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Benefit-risk assessment for sports and recreational facilities, activities and equipment

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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 documents 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).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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 Technical Committee ISO/TC 83, *Sports and other recreational facilities and equipment*.

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.

Introduction

A system is needed for identifying benefits and hazards and assessing risks related to sport and recreation for all ages and abilities. In many jurisdictions, there is a requirement for the designers, builders, owners/operators, including inspectors and maintainers of a sport and other recreational facilities and equipment, to carry out a risk assessment and, in some cases, to record it.

International Standards have been published on risk assessment and general risk management including ISO 31000^[1], IEC 31010^[2] and ISO 45001^[3] on occupational health and safety. These International Standards were written with the intention of providing methods for managing risk and preventing work-related injury and ill-health via the elimination of hazards and the minimization of occupational health and safety (OH&S) risks by taking effective preventive and protective measures. As the sport and recreation sectors have specific characteristics and face different challenges, there is a need for an additional International Standard. There is an expectation in sport and recreational activities that the user is making an implicit trade-off between the benefits and the inherent risks of the activity, including of the potential for harm.

Risks and benefits only have meaning in relation to the objectives pursued within the context of a project (i.e. the project scope). Regarding measuring the risks and benefits, any risk analysis should include at least the following objectives:

- injury and lethality (risk);
- improvement of health and wellbeing in a broad sense (benefit);
- compliance with legal requirements.

It is up to the user to determine the degree of acceptable risks and the minimum benefits to be achieved regarding the set objectives.

The terms “sports” and “recreation” describe diverse activities and the necessary equipment for all ages and abilities. For example, camping, hockey, high ropes and challenge course equipment, martial arts, games with rules such as football (soccer), kiteboarding, summer tobogganing, play spaces, etcetera all fall within “sports” and “recreation.”

It is recognized that sports and recreation involve numerous stakeholders including, but not limited to, designers, manufacturers, installers, owner/operators, maintainers, inspectors of sports and recreation equipment and facilities, and any park rangers, playworkers or activity leaders who may be present at these venues.

Due to the varied interests of the different stakeholders, a single system of hazard identification and risk assessment for the sport and recreation sector is not feasible. What can be achieved, however, is to identify principles and provide guidance on selecting appropriate techniques.

A key issue identified is the differentiation of sports and recreational activities from a work activity. Sports and recreational activities are designed for the public good; therefore public interests are paramount. The public good can include the social, physical, psychological health and welfare of the participant and society. Participation in sport and recreation involves exposure to risk which is not necessarily a bad thing and can be of benefit to the public good. Exposure to risk in daily life can reduce fear and improves the development of human competency.^{[4],[5],[6]} This is to be balanced with the exclusion of unforeseen or unrecognizable sources of harm. For example, in adventure sports, exposure to risk is what provides part of the enjoyment. Even in the case of children's play provision, it is now widely recognized that children seek risky situations. Graduated challenge provides opportunities for children to develop internal hazard references. Therefore, the age of participants should be a consideration when assessing benefits and risks.

It is common to conduct a benefit-risk analysis that explicitly brings together the consideration of benefits as well as the risks of sport and recreation to a single evaluation. This immediately separates sport and recreation from the world of occupational health and safety where the goal, as noted above, is generally seen as one of eliminating or minimizing risk.

Within sport and recreation, there are many different goals of which prevention of injury is but one. Using a benefit-risk approach recognizes the need for making trade-offs in achieving a balance that maximizes the overall social utility and public good. These are not the only considerations, though they are important ones. Whether provided on a commercial, not-for-profit, or charitable basis, sport and recreational activities involve an accepted, inherent element of risk and challenge. Taking risks brings rewards but also dangers.

The range of stakeholders involved in sport and recreation is so diverse, different types of benefit-risk assessment is needed. Generally, there are three types of assessments that can be used: the generic risk assessment, the site-specific risk assessment, and the dynamic risk assessment. This document helps providers of products, activities, and operators of facilities to better understand the risks associated with their products, activities, and facilities, and to evaluate, implement, and document a suitable benefit-risk analysis. For example, a generic risk assessment technique can be used to analyse the risks related to skis, while a site-specific risk assessment can be used by the owner/operator to evaluate the ski hill; and the skier and the ski instructor are dynamically assessing the risk during the skiing activity.

Those responsible for reviewing proposed research must ultimately weigh the risks and benefits to determine whether the relationship between them is acceptable. This process is complicated by the fact that risks and benefits often cannot be measured on a uniform scale. First, 'risks and benefits for subjects may affect different domains of health status', as when a risk of physical injury is incurred in an effort to achieve a potential psychological benefit. Second, 'risks and benefits may affect different people'; risks are typically borne by the participants in the research, but most of the benefits will be experienced by patients in the future^[7].

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Benefit-risk assessment for sports and recreational facilities, activities and equipment

1 Scope

This document specifies methods for a benefit and risk assessment for sports, for recreational and sports facilities including equipment. This document also provides guidance and requirements on benefit and risk assessment within this field. It includes examples for injury thresholds.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 3864 (all parts), *Graphical symbols — Safety colours and safety signs*

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

activity

play, recreation or service that engages a *user* (3.23) and provides *benefit* (3.2) which can have an associated *risk* (3.11)

3.2

benefit

helpful or good effect or something intended to help

3.3

benefit-risk

concept which acknowledges that in sports and recreation there is an inevitable and inherent trade-off between the *benefits* (3.2) of a sport or recreational *activity* (3.1) and some of the *risks* (3.11) which it can pose

Note 1 to entry: In some circumstances exposure to risk may in itself be considered to be a benefit, e.g. the benefits of risky play in childhood development.

3.4

benefit-risk assessment

BRA

form of risk assessment that considers both *risks* (3.11) and *benefits* (3.2) in parallel when making decisions

Note 1 to entry: Benefit-risk assessment is a balanced approach that involves judgment and is based on clear values and understandings. Where appropriate it takes account of local circumstances.

Note 2 to entry: Benefit-risk assessment includes an evaluation of the social, physical, and developmental considerations of a given *activity* (3.1).

Note 3 to entry: There can be instances where regulators or governing bodies set thresholds that do not have a rationale with the BRA but are arbitrary and must be adhered to.

Note 4 to entry: The risk is not always apparent to the *user* (3.23) and should focus on the *harm* (3.13) that cannot be evaluated or determined by the user during an activity.

3.5

competence

ability to apply knowledge and skills to achieve expected results

[SOURCE: ISO/IEC 17024:2012, 3.6]

3.6

external context

external environment in which the organization seeks to achieve its objectives

Note 1 to entry: External context can include:

- the cultural, social, political, legal, regulatory, financial, technological, economic, natural and competitive environment, whether international, national, regional or local;
- key drivers and trends having impact on the objectives of the organization; and
- relationships with, and perceptions and values of external stakeholders.

[SOURCE: ISO Guide 73:2009, 3.3.1.1]

3.7

internal context

internal environment in which the organization seeks to achieve its objectives

Note 1 to entry: Internal context can include:

- governance, organizational structure, roles and accountabilities;
- policies, objectives, and the strategies that are in place to achieve them;
- the capabilities, understood in terms of resources and knowledge (e.g. capital, time, people, processes, systems and technologies);
- information systems, information flows and decision-making processes (both formal and informal);
- relationships with, and perceptions and values of internal stakeholders;
- the organization's culture;
- standards, guidelines and models adopted by the organization; and
- form and extent of contractual relationships.

[SOURCE: ISO Guide 73:2009, 3.3.1.2]

3.8

leader

competent person who takes responsibility for people, and is able to lead, guide and supervise an assigned *activity* (3.1)

[SOURCE: ISO 21102:2020, 3.8, modified — Note 1 to entry has been removed.]

3.9**safe**

state of being protected from recognized *hazards* (3.14) that are likely to cause *harm* (3.13)

[SOURCE: ISO/TR 20183:2015, 2.1]

3.10**safety**

freedom from unacceptable *risk* (3.11), but not *safe* (3.8)

Note 1 to entry: Safety is achieved by reducing risk to a tolerable level.

Note 2 to entry: There is no complete absence of risk. In turn, there is no product or system that is without some risk which shall be reduced to a tolerable risk.

[SOURCE: ISO/TR 20183:2015, 2.2]

3.11**risk**

combination of the probability of occurrence of *harm* (3.13) and the severity of that harm

Note 1 to entry: The probability of occurrence includes the exposure to a *hazardous situation* (3.16), the occurrence of a *hazardous event* (3.15) and the possibility to avoid or limit the harm.

Note 2 to entry: The person or team performing the risk assessment should be able to quantify or define the harm

[SOURCE: ISO/IEC Guide 51:2014, 3.9, modified — Note 2 to entry has been added.]

3.12**risk criteria**

terms of reference against which the significance of *risk* (3.11) is evaluated

Note 1 to entry: Risk criteria are based on organizational objectives, and *external context* (3.6) and *internal context* (3.7).

Note 2 to entry: Risk criteria can be derived from standards, laws, policies and other requirements.

