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Enhancing Risk Management in Pharma Industries: Analysing Hazardous Events, Assessing Barrier Efficacy and Calculating Mitigated Event Frequency Through Layer of Protection Analysis (LOPA)

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KEYWORDS

Layer of Protection Analysis, Risk Assessment, LOPA in Pharma, Initiating Event, Barrier analysis, Mitigated Event Frequency HAZOP, PHA

ABSTRACT:

Pharma manufacturing involves handling and processing various potent and hazardous chemicals that pose risks such as toxicity, flammability, and reactivity, which can lead to catastrophic events such as fire, explosion, and toxic releases. Risk Management plays a major role in ensuring the safety of the people, process and plant. This paper presents the application of Layers of Protection Analysis (LOPA) in the pharmaceutical industry to assess and mitigate process risks. Through a case study approach, various hazardous scenarios within a pharmaceutical plant are analyzed, demonstrating the effectiveness of existing control measures and identifying areas for additional risk reduction. The study particularly focuses on the management of fire and explosion risks arising from various hazardous scenarios such as inadequate intertisation, exothermicity, runaway reactions, and static charge in centrifuges. By implementing various protection layers using the LOPA methodology, the risk associated with this scenario is significantly reduced. The LOPA methodology provides a systematic framework for safety engineers to evaluate process risks, assess the reliability of existing safeguards, and determine the need for supplementary risk mitigation measures. Furthermore, it facilitates comparative risk assessments across different pharmaceutical plants, emphasizing the importance of initiating event frequency and promoting the adoption of inherent safety principles in process design.

Introduction

Pharma manufacturing involves handling and processing various potent and hazardous chemicals, which pose risks such as toxicity, flammability, and reactivity. These can lead to catastrophic events such as fire, explosion, and toxic releases. Risk Management plays a major role in ensuring the safety of the people, process, and plant.

A Hazard and Operability Study (HAZOP) [1][17][18]serves as a proactive measure for organizations to categorize and mitigate possible risks within process and equipment. This integrated and meticulous approach is commonly employed throughout the adapted and constructed phases of facilities to verify that systems or plants operate according to expectations. Moreover, HAZOP is also utilized in ongoing operations and maintenance processes to ensure ongoing safety and efficiency [19]

With an increased focus on risk management, industries are making a lot of efforts to analyze risk, but the desired risk mitigation still needs to be achieved. One of the reasons could be the reliability and availability of safeguards. The main questions to be asked to understand and mitigate risks are

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a) What can go wrong?
b) How often might it happen?
c) How badly can it impact?
d) Are barriers available and reliable?

The fourth question makes all the difference to the overall risk management process. A layer of Protection plays a major role in achieving it. *Layer of Protection Analysis* (*LOPA*) [2], characterized by the Centre for *Chemical Process Safety* as a technique that scrutinizes emergency scenarios to match an outline risk approximation to its risk standards. *LOPA* assists Industries in regulating several desirable autonomous barrier systems and mitigating the risks every layer entails so that the situation falls within the business's risk appetite.

Although the *LOPA* and *HAZOP* are separate assessments, they work together synergistically to enhance overall risk assessment. While *HAZOP* sheds light on existing risks by exploring all potential scenarios comprehensively, LOPA delves into the layers of Protection in place should any of these scenarios materialize. By doing so, LOPA pinpoints any vulnerabilities within these protective layers, enabling companies to address them effectively.

The objective of this paper is to analyze multiple hazardous events arising out of various operations in the pharma manufacturing process from the HAZOP methodology and evaluate the effectiveness of barriers recommended in the HAZOP and the calculation of mitigated frequency through the Layer of Protection Analysis technique. This approach allows for the evaluation of safeguards' effectiveness in risk reduction in a semi-quantitative approach and efficient manner.

