, and auditability requirements. This means that the IPL must be completely independent from the initiating cause, e.g., if a process control loop is the initiating cause, an alarm generated by the process control transmitter can not be used for risk reduction.

For each IPL, determine the probability to fail on demand (PFD). The PFD is a measure of the risk reduction that can be obtained using the IPL. For safety instrumented systems, the PFD is equivalent to the Safety Integrity Level (SIL), which serves as the benchmark for Safety Instrumented System design, operation, and maintenance according to ANSI/ISA 84.01-1996 (2) and IEC 61511 (3).

As in Step 3, it is important to provide the team with a list of acceptable IPLs, including design criteria and limitations. Also, for each IPL provide a PFD or range of PFDs based on the design criteria. Having a pre-approved list will substantially improve the consistency of the assessment and reduce the amount of time required for the analysis.

6) Provide specific implementable recommendations. The recommendations from the LOPA team must be considered options for implementation. The LOPA team should be encouraged to develop as many recommendations as possible to allow the project team to select the best option from an implementation ease and cost standpoint.

What is the Benefit of Using LOPA?

There are four primary benefits to implementing LOPA over other SIL assignment methodologies procedures.

1) Due to its scenario-related focus on the process risk, LOPA often reveals process safety issues that were not identified in previous qualitative hazards analysis.

2) Process hazards are directly connected to the safety actions that must take place, providing clear identification of the safety instrumented systems and associated SIL.

3) It has been proven effective in resolving disagreements related to qualitative hazards analysis findings.

4) LOPA often identifies acceptable alternatives to the SIS, such as adding other layers of protection, modifying the process, or changing procedures. This provides options for the project team to evaluate using cost/benefit analysis, allowing the most cost effective means of risk reduction to be selected.

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Appendix 3 – Near - Consumer Applications - Field Data Collection Checklist

Near - Consumer Applications - Field Data Collection Checklist

(to be completed at the client \ customer site for new uses not previously assessed or approved)

It is anticipated that the same Checklist can be used both for a preliminary completion by field personnel and a more detailed assessment at a later visit by a safety professional (e.g. EH&S, engineering, etc) if needed.

Application:	______________	**Date:**	______________
Customer:	______________	**Contact:**	______________
Address:	______________	**Tel:**	______________
	______________	**Email:**	______________
	______________		

Non Supported Use

Before completing this form please check if the intended use is already listed on the gas supplier's list of non-supported/prohibited uses or whether it has already been assessed and (a minimum set of)risk management measures (RMM's) already defined. In the case that RMM's are already defined, completing this form will facilitate further decision-making regarding which RMM's to apply in this specific case

1. Use Description[1a]

Which cryogenic liquid or gaseous product is being offered? Describe its application. Provide a description of the process in as much detail as possible (in attachments/photos if necessary). What is the service or treatment or benefit being offering to the final customer/consumer?

2. Factors Contributing to Likelihood of Unintended Consequences (circle / insert answer)

2.1. Location of Use	Inside	Outside	If inside estimate dimensions of space (m^3)	
2.2. Type of End Use	Retail	Cosmetic / Beauty / Spa / Fitness	Medical / Therapeutic	Other (describe)
2.3. Application Method	Intentional Exposure	Open system with high potential for exposure	Open system with low potential for exposure	Closed system

Near - Consumer Applications - Field Data Collection Checklist

(to be completed at the client \ customer site for new uses not previously assessed or approved)