[SOURCE: ISO Guide 73:2009, 3.3.1.3]

3.13**harm**

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

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

3.14**hazard**

potential source of *harm* (3.13)

[SOURCE: ISO/IEC Guide 51:2014, 3.2]

3.15**hazardous event**

event that can cause *harm* (3.13)

[SOURCE: ISO/IEC Guide 51:2014, 3.3]

3.16**hazardous situation**

circumstance in which people, property or the environment is/are exposed to one or more *hazards* (3.14)

[SOURCE: ISO/IEC Guide 51:2014, 3.4]

3.17

residual risk

risk (3.11) remaining after *risk reduction measures (protective measures)* (3.36) have been taken

Note 1 to entry: Following risk reduction measures, the residual risk should be less than tolerable risk, thus providing *safety* (3.10).

[SOURCE: ISO/IEC Guide 51:2014, 3.8, modified — "(protective measures)" has been added; note 1 to entry has been added.]

3.18

risk analysis

systematic use of available information to identify *hazards* (3.14) and to estimate *risk* (3.11)

3.19

risk evaluation

procedure based on the *risk analysis* (3.18) to determine whether a tolerable *risk* (3.11) has been achieved

3.20

risk assessment

overall process comprising a *risk analysis* (3.18) and *risk evaluation* (3.19)

Note 1 to entry: The degree of exposure to *risk* (3.11) is comprised of the potential severity of the *harm* (3.13) and the probability of that harm occurring. In determining the probability of occurrence of harm, the exposure of a *user* (3.23) to a *hazardous situation* (3.16), the possibility of a *hazardous event* (3.15), and the potential means of limiting the harm should all be considered.

3.21

intended use

use of a product or system in accordance with the information provided by the supplier

3.22

reasonably foreseeable misuse

foreseeable misuse

use of a product or system in a manner not intended by the supplier, where that manner of misuse can be anticipated based on predictable human behaviour

Note 1 to entry: In evaluating readily predictable human behaviours, all relevant demographics should be considered, including, but not limited to, elderly, children, and persons with disabilities.

Note 2 to entry: In the context of consumer *safety* (3.10), "reasonably foreseeable use" is often used to encompass both *intended use* (3.21) and reasonably foreseeable misuse.

3.23

user

ultimate organization or person engaged in the use of a product, facility or an *activity* (3.1)

Note 1 to entry: The user can be a parent, legal guardian, qualified caregiver, or another decision-maker where consent is required.

3.24

inspection

act of careful examination or scrutiny to identify *hazards* (3.14), and *hazardous situations* (3.16) and to evaluate compliance with regulations, codes, and standards

Note 1 to entry: Inspection should include, but not be limited to, consideration of hazards that can emerge during or as a result of intended operation, *reasonably foreseeable misuse* (3.22), vandalism, aging of the product/environment, and weather conditions.

3.25

manufacturer

party responsible for the design or fabrication of a portion or all of a product intended for a consumer

3.26**installer**

party responsible for the assembly or installation, or both, of a product to its final configuration intended by the *manufacturer* (3.25) and destined for use by a consumer

Note 1 to entry: The installer makes the product ready to use, brings it into the market and has the same responsibility as the manufacturer; they may even combine several products to a system and act on behalf of the manufacturer.

3.27**operator**

person(s) or organization(s) who allow a product to be used

Note 1 to entry: An operator may implement an active role as a designated supervisor during use.

3.28**protective device**

apparatus, that blocks, shields, or otherwise prevents access to a *hazard* (3.14) or reduces the degree of *harm* (3.13) that can be caused by a hazard

EXAMPLE A guard.

Note 1 to entry: A protective device can be an element such as a railing.

3.29**graduated challenge**

activity (3.1) that tests *users'* (3.23) physical, mental, emotional or social skills to achieve a given, intended outcome

Note 1 to entry: Based on the ability of the user, there can be circumstances where a user is presented with *hazards* (3.14) that shall be eliminated or reduced for the intended user group and unintended users should be warned away. The user group can be identified by age or ability within the appropriate standard.

3.30**user information**

instructions, *warning* (3.31) labels, or other documentation provided by the *manufacturer* (3.25) regarding use and maintenance requirements for the product, as well as issues of potential *residual risk* (3.17) that can be related to aging of the product or skill of the *user* (3.23)

Note 1 to entry: This documentation can be provided by the manufacturer prior to purchase, installation, or acquisition of the product by the owner or *operator* (3.27), or both. The documentation should be available to the user prior to initial use.

Note 2 to entry: Information should be provided in a clear and understandable language. Where provided as graphical symbols or signage, this shall be clearly visible and understandable by the user.

3.31**warning**

notice or communication to indicate a potentially *hazardous situation* (3.16) that if not avoided can result in *risk* (3.11)

Note 1 to entry: "Warning", along with "Danger", "Caution", and "Notice" are keywords whose meaning is defined in ANSI Z535.4. These keywords are used in *safety* (3.10) labels and follow specific requirements.

3.32**life-threatening injury**

injury to any part of the human body which is severe or resulting in permanent impairment that would be categorized as abbreviated injury scale (AIS) of 4 or greater

[SOURCE: ISO/TR 20183:2015, 2.33, modified — "(severe with survival probable)" has been removed.]

3.33

debilitating injury

injury that diminishes or weakens the human body and has a legacy of greater than one month and that could be categorized as abbreviated injury scale (AIS) of 3

Note 1 to entry: Debilitating injuries would include requiring surgery concussions that require removal from play to medical attention.

[SOURCE: ISO/TR 20183:2015, 2.34 modified — "(serious, but not life-threatening)" has been removed.]

3.34

serious injury

acute physical injury requiring medical or surgical treatment or under the supervision of a qualified doctor or nurse provided in a hospital or clinic and includes injuries such as burns, fractures, lacerations, internal injury, injury to organ, concussion, internal bleeding, etc. that can be categorized as abbreviated injury scale (AIS) of 3

Note 1 to entry: All evaluations shall be considered in the light of the age of the *user* (3.23).

[SOURCE: ISO/TR 20183:2015, 2.35, modified — "that can be categorized as abbreviated injury scale (AIS) of 3" has been added; in note 1 to entry, "have to" has been changed to "shall".]

3.35

inherently safe design

measures taken to eliminate *hazards* (3.14) and/or to reduce *risks* (3.11) by changing the design or operating characteristics of the product or system

[SOURCE: ISO/IEC Guide 51:2014, 3.5]

3.36

risk reduction measure

protective measure

action or means to eliminate *hazards* (3.14) or reduce *risks* (3.11)

EXAMPLE *Inherently safe design* (3.35); *protective devices* (3.28); personal protective equipment; information for use and installation; organization of work; training; application of equipment; supervision.

[SOURCE: ISO/IEC Guide 51:2014, 3.13]

3.37

risk source

element which alone or in combination has the intrinsic potential to give rise to *risk* (3.11)

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

[SOURCE: ISO 31000:2018, 3.4, modified — "intrinsic" has been added; note 1 to entry has been added.]

3.38

surface

point of contact between the *user* (3.23) and an element in an *activity* (3.1) whose properties that can create a *hazardous situation* (3.16)

Note 1 to entry: A surface can be one that the user is in regular contact and be the potential for a hazardous situation such as contain sharp points or edges; alternatively, the user can lose contact with the surface unexpectedly due to lack of friction.

Note 2 to entry: A surface can be a point of contact that a user can fall onto and resulting in an injury. This can also be a point of contact within the play, sport and recreation facility or environment.

3.39**activity leader**

person assigned by a group or organization to lead an *activity* (3.1)

EXAMPLE Games leader, orienteering leader, canoe trip leader.

Note 1 to entry: Specific levels of training or competency in leadership and skills may be required by the group or organization before an individual is permitted to lead an activity.

4 Benefit-risk assessment — Process overview**4.1 Assessment team**

Benefit-risk assessments should be conducted by a team of at least three members with relevant expertise in an activity, facility, or product. Teams should be kept to the minimum number of participants necessary to include all relevant expertise.

Team membership should be maintained for at least the duration of the first review cycle; see 8.2 to help ensure the continuity of team wisdom.

The person designated as the team leader should have training and experience according to the requirements of [Clause 9](#) and have experience facilitating effective committee work, including the development of consensus.

The team leader should determine the types of expertise needed in the team.

Team members are typically drawn from one of the following three groups:

- product and facility designers;
- site managers;
- activity leaders.

4.2 Project scope**4.2.1 General****4.2.1.1 Overview**

The benefit-risk assessment shall be a total package, consisting of three distinct processes:

- a) definition of context;
- b) identification of user (parallel process);
- c) evaluation of the risk and benefit.

[Figure 1](#) illustrates the flow of the procedures specified in this document.

4.2.1.2 Establishing the context

The establishment of the context shall be the first task performed when conducting a benefit-risk analysis. Developing context involves communication between stakeholders.

The context is related to the requirement to assess a product, facility/location, or activity during its conduct.

The purpose of establishing the context is to define which of the assessment approaches (see [4.2.1](#)) is most appropriate to the circumstances, enabling effective risk assessment and appropriate management

of the activity. There are two contexts that should be considered, the internal and the external. Both the internal and the external contexts are important.

The overall context includes the goals of the organization and the nature of the facility or activity, and the social acceptance of the risks related to the activity, e.g. the type of recreational or sporting experience that the organization intends to provide, the nature of the activity itself and the inherent benefits and risks created by that activity, any unique benefits or risks related to the geographic location or other relevant factors.

