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Consumer incident investigation — Requirements and guidance

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO document should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

ISO draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at www.iso.org/patents. ISO shall not be held responsible for identifying any or all such patent rights.

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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Project Committee ISO/PC 329, *Consumer incident investigation guideline*.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

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Introduction

The objective of this document is to provide a process ~~and guidance~~ to any person, or ~~any~~ organization of any size, whether ~~it is~~ public, private or ~~not-for-profit~~, to investigate consumer incidents in order to prevent them from occurring in the future.

To prevent incidents from recurring, it is essential to conduct incident investigations that can lead to effective measures.

~~Some~~ manuals and guides describing the principles and methods of incident investigation ~~already~~ exist in ~~the many~~ fields ~~of (e.g. the aviation industry, etc.~~

~~)~~ Even though the fields are different, ~~they~~ ~~the literature~~ have a common investigative purpose, ~~to analyze~~ ~~analyze~~ the causal factors leading to the incident and propose preventative measures. ~~The purpose of the investigation is not to apportion blame or liability. The development of highly effective incident investigation principles and methods in these fields arose from a strong need to prevent recurrence when incidents occur.~~

However, the development of effective incident investigation guidelines has yet to include incidents that affect consumers involving the use of products, services or facilities. These incidents can occur anywhere.

This document focuses on the investigation of consumer incidents. Thus, the incident investigation organization can trust other organizations conducting investigations according to this document. It would activate data sharing, respecting confidentiality policy or regulation, among organizations including full and complete data and related information on consumer incidents. This document encourages the full and complete sharing of information arising from an investigation, including the final report and all of the data developed during the investigation.

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Consumer incident investigation — Requirements and guidance

1 Scope

This document provides general requirements and recommendations on the principles, procedures, and methods for investigating incidents where there have been injuries, illnesses, damage to health, ~~or~~ fatalities to consumers, damage to property, ~~or an~~ environmental damage related to the use of products, services, or facilities by consumers.

NOTE 1 — These incidents can occur anywhere.

This document is applicable to ~~a~~any person or ~~any~~ organization of any size, whether ~~it's~~it is public, private or community-based.

NOTE — ~~The scope of 2~~ This document is not limited to incidents while products, services or facilities are in use, but also includes incidents that occur when products, services or facilities are not in use, such as during transportation or storage by consumers.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

- ~~ISO~~ Online browsing platform: available at <https://www.iso.org/obp>
- ~~IEC~~ Electropedia: available at <https://www.electropedia.org/>

3.1

causal factor

condition, event, omission, deficiency or action that contributed directly to the incident

3.2

conflict of interest

situation where business, financial, family, political or personal interests can interfere with the impartial judgment of persons in carrying out their duties for the *incident investigation organization* ~~(3.10)~~

3.3

consumer

individual member of the general public purchasing or using products, services or facilities for private purpose

[SOURCE: ISO 26000:2010, 2.2 modified — ~~Omission of —~~"property, ~~addition of~~ " was deleted from the definition "facilities;" has been added to the definition.]

3.4

consumer incident incident

occurrence, condition, or situation that resulted in, or can result in injuries, illnesses, damage to health, or fatalities to *consumers* ~~(3.3)~~, damage to property, or an environmental damage related to use of products, services or facilities by consumers.

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Note 1 to entry: The term “accident” is used in some sectors as a synonym for incident but it is not used synonymously in this document.

3.5 consumer incident investigation incident investigation investigation

series of processes to collect as much *data* (3.6) as possible related to the incident to be investigated, to understand the events that occurred, to analyze the factors, to identify or estimate the causes and factors of the incident, and to develop and submit *recommendations* (3.13) on measures to prevent the incident from recurring-

3.6 data

information collected during the course of an investigation for reference or analysis

Note 1 to entry: Data can be in, but is not limited to, the following forms: documents, records, dictations, interview transcripts, photographs, videos, materials, instruments, tools, statistical information, analytical results, research data, papers, hospital records and coroner’s records, social media posts.

Note 2 to entry: Data can include discovery of non-incident related data that, although not directly related to the incident, can potentially pose a hazard or identify a deficiency.

[SOURCE: CSA Z1005–17:2017, 3.1]

3.7 direct cause

last *causal factor* (3.1(3.4)) in the chain of causation leading to the incident

Note 1 to entry: There can be more than one direct cause.