2.4. Exposure Amount	Quantity sufficient to cause a hazardous consequence	Quantity limited so as unable to cause a hazardous consequence	Estimated usage rate of product (m^3/hour)	
2.5. Exposure Frequencies[2]	Comment:			
Employee/operator	Continuous	Frequent	Once per day	Sporadic \ Rare
Customer/consumer	Continuous	Frequent	Once per day	Sporadic \ Rare
2.6. Number Exposed[2]	Specify number of people exposed and distinguish between customers/consumers and employees/operators			
2.7.Technical Competencies of Employees[3]	Low	Not Known	High	Specify if known (e.g. medically trained, professional qualification, etc)
2.8.Level of HSE maturity of the client[4]	Low	Not Known	High	Describe
2.9.Safety level of equipment used for application[1b]	Relying predominantly on procedural/admin risk control	Not known	Relying partially on procedural/admin risk control	Risk is substantially reduced by instrumented or mechanical protective systems
	Describe existing risk mitigation measures: (e.g. ventilation system, gas analysers, process interlocks, etc)			

Near - Consumer Applications - Field Data Collection Checklist

(to be completed at the client \ customer site for new uses not previously assessed or approved)

3. Scope of Supply (circle answer)			
Gas only	Gas + Equipment	Gas + Equipment + Maintenance	Overall Service / Treatment
Details if applicable:	Details if applicable:	Details if applicable:	Details if applicable:

4. Product Supply			
What is the package type (e.g. aerosol, cylinder, dewar, bulk tank) and specification (e.g. container size)? Is package/container/tank owned by customer? (circle) YES / NO			
4.1. Storage Location	Inside	Outside	If inside estimate dimensions of space (m^3)
	Description:		

Near - Consumer Applications - Field Data Collection Checklist

(to be completed at the client \ customer site for new uses not previously assessed or approved)

5. Regulatory Obligations: (circle answer) Are applicable laws and regulations for such kind of activities/applications known by customer and/or supplier?		
Yes	No	Unclear \ unknown
5.1. Specify regulation if known: (e.g. Medical Device Directive, etc)		
6. Enclosed documents:		
6.1. SDS Yes \ No	**Other docs**	**Other docs**
6.2. P&ID (elementary) Yes \ No	**Other docs**	**Other docs**
6.3. Process \ application detailed description Yes \ No	**Other docs**	**Other docs**

Data collection performed by (name \ position):

____

Signature: ____

Appendix 4 – Risk Assessment Matrix

RISK ASSESSMENT MATRIX (RAM)

Guidance Notes:

- The position on the RAM grid is determined by the ranking along each axis for both "Likelihood of Occurrence" and "Potential Consequence"

- The Risk Assessment must be completed by a trained / qualified Safety Professional

- The threshold for risk tolerance (i.e. what is/is not acceptable) is determined by each Gas Supplier based on their own Corporate Risk determination.

  - if an initial risk assessment (following initial completion of the Risk Assessment Checklist by field personnel) is considered borderline (e.g. "H" = High on RAM grid), additional Risk Manamgement Measures may be recommended followed by a further risk assessment to re-determine the position on the RAM in order to achieve a tolerable level of risk.

  - if an initial risk assessment indicates that the risk is not tolerable, either the customer use will be considered as prohibited/not supported by the Gas Supplier or a more in-depth Risk Assessment (e.g. "What-If" analysis on each process control node) can be undertaken to define further additional appropriate Risk Management Measures after which the customer use is again re-assessed to validate its new position on the RAM grid.

- The Likelihood position is determined by completing the ranking of Predictive Factors in cells M5-M12 to provide an overall score M13 which will determine its overall ranking against the rating system defined in cells P5-R9

  - the relative weighting of these Predictive Factors, as determined by the maximum scores in column N5-N12, may need to be adjusted based on each Gas Supplier's risk tolerance and also based on experience. In addition, these weighting factors may need to be adjusted from use to use at the discretion of each Gas Supplier.

- The Potential Consequence ratings are described in lines 13-43 and are assessed independently by each Gas Supplier.

  - the highest rating for any one category ("People", "Impact on Reputation" or "Asset Damage") will determine the overall Potential Consequence rating e.g. If "People" rates as 5, but "Impact on Reputation" or "Asset Damage" both only rate as 2, the overall rating is 5

  - In the case of use of LIN and CO2, potential environmental was not considered as a factor.

