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INTERNATIONAL STANDARD

NORME INTERNATIONALE

Hazard and operability studies (HAZOP studies) – Application guide

Études de danger et d'exploitabilité (études HAZOP) – Guide d'application



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IEC Central Office
 3, rue de Varembe
 CH-1211 Geneva 20
 Switzerland

Tel.: +41 22 919 02 11
 Fax: +41 22 919 03 00
info@iec.ch
www.iec.ch

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Hazard and operability studies (HAZOP studies) – Application guide

Études de danger et d'exploitabilité (études HAZOP) – Guide d'application

INTERNATIONAL
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INTERNATIONAL ELECTROTECHNICAL COMMISSION

HAZARD AND OPERABILITY STUDIES (HAZOP STUDIES) – APPLICATION GUIDE

FOREWORD

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International Standard IEC 61882 has been prepared by IEC technical committee 56: Dependability.

This second edition cancels and replaces the first edition published in 2001. This edition constitutes a technical revision.

This edition includes the following significant technical changes with respect to the previous edition:

- a) clarification of terminology as well as alignment with terms and definitions within ISO 31000:2009 and ISO Guide 73:2009;
- b) addition of an improved case study of a procedural HAZOP.

The text of this standard is based on the following documents:

| FDIS | Report on voting |
|--------------|------------------|
| 56/1653/FDIS | 56/1666/RVD |

Full information on the voting for the approval of this standard can be found in the report on voting indicated in the above table.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

The committee has decided that the contents of this publication will remain unchanged until the stability date indicated on the IEC website under "<http://webstore.iec.ch>" in the data related to the specific publication. At this date, the publication will be

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

INTRODUCTION

This standard describes the principles for and approach to guide word-driven risk identification. Historically this approach to risk identification has been called a hazard and operability study or HAZOP study for short. This is a structured and systematic technique for examining a defined system, with the objectives of:

- identifying risks associated with the operation and maintenance of the system. The hazards or other risk sources involved can include both those essentially relevant only to the immediate area of the system and those with a much wider sphere of influence, for example some environmental hazards;
- identifying potential operability problems with the system and in particular identifying causes of operational disturbances and production deviations likely to lead to non-conforming products.

An important benefit of HAZOP studies is that the resulting knowledge, obtained by identifying risks and operability problems in a structured and systematic manner, is of great assistance in determining appropriate remedial measures.

A characteristic feature of a HAZOP study is the examination session during which a multi-disciplinary team under the guidance of a study leader systematically examines all relevant parts of a design or system. It identifies deviations from the system design intent utilizing a set of guide words. The technique aims to stimulate the imagination of participants in a systematic way to identify risks and operability problems. A HAZOP study should be seen as an enhancement to sound design using experience-based approaches such as codes of practice rather than a substitute for such approaches.

Historically, HAZOP and similar studies were described as hazard identification as their primary purpose is to test in a systematic way whether hazards are present and, if so, understand both how they could result in adverse consequences and how such consequences could be avoided through process redesign. ISO 31000:2009 defines risk as the effect of uncertainty on objectives, with a note that an effect is a deviation from the expected. Therefore HAZOP studies, which consider deviations from the expected, their causes and their effect on objectives in the context of process design, are now correctly characterized as powerful risk identification tools.

There are many different tools and techniques available for the identification of risks, ranging from checklists, failure modes and effects analysis (FMEA) to HAZOP. Some techniques, such as checklists and what-if/analysis, can be used early in the system life cycle when little information is available, or in later phases if a less detailed analysis is needed. HAZOP studies require more detail regarding the systems under consideration, but produce more comprehensive information on risks and weaknesses in the system design.

The term HAZOP is sometimes associated, in a generic sense, with some other hazard identification techniques (e.g. checklist HAZOP, HAZOP 1 or 2, knowledge-based HAZOP). The use of the term with such techniques is considered to be inappropriate and is specifically excluded from this document.