LOPA methodology is instrumental in assessing the efficacy of *Safety Instrumented Functions* (*SIF*), such as automated critical interlocks and alarms, in achieving acceptable risk levels. Additionally, the LOPA methodology ensures consistency in risk assessment approaches and communication practices. It also facilitates the establishment of an effective mechanical integrity or risk-based maintenance system for critical components.

1. LOPA and its Importance

LOPA serves as a streamlined risk assessment method [3] [1] that employs broad categories for factors like trigger event, severity of consequence, and the effectiveness of *independent protection layers* (*IPLs*) to estimate the *risk* associated with a particular setup. It offers a systematic approach for risk analysts to evaluate the likelihood of selected accident scenarios consistently. Typically, these scenarios are identified through qualitative hazard evaluations like PHAs, *management of change* assessments, or project reviews. *LOPA* is utilized once an intolerable result and its plausible origin have been determined, providing a rough estimate of the scenario's risk level.

With many more hazard scrutiny approaches, the most important determination of *LOPA* is to regulate if there are adequate layers of protection in contradiction of coincidence circumstances.

High Impact Scenario refers to an unforeseen event or series of events that leads to an undesirable catastrophic outcome. This will consist of hazardous events and consequences. A Hazardous Event is an initiating event, such as the loss of cooling, that initiates a sequence of events. A consequence, which could include over-pressuring the system, the release of toxic or flammable materials into the atmosphere, fatalities, etc., occurs if the sequence of events persists without intervention.

Depending on the intricacy of the procedure and the possible severity of the outcome, a scenario can need one or more levels of protection. Keep in mind that in a particular scenario, the prevention of a consequence requires the successful operation of only one layer. However, since no layer is impenetrably effective, there needs to be enough protection layers in place to make the accident risk bearable.

2. Application of LOPA for the Key Hazardous Scenarios

The *LOPA* method intends to monitor the stages exposed in Figure 1 [2] [3] [1], and the detailed descriptions are given below.

- Classify hazardous events that are upshot in important stages necessitating a *LOPA* and the

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subsequent information might be attained from the *HAZOP*:

- *Scenario description.*
- *Consequence ranking.*
- *List of initiating causes.*
- *List of safeguards for consideration as an Independent Protection Layer (IPL)*
- Determine the initiating cause of the hazardous event and its frequency of failure as given in Table 1 for equipment, Table 2, and Table 3 for human error [3].
- Determining the effect of initiating cause with respect to harmful concerns on working conditions and environment and with regard to *business value*. Calculate the Mitigated Event Likelihood/frequency for the hazardous scenario.
- Determine whether the frequency of the initiating event is either below or equal to the MEL or mitigated event likelihood. If so, go on to the situation. If not, move on to the following action.
- Enumerate the Independent Protection Layer (IPL) (current and emerging) that could alleviate the triggering cause. Consider the category and reliability of the *IPL*.[2] [3, 4]
- Adopt if the Initiating Event Likelihood (IEL) is smaller or equal to the Mitigated Event Likelihood (MEL). If it is, progress to the subsequent situation. If not, continue to the ensuing phase.[3] [5]
- Check if there's a safer design option that we can use. If there is, let's go with that. If there isn't, we'll move on to the next step.
- Identify any existing Safety Instrumented Systems (SIS)
- Ensure the following setup until all scenarios are examined.