The context of the benefit-risk management process should be established from an understanding of the external and internal environment in which the organization operates, and the environment where the activity takes place.

Understanding the context is important because:

- benefit assessment is directly connected to the type and geographic location of the activity, and the social aspects, i.e. individual, family or team oriented, competitive or non-competitive, etc.;
- risk management takes place in the context of the objectives and activities of the organization;
- organizational factors can be a source of both benefits and risks;
- purpose and scope of the benefit-risk management process may be interrelated with the objectives of the organization.

In establishing the context, benefit-risk assessors should determine whether participation in an activity is mandatory or voluntary. Voluntary participation can take the form of being a member of a sport association and being active in a competition, while participation is mandatory during a gym class. A weighing of the risks and benefits of, for example, mandatory participation in a rugby activity as part of an obligatory physical education class or as a competition from a sport association, results in a different risk appetite.

4.2.1.3 Parallel processes

The benefit-risk assessment shall be a total package with two parallel processes: the benefits assessment and the risk assessment, concluding with a final evaluation of the benefit-risk balance and ongoing maintenance activities.

4.2.1.4 Identification of users

Following the establishment of the context, the next step is to determine the expected users of the activity, product or service and any spectators. Consideration should be given to the following:

- age;
- physical size;
- skills;
- capacity for judgement;
- capacity for supervision.

Once the user is identified, the process moves to two parallel processes. The order in which they are performed can be determined by the assessment team.

- a) The identification and evaluation of the benefits from the activity begins with the identification of the expected benefits. The context that can increase the benefit in relation to the same activity, service or facility being in another location are identified. At this point a benefit analysis can be performed, including identification of any precedents and comparisons.

- b) The performance of a risk assessment takes into consideration the user and the reasonably foreseeable misuse(s). The process continues with hazard identification and development of an understanding of the potential severity of injury or a specified harm. At this point an estimation of the risk can be performed, resulting in the overall evaluation of the risk. Any risk limitations set by the context shall be considered during this process.

4.2.1.5 Evaluation of benefit and risk

Following the benefits and risk assessments, a further evaluation of the risk and benefit shall be completed. This process results in a decision as to whether the risk is tolerable or whether the benefits outweigh the risks, or both. At this stage, the external and internal contexts shall be taken into consideration in determining whether an activity can move forward.

The decision related to the benefits outweighing the risk either results in the activity moving forward or being re-evaluated for further risk reduction.

Where the decision results in a need for further risk reduction, the team has the option of:

- a) returning to the hazard identification and determining if the risk(s) have been adequately reduced for the project to proceed; or
- b) returning to the beginning of the start of the entire process, re-evaluating both the benefits and the risks with different starting parameters, such as the types of users or other parameters.

Where the activity moves forward, the decision shall be validated and documented.

4.2.1.6 Monitoring and periodic re-evaluation

Periodic monitoring and re-evaluation of the benefits and risks shall be conducted, which means performing the entire process again.

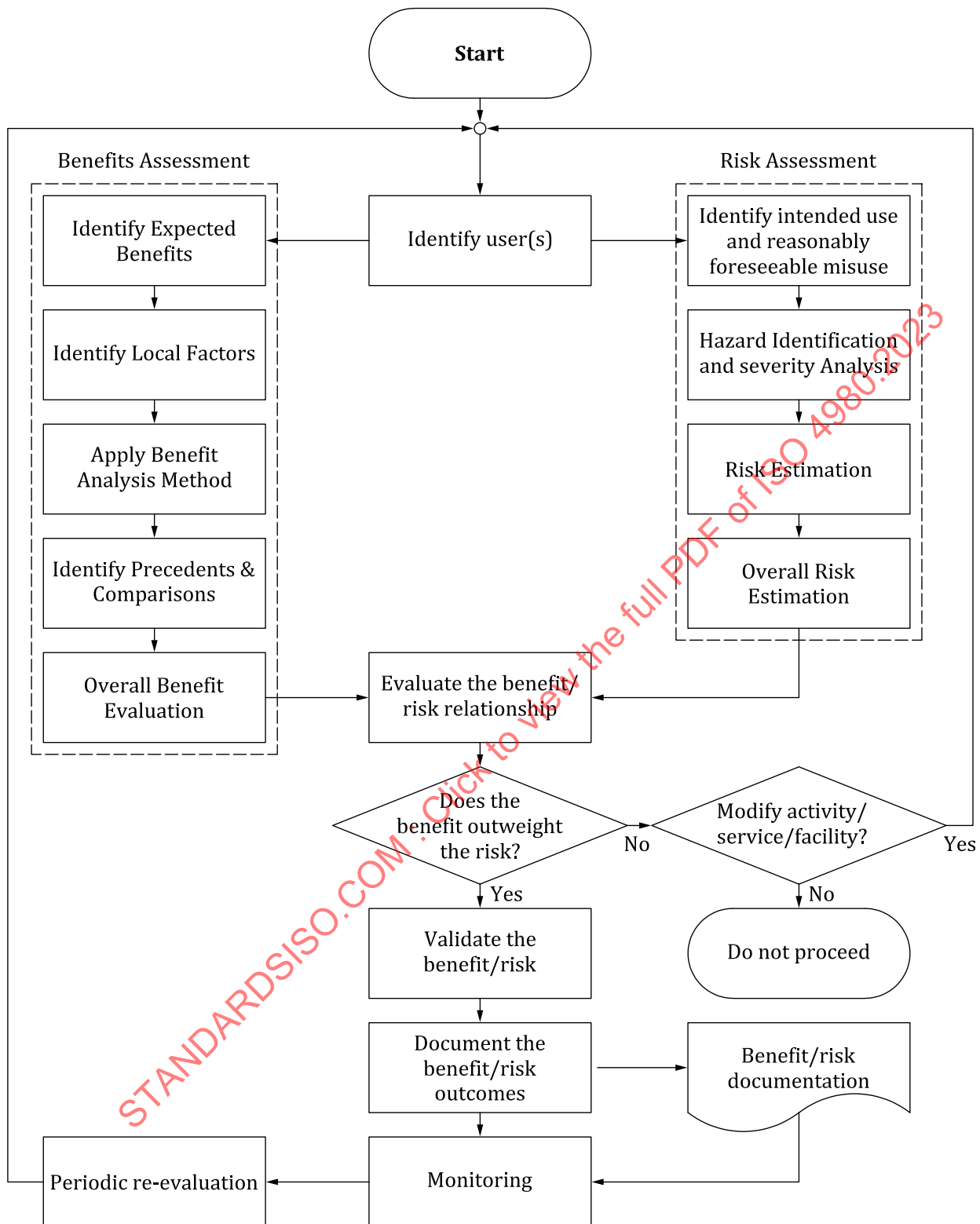


Figure 1 — Benefit-risk assessment process

4.2.2 External and internal context

4.2.2.1 General

The context of the benefit-risk assessment provides an understanding of the background against which the benefits and risks are considered. The context forms part of the scope of the benefit-risk assessment in that it informs both the benefit assessment and the risk assessment regarding the legal limitations placed upon the assessors, and the limits for risk tolerability, in addition to other considerations described in this document. The limits on risk tolerability are described as risk criteria; see [5.3.2](#).

Cultural and legal aspects affecting the level of risk appetite shall be part of establishing the context. The level of risk from unknown factors shall not be overestimated.

4.2.2.2 Consideration of contexts

At least two contexts should be considered when developing the scope of the benefit-risk assessment, the external and the internal. The analyst shall examine both the internal and the external contexts before selecting a benefit-risk assessment approach.

Examination of the external context may include, but is not limited to:

- the environment (e.g. urban, rural, remote);
- the social, cultural, political, legal, regulatory, financial, educational, technological, economic and environmental factors, whether international, national, regional or local;
- community values;
- types of users/participants;
- user needs.

Examination of the internal context may include, but is not limited to:

- vision, mission and values of the organization providing the product, facility, or activity;
- the governance, organizational structure, roles and accountabilities;
- strategy, objectives and policies;
- the organization's culture;
- standards, guidelines and models adopted by the organization;
- capabilities, understood in terms of resources and knowledge (e.g. capital, time, people, intellectual property, processes, systems and technologies);
- data, information systems and information flows;
- relationships with internal stakeholders, taking into account their perceptions and values;
- contractual relationships and commitments;
- interdependencies and interconnections;
- environment (urban, rural, remote);
- local policy, community values;
- types of users;
- user needs.

Determination of the factors that need to be included involves communication between stakeholders.

For example, childcare centres are likely to emphasize safety and seek to minimise risks. It is considered a part of good service that children are unharmed when they are given back to their parents, whereas a school can place greater value on the educational, physical, and social value of some degree of risk of harm in activities participated in by students. In both situations, there is always some risk of harm.