3.8 harm

injury or damage to the health of people, or damage to property or the environment

[SOURCE: ISO/IEC Guide 51:2014, 3.1]

3.9 human error

discrepancy between the human action taken or omitted, and that intended or required

[SOURCE: IEC 62740:2015, 3.1.10]

3.10 incident investigation organization

organization whose purpose is to conduct *consumer incident investigations* (3.5(3.5))

3.11 incident investigation team

people assigned by an *incident investigation organization* (3.10(3.10)) to perform *consumer incident investigations* (3.5(3.5))

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3.12

reasonably foreseeable misuse

use of a product or system in a way not intended by the supplier, but which can result from readily predictable human behaviour

[SOURCE: ISO/IEC Guide 51:2014, 3.7, ~~modified — Notes 1 and 2 to entry have been deleted.~~]

3.13

recommendation

advice to the relevant department or organization regarding matters identified as needing to be corrected to prevent recurrence as a result of the incident investigation.

Note 1 to entry: Corrective actions to remove potential for *harm* (3.8) and to reduce *risk* (3.14) can include, but are not limited to: additional product, or facility redesign, instructions, warning statements, signage, service procedures, training for service providers, and organizational management issues.

3.14

risk

combination of the probability of occurrence of *harm* (3.8) and the severity of that harm

[SOURCE: ISO/IEC Guide 51:2014, 3.9, ~~modified — Note 1 to entry has been deleted.~~]

3.15

root cause

causal factor (3.1) or *underlying factor* (3.17) with no predecessor, that is relevant for the purpose of the investigation

Note 1 to entry: ~~An~~ incident normally has more than one root cause.

3.16

safety

freedom from *risk* (3.14) which is not tolerable

[SOURCE: ISO/IEC Guide 51:2014, 3.14]

3.17

underlying factor

condition, event, omission, deficiency or action that contributed indirectly to the incident

Note 1 to entry: Underlying factors are factors, if eliminated, that would not necessarily prevent the incident, but can help prevent future incidents.

Note 2 to entry: Underlying factors include management and organizational factors.

Note 3 to entry: Some documents apply the term "contributing factor" to this definition.

3.18

vulnerable consumer

consumer (3.3) who can be at greater *risk* (3.14) of *harm* (3.8) from products, services or facilities due to their demographic, level of literacy, physical condition or limitations, or inability to access *product safety* (3.16) information

[SOURCE: ISO 10377:2013, 2.30, modified—, —"service or facility." has been added and "age" has been replaced by "demographic in the definition."]

4 Principles of consumer incident investigation

4.1 General

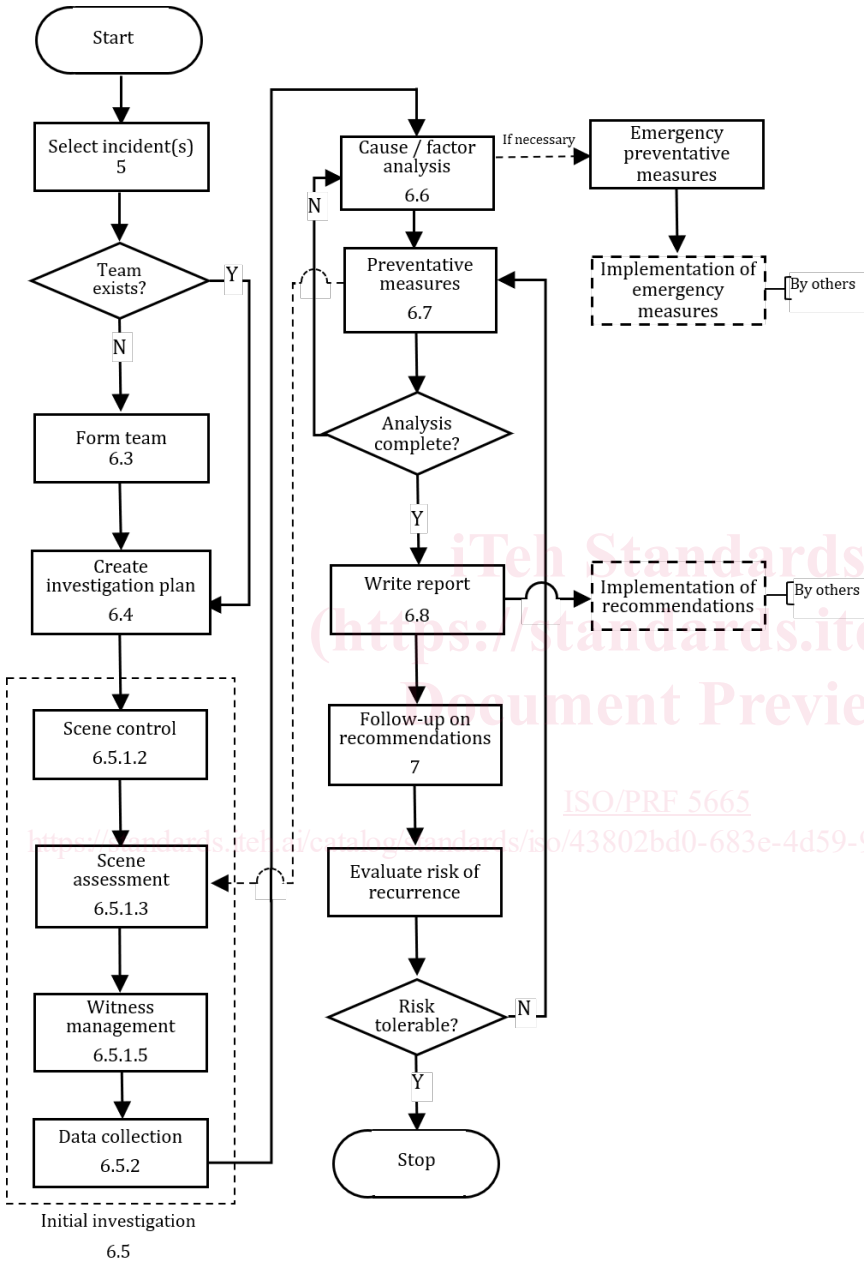
The incident investigation process described in this document is shown in [Figure 1](#). Each stage in the process is discussed in detail in the [subclauses of Clause 4](#) following [clauses](#). [Figure 1](#) includes the relevant clause numbers at each step to help [readers](#) find the relevant information.

