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An Implimentation of Safety Management Practices and Hazard & Operability Study in Multinational Api Bulk Drugs Company

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***Abstract*–Hazard and Operability Analysis is a structured and systematic technique for system examination and risk management. In particular, HAZOP is often used as a technique for identifying potential hazards in a system and identifying operability problems likely to lead to nonconforming products. HAZOP is based on a theory that assumes risk events are caused by deviations from design or operating intentions. Identification of such deviations is facilitated by using sets of "guide words" as a systematic list of deviation perspectives. This approach is a unique feature of the HAZOP methodology that helps stimulate the imagination of team members when exploring potential deviations.**

***Keywords*- HOZOP, deviations, SAFTY, HIRA. etc**

I.INTRODUCTION

The HAZOP concept is to review the plant in a series of meetings, during which a multidisciplinary team methodically "brainstorms" the plant design, following the structure provided by the guide words and the team leader's experience. The primary advantage of this brainstorming is that it stimulates creativity and generates ideas. This creativity results from the interaction of the team and their diverse backgrounds. Consequently the process requires that all team members participate (quantity breeds quality in this case), and team members must refrain from criticizing each other to the point that members hesitate to suggest ideas. The team focuses on specific points of the design (called "study nodes"), one at a time.

At each of these study nodes, deviations in the process parameters are examined using the guide words. The guide words are used to ensure that the design is explored in every conceivable way. Thus the team must identify a fairly large number of deviations, each of which must then be considered so that their potential causes and consequences can be identified. The best time to conduct a HAZOP is when the design is fairly firm. At this point, the design is well enough defined to allow meaningful answers to the questions raised in the HAZOP process. Also, at this point it is still possible to change the design without a major cost. However, HAZOPs can be done at any stage after the design is nearly firm. For example, many older plants are upgrading their control and instrumentation systems.

The success or failure of the HAZOP depends on several factors:

- The completeness and accuracy of drawings and other data used as a basis for the study
- The technical skills and insights of the team
- The ability of the team to use the approach as an aid to their imagination in visualizing deviations, causes, and consequences
- The ability of the team to concentrate on the more serious hazards which are identified. The process is systematic and it is helpful to define the terms that are used.

1. Study Nodes - The Locations (On Piping And Instrumentation Drawings And Procedures) At Which The Process Parameters Are Investigated For Deviations.
2. Intention - The Intention Defines How The Plant Is Expected To Operate In The Absence Of Deviations At The Study Nodes. This Can Take A Number Of Forms And Can Either Be Descriptive Or Diagrammatic; E.G., Flow Sheets, Line Diagrams, P&Ids.
3. Deviations - These Are Departures From The Intention Which Are Discovered By Systematically Applying The Guide Words (E.G., "More Pressure").
4. Causes - These are the reasons why deviations might occur. Once a deviation has been shown to have a credible cause, it can be treated as a meaningful deviation. These causes can be hardware failures, human errors, an unanticipated process state (e.g., change of composition), external disruptions (e.g., loss of power), etc.
5. Consequences - These are the results of the deviations should they occur (e.g., release of toxic materials).

Trivial consequences, relative to the study objective, are Dropped.

6. Guide Words - These are simple words which are used to qualify or quantify the intention in order to guide and stimulate the brainstorming process and so discover deviations. The guide words shown in the following table are the ones most often used in a HAZOP; some organizations have made this list specific to their operations, to guide the team more quickly to the areas where they have previously found problems. Each guide word is applied to the process variables at the point in the plant (study node) which is being examined.

II.GUIDELINES FOR USING PROCEDURE

The concepts presented above are put into practice in the following steps: 1. Define the purpose, objectives, and scope of the study 2. Select the team 3.- Prepare for the study 4. Carry out the team review 5. Record the results. 6. Follow up to ensure results are implemented. It is important to recognize that some of these steps can take place at the same time. For example, the team reviews the design, records the findings, and follows up on the findings continuously. (Refer also to the diagrammatic representation of the HAZOP procedure attached).