RISK ASSESSMENT MATRIX (RAM)

Potential Consequences				Likelihood of occurrence				
	PEOPLE	REPUTATION	ASSETS	Very low *Rare*	Low *Unlikely*	Medium *Possible*	High *Likely*	Extremely High *Almost Certain*
0	*No injury / disease*	*No impact*	*No damage*	N	N	N	N	N
1	*Slight injury / disease*	*Slight impact*	*Slight damage*	VL	VL	L	L	M
2	*Minor injury / disease*	*Limited impact*	*Minor damage*	VL	L	L	M	H
3	*Major injury / disease*	*Considerable impact*	*Localised damage*	L	L	M	H	H
4	*Single fatality / permanent disability*	*Major national impact*	*Major damage*	L	M	H	H	EH
5	*Multiple fatalities / permanent disability*	*Major international impact*	*Extensive damage*	M	H	H	EH	EH

Likelihood Scoring

Predictive Factors to help determine likelihood of occurence	Score	Max score
Application method		10
Type of end use		5
Location		3
Exposure frequencies		5
Exposure Amount		5
Technical competencies		5
Level of HSE maturity of the client		5
Safety level of the equipment used for application		5
	0	43

Cross-check Likelihood Scoring to RAM Likelihood

Likelihood scores / rating			Description of Likelihood of consequence	Failures of protective systems
VL	RARE	3-7	Conceivable but very unlikely	Multiple
L	UNLIKELY	8-11	Has occurred somewhere with this general type of application, but unlikely with the specific application	Two
M	POSSIBLE	12-27	Possible at one location during the period these applications are expected to be installed	One
H	LIKELY	28-37	Possible at one application during the period it is installed there. Root cause of consequence likely to have occurred somewhere	n/a
EH	ALMOST CERTAIN	38-43	Expected to occur one or more times during period one application is installed	n/a

Potential Consequences (details)

PEOPLE

RATI	DESCRIPTION
0	No injury or damage to health.
1	Slight injury or health effects (including first aid care and minor medical treatment care) – Not affecting work performance or causing disability.
2	Minor injury or health effects – Affecting work performance, such as restriction to activities (Restricted Work Case). Limited health effects, which are reversible, Example: skin irritation.
3	Major injury or health effects – Affecting work performance, such as Lost Time Injury/Recordable Case. Irreversible health damage without loss of life, Examples: noise induced hearing loss, chronic back
4	Single fatality or permanent total disability (including permanent Partial Disability) – From an accident or occupational illness.
5	Multiple fatalities or permanent total disability – From an accident or occupational illness.

IMPACT ON REPUTATION

RATI	DESCRIPTION
0	No impact – No public awareness.
1	Slight impact – Public awareness may exist but there is no public concern.
2	Limited impact – Some local public concern. Some political attention with potentially adverse aspects for company operations.
3	Considerable impact – Local public concern with attention in local media. Extensive political attention. Adverse stance from government and/or action groups.
4	National impact – National public concern. Extensive adverse attention in the national media. Regional/national action with potential restrictive measures and/or impact on grant of licences.
5	International impact – International public attention. Extensive adverse attention in international media. National/international action with potentially severe impact on access to new areas, grants of

ASSET DAMAGE (cost of the damage can be modified / figures used are for example)

RATI	DESCRIPTION ([illegible] OF TOTAL COSTS, EUR)
0	Zero damage
1	Slight damage – No disruption to operation (costs less than EUR 1,000)
2	Minor damage – Brief disruption (costs less than EUR 10,000)
3	Local damage – Partial shutdown (can be restarted but costs up to EUR 100,000)
4	Major damage – Partial operation loss (1 week shutdown costs up to EUR 500,000)
5	Extensive damage – Substantial or total loss of operation (costs in excess of EUR 500,000)

RISK ASSESSMENT MATRIX (RAM)