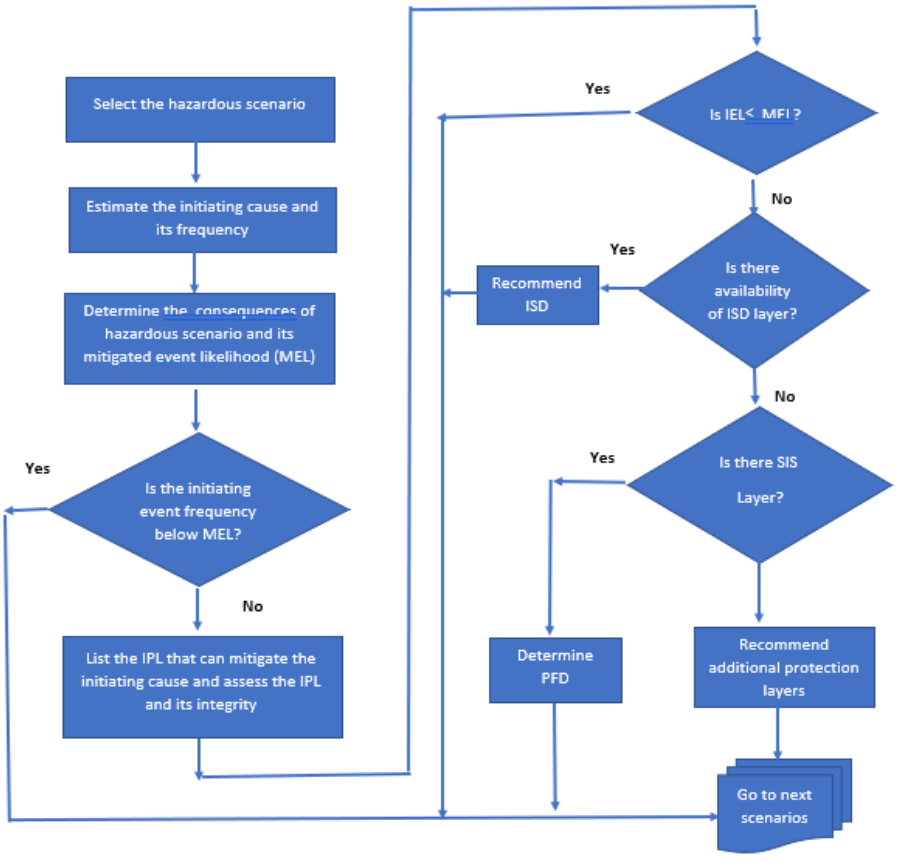

Fig 1: Overview of Layer of Protection Analysis

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3. Initiating causes and Likelihood of hazardous Scenario

Initiating causes of hazardous scenarios normally identified in HAZOPs generally fall into two categories [3] [5]

1. Equipment and Basic Process Control System failure

BPCS is referred to as Distributed Control Systems (DCS) or Instrumented Control Systems.

a. Equipment-related initiating events may stem from either basic process control system failures or mechanical malfunctions. For instance, a pump failure serves as an initiating cause for LOPA, encompassing mechanical and electrical issues such as impeller or pump failures, as well as electrical system failures.
b. Control system events can arise from module collapse (e.g., *transmitters*, *switches*, *valves*), *software* glitches, human activity, or support system malfunction such as air failure and electric malfunction.
c. Mechanical failures can result from various factors such as corrosion, fatigue, inadequate design, vibration, and hydraulic hammer. It's important to note that design errors are not suitable for consideration within LOPA. Moreover, Independent Protection Layers (IPLs) should be kept from rectifying process conditions stemming from design errors. However, instances like corrosion triggered by the failure of inhibitor injection systems or abnormal corrosive conditions due to other process control failures are valid LOPA-initiating events. Nonetheless, it's essential to distinguish that general corrosion falls under integrity management and maintenance rather than being considered a LOPA-initiating cause.

2. Human error events are categorized as mistakes of inadvertence or faults of the directive, comprising:

a. Fiasco to accurately accomplish phases of a task in suitable order or ignoring stages, e.g., wrong sequence of addition.
b. Breakdown to perceive or reply suitably to circumstances or other stimuli by system o (somewhat finished mistakenly).