4.2.2.3 Benefit-risk assessment approaches

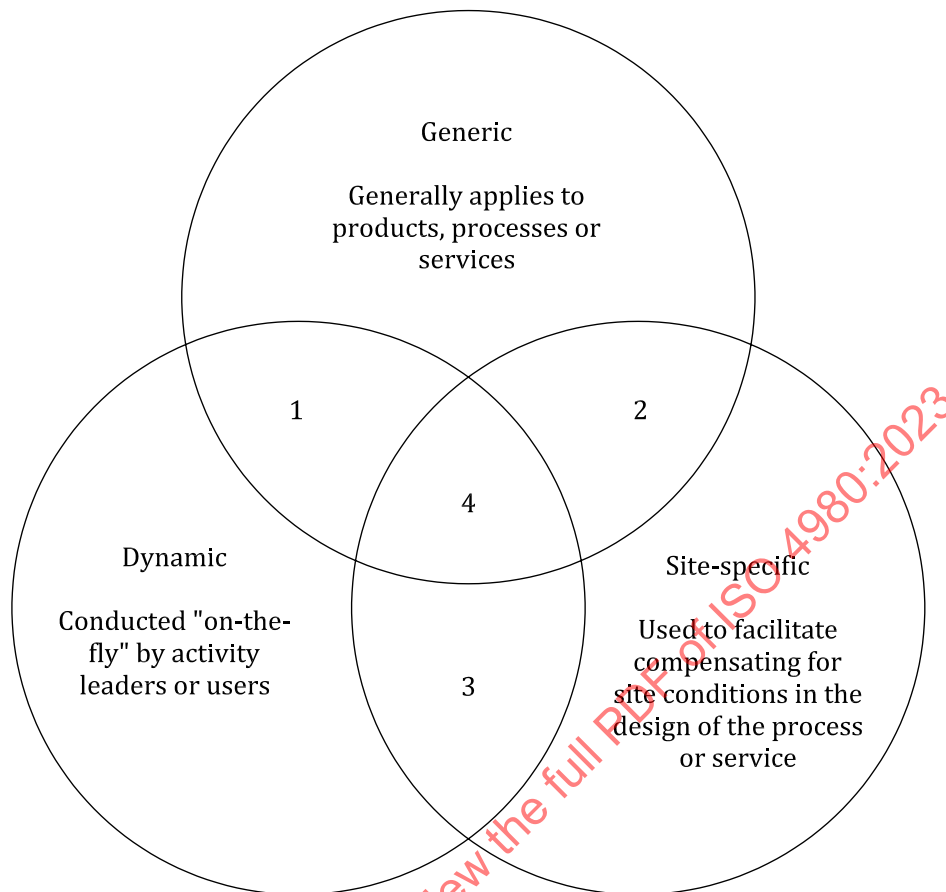
The approach chosen is dependent on the organization conducting the benefit-risk assessment.

In general, for product and facility designers, the generic benefit-risk assessment method can be used for product risk assessment (see 4.2.4.2), while for site operators, some form of site-specific benefit-risk assessment (see 4.2.4.3) is preferred; and for activity leaders, dynamic benefit-risk assessment (see 4.2.4.4) is preferred.

- a) Generic benefit-risk assessment: At the product design stage, the generic benefit-risk assessment is used by the product designer or manufacturer. This process is considered generic because in most cases it is conducted without specific knowledge of the location where the product is used or any personal details about the users.
- b) Site-specific benefit-risk assessment: At the installation and operational stage, a site-specific benefit-risk assessment is required. This process can be conducted by the site designer, the installer, the owner/operator or others. The process takes into account the local environmental circumstances, expected user capabilities, local policies etc.
- c) Dynamic benefit-risk assessment: At the activity stage, a dynamic benefit-risk assessment is used. This process can be conducted by activity leaders, participants, or others. This process takes into account the local environmental factors (e.g. weather), and actual user abilities and fitness.

Figure 2 illustrates the fact that the three approaches to risk assessment overlap, i.e. they do not operate in total isolation. For example, a person leading a mountain walking activity needs some knowledge of products, some knowledge of terrain, and detailed knowledge of the dynamic situation. Likewise, a product or facility designer needs to consider the likely demands on products or the facility in the situations in which they are likely to be used.

It is not implied that, for example, designers only use generic benefit-risk assessment. Designers should be aware of the benefits of their designs. Site owners or operators should understand the benefits of the equipment on their site and the capabilities of the users they intend to attract; and activity leaders should have some awareness of product design issues and which products are fit for the intended purpose.



Key

- 1 dynamic and generic – need to blend immediacy with an understanding of the activity, product, or facility
- 2 generic and site-specific – understanding of the activity, product or facility applied to a location of the activity
- 3 dynamic and site-specific – need to blend immediacy with an understanding of the location
- 4 all methods – a blend of all aspects of risk assessment

Figure 2 — Interrelationship of generic, site-specific and dynamic benefit-risk assessments

The following examples help to differentiate the three main approaches as well as the overlapping areas where more than one method is applicable.

EXAMPLE 1 Generic

Manufacturer of handrails makes generic risk assessment and decides to use smaller cross-section for a handrail that is often used in kindergartens/childcare.

EXAMPLE 2 Dynamic

A class teacher makes dynamic risk assessment when taking students out to the park and calls for attention of the class when a maintenance truck approaches.

EXAMPLE 3 Site-specific

A park designer or installer makes a site-specific risk assessment in connection to a plan. A decision is made to add a handrail to the place where ice can appear creating a slip and fall hazard, even though the design guidelines did not necessarily require it.

In another location, a decision is made to not add a barrier where there is a possibility of a fall from height in order to preserve the aesthetic value of the site.

EXAMPLE 4 Generic and dynamic

The manufacturer of white-water canoes conducts a generic risk assessment on the design of their canoes and the expected conditions where these types of canoes are used. They decide that offering the canoes with inflatable flotation bags as a standard feature provides a significant risk reduction for the canoeists, so they sell all their canoes so equipped. A pair of white-water canoeists takes one of the manufacturer's canoes to a portion of a river with mild rapids to test the canoe's handling. They conduct a dynamic risk assessment based on their own skills and the water conditions on the day and decide that the flotation bags do not need to be inflated for the handling test.

EXAMPLE 5 Generic and site-specific

The manufacturer of a football goal also offers an optional ball-stop screen based on the results of a generic risk assessment of the hazards that people sitting behind the goal are exposed to during a football match. The site designer conducts a site-specific risk assessment and chooses to use a ball-stop screen that is even higher than what the manufacturer offers due to buildings with windows located behind the goal.

EXAMPLE 6 Site-specific and dynamic

A mountain bike trail is designed using site-specific risk assessment using curves and signs to guide bikers and reduce speeds in more hazardous sections of the trails. Bikers make their own dynamic risk assessment to decide the speed that they are comfortable with.

EXAMPLE 7 Generic, site-specific and dynamic

A grass area in the park is designed for recreation with various activities. Following a site-specific risk assessment, appropriate signs are placed. People are playing in the field using sports equipment that come with safety instructions that result from generic risk assessment of the sports equipment designs. While playing, players make dynamic risk assessments to decide to keep the playing intensity low to avoid harming people nearby.

4.2.3 Analytical techniques

The user of this document shall make a choice between quantitative analysis methods and qualitative methods. Since truly quantitative data are seldom available in the sport and recreation sector, the use of qualitative techniques is more common. Either approach may be used, as suited to the available information^[13],^[14].

4.2.4 Process

4.2.4.1 General

Every benefit-risk assessment is different; and the context plays an important role in the generic, site-specific and dynamic assessment.

Each benefit-risk assessment shall take into consideration both the opportunities for benefits to a larger group of participants and the risks for that specific product or activity.

The context can affect decisions. For example, the skill level of participants influences the benefit-risk decision, as does the local policy. If the user is new to a particular sport or recreation activity, this increases the risk; whereas a user who is highly experienced and competent in the same sport or recreation activity has a lower risk.

The risk assessment process described in this document is based on ISO/IEC Guide 51, following the qualitative approach to risk analysis. The basic process used remains the same regardless of the scoring methodology chosen. [Figure 1](#) illustrates the process flow.

The risk assessment shall include a review for compliance with established and related facility, equipment and operational standards or regulations, where these exist. In the absence of evidence of compliance, those identified residual risks shall be evaluated and mitigated as necessary throughout the useful life of the sport and recreation site and its related facilities including all related equipment and operating procedures.

4.2.4.2 Life cycle

Benefit-risk assessment should be carried out at each stage in the life cycle of the product, site or facility, or activity, as appropriate to the scope and purpose of the assessment.

At least the following life cycle stages shall be taken into consideration during analysis:

- a) human interaction during the entire life cycle of the product, site, or activity with respect to:
 - 1) design of the product or a facility or environment, or a particular sport or recreational activity;
 - 2) construction or development of the product or a facility or environment;
 - 3) transport, assembly, and installation of structures, components and surfacing or other components in the environment;
 - 4) commissioning or setting into use;
 - 5) intended use of the structures, components and surfacing or other components in the environment;
 - 6) decommissioning, dismantling and disposal;
- b) the possible state of the structures, components and surfacing or other components in the environment:
 - 1) the structures, components and surfacing or other components in the facility or environment perform the intended function (i.e. it operates as expected);
 - 2) the structures, components and surfacing or other components in the facility or environment do not perform the intended function (i.e. it malfunctions, or emergencies occur) for a variety of reasons;
- c) expected use or reasonably foreseeable misuse of the structures, and other components in the facility or environment result in:
 - 1) loss of control by users of the structures and components in the facility or environment;
 - 2) reflex actions of a person in case of malfunction, incident, or failure during the use of the structures and components in the facility or environment;
 - 3) hazardous situations resulting from lack of concentration caused by the challenges of the activity or interaction with other users;
 - 4) hazardous situations resulting from taking the path of least resistance in achieving success with a challenge, resulting from pressures to keep the structures and components in the facility or environment operational in all circumstances;
 - 5) hazardous situations arising from actions of persons in and around the facility or environment.