Before commencing a HAZOP study, it should be confirmed that it is the most appropriate technique (either individually or in combination with other techniques) for the task in hand. In making this judgment, consideration should be given to the purpose of the study, the possible severity of any consequences, the appropriate level of detail, the availability of relevant data and resources and the needs of decision-makers.

This standard has been developed to provide guidance across many industries and types of system. There are more specific standards and guides within some industries, notably the process industries where the technique originated, which establish preferred methods of application for these industries. For details see the bibliography at the end of this standard.

HAZARD AND OPERABILITY STUDIES (HAZOP STUDIES) – APPLICATION GUIDE

1 Scope

This International Standard provides a guide for HAZOP studies of systems using guide words. It gives guidance on application of the technique and on the HAZOP study procedure, including definition, preparation, examination sessions and resulting documentation and follow-up.

Documentation examples, as well as a broad set of examples encompassing various applications, illustrating HAZOP studies are also provided.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

IEC 60050-192, *International electrotechnical vocabulary – Part 192: Dependability* (available at <http://www.electropedia.org>)

3 Terms, definitions and abbreviations

3.1 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60050-192 and the following apply.

NOTE Within this clause, the terms defined are in *italic* type.

3.1.1

characteristic

qualitative or quantitative property

EXAMPLE Pressure, temperature, voltage.

3.1.2

consequence

outcome of an event affecting objectives

Note 1 to entry: An event can lead to a range of consequences.

Note 2 to entry: A consequence can be certain or uncertain and can have positive or negative effects on objectives.

Note 3 to entry: Consequences can be expressed qualitatively or quantitatively.

Note 4 to entry: Initial consequences can escalate through knock-on effects.

[SOURCE: ISO Guide 73:2009, 3.6.1.3]

**3.1.3
control**

measure that is modifying *risk* (3.1.12)

Note 1 to entry: Controls include any process, policy, device, practice, or other actions which modify risk.

Note 2 to entry: Controls may not always exert the intended or assumed modifying effect.

[SOURCE: ISO Guide 73:2009, 3.8.1.1]

**3.1.4
design intent**

designer's desired, or specified range of behaviour for properties which ensure that the item fulfills its requirements

**3.1.5
property**

constituent of a part which serves to identify the part's essential features

Note 1 to entry: The choice of properties can depend upon the particular application, but properties can include features such as the material involved, the activity being carried out, the equipment employed, etc. Material should be considered in a general sense and includes data, software, etc.

**3.1.6
guide word**

word or phrase which expresses and defines a specific type of deviation from a property's design intent

**3.1.7
harm**

physical injury or damage to the health of people or damage to assets or the environment

**3.1.8
hazard**

source of potential *harm* (3.1.7)

Note 1 to entry: Hazard can be a *risk source* (3.1.14).

[SOURCE: ISO Guide 73:2009, 3.5.1.4]

**3.1.9
level of risk**

magnitude of a *risk* (3.1.12) or combination of risks, expressed in terms of the combination of *consequences* (3.1.2) and their likelihood

[SOURCE: ISO Guide 73:2009, 3.6.1.8]

**3.1.10
manager**

person with responsibility for a project, activity or organization.

**3.1.11
part**

section of the system which is the subject of immediate study

Note 1 to entry: A part can be physical (e.g. hardware) or logical (e.g. step in an operational sequence).

**3.1.12
risk**

effect of uncertainty on objectives

Note 1 to entry: An effect is a deviation from the expected – positive and/or negative.

Note 2 to entry: Objectives can have different aspects (such as financial, health and safety, and environmental goals) and can apply at different levels (such as strategic, organization-wide, project, product and process).

Note 3 to entry: Risk is often characterized by reference to potential events and *consequences* (3.1.2) or a combination of these.

Note 4 to entry: Risk is often expressed in terms of a combination of the consequences of an event (including changes in circumstances) and the associated likelihood of occurrence.

Note 5 to entry: Uncertainty is the state, even partial, or deficiency of information related to, understanding or knowledge of an event, its *consequence*, or likelihood.