4.1 Initiating cause likelihood

1. Initiating cause likelihood values shall be taken from the lookup tables provided as Table 1, Table 2, and Table 3 [6] [7] [8] [9] [10]
2. If the action is more frequent than once per month, Table 2 shows the suggested base human error rate that can be used for the estimation of human error frequency.
3. If the action is less frequent than once per month, then the frequency of human error likelihood can be estimated based on the human error rate and the number of operations per year using Tables 2 and 3 [3] [9] [11]

Table 1 – Equipment initiating causes and likelihood of failure

Initiating Cause	Likelihood of failures event/yr.
BPCS instrument loop failure	1×10^{-1}
Regulator failure	1×10^{-1}
Fixed equipment failure (e.g., exchanger tube failure)	1×10^{-2}
Pumps and other rotating equipment	1×10^{-1}
failure Cooling water failure (e.g., redundant cold water pumps, diverse drivers)	1×10^{-1}
Loss of power (e.g., redundant power supplies)	1×10^{-1}
Safety valve opens spuriously (PSV)	1×10^{-2}
Pump seal failure	1×10^{-1}
Valve failure	1×10^{-1}
Atmospheric Tank failure	1×10^{-4}
Unloading/loading hose failure	1×10^{-1}

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Table 2 – Human error frequency for actions taken at least once per month

Conditions	Likelihood of error
Operator well trained with stress	1/yr
Operator well trained with no stress	$1x10^{-1}$ /yr
Operator well trained with no stress, and with independent verification	$1x10^{-2}$ /yr

Table 3 – Base human error rate

Conditions	Probability of error
Operator well trained with stress	$1x10^{-1}$ /opportunity
Operator well trained with no stress	$1x10^{-2}$/opportunity
Operator well trained with no stress, and with independent verification	$1x10^{-3}$ /opportunity

4. Independent protection layers

In *Layers of Protection Analysis* (*LOPA*), safeguards are evaluated based on their compliance with IPL criteria, focusing solely on *Independent Protection Layers* (*IPLs*). An *Independent Protection Layer* (*IPL*) [3]is a mechanism, structure, or measure that might halt the progression of a scenario towards its undesirable outcome, regardless of the initiating event or the functioning of any other protective layer linked to the scenario. The effectiveness and autonomy of an IPL need to be verifiable through audits.

The efficacy of an IPL is measured by its *Probability of Failure on Demand* (*PFD*), representing the prospect that the structure, such as the *IPL*, will be unsuccessful in implementing a chosen occasion upon request. *PFD* is a unitless figure ranging from 0 to 1. A lower PFD [3] signifies a greater decrease in the incidence of concern, allied with a specific commencing result. The decrease in *frequency* brought about by an *IPL* is occasionally referred to as the "risk reduction factor.

These IPLs must adhere to the following criteria:

***Specificity*:** An IPL is engineered to halt a potential accident sequence before it reaches a defined undesirable endpoint (e.g., a runaway reaction, release of toxic materials, loss of containment, or fire). Since multiple initiating causes can lead to the same hazardous event, various event scenarios may trigger the activation of a single IPL [12]. Different IPLs may apply to distinct initiating causes.

***Independence*:** An IPL operates autonomously from all additional protective *layers* affiliated with the noted potentially unsafe happenings. Independence necessitates that the IPL remains unaffected by the fiasco of an alternative protective layer or the conditions causing such failure. Furthermore, IPLs must remain autonomous of the originating cause.

***Dependability*:** The fortification catalysed by an *IPL* must reliably reduce the delineated risks by a targeted quantity.

***Auditability*:** IPLs are designed to facilitate intermittent substantiation of their defensive function. Regular testing and maintenance are essential to ensure the IPL's effectiveness. A typical layer of protection diagram is shown in Fig .2

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Fig 2: Layers of Protection Analysis (LOPA)

a. There are two types of Independent Protection Layers (IPL):

1. Passive IPL

- Dike/bund.
- Open vent.
- Blast wall/bunker.
- Flame/detonation arrestors.
- Restriction orifice.