III.WORKING GROUPS

The analysis and assessment of different issues should be carried out by one or more working groups under the guidance of the Implementation Committee. For example, separate working groups may be established to undertake analysis of continuous emissions, the risk of accidents, legislative provisions, etc. The whole study, considered as a system, can often be divided into sub-studies mat can be carried out by different working groups in their own specific operations. Possible subdivisions of the study are reflected in the various sections of this manual, but other forms of subdivision of the total study are also possible.

When subdividing the work of the main study into sub-studies with a view to allocate specific tasks to the different working groups, data collection should be organized as efficiently as possible in order to avoid the same information sources being collected by more than one working group.

The working groups should consist of technical experts in the particular fields required by the specific study. There is a wide range of expertise required for the specific sub-studies, e.g. environmental sciences, biology, ecology, chemistry, chemical engineering, mechanical engineering, civil engineering, toxicology, epidemiology, safety science and risk analysis, meteorology, physical planning, economy, legislation, administration, political sciences, etc. Each working group should consist of three to six people. If more experts are needed, they can be consulted by the working group on an ad hoc basis. The working group itself should remain small, to be able to work informally and efficiently. Larger topics of work, requiring more manpower and expertise should be further subdivided by the Implementation Committee, so that they can be carried out by working groups of the size of three to six people.

IV.METHADOLOGY & OBSERVATIONTABLES

1. Hazard and Operability Study

When to Conduct HAZOP?

1.1 HAZOP study shall be conducted for the following

- For processes transferred from LRP to Vadodara as exhibit batches.
- For processes transferred from R&D kilo lab to manufacturing unit at site.
- For processes transferred from PD lab/ R&D to R&D kilo lab at site.
- For processes transferred to Vadodara site from other Alembic site./ In case of site transfer product

2. HAZOP shall be revised if

- There are major changes in equipment's or process.
- Transferred process from one plant to another.

3. For minor changes in process addendum shall be taken. (If required)

In addendum only changes in the particular node shall be discussed & recorded.

3. Detailed HAZOP

Hazard Operability Study (HAZOP) examines fully the process and systematically questions every part of the process in order to discover how deviations from the intention of the design can occur and decides whether these deviations can give rise to hazardous conditions. For this purposes, a series of guide words are used to ensure that the questions which are posed to test the integrity of each part of the design intention.

This usually produces a number of theoretical deviations and each deviation is then considered to decide how it could be caused and what would be the consequence.Some of the causes may be unrealistic and are rejected. Some of the consequences may be trivial and are not to be considered any further. However, there are some deviations that are conceivable and consequences are potentially serious. These are only noted for remedial action.

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Table 1 Guide words for HAZOP study

GUIDE WORD	MEANING	EXAMPLES
None of	Negation of Intention	No forward flow when there should be. Sequential process step omitted.
More of	Quantitative Increase	More of any relevant physical parameter than there should be, such as more flow (rate, quantity), more pressure, higher temperature, or higher viscosity. Batch step allowed to proceed for too long.
Less of	Quantitative Decrease	Opposite of "MORE OF"
Part of	Qualitative Decrease	System composition different from what it should be (in multi-component stream).
As well as	Qualitative Increase	More things present than should be (extra phases, impurities). Transfer from more than one source or to more than one destination.
Reverse	Logical Opposite	Reverse flow. Sequential process steps performed in reverse order.
Other than	Complete Substitution	What may happen other than normal continuous operation (start-up, normal shutdown, emergency shutdown, maintenance, testing, sampling). Transfer from wrong source or to wrong destination.

V.RESULT AND SIMULATION

Table 2 Target and Heat Flux Effect.

Target	Heat flux (kw/m^2)	Effect
Human body	4.7	Threshold of pain experienced for 14.5 sec
Building	12.6	Resins in bldgs., wood produce Flammable vapours will ignite.
Storage Tank	37.8	Hazardous for a tank adjacent to a tank fire to receive this flux.

Table 3 Damage caused at different radiative levels of thermal radiation.

Radiative flux (kw/m^2)	Types of damage: Damage to equipment	Damage to people
37.5	Damage to process equipment	- 100% lethality in 1min. - 1% lethality in 10 sec.
25.0	Minimum energy to ignite wood at exposure without a flame	100% lethality in 1 min. And Significant injury in 10 sec.
12.5	Minimum energy to ignite wood with a flame, plastic tubing	1% lethality in 1 min. 1st degree burning in 10 sec.
4.0		Cause pain if duration is more than 20 sec
1.6		Cause not discomfort for long period.