Potential Consequences				Likelihood of occurrence				
				Very low	Low	Medium	High	Extremely High
	PEOPLE	*REPUTATION*	*ASSETS*	*Rare*	*Unlikely*	*Possible*	*Likely*	*Almost Certain*
0	*No injury / disease*	*No impact*	*No damage*	N	N	N	N	N
1	*Slight injury / disease*	*Slight impact*	*Slight damage*	VL	VL	L	L	M
2	*Minor injury / disease*	*Limited impact*	*Minor damage*	VL	L	L	M	H
3	*Major injury / disease*	*Considerable impact*	*Localised damage*	L	L	M	H	H
4	*Single fatality / permanent disability*	*Major national impact*	*Major damage*	L	M	H	H	EH
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<u>Potential Consequences (details)</u>

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1	Slight impact – Public awareness may exist but there is no public concern.
2	Limited impact – Some local public concern. Some political attention with potentially adverse aspects for company operations.
3	Considerable impact – Local public concern with attention in local media. Extensive political attention. Adverse stance from government and/or action groups.
4	National impact – National public concern. Extensive adverse attention in the national media. Regional/national action with potential restrictive measures and/or impact on grant of licences. Mobilisation
5	International impact – International public attention. Extensive adverse attention in international media. National/international action with potentially severe impact on access to new areas, grants of licences and/or

ASSET DAMAGE (cost of the damage can be modified / figures used are for example)

RATING	DESCRIPTION (100% OF TOTAL COSTS, EUR)
0	Zero damage
1	Slight damage – No disruption to operation (costs less than EUR 1,000)
2	Minor damage – Brief disruption (costs less than EUR 10,000)
3	Local damage – Partial shutdown (can be restarted but costs up to EUR 100,000)
4	Major damage – Partial operation loss (1 week shutdown costs up to EUR 500,000)
5	Extensive damage – Substantial or total loss of operation (costs in excess of EUR 500,000)

Likelihood Scoring

Predictive Factors to help determine likelihood of occurence	Score	Max score
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Safety level of the equipment used for application		5
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Cross-check Likelihood Scoring to RAM Likelihood