4.2.4.3 Intended use

When preparing a benefit-risk assessment, developing an understanding of the intended use of the product, site, or activity is fundamental. The intended use shall consider at least:

- a) the intended use of the sport or recreation product, site, or activity, i.e. following rules of the game;
- b) the reasonably foreseeable misuses of the sport or recreation product, site, or activity;
- c) the ergonomics aspects, including the body sizes likely to be found in the intended user population;

- d) the expected cognitive and intellectual level of development in the intended user population, including any limitations this can place on the user's ability to use the sport or recreation product, site, or activity safely;
- e) the use of the sport or recreation product, process or activity by persons identified by sex, age, dominant hand usage, or limiting physical abilities (visual or hearing impairment, size, strength, etc.);
- f) any training or experience that can be required to allow for the safe use of the sport or recreation product, site, or activity;
- g) exposure of persons to the hazards associated with the sport or recreation product, site, or activity where it can be reasonably foreseen:
 - 1) persons likely to have a good awareness of the specific hazards;
 - 2) persons with little awareness of the specific hazards but likely to have a good awareness of site;
 - 3) persons likely to have very little awareness of the specific hazards.

The ergonomics of the intended user shall be considered and have direct relation to strengths and postures, movement amplitudes, frequency of cyclic actions. See locally relevant anthropometric data, for example, local or national sources, for additional guidance.^[8] If specific information is not available in relation to 4.2.4.3 c), the responsible person(s) should take into account general information on the intended user population.

Intended use information should be assembled into an intended use statement that encompasses all of the information related to the intended use(s) and reasonably foreseeable misuse(s) of the sport or recreation product, site, or activity. See [Clause 7](#) for more information.

4.2.4.4 Reasonably foreseeable misuse

Reasonably foreseeable misuse can occur when a product, site, or activity is used by an unintended user, i.e. a mismatch exists in physical size, age, skill, or physical ability, or when an intended user does something unintended with the product, site, or activity.

Local play culture can result in reasonably foreseeable misuse when a mismatch exists between the design of the product, process or activity and the way the product, process or activity is used.

Reasonably foreseeable misuse converts to abuse when:

- the behaviour becomes culturally unacceptable;
- the behaviour is impaired by substances; or
- the user wilfully fails to heed conspicuously posted, clearly understandable, hazard warning signs and labels.

4.2.4.5 Generic benefit-risk assessment

4.2.4.5.1 General

Generic risk assessments have the following broad characteristics. They:

- are more product focused;
- are used on equipment designs;
- tend to be more theoretical due to the probability/likelihood aspects;
- include reference to intended use and reasonably foreseeable misuses.

NOTE The term “equipment” includes elements that are intentionally brought into an environment for use in activities.

Product risk assessments follow more closely the occupational health and safety model of risk assessment. Risk minimization should be the norm during product development. Products should not fail under foreseeable conditions of use, e.g. climbing ropes, carabineers, play equipment structures.

See [5.3](#).

4.2.4.5.2 Requirements

The generic benefit-risk assessment shall be documented in writing.

4.2.4.6 Site-specific benefit-risk assessment

4.2.4.6.1 General

The site-specific benefit-risk assessment shall address the benefits and risks associated with the intended use(s) and the reasonably foreseeable misuse(s) of a specific sport and/or recreation environment that includes all related facilities and equipment necessary for the intended activity.

4.2.4.6.2 Requirements and recommendations

Site-specific benefit-risk assessment should refer to the policy of the organization that is providing the facility or activity, e.g., physical fitness programs for senior citizens. Also included is consideration of the environmental factors, and the users that may be accessing the facility or the activity. Both physical site and the activity(ies) provided on the site by the owner/operator should be assessed.

The steps included in the generic-risk assessment technique, apply to the site-specific assessment technique, with the addition of the following considerations:

Site-specific benefit-risk assessment can be used for permanent or temporary installations. The following are some examples.

- a) A site-specific benefit-risk assessment for a swimming pool can include identifying a damaged diving board, identifying a need to repair or replace the board.
- b) An infant/toddler pool intended for non-swimmers can be located close to the deep end of a swimming pool. The owner/operator can decide to install a barrier and signage to help keep separation between small children and deep water. As the age and ability of children in the community increase, more challenging recreational facilities can be needed to avoid misuse of existing facilities.
- c) The age and ability of children in the community has increased. More challenging play facilities including a skate park are desirable.
- d) Access to wilderness areas should be encouraged for those with the capability.
- e) A playground is near a major roadway. The owner/operator can consider installing fencing or other appropriate barriers to maintain separation between the children and the traffic considering whether the primary objective for installing some type of barrier is to keep the children within the play space or is the barrier intended to keep the motor traffic out of the play area.
- f) Consideration of a variety of layouts for activity areas on a site can be part of a site-specific risk assessment.
- g) Consideration of a variety of layouts for individual pieces of play equipment on a site can be part of a site-specific risk assessment.
- h) The risk of cliff diving is too high, and the activity should be prohibited at this location.

The site-specific risk assessment shall address the risks associated with the site selection and layout of all pieces of free-standing equipment related to the intended use(s) and intended users while considering reasonably foreseeable misuse(s), and between individual pieces of equipment, the site where the equipment is to be installed, and the intended users. The site designer shall review the compliance with the manufacturer's installation specification, established equipment standards, and local regulations.

The site-specific benefit-risk assessment shall be documented in writing.

See [5.3](#).

4.2.4.6.3 Facility or activity

4.2.4.6.3.1 General

A sport or recreation facility or an activity area can be a formal structure or a location set aside for the activity. How the facility or activity area is structured is determined by the facility policies, activity leadership provided, environmental conditions and the abilities of the intended and reasonably foreseeable users. Accessibility of the facility or activity should be considered. There can be the need to consider the removal of physical barriers for those with disabilities that are intended to participate in the activity.

4.2.4.6.3.2 Facility policy

The facility policy determines the desired benefits and the risk appetites.

For example, day-care centres likely emphasise safety and pursue to minimise risks. It is considered a part of good service that children are unharmed when they are given back to their parents.

Mountain bike trails on the other hand may accept relatively high risks in exchange of offering extreme experiences for users. Safety management can be limited to informing users about trail-sections that have increased risk level and ensuring they wear the appropriate personal protective equipment (PPE).

4.2.4.6.3.3 Activity leader

When the service is offered for inexperienced users or the activity requires monitoring for any other reason, the activity leader's responsibility is to instruct and guide users and to intervene when the situation seems to have too high a risk.

The activity leader shall determine the acceptable risk for the user(s) in their care by engaging in a discussion as to the skills, hazards and other factors related to the service to allow the user to determine the risk they are willing to take, and that the activity leader shall provide guidance about during the activity.

4.2.4.6.3.4 Environmental factors

Environmental factors can have a variety of effects that should be considered in the analysis, for example:

- how the environment can affect the activity or equipment;
- how the environment can affect the lifetime of the product;
- how the changes such as day/night affect the activity or the benefit-risk to the user;
- how changes in weather (rain, snow, ice, heat, cold, etc.) affect the activity.

4.2.4.7 Dynamic benefit-risk assessment

4.2.4.7.1 General

The dynamic benefit-risk assessment method applies to active situations in which participants and activity leaders are involved in some challenging activity. The dynamic benefit-risk assessment is an on-going mental process predicated upon the prior experience and abilities of participants. This leads to increased skill in the performance of an activity by the participant.

The dynamic benefit-risk assessment is specifically conducted by activity leaders (park rangers, sports coaches, trainers, etc.) and participants. Participants should be encouraged to do their own dynamic benefit-risk assessments.

Dynamic benefit-risk assessments are usually not documented. During any debriefing following an incident, i.e. a close call or an accident, caution should be exercised to prevent hindsight bias influencing post-incident documentation.

4.2.4.7.2 Features

The dynamic benefit-risk assessment is an on-going process in which a leader continuously updates their risk assessment through observing such things as the behaviour of participants, their capabilities, fitness and endurance, the environment, and the weather. Decision-making is largely subconscious. Because of this and its on-going nature, it is not to be expected that it can be recorded, and it can be that the reasons for a particular choice at a specific moment are elusive.

The activity leader shall conduct a dynamic benefit-risk assessment in real time during the activity. Dynamic benefit-risk assessments are not documented because the act of assessing the risk and taking action to mitigate it occurs in the moment. Dynamic benefit-risk assessments typically result in immediate changes to the site conditions or activity.

EXAMPLE 1 A lifeguard notices changes in water or weather conditions and adjusts the activity of the participants dynamically during the activity.

EXAMPLE 2 A lifeguard notices that users are behaving in an unacceptable way, instituting a change in signage or behaviour.

EXAMPLE 3 A hike-leader notices that their group is coping well. They decide to take a more challenging route because of the increased benefits to the participants, due to an evaluation of skill level or a heightened experience.