[SOURCE: ISO Guide 73:2009, 1.1]

3.1.13 risk identification

process of finding, recognizing and describing *risks* (3.1.12)

Note 1 to entry: Risk identification involves the identification of *risk sources* (3.1.14), events, their causes and their potential *consequences* (3.1.2).

Note 2 to entry: Risk identification can involve historical data, theoretical analysis, informed and expert opinions, and stakeholder's needs.

[SOURCE: ISO Guide 73:2009, 3.5.1]

3.1.14 risk source

element which alone or in combination has the intrinsic potential to give rise to *risk* (3.1.12)

Note 1 to entry: A risk source can be tangible or intangible.

[SOURCE: ISO Guide 73:2009, 3.5.1.2]

3.1.15 risk treatment

process to modify *risk* (3.1.12)

Note 1 to entry: Risk treatment can involve:

- avoiding the risk by deciding not to start or continue with the activity that gives rise to the risk;
- taking or increasing risk in order to pursue an opportunity;
- removing the *risk source* (3.1.14);
- changing the likelihood;
- changing the *consequences* (3.1.2);
- sharing the risk with another party or parties (including contracts and risk financing); and
- retaining the risk by informed decision.

Note 2 to entry: Risk treatments that deal with negative consequences are sometimes referred to as “risk mitigation”, “risk elimination”, “risk prevention” and “risk reduction”.

Note 3 to entry: Clarification of risk treatment and risk *control* (3.1.3) – a risk control is already in place whereas a risk treatment is an activity to improve risk controls. Hence, an implemented treatment becomes a control.

[SOURCE: ISO Guide 73:2009, 3.8.1, modified — Note 3 to entry replaces the existing note 3]

3.2 Abbreviations

| | |
|-----|-------------------------------|
| ATP | automatic train protection |
| EER | escape, evacuation and rescue |
| ETA | event tree analysis |

| | |
|-------|--------------------------------------|
| FMEA | failure mode and effects analysis |
| FTA | fault tree analysis |
| GPA | general purpose alarm |
| HAZOP | hazard and operability |
| LH | left hand |
| LOPA | layer of protection analysis |
| OIM | offshore installation manager |
| P&IDs | process and instrumentation diagrams |
| PAPA | prepare to abandon platform alarm |
| PA | public address |
| PES | programmable electronic system |
| PPE | personal protective equipment |
| QP | qualified person |
| RH | right hand |

4 Key features of HAZOP

4.1 General

A HAZOP study is a detailed process carried out by a dedicated team to identify risks and operability problems. HAZOP studies deal with the identification of potential deviations from the design intent, examination of their possible causes and assessment of their consequences.

Key features of a HAZOP study include the following.

- The study is a creative process that proceeds by systematically using a series of guide words to identify potential deviations from the design intent and employing these to stimulate team members to envisage how the deviation might occur and what might be the consequences.
- The study is carried out under the guidance of a trained and experienced study leader, who has to ensure comprehensive coverage of the system under study, using logical, analytical thinking. The study leader is preferably assisted by a recorder who records pertinent data associated with identified risks and/or operational disturbances for risk analysis, evaluation and treatment.
- The study relies on specialists from various disciplines with appropriate skills and experience who display intuition and good judgement.
- The study should be carried out in an atmosphere of critical thinking in a frank and open atmosphere.
- A HAZOP study produces minutes or software to record the deviations, their causes, consequences and recommended actions together with marked up drawings, documents or other representations of the system that indicate the associated minute number and where possible the recommended action.
- The development of risk treatment actions for identified risks or operability problems is not a primary objective of the HAZOP examination, but recommendations should be made where appropriate and recorded for consideration by those responsible for the design of the system.
- The initial HAZOP study might be done in a progressive fashion so that design changes can be incorporated but the completed HAZOP study has to correlate to the final design intent.

- Existing HAZOP studies should be reviewed at regular intervals to evaluate whether there have been any changes to the design intent or hazards and also during other stages in the life cycle such as the enhancement stage.