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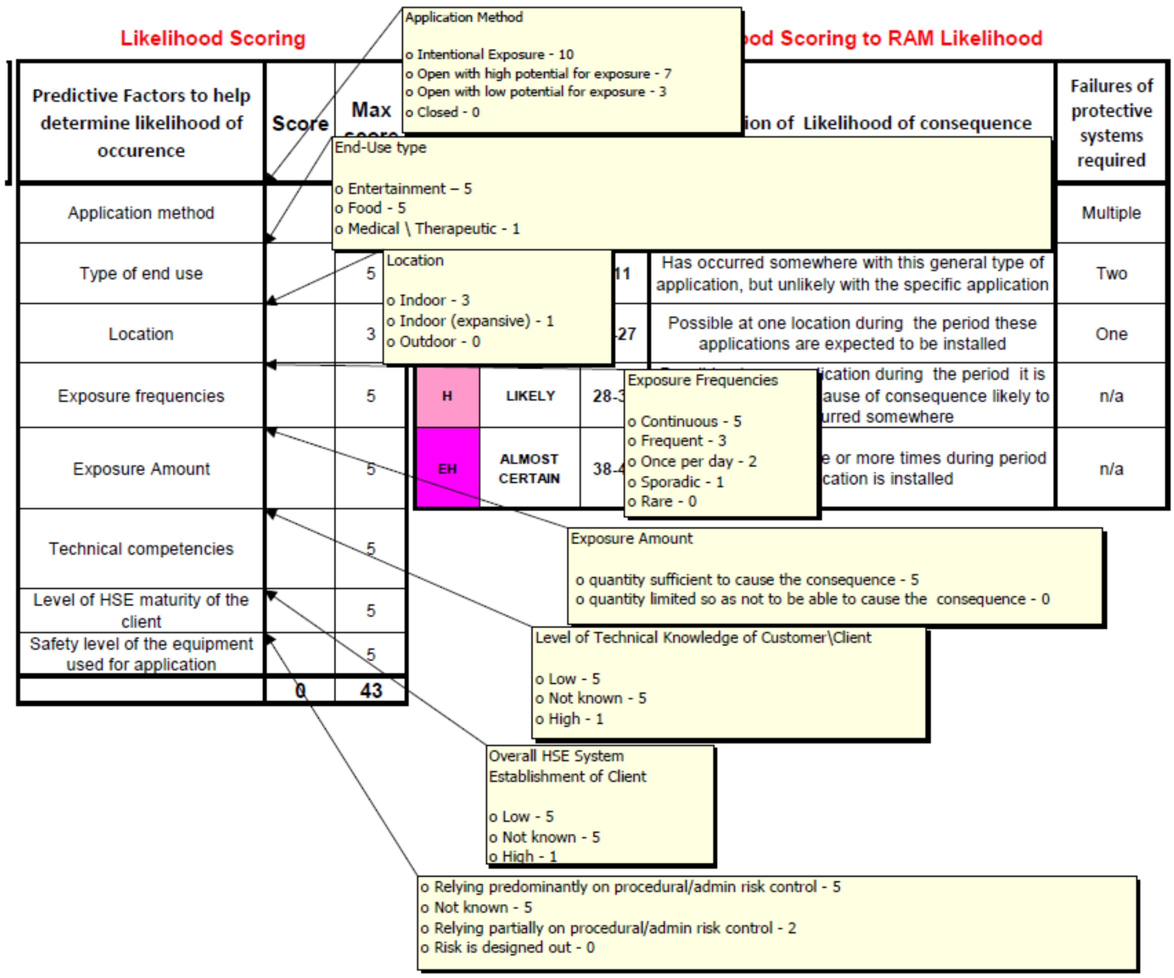
H	LIKELY	28-37	Possible at one application during the period it is installed there. Root cause of consequence likely to have occurred somewhere	n/a
EH	ALMOST CERTAIN	38-43	Expected to occur one or more times during period one application is installed	n/a



Appendix 5 – What If analysis Near Consumer Examples

Facility: EXAMPLE
Session:
Revision:
System:
Drawings:
Subsystem:

WHAT IF...	HAZARD	CONSEQUENCES	SAFEGUARDS	ORIGINAL SLR RATING FROM RAM MATRIX			REF#	RECOMMENDATIONS	BY	CAT	SLR RATING AFTER RECOMMENDATIONS		
				Severity	Likelihood	Risk					Severity	Likelihood	Risk

Facility: EXAMPLE
Session:
Revision:
System:
Drawings:
Subsystem:

5=MULTIPLE FATALITIES
4=SINGLE FATALITY
3 =MAJOR INJURY
2=MINOR INJURY
1=SLIGHT INJURY
0=NO INJURY

VL=RARE
L=UNLIKELY
M=POSSIBLE
H=LIKELY
VH=ALMOST CERTAIN

N = NONE
VL = VERY LOW
L = LOW
M = MEDIUM
H = HIGH
EH = EXTREMELY HIGH

name / initials of person completing what-if

5=MULTIPLE FATALITIES
4=SINGLE FATALITY
3 =MAJOR INJURY
2=MINOR INJURY
1=SLIGHT INJURY
0=NO INJURY

N = NONE
VL = VERY LOW
L = LOW
M = MEDIUM
H = HIGH
EH = EXTREMELY HIGH

				ORIGINAL SLR RATING FROM RAM MATRIX							SLR RATING AFTER RECOMMENDATIONS		
WHAT IF...	HAZARD	CONSEQUENCES	SAFEGUARDS	Severity	Likelihood	Risk	REF#	RECOMMENDATIONS	BY	CAT	Severity	Likelihood	Risk