2. Active IPL

- Basic PCS.
- Human response to alarm.
- Pressure relief device.
- SIS.
- *Other design – specific IPLs (e.g., mechanical stop for a valve)* are also included.

b. The LOPA team should review safeguards from the HAZOP and identify those that meet the criteria for an IPL. Many safeguards identified in the HAZOP will not meet the criteria specified for IPLs in a LOPA analysis.

c. Assessment of IPLs shall be performed to determine the amount of risk reduction provided by each, its dependability, and its independence from other IPLs

Examples of precautions excluded *IPLs*

- *Training and certification*
- *Standards and Procedures*
- *Communications*
- *Signages*

5.1

Probability of Failure on Demand (PFD) for Independer

a. Mitigating risks for each IPL is based on its PFD. [2] [3] [10] [13]

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b. The PFD values given in Table 4, Table 5, Table 6, and Table 7 shall be used to estimate the PFD.

Table 4 – Probability of Failure on Demand for Passive Independent Protection Layer

Risk Reduction Measures	PFD
Dike/Bund	1×10^{-2}
Underground drainage system	1×10^{-2}
Open vent (no valve)	1×10^{-2}
Fireproofing	1×10^{-2}
Blast wall/bunke	1×10^{-3}
Flame arrestors	1×10^{-2}

Table 5 – Probability of Failure on Demand for Active Mechanical Independent Protection Layers

Risk Reduction Measures	PFD
Relief valve	1×10^{-2}
Vessel rupture disc	1×10^{-2}
Vacuum breaker	1×10^{-2}

Table 6 – Probability of Failure on Demand for Active Independent Protection Layers

Risk Reduction Measures	PFD
Basic process control system (BPCS) control loop	1×10^{-1}
SIL 1 SIS Typically consists of single sensor, single logic solver, and single final element.	1×10^{-2} to 1×10^{-1}
SIL 2 SIS Typically consists of multiple sensors (for fault tolerance),	1×10^{-3} to 1×10^{-2}
SIL 3 SIS Typically consists of multiple sensors, multiple channel logic solver, and multiple final elements	1×10^{-4} to 1×10^{-3}

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Table 7 – Example PFD for human actions

Risk Reduction Measures	PFD
Human action with 10 min response time	0.1 to 0.5
Human response with 20 min response time	0.1

5. Pharma Manufacturing Process

A typical unit operation involved in the Pharma manufacturing process is depicted in Fig. 3.