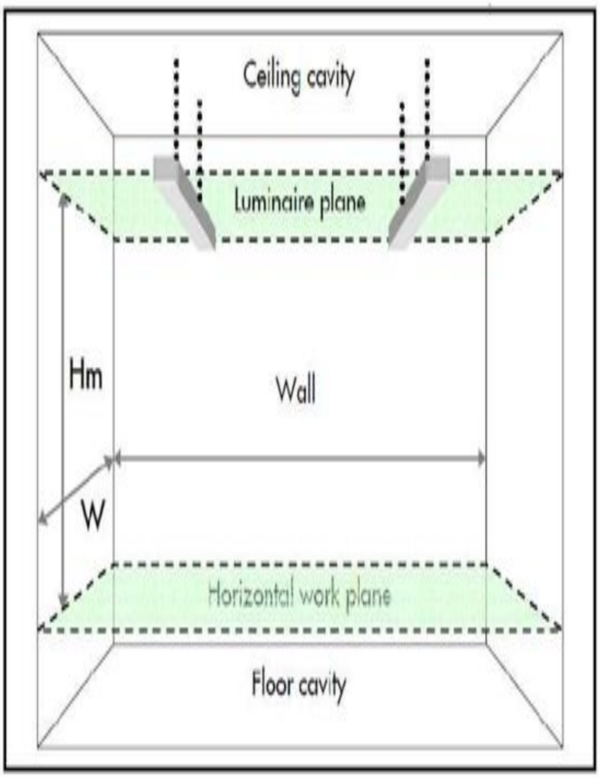

Fig. 1 Room index.

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1.Observations

Table 4 Damage caused at different Radiative levels of thermal radiation.

For 125 watt HPMV	For 80 watt HPMV
SHR = $1/H_m$ x √A/N = 1/2.20 x √ 260/10 = 0.45(5.009) = 2.29	SHR = $1/H_m$ x √A/N = 1/2.20 x √ 260/18 = 0.45(3.8) = 1.7
SHR MAX = SHR X H_m = 2.29 x 2.71 = 6.2 m	SHR MAX = SHR X H_m = 1.7 x 2.71 =4.09m ~4m

Table 5 Damage caused at different Radiative levels of thermal radiation.

Radiative flux	Types of damage	
(kw/m^2)	Damage to equipment	Damage to people
37.5	Damage to process equipment	- 100% lethality in 1min. - 1% lethality in 10 sec.
25.0	Minimum energy to ignite wood at exposure without a flame	100% lethality in 1 min. And Significant injury in 10 sec.
12.5	Minimum energy to ignite wood with a flame, plastic tubing	1% lethality in 1 min. 1st degree burning in 10 sec.
4.0		Cause pain if duration is more than 20 sec
1.6		Cause not discomfort for long period.

VI.CONCLUSION

In HAZOP study of ABC final product processing, all the precautionary measures are taken and acceptable risk level can be predicted. However the Ratio controller installation is recommended. In HIRA studies, given recommendations are accepted by respective departments and risk is brought up to the ALARP level. The same condition in JSA, that acceptable risk level is obtained. In ramp gradient assessment study, some of the gradients of plant found doubt regarding the angle, which are shown in the observation table. They are to be corrected. Emergency light requirement at the specific points in plant according to need and legal requirement is assessed, which is to be ensured. Evaluation of Air borne Organic vapour and Gas study shown that exposure is within limit. Regular measurement and maintenance of machineries is to be done. In Noise Monitoring, the exposure is within limit in the separate cabin for operators. Light indicator and buzzer installation is suggested. In illumination assessment study, the lighting level is not up to the mark. Which can be easily overcome by following given suggestions in above section.In Consequence analysis of above ground toluene tank, conclusion is as followed: As stated earlier 20 ton toluene storage tank can get involved in three major emergencies:

- Causing a leak and cloud drifts to a distance and explodes.
- Explosion & Damage to the people and property due to it.
- BLEVE situation.

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