Severity = Consequence from RAM
Risk = grid rating from RAM

VL=RARE
L=UNLIKELY
M=POSSIBLE
H=LIKELY
VH=ALMOST CERTAIN

MP - Material Problems
EE/I - External Effects or Influences
OE&HF - Operating Errors & other Human Factors
A/SE - Analytical or Sampling Errors
E/IM - Equipment/Instrument Malfunction
PUUO - Process Upsets of Unspecified Origin
UF - Utility Failures
IF/LOC - Integrity Failure or Loss Of Containment
EO - Emergency Operations
ER - Environmental Release

EXAMPLE WHAT-IF ANALYSIS FOR USE OF CO_2 FOR FOGGING EFFECT IN NIGHTCLUB, ETC

WHAT IF...	HAZARD	CONSEQUENCES	SAFEGUARDS	SEVERITY	LIKELIHOOD	RISK	REF#	RECOMMENDATIONS	BY
CO2 flow from ceiling nozzle does not stop after operator/DJ releases the button due to valve mechanical failure, dry ice blockage, etc	High CO2 level accumulates in the dance floor area causing toxic/asphyxiant effects	Effects on people on the dance floor : 3% - Increased breathing rate, dizziness, headaches, 4-5% - Choking sensation. 5-10% - tiredness, impaired vision, confusion, unconsciousness after a few minutes. Above 10% - depending on concentration and exposure time, death may occur	Ventilation in room limits CO2 accumulation rate Emergency shut off valve at CO2 Evacuation procedures Adequate emergency exits	H	L	M		Emergency shut off valve at CO2 storage source, operated remotely from dance area	
CO2 flow from ceiling nozzle does not stop after operator/DJ releases the button - due to valve mechanical failure, dry ice blockage, etc. Ventilation in the room failed	As above, but accumulation rate will be higher due to lack of air dilution	As above, the effects will occur more rapidly. Higher risk of fatality	Limit CO2 storage to a calculated fraction of room volume so the fatality is unlikely even if full inventory is discharged Evacuation procedures Adequate emergency exits	H	L	M		Emergency shut off valve at CO2 storage source, operated remotely from dance area	
Dancer stands directly below CO2 jet	Low temperature of jet (-78 deg C), dry ice particles formed	risk of cold burns, injury from impact of dry ice particles	Due to discomfort, the dancer is likely to move away	L	L	L			
Person is lying on the floor , due to slipping, or intoxication due to alcohol or drugs	Higher CO2 levels near the floor, increases risk to person lying there when CO2 jet is operated	Higher risk of fatality	Nightclub personnel intervention	H	L	M			