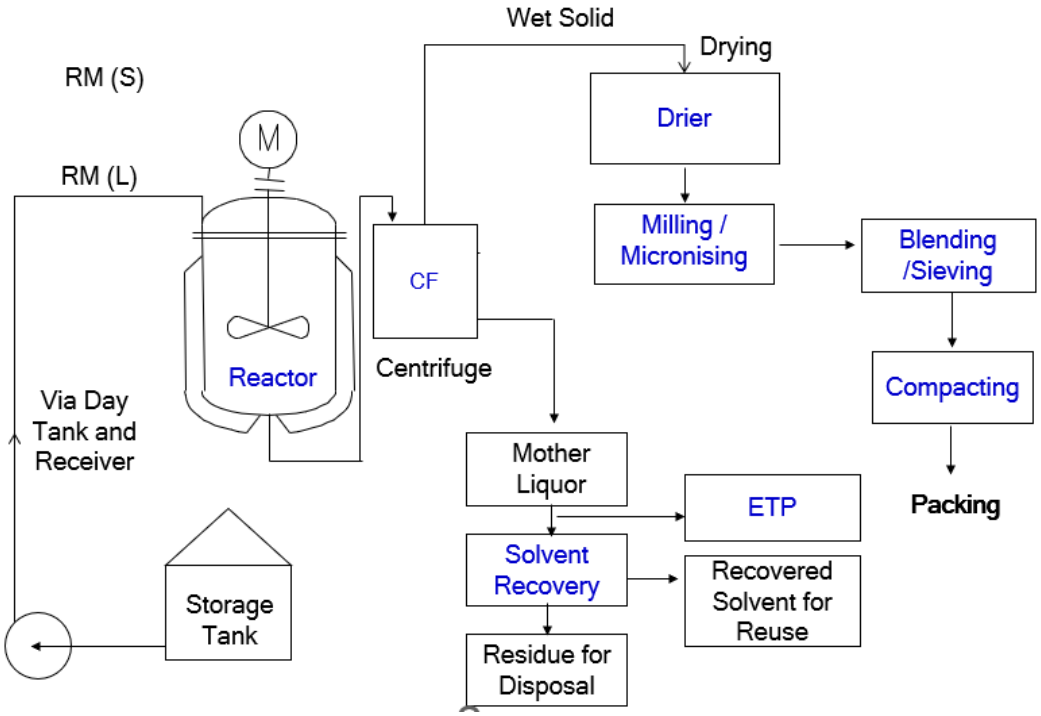

Fig.3: Unit Operations and Process in Pharma Manufacturing

Solvents and reactants are added to the reactor. The mass is heated with hot water at 70ºC. Acid addition and kept for 15 hrs. for cooling the mass to 40ºC. Vapours from the reactor will be refluxed, and the bottom layer will be separated and sent to the Centrifuge for further processing. The reactor is fitted with a vent line that is connected to the scrubber to scrub any fumes and gases. After centrifuge separation, the product layer is sent to the Agitated Gutsche filter and then to the vacuum tray dryer for drying. The dried product is sent for further powder processing and packing.

Let us analyze critical hazardous events from each stage derived from the HAZOP study and safeguards through LOPA for critical operations as given in Table 8. [14] [15] [16] [17]

Table 8 – Key Hazardous Events from HAZOP

Deviation	Cause	Consequence	Safeguard
No flow	valves stuck in the	A dry run of the pump can lead to pump	pressure transmitter/ switch on the

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	closed position on the suction side of the pump	damage and a potential fire scenario (Scenario-1)	pump discharge with the interlock to trip the pump
Less flow	Leakage from tank	Loss of Containment leads to fire and explosion (Scenario – 2)	Physical Containment Bunds
Sequence of addition not followed	Human error	Exothermic reaction leading to High-pressure and Runway reaction (Scenario – 3)	Pressure Transmitter with HH alarm
No flow of Nitrogen	Inlet valve failure	Formation of flammable mixture leads to Fire Hazard (Scenario -4)	APT (Absolute pressure transmitter) is available with the reactor and interlocked with day tank outlet valves
No flow to the scrubber	Blower failure	Condensers will be pressurized, and back pressure will be developed on the reactor (Scenario – 5)	pressure transmitter is available with HH, and LL on the reactor
High Temperature	Malfunctioning of Temperature Control Valve	Excessive vaporization of solvent leads to high pressure and fire hazard (Scenario – 6)	Availability of Safety Relief Valve and Rupture Disc
High reaction rate	Agitator Jamming	Possibility of runaway reaction due to improper mixing and heat transfer (Scenario – 7)	Alarm provision for agitator failure
More flow from the reactor to the Centrifuge	Human error due to manual feed	Imbalance of Centrifuge (Scenario – 8)	The vibration sensor interlocked with the motor
Static charge generation in Centrifuge	Discontinuity in Earthing and bonding	Potential ignition source leads to fire and explosion (Scenario-9)	A start-up checklist is available
No vacuum	Vacuum pump failure	High temperature leading to fire and explosion (scenario-10)	Temperature Transmitter interlocked with Hot water cut off and supply of cooling water.