4.2.4.7.3 Factors

User or participant factors that should be considered during a dynamic benefit-risk analysis may include but should not be limited to:

- the number of users;
- the types of users (competence, age, ability, etc.);
- the size;
- the weight of users;
- the skills of users;
- user traffic flow patterns;
- ultraviolet (UV) or infrared (IR) protection of users;
- peer pressure – showing off;
- concentration of people on the site;

- boredom/thrill-seeking;
- impairment;
- terrorism, bullying;
- vandalism;
- environment, weather conditions, lighting.

4.2.4.7.4 Real-time elements of dynamic risk assessment

The elements of the dynamic benefit-risk assessment are:

- based on subconscious or implicit previous experiences;
- not necessarily documented;
- part of the feedback loop in thinking;
- learned protective component;
- biased based on experience;
- instinctually protective;
- done by everyone (e.g. owner/operator, activity leaders, country rangers, users);
- observational and immediate;
- based on environmental observations;
- variable based on experiential and cognitive ability.

Examples of dynamic benefit-risk assessment are:

- white-water canoeists assessing a rapid before attempting to run it;
- skiers assessing the difficulty of a run before attempting it (i.e. black diamond runs versus bunny hills);
- marathon runners assessing the weather conditions on the day of the marathon to determine their pace, nutrition, and hydration requirements;
- skydivers assessing weather and wind conditions aloft before a jump;
- scuba divers assessing water temperature and weather conditions before a dive.

4.2.4.7.5 Review of existing dynamic benefit-risk assessment

A review of the dynamic benefit-risk assessment considers preventive measures or benefit enhancements that can have been used. Following the activity, reflection on the results of the activity may be beneficial in improving future activities by reducing the risk or increasing the benefits to participants.

NOTE Hindsight bias can lead to either a positive or a negative distortion of the understanding of what occurred during the activity. For example, riders on a mountain biking course can believe that they handled the course with more skill than they have. During a second lap, they crash and are injured due to their own overestimation of their skills. Hindsight bias can also lead participants to avoid situations they can benefit from due to their overestimation of the risk.

5 Assessment of benefits and risks

5.1 Quantitative and qualitative analysis and scales

Quantitative analysis describes statistical analysis techniques that rely upon numeric data. Whenever possible, facility, service, or product providers should gather numeric data relating to the types, severities and frequencies of injuries suffered by users, so that the data are used for quantitative analysis.

Qualitative analysis describes a wide range of methods that, while not mathematically rigorous, provide practitioners with tools that can facilitate decision-making in the absence of numeric data. These methods can be quite simple or complex. Selection of an appropriate tool by the practitioner is important since many of the available tools come from the occupational health and safety or the consumer product safety sectors and these tools may not be suitable for sport and recreation.

Selection of scales for the type and severity of injuries are not specified in this document; however, there are existing systems, such as the abbreviated injury scale (AIS) system, that should be used for this purpose.

Some examples of scales are provided in [Annex A](#) and [Annex B](#).

5.2 Benefits assessment

5.2.1 General

The public health benefits of sport and recreation are now widely recognized and are probably still under-valued. As research progresses new and surprising benefits are constantly identified for persons of all ages and circumstances. The main objective for activity providers, such as sport and recreational facilities is to maximize the public's gain, which includes physical, mental, emotional, and social well-being and enjoyment^[26].

In theory, benefits can be assessed quantitatively or qualitatively. Quantitative assessment of the benefits of sport and recreational activities is, however, a developing area and there is disagreement on the extent to which quantitative methods are truly quantitative. [Annex E](#) sets out a prototype semi-quantitative methodology. An example of a qualitative methodology is included in [Annex F](#). Users of this document are invited to make their own choice which may depend on their circumstances, knowledge base and preferences.

So far as the benefit assessment process is concerned, the stages of the quantitative and qualitative approaches are the same and are as shown in [Figure 1](#).

5.2.2 Procedure

5.2.2.1 General

The procedure for the assessment of the benefit includes the identification of the expected benefits and local factors, the application of the benefit analysis method.

5.2.2.2 Application of analysis method

Whether to attempt a quantitative analysis or to use a qualitative approach is a decision for the local decision-maker.

5.2.2.3 Identification of expected benefits

Types of benefits to be considered include physical, cognitive, emotional, and social. There are many more examples of specific benefits than can be enumerated, but they all fall within one or more of these four categories. Some of these benefits are immediate and some accrue over long periods of

time (e.g. increased physical fitness, improved psychological outlook). This is one of the reasons why a quantitative assessment is difficult.

5.2.2.4 Identification of local factors

Each location and/or jurisdiction may view benefits provided by sport and recreation differently based on societal objectives and norms. In one place a child falling on a playground is seen as part of their development, whereas in another location it can be viewed as unwanted and too dangerous.

5.2.2.5 Identification of precedents and comparisons

Sports and recreational products, facilities and activities that are identical or even similar are valuable in determining the benefits to the users. Using previous knowledge and experience derived from existing products or facilities may assist in determining benefits that may otherwise be overlooked.

5.2.2.6 Overall benefit evaluation

After performing the steps given in [5.2.2.2](#) to [5.2.2.5](#), the information shall be compiled and documented in a format that can be used to evaluate the benefit/risk relationship, see [Clause 6](#).

5.3 Risk assessment

5.3.1 General

The purpose of risk assessment is to gather information to later evaluate the benefit-risk relationship. The following steps shall be considered:

- a) identification of intended use and reasonably foreseeable misuse;
- b) hazard identification and severity analysis;
- c) risk estimation;
- d) overall risk evaluation.

5.3.2 Criteria for risk acceptability

It is presupposed that the risk criteria follow local legislation and regulations. Where no risk criteria are set by legislation or regulation, the risk criteria may be set by the responsible person, sports federation or by national or regional bodies based on risk appetite.

The risk criteria shall at least take the following into consideration:

- a) the external context;
- b) the relevant national and international standards;
- c) the internal context.

Other relevant information may also be included.

5.3.3 Hazard identification and analysis

5.3.3.1 General

The facility owner, service, or activity provider or their designates should identify and analyse hazards and hazardous situations.

5.3.3.2 Hazard identification

5.3.3.2.1 General

Harm to a person is created by exposure to hazards. Hazards may include the conventional concepts and may also include prevention of participation in activities that bring benefit to the user.

Hazard identification shall take into account:

- a) reasonably foreseeable hazards, hazardous situations, and hazardous events, and the potential harm to users of the facility or environment;
- b) the different materials, parts, mechanisms, and activities provided by the structures, components or apparatus, including cybersecurity related hazards for products using IoT technology, see ISO/IEC 27400^[15] for guidance;
- c) the environment in which the activities are intended to be used;
- d) reasonably foreseeable misuse of the structures, components or apparatus;
- e) cognitive demands and psychosocial aspects that may contribute to the presence of hazards or hazardous situations^{[12],[13]};
- f) all relevant phases of the lifecycle of the product, environment, or space.

NOTE Monitoring of facility and space and over time can contribute to hazard identification

5.3.3.2.2 Identification of hazards

Hazards and hazardous situations shall be identified. Hazards can include, but are not limited to, the following:

- a) objects (e.g. equipment, materials);
- b) chemicals;
- c) biological agents;
- d) physical agents (e.g. sources of energy, high or low temperatures);
- e) animals;
- f) people and play, recreation or sport environment users;
- g) physical or cognitive interaction of the user with the product or space.

5.3.3.2.3 Analysis of hazards

Each hazard should be analysed, based on available data, to determine how it can potentially harm a user of or bystander in the environment.

The analysis should include:

- a) characteristics of the hazard;
- b) conditions under which the hazard can cause harm, including the:
 - 1) amount (i.e. concentration, intensity, or force) of the hazard that can cause harm through a particular means;
 - 2) means by which the hazard can cause harm (e.g. inhalation, ingestion, absorption, injection, or transference of energy);

- 3) frequency or duration, or both, of exposure of a user to the hazard at the amount and through a particular means at which the hazard can cause harm;
- c) interaction of the user with the hazard;
- d) the potential severity of harm presented by the hazard^{[13],[14],[16],[17]}.

NOTE Frequency and severity are used as inputs to the analysis of hazards to help determine whether and how the hazard has the potential to cause harm.

The risk scoring tool described in the EU Commission Decision^[18] includes a scenario-based approach using a severity scale that includes four degrees of severity with variable meaning depending on the type of injury, e.g. bruise, laceration, concussion, entrapment.

5.3.3.2.4 Analysis of multiple hazards

When multiple hazards have been identified, the analysis shall include the effect of any overlap, interaction, or accumulation of the risks related to the hazards. When two or more risks in a single scenario are not connected to a single user scenario, they are assessed as separate risks.

Analysis of hazards should be based on:

- a) scientific data (e.g. material safety data sheets, engineering data sheets, and physical demands tables);
- b) systematic team approaches;
- c) inductive reasoning techniques;
- d) incident histories;
- e) taking of measurements (e.g. air samples and noise, force, and distance measurements);
- f) reviewing activity space organization;
- g) observation of users in similar circumstances;
- h) consultation with users, caregivers, and other stakeholders.

5.3.3.3 Activity identification

User activities associated with risk sources should be identified. The identification of activities should include:

- a) user interaction with structures, components and surfacing and other components in the facility, environment and space;
- b) the environment;
- c) cognitive demands.