EXAMPLE WHAT-IF ANALYSIS FOR USE OF LIQUID NITROGEN FOR CRYO-COOKING

CATEGORY	REF #	WHAT IF ...	CONSEQUENCES	RISK LEVEL	RECOMMENDATIONS	FURTHER COMMENTS
	1	**INLETS OPERATING AREAS**				
OE&HF	1.1	Cryogenic gas directed towards the operator or other persons	Cold burns	H	Install an "L" connection on outlet to direct flow toward the floor	Also recommend use of personal protective equipment (e.g. gloves, goggles/visor, etc)
			Oxygen deficiency	M	Ensure sufficient ventilation where dispenser is used	Only operate in well ventilated areas
			Overcome the TLV-TWA value	M	Install O2 detector (where LCO2is used also install CO2 detector)	Ensure O2 & CO2 detectors are installed close to the area used for cryocooking operation
MP	1.2	Leakage of the hose connecting cryogenic gas bulk-tank	Leakage outside the hose	L	Sufficient ventilation to be ensured where the dispenser is used	Better to install the bulk-tank outside the operating area
			Cold burns	L	Recommend use of personal protective equipment (e.g. gloves, goggles/visor, etc)	
			Oxygen deficiency	M	Ensure sufficient ventilation where dispenser is used	Only operate in well ventilated areas
			Overcome the TLV-TWA value	M	Install O2 detector (where LCO2is used also install CO2 detector)	Ensure O2 & CO2 detectors are installed close to the area used for cryocooking operation
OE&HF	1.3	Loose/insufficiently tight connections	Uncontrolled gas release	L	Sufficient ventilation to be ensured where the dispenser is used	Leak test connections before opening valves
			Cold burns	L	Recommend use of personal protective equipment (e.g. gloves, goggles/visor, etc)	
OE&HF	1.4	Overtight connection	Damaging connection threads	L	Check tightness of connection before opening valves	Leak test connections before opening valves
			Cold burns	L	Recommend use of personal protective equipment (e.g. gloves, goggles/visor, etc)	
UF	1.5	Unexpected electricity shut down	No consequences	N		
UF	1.6	Unstable power supply	No consequences	N		
IF/LOC	1.7	Labels damaged	Connections not identified	L	Improve quality of the labels	Do not start to operate until label content clarified
			Wrong connections	L	Check tightness of connection before opening valves	
	2	**CRYOGENIC GAS FLOW**				
OE&HF	2.1	Liquid trapped between bulk-tank and valve	Overpressure of the line	L	Install overpressure safety valve in the line	
			Liquid released from the purge outlet	L	Overpressure safety valve shall be installed outside the operating area	
E/IM	2.2	Safety valve does not work	If not used according the instruction manual:Overpressure of the line	L	Install a second, back-up overpressure safety valve	
E/IM	2.3	Pressure indicator does not work	Flow incorrect	L	To stop and check the dispenser	
MP	2.4	Orifice blocked	Flow incorrect	L	To stop and check the dispenser	
	3	**DOSING VALVE**				
E/IM	3.1	Dosing valve blocked (closed)	No gas at the outlet	N	Shut-off procedure to be defined	
E/IM	3.2	Dosing valve blocked (open)	Gas continuously flowing at the outlet	L	Shut-off procedure to be defined	
OE&HF	3.3	Liquid trapped between the dosing valve and the check valves	If not used according to instruction manual: Overpressure of the line	M	Install a safety valve	
	4	**ENVIRONMENT CONDITION**				
EE/I	4.1	High ambient humidity	No consequences	N		
EE/I	4.2	Low ambient temperature	No consequences	N		
EE/I	4.3	High ambient temperature	Overpressure in the tank	L	Install a safety valve on the tank	
			Uncontrolled gas release from the bulk-tank	L	Install the container outside the operating area in a ventilated areas	