6. Risk Matrix

A sample Severity and frequency matrix are given in Table 9 [18] and Table 10 [18]. Using the Severity and frequency, the risk ranking matrix is given in Table 11.[18]

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Table 9 – Severity Matrix

	S1 Negligible	S2 Minor	S3 Significant	S4 Major	S5 Catastrophic
1 Safety	First Aid	Restricted work case	Lost time injury	Permanent disability	Fatality
2 Environment	Localized short-term effect on non-sensitive habitat	Localized short-term effect on sensitive habitat	Large-scale effect on sensitive resources, species	Permanent changes in sensitive populations/habitats	Species or habitat extinction or endangerment
3 Finance	<$1)K	$10K-$100K	$100K-$1M	$1M-$10M	>$10M

Table 10 – Frequency Matrix

Class	Frequency of Occurrence
F1 – Improbable	Subjectively will not occur($<10^{-6}$)
F2 – Remote	Not expected or anticipated to occur (10^{-6} -10^{-4})
F3 - Rare	Occurrence considered rare (10^{-4} – 10^{-3})
F4 – Probable	Expected to occur once in 10 years (10^{-3} – 10^{-1})
F5 - Frequent	Likely to occur at least one time a year ($>10^{-1}$)

Table11 – Risk Matrix

Frequency						
	F5	5	10	15	20	25
	F4	4	8	12	16	20
	F3	3	6	9	12	15
	F2	2	4	6	8	10
	F1	1	2	3	4	5
		S1	S2	S3	S4	S5
Severity						

7. Results and Discussion

The key hazardous scenarios from Table 8 are considered, and Mitigated Event Frequency is calculated for each scenario using the values of Initiating Event Frequency and Probability of Failure on Demand. A sample calculation of Mitigated Event frequency by considering the existing safeguards is explained. The Mitigated Event Frequency is compared with the company's tolerable risk frequency for the

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listed hazardous scenario. If it is below the Tolerable risk frequency, the existing safeguards are adequate. If it is greater than the Tolerable risk frequency, the existing safeguards are not adequate, and additional layers of Protection are required. The process is repeated for all the scenarios mentioned in Table 8, and results are summarised in Table 12.

The establishment's bearable $risk\ frequency$ for listed hazardous scenarios is $no\ more\ often\ than\ 10-5/yr$

$$Fi\ MEF = IEFi \times PFDi1 \times PFDi2 \times \ldots \times PFDij \quad (1)$$

where:

Fi MEF = Mitigated Event Frequency for $scenario$ i.,

$IEFi = Frequency\ of\ the\ IE\ for\ scenario\ i.,Typical\ units\ are\ per\ year$

$PFDij = Probability\ of\ Failure\ on\ Demand\ of\ Independent\ Protection\ Layer\ j\ for\ scenario\ i.$

Scenario-1

Scenario 1 describes the condition of the solvent pump's dry run due to the valve failure scenario. This particular activity is routine and happens daily. This scenario has an existing safeguard of an interlock connected to pressure transmitted with pump discharge. The other safeguards are good process design, operator intervention, and other passive fire protection requirements.

Initiating event frequency for the valve failure scenario is 0.1 / year 95] [15, 19] [16] [17]

Layer* 1 *Process design

"Effective process design creates a strong and reliable system that can withstand unexpected changes in operating conditions. By using the principles of characteristically harmless design, we can diminish the possible significance of any setup. For this particular case, let's assume a $PFD\ of$ 1.0 $for\ this\ layer$."

Layer* 2: *Basic controls, process alarms, operator supervi

The reliability of basic process control systems and process alarms is ensured by a minimum PFD of 0.1 for operator response or control loop action.

Layer* 3: *Critical alarms, operator supervision, and manu
;

It is essential to take into consideration that the layer of Protection being discussed has a PFD of 0.1. Nonetheless, it is crucial to bear in mind that an IPL must be completely separate from the initiating event. Given that the dry run of pumps was initiated due to an operator failure, LOPA credit cannot be attributed to the same operator who responds to a process alarm [20]. Consequently, in this particular incident, the PFD for an operator response to an alarm would be 1.0.

Layer* 4: *Automatic action SIS or ESD

This statement suggests that there is a safety instrumented technique or a crisis shutdown appliance that does not mandate any operator intervention. The loop is conceived with a $Safety\ Integrity\ Level\ (SIL)$ of 1 and is allocated a PFD of 0.1.

