

Hazard & Operability Analysis (HAZOP)

1 Overview

Hazard and Operability Analysis (HAZOP) 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.

Definition: *SYSTEM is the subject of a risk assessment and generally includes a process, product, activity, facility or logical system.*

As a risk assessment tool, HAZOP is often described as:

- A brainstorming technique
- A qualitative risk assessment tool
- An inductive risk assessment tool, meaning that it is a “bottom-up” risk identification approach, where success relies on the ability of subject matter experts (SMEs) to predict deviations based on past experiences and general subject matter expertise

The ICHQ9 Guideline, *Quality Risk Management* endorses the use of HAZOP (amongst other allowable tools) for pharmaceutical quality risk management. In addition to its utility in Quality Risk Management, HAZOP is also commonly used in risk assessments for industrial and environmental health and safety applications. Additional details on the HAZOP methodology may be found within IEC International Standard 61882, *Hazard and Operability Studies (HAZOP) Application Guide*.

This document presents some guiding principles in the execution of HAZOP analyses. Successful application of any risk management model requires that tools are used in concert with the overall quality risk management process. This guide will present the principles of HAZOP in the context of the accepted Quality Risk Management process consisting of Risk Assessment, Risk Control, Risk Review and Communication and is intended to compliment (not replace or repeat) the guidance available within IEC International Standard 61882.

1.1 Definitions

When describing the HAZOP methodology, the following definitions¹ are useful:

Hazard - Potential source of harm. Deviations from design or operational intent may constitute or produce a hazard. Hazards are the focus of HAZOP studies, and it should be noted that a single hazard could potentially lead to multiple forms of harm.

Training Guide: Hazard & Operability Analysis (HAZOP)

Harm - Physical injury or damage to the health of people or damage to property or the environment. Harm is the consequence of a hazard occurring and may take many forms: patient or user safety, employee safety, business risks, regulatory risks, environmental risks, etc.

Risk - Combination of probability of occurrence of harm and the severity of that harm. In a strict sense, “risk” is not always explicitly identified in HAZOP studies since the core methodology does not require identification (also referred to as rating) of the probability or severity of harm. However, risk assessment teams may choose to rate these factors in order to further quantify and prioritize risks if needed.

1.2 Usage

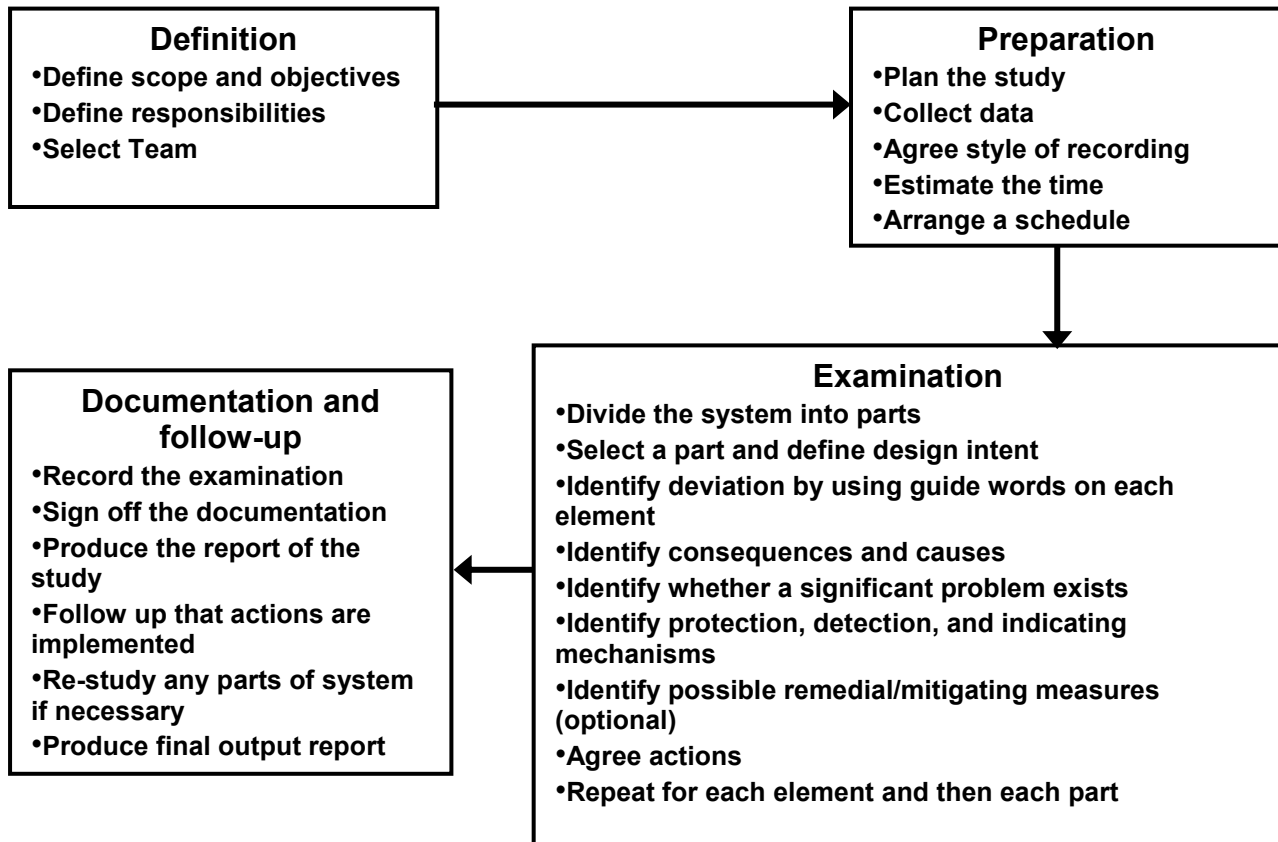
HAZOP is best suited for assessing hazards in facilities, equipment, and processes and is capable of assessing systems from multiple perspectives:

- Design
 - Assessing system design capability to meet user specifications and safety standards
 - Identifying weaknesses in systems
- Physical and operational environments
 - Assessing environment to ensure system is appropriately situated, supported, serviced, contained, etc.
- Operational and procedural controls
 - Assessing engineered controls (ex: automation), sequences of operations, procedural controls (ex: human interactions) etc.
 - Assessing different operational modes – start-up, standby, normal operation, steady & unsteady states, normal shutdown, emergency shutdown, etc.

<i>Advantages</i>	<i>Disadvantages</i>
<ul style="list-style-type: none"> + Helpful when confronting hazards that are difficult to quantify <ul style="list-style-type: none"> ▪ Hazards rooted in human performance and behaviors ▪ Hazards that are difficult to detect, analyze, isolate, count, predict, etc. ▪ Methodology doesn't force you to explicitly rate or measure deviation probability of occurrence, severity of impact, or ability to detect + Built-in brainstorming methodology + Systematic & comprehensive methodology + More simple and intuitive than other commonly used risk management tools 	<ul style="list-style-type: none"> - No means to assess hazards involving interactions between different parts of a system or process - No risk ranking or prioritization capability <ul style="list-style-type: none"> ▪ Teams may optionally build-in such capability as required - No means to assess effectiveness of existing or proposed controls (safeguards) <ul style="list-style-type: none"> ▪ May need to interface HAZOP with other risk management tools (ex: HACCP) for this purpose

2 HAZOP Methodology¹

The HAZOP analysis process is executed in four phases as illustrated below:



2.1 Definition Phase

The Definition Phase typically begins with preliminary identification of risk assessment team members. HAZOP is intended to be a cross-functional team effort, and relies on specialists (SMEs) from various disciplines with appropriate skills and experience who display intuition and good judgment.¹ SMEs should be carefully chosen to include those with a broad and current knowledge of system deviations. HAZOP should always be carried out in a climate of positive thinking and frank discussion.¹

During the Definition Phase, the risk assessment team must identify the assessment scope carefully in order to focus effort. This includes defining study boundaries and key interfaces as well as key assumptions that the assessment will be performed under.

2.2 Preparation Phase

The Preparation Phase typically includes the following activities:

- Identifying and locating supporting data and information

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- Identification of the audience and users of the study outputs
- Project management preparations (ex: scheduling meetings, transcribing proceedings, etc.)
- Consensus on template format for recording study outputs
- Consensus on HAZOP guide words to be used during the study

HAZOP guide words are key supporting elements in the execution of a HAZOP analysis. According to IEC Standard 61882:

The identification of deviations from the design intent is achieved by a questioning process using predetermined “guide words”. The role of the guide word is to stimulate imaginative thinking, to focus the study and elicit ideas and discussion.