4.2 Principles of examination

The basis of a HAZOP study is a “guide word examination” which is a deliberate search for deviations from the design intent. To facilitate the examination, a system is divided into parts in such a way that the design intent or function for each part can be adequately defined. The size of the part chosen is likely to depend on the complexity of the system and the potential magnitude and significance of the consequence. In complex systems or those where the level of risk might be expected to be high, the parts are likely to be small in comparison to the system. In simple systems or those where the level of risk might be expected to be low, the use of larger parts will expedite the study.

The design intent for a given part of a system is expressed in terms of properties, which convey the essential characteristics of the part and which represent natural divisions of the part. The selection of properties to be examined is to some extent a subjective decision in that there might be several combinations which will achieve the required purpose and the choice can also depend upon the particular application. Parts can be discrete steps or stages in a procedure, clauses in a contract, individual signals and equipment items in a control system, equipment or components in a process or electronic system, etc.

In some cases it might be helpful to express the function of a part in terms of:

- the input material taken from a source;
- an activity which is performed on that material;
- an output which is taken to a destination.

Thus the design intent will contain the following elements: inputs and outputs, functions, activities, sources and destinations, which can be viewed as properties of the part.

Properties can often be usefully defined further in terms of characteristics that can be either quantitative or qualitative. For example, in a chemical system, the inputs could be defined further in terms of characteristics such as temperature, pressure and composition. For a transport activity, characteristics such as the rate of movement, the load or the number of passengers might be relevant. For computer-based systems, communication, interfaces, and data processing are likely to be the characteristic of each part.

For each part in turn, the HAZOP study team examines each property for deviation from the design intent which can lead to undesirable (or desirable) consequences. 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, thereby maximizing the chances of study completeness. An example of basic guide words and their meanings is given in Table 1.

Table 1 – Example of basic guide words and their generic meanings

| Guide word | Meaning |
|------------|--|
| NO OR NOT | Complete negation of the design intent |
| MORE | Quantitative increase |
| LESS | Quantitative decrease |
| AS WELL AS | Qualitative modification/increase |
| PART OF | Qualitative modification/decrease |
| REVERSE | Logical opposite of the design intent |
| OTHER THAN | Complete substitution |

A further example of additional guide words relating to clock time and order or sequence is given in Table 2.

Table 2 – Example of guide words relating to clock time and order or sequence

| Guide word | Meaning |
|------------|-------------------------------|
| EARLY | Relative to the clock time |
| LATE | Relative to the clock time |
| BEFORE | Relating to order or sequence |
| AFTER | Relating to order or sequence |

Additional guide words can be used to facilitate identification of deviation, provided they are identified before the examination commences.

Having selected a part for examination, the design intent of that part is specified in terms of discrete properties. Each relevant guide word is then applied to each property, thus a thorough search for deviations is carried out in a systematic manner. Having applied a guide word, possible causes and consequences of a given deviation are examined and mechanisms for control of the predicted consequences can also be investigated. The results of the examination are recorded in an agreed format (see 6.5.2).

Guide word/property associations can be regarded as a matrix. Within each cell of the matrix thus formed will be a specific guide word/property combination. To achieve a comprehensive risk identification, it is necessary that the properties cover all aspects of the design intent and guide words cover all possible deviations. Not all combinations will give credible deviations, so the matrix can have several empty spaces when all guide word/property combinations are considered.

In general the study leader will predefine the applicable guide word/property combinations to make the risk identification process more efficient and make best use of the participant expertise and time.

There are two possible sequences in which the cells of the matrix can be used for the examination of the chosen part: column by column (i.e. property first), or row by row (i.e. guide word first). The details of examination are outlined in 6.4 and both forms of examination are illustrated in Figures 2 and 3. In principle the results of the examination should be the same.

As well as applying guide words to defined properties of a part there can be other attributes such as access, isolation, control, and the work environment (noise, lighting, etc.) that are important to the desired operation of the system and to which a subset of the guide words can be applied.