EXAMPLE WHAT-IF ANALYSIS FOR USE OF LIQUID NITROGEN FOR CRYO-COOKING

CATEGORY	REF #	WHAT IF ...	CONSEQUENCES	RISK LEVEL	RECOMMENDATIONS	FURTHER COMMENTS
	5	**HANDLING and TRANSPORT BULK-TANK**				
OE&HF	5.1	Dropping cryogenic from bulk-tank	Damaging bulk-tank	L	Recommend use of personal protective equipment (e.g. gloves, goggles/visor, etc)	
OE&HF	5.2	Wrong transport gas condition	Damages to the bulk-tank	M	Check the integrity before using the bulk-tank	
OE&HF	5.3	Maintenance service not done properly	Basically all other risks	L	Define a periodic check to be carried out by gas company or authorised persons	
	6	**TRAINING and COMPETENCY**				
E/IM	6.1	Work instructions not available or incorrect	Basically all other risks	M	Improve training and competencies	Instructions periodically revised
OE&HF	6.2	Operators do not follow work instructions	Basically all other risks	H	Improve training and competencies	Training of users to be delivered
OE&HF	6.3	Operators' mistakes	Basically all other risks	H	Improve training and competencies	Training of users to be delivered
	7	**EMERGENCY**				
EO	7.1	Cold burns	Injury	H	Safety instructions summarised in the manual	
EO	7.2	Oxygen deficiency-High CO2 concentration	Serious injury / death	M	Safety instructions summarised in the manual	
EO	7.3	Exceed TLV-TWA value	Death	L	Safety instructions summarised in the manual	
	8	**EXTERNAL**				
EE/I	8.1	Manipulation of the bulk-tank by user or third parties	Basically all other risks	M	Training and competency in the manipulation of bulk-tank	Avoid the use of the cryogenic containers by untrained third parties
EE/I	8.2	Misuse of the dispenser or tools	Basically all other risks	H	Improve training and competencies	Avoid the use of the cryogenic containers by untrained third parties
	9	**TOOLS AND EQUIPMENTS USED FOR CRYOCOOKING**				
EE/I	9.1	Tools or equipment made from materials not suitable with cryogenic temperature	Tools/equipment can be damaged, broken or destroyed	M	Use only tools and equipment made from materials suitable for cryogenic temperature	Tools and equipment for CryoCooking shall be suitable for food use
			Leakage of cryogenic gas to the outside the tools/equipment	M	Use only tools and equipment made from materials suitable for cryogenic temperature	
			Cold burns	M	Recommend use of personal protective equipment (e.g. gloves, goggles/visor, etc)	
EE/I	9.2	Tools or equipment produced with materials not suitable for food use	Food contamination in the final product -Health risk	M	Tools and equipment for CryoCooking shall be suitable for food use	
MP	9.4	Tools and equipment for containing cryogenic gas without adequate thermal insulation	Overpressure in the closed tools or equipments	L	Equipment-tool shall equiped with a safety valve	Only use purpose designed eqipment suitable for handling cryogenic materials
			Uncontrolled gas release and gas continuously flowing at the outlet of the tools/equipments	L	Recommend use of personal protective equipment (e.g. gloves, goggles/visor, etc)	
OE&HF	9.5	Mis-handling of tools/equipment	Cold burns	H	Recommend use of personal protective equipment (e.g. gloves, goggles/visor, etc)	
			Basically all other risks	H	To improve Training and Competencies	Training of users to be delivered
	10	**CRYOGENIC GAS**				
A/SE	10.1	Gas not suitable for food use - Non Food Additive grade	Food contamination in the final product -Health risk	M	Use only food grade gas (Food Additive)	
	10.2	Presence of cryogenic gas in the final food products that can be ingested	Cold Burns - Serious injury / death	H	Check the final food products have not presence of residual cryogenic gas	The cryogenic gas in contact with the food final product shall be evaporated

PROVISIONAL LIST OF RISK MANAGEMENT MEASURES

(List not intended to be comprehensive, but provided as examples; RMM's in approximate hierarchy order in terms of effectiveness in mitigating risk and difficulty

> Building customer risk awareness e.g. provide SDS, EIGA Info, etc
> Customer Training
> Customer Self-Assessment (and sign-off)
- Against generic checklist defined for a particular use based on prior customer assessments e.g. list of recommended RMM's
> Individual Customer Assessment/Qualification by Gas Supplier
- Technical sophistication, experience, commitment to safe operation, monitor operation/ maintenance, background of employees, full-time operating supervision
> Assess generic P&ID/Process Flowsheet for recommended safeguards
- Against generic checklist defined for a particular use based on prior customer assessments e.g. list of recommended RMM's
> Periodic (annual?) customer audits
> Assess Each Customer's Installation for recommended safeguards
- Or recommend (independent) 3rd party assessment
> Individual Equipment Supplier Safety Assessments
> Partner with Equipment Supplier
> Gas supplier engineering control measures / engineered offering

Additional consideration in order to manage confirm customers acknowledgement of hazards of product supplied and use intended, to mitigate liability,to indemnify supplier, to define risk ownership between supplier and customer, confirm recognition of recommended Risk Management Measures

> Insurance and contract review with legal e.g. develop specific contract language to define risk ownership and limit of liability