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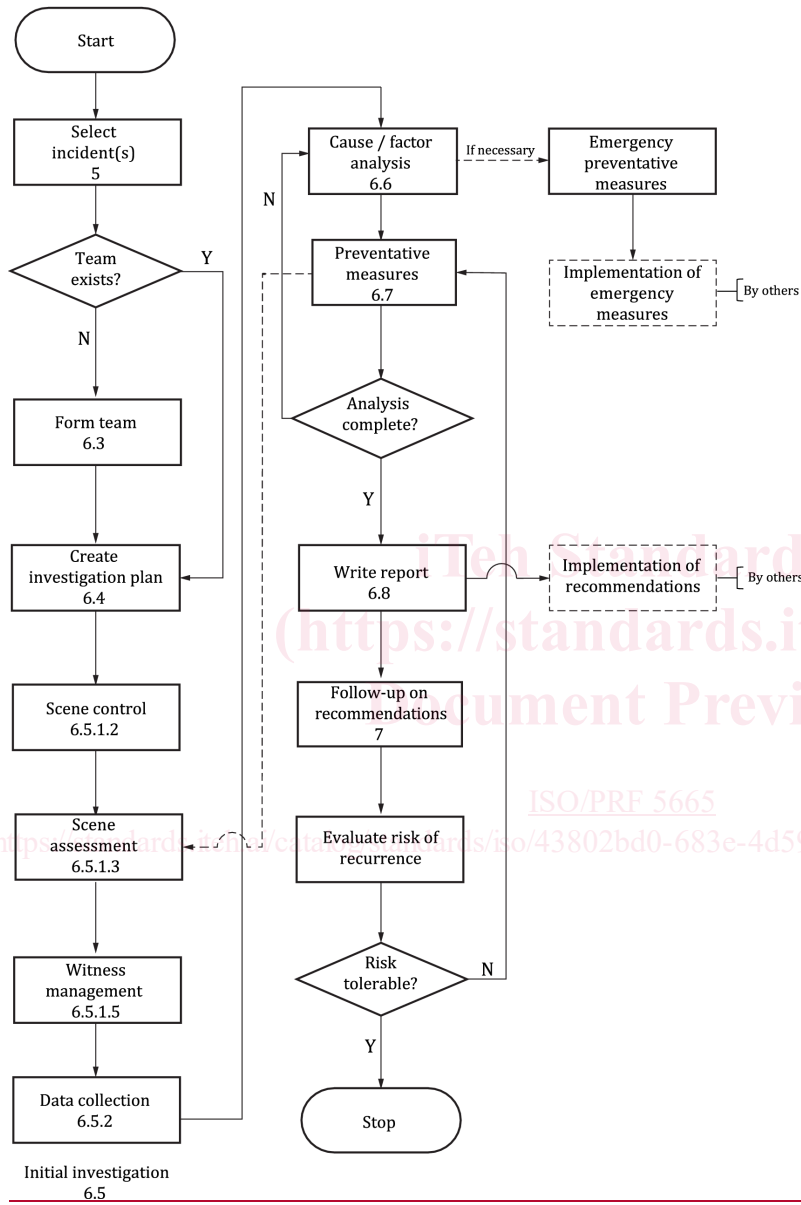