4.3 Design representation

4.3.1 General

An accurate and complete design representation of the system under study is a prerequisite to the examination task. A design representation is a descriptive model of the system adequately describing the system under study, its parts and identifying their properties. The representation could be of the physical design or of the logical design and it should be made clear what is represented.

The design representation should convey the system function of each part and element in a qualitative or quantitative manner. It should also describe the interactions of the system with other systems, with its operator/user and possibly with the environment. For example, P&IDs are likely to provide the level of detail required for the design representation. The

conformance of properties or characteristics to their design intent determines the correctness of operations and in some cases the safety of the system.

The representation of the system consists of two basic components:

- the system requirements; and
- a physical and/or logical description of the design.

The value of a HAZOP study depends on the completeness, adequacy and accuracy of the design representation including the design intent. Any modifications from the original design should be shown in the design representation. Before starting the examination, the team should review this information package, and if necessary have it revised so that it accurately represents the system.

4.3.2 Design requirements and design intent

The design requirements consist of qualitative and quantitative requirements that the system has to satisfy, and provide the basis for development of system design and design intent. All reasonably foreseen ways in which the system could be used or misused should be identified. Both the design requirements and resulting design intent have to meet customer requirements and those of any relevant legislation, norms or standards.

On the basis of system requirements, a designer develops the system design; for instance, a system configuration is arrived at, and specific functions are assigned to subsystems and components. Components are specified and selected. The designer should not only consider what the system should do, but also ensure that it will not fail under any foreseeable set of conditions, or that it will not fail or degrade during the specified lifetime. Undesirable behaviours or features should also be identified so they can be designed out, or their effects minimized by appropriate design or maintenance.

The design intent forms a baseline for the examination and should be accurate and correct, as far as possible. The verification of design intent (see IEC 61160) is outside of the scope of the HAZOP study, but the study leader should ascertain that it is accurate and correct to allow the study to proceed. In general most documented design intents are limited to basic system functions and parameters under normal operating conditions.

Reasonably foreseeable abnormal operating conditions and undesirable activities that might occur (e.g., severe vibrations, extreme weather events, abnormal stoppages or third party interventions) should be identified and considered during the examination. Also deterioration mechanisms such as decay, corrosion and non-compliance of procedures and other mechanisms which cause deterioration in system properties should be identified and considered in a study using appropriate guide words. If necessary, a more detailed study looking specifically at failure modes and effects may be required (see IEC 60812).

Expected life, reliability, maintainability and supportability should also be identified and considered together with risk sources which could be encountered during maintenance and logistic support activities, provided they are included in the scope of the HAZOP study.

5 Applications of HAZOP

5.1 General

Originally a HAZOP study was a technique developed for systems involving the treatment of a fluid medium or other material flow in the process industries where it is now a major element of process safety management. However its area of application has steadily widened in recent years and for example includes usage for:

- software applications including programmable electronic systems;

- systems involving the movement of people by transport modes such as road, rail, and air;
- examining different operating sequences and procedures;
- assessing administrative procedures in different industries;
- assessing specific systems, for example medical devices;
- software and code development;
- assessing proposed organizational change and defining the mechanisms to achieve those changes;
- testing and improving draft contracts and other legal documents;
- testing and improving documents including instructions and procedures for critical activities.

A HAZOP study is particularly useful for identifying weaknesses in systems (existing or proposed) involving the flow of materials, people or information, or a number of events or activities in a planned sequence or the procedures controlling such a sequence. HAZOP studies can also be used for non-operational conditions such as storage and transport. As well as being a valuable tool in the design and development of new systems, HAZOP can also be profitably employed to identify risks and potential problems associated with different operating states of a given system: for example, for start-up, standby, normal operation, normal shutdown, emergency shutdown states. It can also be employed for batch and unsteady-state processes and sequences as well as for continuous ones. HAZOP is an integral part of the overall design process and one of the methods that can be employed for risk identification as part of the risk management process (see ISO 31000).