5.3.3.4 Hazard elimination

A decision can only be made after hazards have been identified as to whether steps should be taken to eliminate them or to reduce risks. For the purpose of risk assessment, it is assumed that a hazard or a combination of hazards will lead to harm unless measures are taken to eliminate the hazards or implement protective measures.

When a hazard cannot immediately be eliminated, interim controls shall be implemented until the risk assessment is complete and permanent controls can be implemented. This applies to existing facilities or environments installed prior to the publishing of this document.

5.3.4 Likelihood analysis

5.3.4.1 Likelihood of occurrence of potential severity of harm

5.3.4.1.1 General

The likelihood of occurrence of potential severity of harm is a function of:

- a) exposure of users and bystanders to the hazard(s) or hazardous situation(s), including any overlap, interaction, or accumulation from multiple risk sources;
- b) the occurrence of the hazardous event;
- c) the possibility of avoiding or limiting the harm.

5.3.4.1.2 Determining exposure

When determining the overall exposure of users to a hazard or hazardous situation, the following should be considered:

- a) need for exposure;
- b) nature of exposure;
- c) time spent exposed;
- d) number of persons exposed;
- e) frequency of exposure.

5.3.4.1.3 Estimating the likelihood of occurrence of the hazardous event

When estimating the likelihood of the occurrence of a hazardous event, the following factors should be considered:

- a) reliability and other statistical data;
- b) accident history;
- c) history of damage to health.

5.3.4.1.4 Estimating the possibility of avoiding or limiting harm

When estimating the possibility of avoiding or limiting harm, the following factors should be considered:

- a) how quickly the hazardous situation could lead to harm (e.g. suddenly, quickly, or slowly);
- b) the physical ability of the user to avoid or limit harm (e.g. physical condition, physical attributes, reflexes, and agility);

NOTE The intent of b) is to identify situations where the physical demands of the activity can exceed the user's physical, or cognitive abilities, which can result in harm. This information can be used to help identify effective controls to protect the user.

- c) cognitive ability of the user to detect and understand the sequence of events that can lead to a hazardous situation or harm and the consequences that can result from the action. This includes an assessment of the user to judge the level of challenge being presented and applying their ability to avoid the hazard.

5.3.5 Risk evaluation

5.3.5.1 General

The estimation of likelihood and severity of harm shall be combined to determine the level of risk of a hazard or hazardous situation. The level of risk shall be expressed in suitable terms for the type of risk and in a form that aids risk evaluation.

5.3.5.2 Comparison to risk criteria

Where risk criteria exist, the level of risk shall be compared to the risk criteria to make risk control decisions. Residual risks should be considered in light of the benefits considered in [5.3.2](#).

5.4 Risk control measures

5.4.1 Differences of information for safety and disclosure of residual risk

5.4.1.1 Difference between “information for safety” and “disclosure of residual risk”

Posted information signs, labels, hazard warnings, manuals, instructions, and other types of information such as weather reports are risk control measures.

Residual risk(s) can be disclosed in such a way as to control risks and promote risk awareness. Information for safety is the last method of risk control, to be used only when other risk control measures have been exhausted. Information for safety gives instructions on action(s) to take or not to take to avoid a risk.

Information for safety is instructive and should be verified for effectiveness. It can be provided in the form of warnings or (pre)cautions.

Disclosure of individual and overall residual risk(s) gives background and relevant information necessary to explain the residual risk so users can proactively take appropriate actions to minimize exposure to the residual risk(s).

It should be recognised that both the structure and contents of the information as well as the implementation methods may need to be taken into consideration. Information for safety may need to be communicated in different ways, depending on when in the life cycle the information is to be communicated, e.g. as cautionary statements in the accompanying documents or in an advisory notice, or via the user interface of a menu driven device.

5.4.1.2 Information for safety

When developing information for safety, the target audience for the information shall be identified; and the method to be used for delivery of the information shall be determined. The facility owner, service, or activity provider or their designates should provide an explanation of the risk, the consequences of exposure and what should be done or avoided to prevent harm.

In developing the information, the facility owner, service, or activity provider or their designates should consider among others:

- the level of priority appropriate to classify an action (danger, warning, caution, note, etc.);
- the level or detail of information needed;
- the location for the information for safety (e.g. a warning label);
- the wording or pictures to be used to ensure clarity and understandability;
- the immediate recipients (e.g. users, service personnel, installers, patients);

- the appropriate media for providing the information, (e.g. instructions for use, labels, alarms, warnings in the user interface);
- regulatory requirements.

The text for information for safety can be prescribed by local regulations. Information for safety shall give the user clear instructions of what actions to take or to avoid, to avoid a hazardous situation or harm from occurring. This is usually provided in the form of hazard warning signs or labels, see the ISO 3864 series or ANSI Z535.4, or as a hazard warning statement in the instructions according to ANSI Z535.6. Graphical symbols for hazard warnings should be explained in the instructions for use.

5.4.1.3 Disclosure of residual risk(s)

When developing the disclosure of individual or overall residual risk(s). The target audience for the information shall be identified; and the method to be used for delivery of the information shall be determined in order to inform, motivate and enable the user to use the equipment, activity or facility safely and effectively. The facility owner, service, or activity provider or their designates should examine the residual risk(s) identified in the risk assessment to determine what should be disclosed.

The facility owner, service, or activity provider or their designates should consider:

- the level or detail needed;
- the wording to be used to ensure clarity and understandability;
- the immediate recipients (e.g. users, service personnel, installers, users);
- the means/media to be used.

Some examples are given below to illustrate the residual risks associated with using an equipment, activity or facility.

EXAMPLE 1 Skiing involves the risk of falling or running into other skiers and objects such as trees that border the hill. Ski helmets are worn to reduce the severity of a head injury when a fall or collision occurs.

EXAMPLE 2 Internal combustion engines used to power go-karts produce carbon monoxide gas which is toxic at levels exceeding 20 ppm time-weighted average.^[19] Go-karts powered by internal combustion engines can only be used safely in well-ventilated conditions indoors, or preferably outdoors.

6 Comparison of benefits and risks

6.1 General

The process of comparing benefits and risks brings the benefit assessment (see 5.2) and risk assessment (see 5.3) together for a further evaluation and conclusion (see [Figure 1](#) and [Annex D](#)).

The benefit- and risk-related information shall be synthesized to provide a platform upon which to evaluate the balance and to determine if the project moves forward.

Balance between risks and benefits shall be evaluated to:

- provide information to justify decisions;
- inform stakeholders of management's operational intent to achieve objectives;
- establish a baseline metric from which to objectively assess operations in the future.

The results of the evaluation shall be documented.

In some cases, benefit-risk comparison may not be applicable, for example, some leisure activities may be banned, and some equipment designs are not permitted under any circumstances because of the high risk involved.

In assessing the applicability of the benefit-risk comparison, one should consider:

- a) the external and internal contexts;
- b) quality of information:
 - 1) verifying that the risks and benefits are well known;
 - 2) ensuring that risks and benefits are comparable and have been identified in same detail and logic (i.e. for same facility or activities, user groups, time span, surroundings, and other variables).

NOTE 1 The external context can be a factor in setting the tolerable risk. This mainly applies at the facility or product design stage.

NOTE 2 The internal context is relevant to the risk appetite of the facility operator or activity provider.

NOTE 3 The problem with some benefits, such as increased health, is that they accrue over a longer term than the immediate engagement with the product, process, or service and often are not fully credited.

NOTE 4 The benefit-risk comparison can be expressed in terms of a comparison to other marketed products, activities, facilities or services.

6.2 Methodology

6.2.1 General

As a result of the benefit-risk assessment, there are two possible outcomes:

- a) the benefits outweigh the risks, and the activity is viable;
- b) the risks exceed the risk criteria, and the benefits are not sufficient to make the activity viable in its current form.

The decision related to the benefits outweighing the risk either results in the facility or activity moving forward or being re-evaluated for further risk reduction or benefit enhancement, or both.

Where the benefits outweigh the risks and the facility or activity moves forward, the decision shall be validated and documented (see 7.2). Because a residual risk is included in all activities, a periodic re-evaluation shall be done as determined by the facility owner, service, or activity provider or their designates, at least:

- once per year; or
- once per activity season; and
- after a near miss or an accident.

Where the risks outweigh the benefits, the decision may result in a need for further risk reduction and the project needs to return to one of the following two options once risk controls are identified and applied.

- The first is to return the hazard identification and determine if the risks have been adequately reduced for the project to proceed.
- The second option is to return to the beginning of the entire process of the benefit-risk assessment and to begin again with the potential of identifying other users, see 4.2.1.4.

If the balance is unsuitable, the risks may be controlled, or the benefits may be enhanced to achieve a suitable balance.

6.2.2 Benefit enhancement

Benefit enhancement is the process of improving the health and welfare of the group served by the activity, facility, or service. The benefits can be enhanced in many ways, for example, by:

- inclusive design improving the overall safety for all users including those with mobility devices increasing the social benefits of the activity;
- increasing social benefits to users;
- increasing information to the users;
- increasing the exposure to nature and the elements;
- making the activity available to new user groups;
- improving the local environment and/or aesthetics;
- having a positive economic impact.

If benefits are increased following the initial assessment, changes to the benefits assessment shall be updated with the relevant benefit enhancements.