Figure 1 — Consumer incident investigation process

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4.2 Objective

The sole objective of the investigation of an incident is the prevention of further incidents. It is not the purpose of this activity to apportion blame or liability.

4.3 Mission

The mission of an incident investigation team is the identification of hidden risk factors, improvement of the safety of the organization, prevention of the recurrence of incidents widely and ultimately to contribute to the advancement of safety in society.

The mission of the incident investigation team is encapsulated in these goals:

- the analysis of the causes and factors related to the incident under investigation,
- the determination of safety measures to prevent the recurrence or to reduce the severity of the same or similar incidents,
- to make recommendations to the organization, department regulatory authorities, standardization bodies and those involved in the incident where appropriate, and
- to verify the results after making recommendations.

Through these activities the incident investigation can contribute to the improvement of consumer safety.

In addition to investigating the cause of the incident, the mission shall clarify the factors contributing to the increase in damage.

NOTE 1 See ISO/IEC Guide 51:2014, 4.1 and 4.2 for guidance on the use of the terms "safety" and "safe".

The incident investigation team shall achieve the mission goals by following the evidence as far as possible before coming to any conclusions.

Recommendations shall include at least one of the following two types:

- a) ~~a)~~ measures to prevent recurrence in a narrow sense: measures to prevent the recurrence of the same or similar incidents based on the various factors constituting the cause of the incident;
- b) ~~b)~~ measures to prevent recurrence in a broader sense: measures to eliminate organizational and system risk factors (dangerous events such as oversights, defects and the existence of triggers for human errors in various aspects from design to maintenance and operation) that revealed during the investigation, even if they are not related to the cause of the incident.

The conclusion of the incident investigation report shall reflect the purpose of the investigation.

4.4 Incident investigation organization and incident investigation team characteristics

4.4.1 General

Effective incident investigation organizations and incident investigation team share certain common characteristics. These teams shall have the minimum characteristics as described in ~~4.4.2~~ ~~the 4.4.2~~ to ~~4.4.5~~ ~~4.4.5~~.

4.4.2 Independence

The incident investigation team shall be independent.

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The incident investigation team shall be able to conduct its own investigation and make its own judgments without influence from any source whose mission is different than described in this document. To ensure independence, the incident investigation team shall have the necessary authority to investigate the incident.

4.4.3 Impartiality

The incident investigation ~~organisation~~organization and the incident investigation team shall maintain impartiality during an investigation and the delivery of the investigation report.

To maintain impartiality, the incident investigation organization and team shall avoid influence by organizations or individuals who ~~may~~can have a stake in the outcome of the investigation.

The actions of the incident investigation ~~organisation~~organization and incident investigation team during the investigation shall not raise any suspicion that such influence has occurred.

4.4.4 Expertise

The incident investigation team shall include members with the required expertise to conduct the investigation.

The expertise of incident investigation team members should include expertise in the following areas:

- ~~relevant~~relevant technical fields, e.g. product or service, sustainable development, economy,
- ~~incident investigation~~incident investigation techniques and methods,
- ~~information~~information collection,
- ~~data~~data analysis,
- ~~human~~human factors, and
- ~~medical~~medical.

Over-reliance on expertise can lead to overlooking the perspectives and targets that are necessary for the investigation. To avoid these effects, the perspectives of non-experts, such as victims of incidents, should be taken into consideration during the investigation. See ~~4.5.4.5~~.

4.4.5 Resources

The incident investigation team shall be provided with sufficient resources to complete the investigation in an effective and efficient manner.

The resources can include:

- ~~personnel~~personnel,
- ~~time~~time,
- ~~funding~~funding,
- ~~technical and physical~~technical and physical resources,
- ~~access to the incident~~access to the incident site,
- ~~access to witnesses~~access to witnesses identified during the initial assessment of the incident,
- ~~access to data and records~~access to data and records related to the incident, and
- ~~data and records~~data and records from national and international sources.