5.2 Relation to other analysis tools

A HAZOP study can be used in conjunction with other risk identification and analysis methods (see IEC/ISO 31010) such as FMEA (see IEC 60812) and FTA (see IEC 61025) or LOPA (see IEC 61511-3:2003, Annex F). Such combinations might be utilized in situations when:

- the HAZOP study clearly indicates that the performance of a particular component of a system is critical and needs to be examined in greater depth; the HAZOP study can then be usefully complemented by an FMEA of that component;
- having examined single property deviations by a HAZOP study, it is decided to use FTA and ETA to analyse the effect of multiple deviations or to quantify the likelihood of the failure event and its consequences.

FMEA starts with a possible component/function failure and then proceeds to investigate the consequences of this failure on the system as a whole. Thus the investigation is unidirectional, from cause to consequence. A HAZOP study, on the other hand, is concerned with identifying possible deviations from the design intent and then proceeds to find the potential causes of the deviation and to predict its consequences.

FTA may be used after single property deviations have been identified by HAZOP, to analyse the effect of multiple deviations or to quantify the likelihood of the failure event and its consequences.

LOPA uses the data developed by HAZOP and documents the initiating cause and the protection layers that modify the risk. This can then be used to determine the amount of risk reduction achieved by existing controls and to ascertain whether further treatment is needed.

5.3 HAZOP study limitations

Whilst HAZOP studies have proved to be extremely useful in a variety of different industries, the technique has limitations that should be taken into account when considering a potential application. Some of the limitations are mentioned below.

- A HAZOP study is a risk identification technique which considers system parts individually and methodically examines the effects of deviations on each part. Sometimes a very high risk will involve the interaction between several of parts of the system. In these cases the risk should be analysed in more detail using techniques such as ETA (see IEC 62502) and FTA (see IEC 61025).
- As with any technique for the identification of risks or operability problems, there can be no guarantee that all will be identified in a HAZOP study. The study of a complex system should not, therefore, depend just upon a HAZOP study. The technique should be used in conjunction with other suitable approaches and other relevant studies should be coordinated within an effective, overall management system.
- Many systems are highly interlinked, and a deviation in one part can have causes and consequences in other parts of the system. To understand the risk and take appropriate risk treatment actions, the causes and consequences have to be followed across the system. However, where the system is highly interlinked there is a danger that the follow through is not comprehensive of every eventuality and a more rigorous event analysis might be required.
- The success of a HAZOP study depends greatly on the ability and experience of the study leader and the knowledge, experience and level of interaction between team members.
- A HAZOP study can only consider those parts that appear on the design representation. Activities and operations which do not appear on the representation might not always be considered. This can be partially overcome by applying a set of additional, non-specific guide words to a part that are not strictly properties, such as access and maintenance and also by adding to the process a step whereby, on completion, a final 'common sense check' is applied using a checklist.

5.4 Risk identification studies during different system life cycle stages

5.4.1 Concept stage

In the concept phase of a system's life cycle, the design concept and major system parts are decided but the detailed design and documentation required to conduct the HAZOP study do not exist. However, it is necessary to identify major risks at this time, to allow them to be considered in the design process and to facilitate future HAZOP studies. To carry out these studies, other basic methods should be used (for example descriptions of some of these methods see IEC/ISO 31010).

5.4.2 Development stage

The most cost effective time to carry out a HAZOP study is when the detailed design is available and methods of operation have been decided upon. There can be several iterations as the design is being finalized. It is important to have a process that will assess the implications of any changes made after the study has been carried out. This process should be maintained throughout the life of the system.

5.4.3 Realization stage

During the realization phase, it is advisable to carry out an additional study prior to commissioning, when initial operation or start-up of the system can lead to significant levels of risk and proper operating sequences and instructions are critical. The study should also be carried out or repeated when there has been a substantial change of design or intent at a later stage. Additional data such as commissioning and operating instructions should be available at this time. In addition, the study should also review all actions raised during earlier studies to ensure that these have been completed.