***Layer* 5: *Physical Protection* (*relief devices*);**

This is repeatedly a crucial $protection\ layer$ system. This scenario does not require this layer of Protection. Hence, PFD is not considered.

***Layer* 6: *Physical Protection* (*dikes*)**

This level is frequently irrelevant to a dry run of the pump scenario.

Layer* 7: *Plant emergency response

The facility had well-trained crisis response crews, including a fire squadron and personnel specializing in tracking and retrieval. It's worth considering a PFD of 1.0.

Layer* 8: *Community emergency response

Refrain from depending on this particular layer to avert a potentially dangerous situation. Should this layer be deemed essential, it indicates that the incident has gone beyond the plant site and requires external assistance. It

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is crucial to hold emergency response drills that involve community representatives, such as the fire department, ambulance rescue team, and other emergency response personnel. A PFD of 1.0 must be utilized for this coating.

Calculate the mitigated frequency

fi C = IEFi × PFDi1 × PFDi2 × …× PFDij fi C

= $1X10^{-5}$/yr

The risk of fire and explosion would be once every 10,000 years, which is within the acceptable range of the $risk\ tolerance\ level\ of\ 10^{-5}/yr$.

The $LOPA$ table is summarised for the remaining scenarios in the table.12

Table 12 – LOPA Summary Sheet

Scenario	**IEF**	**Layer-1**	**Layer-2**	**Layer - 3**	**Layer-4**	**Layer-5**	**Layer - 6**	**Layer - 7**	**Layer - 8**	**MEF**
Scenario-1	0.1	0.1	0.1	0.1	0.1	NA	NA	1	1	$1X10^{-5}$
Scenario-2	1X10-4	1	0.1	0.1	0.1	NA	0.01	1	1	$1X10^{-9}$
Scenario-3	1	0.1	0.1	0.1	0.01	0.01	0.01	1	1	$1X10^{-9}$
Scenario-4	0.1	1	0.1	0.1	0.01	NA	NA	1	1	$1X10^{-5}$
Scenario-5	0.1	1	0.1	0.1	0.01	NA	NA	1	1	$1X10^{-5}$
Scenario-6	0.1	0.1	0.1	0.1	0.01	0.01	0.01	1	1	$1X10^{-10}$
Scenario-7	0.1	1	0.1	0.1	0	0.01	0.01	1	1	$1X01^{-7}$
Scenario-8	1	0.1	0	0.1	0.01	NA	NA	1	1	**$1X10^{-4}$**
Scenario-9	0.1	0.1	0	0	0	NA	NA	1	1	$1X10^{-2}$
Scenario-10	0.1	0.1	0.1	0.1	0.01	NA	NA	1	1	**$1X10^{-6}$**

Table 12 shows that Scenario 8 and Scenario 9 are outside the acceptable range.

Scenario 8 will be mitigated using an additional layer of controls, such as an emergency shutdown and Alarm layer. Scenario 9 will be mitigated using an additional layer of controls, such as a static charge interlock system with an alarm system. Let us calculate the re-mitigated event frequency. The re-mitigated event frequency will be $1X10^{-6}$/yr for both scenarios, which is well within the acceptable range.

8. Conclusion

The analysis of various hazardous scenarios in a pharmaceutical plant indicates robust control and mitigation measures across all scenarios. However, the risk associated with fire and explosion due to static charge in the Centrifuge was re-evaluated, leading to the implementation of an additional layer of Protection through an interlock and alarm system.

The LOPA method provides safety engineers with a comprehensive understanding of process risks and the effectiveness of existing independent protection layers. It also identifies areas requiring additional risk reduction measures to achieve acceptable risk levels. The LOPA process facilitates comparative risk assessments across diverse plants and processes. Its implementation underscores the significance of initiating event frequency and prioritizes basic process strategies that incorporate inherent safety principles.

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This approach further emphasizes the importance of ensuring the safety of all involved parties.

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