Risk assessment teams are responsible for identifying the guide words that will best suit the scope and problem statement for their analysis. Some common HAZOP guide words include:

- | | |
|------------------------------|---------------------------------------------|
| ▪ No or not | ▪ Other than |
| ▪ More | ▪ Early |
| ▪ Less | ▪ Late |
| ▪ As well as | ▪ Before |
| ▪ Part of | ▪ After |
| ▪ Reverse (of intent) | ▪ Others can be crafted as needed... |

Tip: *The HAZOP guide word concept can be used to stimulate brainstorming of potential risks within other risk assessment tools as well*

Training Guide: Hazard & Operability Analysis (HAZOP)

HAZOP guide words work by providing a systematic and consistent means of brainstorming potential deviations to operations. The following example shows how different HAZOP guide words might be used to brainstorm deviations around detergent control for a cleaning operation:

▪ No or not - no detergent added	▪ Part of - critical detergent component omitted (ex: surfactant)
▪ More - too much detergent volume added (difficult to rinse)	▪ Reverse - detergent is contaminated with a harmful hazard
▪ More – supplied detergent solution concentration is too high	▪ Other than - wrong detergent used
▪ Less - too little detergent volume added (soil isn't effectively removed)	▪ Early - detergent added too early (ex: if you need to pre-rinse bulk soil to drain before washing with detergent)
▪ Less – supplied detergent solution concentration is too low	▪ Late - detergent added too late in the cleaning cycle

Once the HAZOP guide words are selected, the Examination Phase may begin.

2.3 Examination Phase

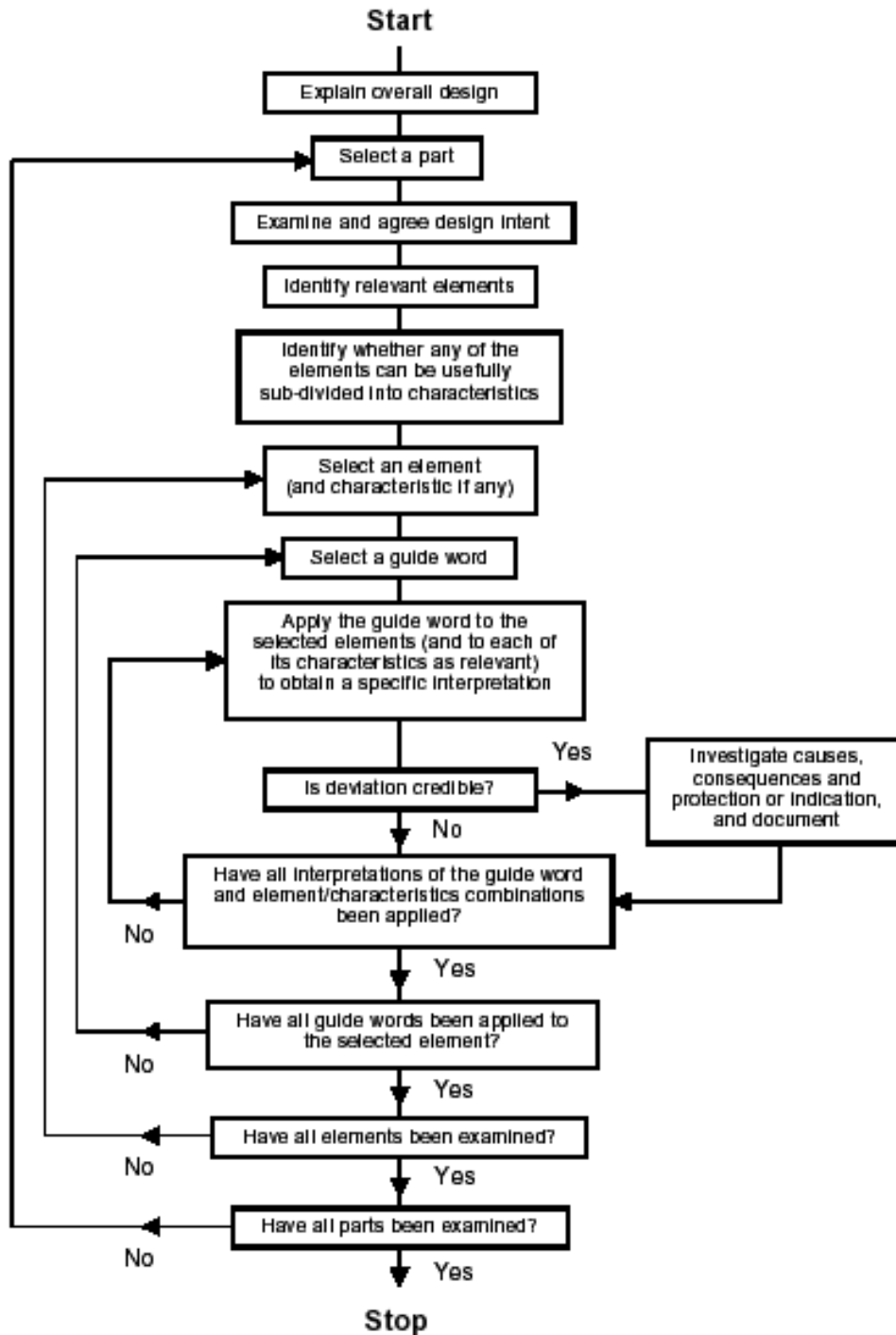
The Examination Phase begins with identification of all elements (parts or steps) of the system or process to be examined. For example:

- Physical systems may be broken down into smaller parts as necessary
- Processes may be broken down into discrete steps or phases
- Similar parts or steps may be grouped together to facilitate assessment

The HAZOP guide words are then applied to each of the elements. In this fashion a thorough search for deviations is carried out in a systematic manner. It must be noted that not all combinations of guide words and elements are expected to yield sensible or credible deviation possibilities. As a general rule, all reasonable use and misuse conditions which are expected by the user should be identified and subsequently challenged to determine if they are “credible” and whether they should be assessed any further.¹ There is no need to explicitly document the instances when combinations of elements and guide words do not yield any credible deviations.

Training Guide: Hazard & Operability Analysis (HAZOP)

The following figure graphically illustrates the HAZOP Examination Phase process flow.¹



2.4 Documentation & Follow-up Phase

The documentation of HAZOP analyses is often facilitated by utilizing a template recording form as detailed in IEC Standard 61882. Risk assessment teams may modify the template as necessary based on factors such as:

- Regulatory requirements
- Need for more explicit risk rating or prioritization (ex: rating deviation probabilities, severities, and/or detection)
- Company documentation policies
- Needs for traceability or audit readiness
- Other factors

A typical HAZOP recording template is shown on the following page, including example entries that correspond to the cleaning process analysis example from section 2.2.

Hazard & Operability Analysis (HAZOP)

No.	Guide Word	Element	Deviation	Possible Causes	Consequences	Safeguards	Comments	Actions Required	Actions Assigned to
Assign each entry a unique tracking number	Insert deviation guide word used	Describe what the guide word pertains to (material, process step, etc.)	Describe the deviation	Describe how the deviation may occur	Describe what may happen if the deviation occurs	List controls (preventive or reactive) that reduce deviation likelihood or severity	Capture key relevant rationale, assumptions, data, etc.	Identify any hazard mitigation or control actions required	Record who is responsible for actions
Examples from Cleaning Agent Deviations that were used to explain HAZOP Guide Words									
1	No	Cleaning Agent	No detergent added during cleaning cycle	Detergent supply reservoir empty	Residues not effectively removed, leaving system in an unclean state	Technicians check detergent reservoir before every cycle	Assumes technicians can reliably estimate volume visually	Consider alarm for low detergent reservoir level	Engineer
2	Other than	Cleaning Agent	Wrong detergent used	Technician retrieves wrong detergent from warehouse	Incorrect detergent may be ineffective at removing residues, leaving system in an unclean state	Cleaning log requires verification of proper detergent use. Detergent is labeled.	Many different detergent containers look alike	Ensure technician training addresses detergent selection	Trainer

Hazard & Operability Analysis (HAZOP)

Once the HAZOP analysis is complete, the study outputs and conclusions should be documented commensurate with the nature of risks assessed in the study and per individual company documentation policies. As part of closure for the HAZOP analysis, it should be verified that a process exists to ensure that assigned actions are closed in a satisfactory manner.

3 Risk Review

On a long-term basis, operational feedback should confirm that the assessment and control steps are adequately addressing the risk question. If this is not the case, it may be necessary to review all assumptions. Feedback should correspond to ensuring that assumptions made about the level of residual risks are still valid. Residual risks are risks that are expected to remain after risk control strategies have been exercised. It is also important to note that new risks may arise from risk control practices. Sometimes risks that were not originally identified or may have been filtered out during the initial risk assessment can become aggravating factors due to the implementation of risk control measures.

4 Risk Communication

HAZOP is a powerful communication tool. The output of the tool should always be presented at a level of detail appropriate for the various stakeholders. This is important not just for presenting results, but also for obtaining early buy-in on the approach.

In cases where HAZOP is used as the basis for a “GxP” decision or some other regulated authorization, the approach should be documented in a Standard Operating Procedure. It may not be necessary to include detailed scoring steps or algorithms in the procedure, but they should be documented in a controlled report. Updates to the portfolio should also be controlled.

¹ per IEC Standard 61882