5.4.4 Utilization stage

The application or update of a HAZOP study should be considered before implementing any changes that could affect the normal operation of a system, particularly if these changes

could lead to high levels of risk. Periodically, the system should also be studied to detect and understand the effects and implications of slowly acting changes. It is important that the design documentation and operating instructions used in such a study are up to date.

5.4.5 Enhancement stage

The enhancement stage is concerned with improving performance, making changes to respond to new operating conditions, extending operating life and addressing obsolescence. HAZOP studies can be used to understand the implications of any proposed changes to judge if they are acceptable and whether new controls or changes to existing controls are required. When conducting studies to identify risks associated with any proposed changes it is important to consider the implications and responses for the whole system and not just restrict the study to the part or property being changed.

5.4.6 Retirement stage

In the retirement stage, a study of activities related to decommissioning, cessation of use or disposal might be required if it leads to different risks from those in normal operations. Once the sequence of activities has been defined HAZOP studies can be applied to the sequence and procedures as well as any interim operating modes.

6 The HAZOP study procedure

6.1 General

HAZOP studies consist of four basic sequential steps, shown in Figure 1.

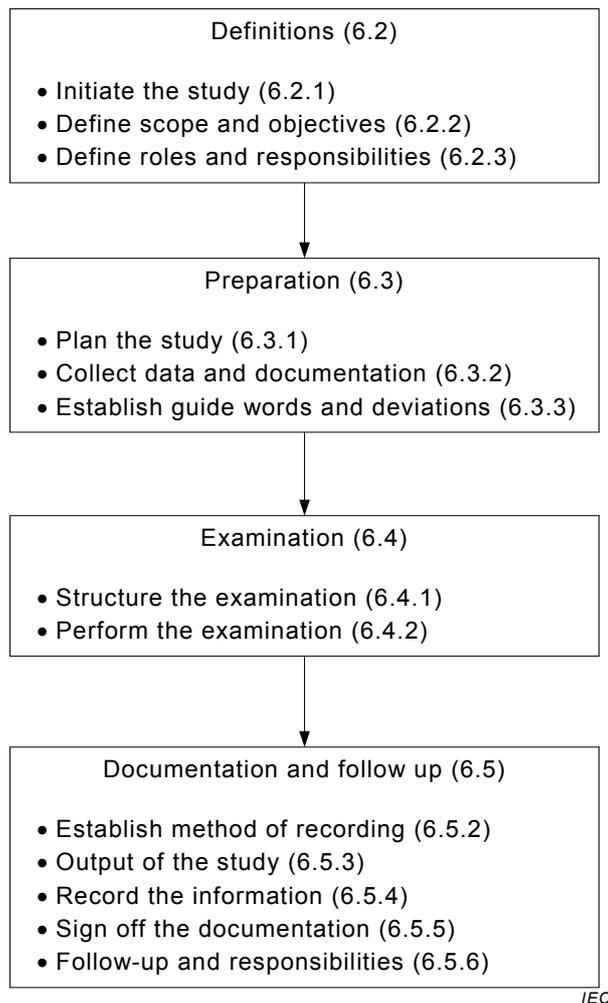


Figure 1 – The HAZOP study procedure

6.2 Definitions

6.2.1 Initiate the study

The study is generally initiated by a person with responsibility for a project, activity or organisation, who in this guide is called the manager. The manager should determine when a study is required, appoint a study leader and provide the necessary resources to carry it out.

The need for such a study will often have been identified during planning, due to legal requirements or because it is an organization's policy. With the assistance of the study leader, the manager should define the scope and objectives of the study and ensure that members appointed to the study team have the appropriate competencies to undertake the study.

The manager is ultimately accountable for ensuring that any actions that arise from the study are completed.

6.2.2 Define scope and objectives

The scope of a study should be clearly stated, to ensure that:

- the system boundaries, and its interfaces with other systems and the environment are clearly defined; and
- the study team is focused, and does not stray into aspects irrelevant to the objectives.