6.2.3 Risk control

Risk control is the process of changing the level of risk to achieve a suitable balance. Decreasing the risk can be the easiest approach to correcting the balance. The risk assessment shall be updated with the risk control measures required.

In some circumstances, increasing the risk can also increase the benefits of the activity, thereby achieving a suitable balance. The risk assessment shall be updated based on any changes determined to be required.

Risk control measures may include (see ISO/IEC Guide 51), but are not limited to:

- a) inherently safe design;
- b) modifying the activity;
- c) delaying the start of an activity;
- d) guards and protective devices;
- e) information for end users;
- f) training of users.

NOTE Inherently safe design can include inclusive design and barrier free design measures. This approach can improve the overall safety for all users including those with mobility devices.

7 Documentation

7.1 General

All the analytical processes shall be documented at a general level.

The particulars and the qualifications of the assessor(s) shall be recorded in the documentation.

7.2 Validation

For the existing facilities and activities, validation of the benefit-risk balance is not a single event, but an ongoing process.

It should consider at least the:

- a) changes in legal regulations, standards, and other regulations;
- b) maturity level of the associated facility or activity;
- c) user information and feedback;
- d) current best practice and best available technologies;
- e) gathered tacit knowledge and competence in organization.

7.3 Benefit assessments

The benefit assessment shall be documented. If an established method ([5.2](#)) is used, the provenance of the method shall be documented. If no established method is used, the approach and rationale used in the analysis shall be documented.

7.4 Risk assessments

The risk assessment shall be documented. If an established method ([5.3](#)), the methods used in the risk assessment shall be documented in the assessment. The provenance of the scoring tools used in the assessment shall be documented.

7.5 Safety-related information

Informational and hazard warnings signs, labels, manuals, instructions shall be documented. Hazard warning signs and labels shall conform to the ISO 3864 series. The hazard warning signs and labels shall be reproduced in the user documentation with an explanation of the meaning of any graphical symbols used.

7.6 Benefit-risk balance

If an established method (see [6.2](#)) is used, the provenance of the method shall be documented. If no established method is used, the method used to determine the benefit-risk balance shall be documented including the approach and rationale used in the analysis. See [Annex D](#).

7.7 Documentation

Prior to launching a new or revised product, activity, facility, or service requiring a benefit-risk analysis, the provider should summarize the available information related to the benefit-risk determination and document the benefit-risk conclusions with rationale as applicable.

At least the following should be documented, as appropriate:

- a) changes in external context;
- b) changes in the internal context, including at least:
 - 1) maturity level of the associated facility or activity;
 - 2) user information and feedback;
 - 3) current best practice and best available technologies;
 - 4) gathered tacit knowledge and competence in organization.

8 Performance and evaluation

8.1 General

The effectiveness of the benefit-risk assessment shall be evaluated using one or more of the common decision-making processes (see [Annex C](#)). The evaluation of the benefits, risks, enhancements, and controls shall include:

- a) the verification, e.g. does the assessment cover the correct service;
- b) validation, e.g. have all aspects of the service been included in the assessment;
- c) acknowledgement of the results of the assessment, e.g., the assessors should affirm the results for the assessment.

The verification shall ensure that the benefit-risk assessment reflects the actual configuration of the service, including the equipment, and site-specific aspects.

8.2 Periodic evaluation

8.2.1 General

The validity and comprehensiveness of the benefit-risk assessment for the service shall be reviewed and evaluated periodically. The frequency of the evaluation shall be determined by the responsible person(s).

The intention of the periodic review process is not to assign blame or recrimination for decisions previously taken, but to improve the benefit-risk assessment.

8.2.2 Revision or updating of the benefit-risk assessment

Any revision to the benefit-risk assessment based on new observations should be subject to the same level of rigor, control, and review as the initial risk assessment. This includes any subsequent identification of risk control measures, if required. Any new safety-related observations shall be assessed using the risk criteria.

New observations related to safety should be compared with the established risk assessment to test the validity of any assumptions made. The following questions should be raised.

- a) Is the intended use still valid?
- b) Are there occurrences of misuse which were not foreseen in the original risk assessment process?
- c) Is there evidence of new hazards or hazardous situations not originally identified in the hazard identification process?
- d) Are the severity and probability estimations for a particular risk still valid?
- e) Is there any evidence that the criteria for risk acceptability should be adjusted?
- f) Is the effectiveness of risk control measures proven adequate?
- g) Does the benefit-risk analysis accurately represent the actual market experience?

If data suggest correction or adjustment of the current risk assessment, the residual risks shall be re-evaluated based on the new data. In addition, the overall residual risk of the equipment, activity or facility should be reviewed.

8.2.3 Action

In a case where the residual risk based on new data is judged unacceptable and the risk/benefit analysis shows the benefit does not outweigh the risk, further risk control is required in two areas:

- a) the equipment, activity or facilities currently installed and used in the market may need to be corrected;
- b) the design of the equipment, activity or facilities manufactured, undertaken or built from that point in time or related processes may need to be revised and implemented.

For equipment currently installed and used in the market, the risk control measures can be different from those applied to equipment in current production. Immediate information (e.g. a customer letter) may be provided to users before risk control measures are developed and verified for effectiveness.

Where modification or replacement of equipment is necessary, the speed of action contributes to the effectiveness of the risk reduction.

When user injury data or manufacturer safety-related notices exist, this information can serve as input to a review of the suitability of the benefit-risk assessment process at planned intervals to ensure continuing effectiveness of the process.

9 Training and competency

9.1 General

A benefit-risk analysis is a thoughtful process, which has an important contribution to make to the operation of sports and recreation. Carrying out a benefit-risk assessment appropriately is a crucial precondition for achieving organizational goals, such as:

- safety;
- health and welfare;
- community coherence.

A benefit-risk assessment shall be conducted by a competent team. This requires an understanding of the relevant principles of the benefit-risk assessments and the field in which it will be carried out.

9.2 Training

9.2.1 General

Where training is required, training shall be provided by a competent trainer or training organization^{[9],[20],[21]}. Training should as a minimum follow the content as outlined in [Figure 1](#). The training program should include documentation of the learning objectives and the extent of the training program.

Instruction about the relevant site-specific equipment and operation aspects according to [4.2.4.6.2](#) and especially [4.2.4.6.3.4](#) should be included.

A certificate may be provided to each trainee following successful completion of the training.

A variety of approaches to training can be useful ^{[22],[23]}.

9.2.2 Content

Training programs for persons who are tasked with conducting benefit-risk assessments should include the following topics:

- a) identification of benefits;
- b) analysis of benefits;
- c) documentation of the benefit assessment;
- d) identification and documentation of risk criteria, e.g. regional or national legislation, regulations, or organizational risk appetite;
- e) identification of activities related to the facility or product;
- f) identification of hazards;
- g) analysis of hazards;
- h) estimation of probability of a specified harm;
- i) evaluation of risk against identified risk criteria;
- j) identification of risk control measures;
- k) evaluation of the benefit-risk relationship;
- l) determination of the appropriate review cycle;
- m) creation of organization-appropriate benefit-risk assessment process;
- n) documentation of the benefit-risk assessment outcome.

9.3 Frequency of training

Trained persons should maintain the currency of their skills and knowledge obtained in the training by regularly attending updated training courses, as appropriate, or required by the relevant professional associations.

Retraining should be done at least once every five years unless a more frequent retraining cycle is determined by a professional organization or the practitioner's employer.

Other mechanisms for controlling the frequency of training may supersede this clause.

9.4 Equivalency to training

Persons who have current relevant benefit-risk assessment experience may be considered equivalent to persons who have received training as described in this clause.

Equivalency may be established through a demonstrated understanding of the subject matter.

9.5 Competency

9.5.1 Persons and teams

A competent person, team or organization is a person or group of persons with current knowledge, training, skill, education, and experience having successfully demonstrated the ability to solve or resolve problems related to the specific scope or subject matter and work through to a solution^[20].

The competent person does not necessarily require any professional licensing related to a specific field of study with a defined scope and governing code of ethics.

There may be circumstances where multiple competencies are required and the assembly of a team of competent persons may be a benefit to the assessment process.

9.5.2 Equivalency

Persons who have current relevant benefit-risk assessment experience should be considered competent.

Equivalency should be established through demonstrated experience.

9.5.3 Organizations

Competent organizations shall demonstrate competency of the persons who conduct benefit-risk assessments for the organization.

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Annex A (informative)

Examples of severity-of-injury scales

A.1 General

The scales provided in this annex are only provided for information. In some jurisdictions, regional or national laws or regulations prescribe the use of a specific approach or methodology.

These scales can be used as part of the risk assessment described in [5.3](#).

A.2 EU RAPEX scale

The following scale in [Table A.1](#) is given for information only.

Table A.1 — Severity of injury

Type of injury	Severity of injury			
	1	2	3	4
Laceration, cut	Superficial	External (deep) (> 10 cm long on body) (> 5 cm long on face) requiring stitches Tendon or into joint White of eye or cornea	Optic nerve Neck artery Trachea Internal organs	Bronchial tube Oesophagus Aorta Spinal cord (low) Deep laceration of internal organs Severed high spinal cord Brain (severe lesion/ dysfunction)
Bruising (abrasion/ contusion, swelling, oedema)	Superficial ≤ 25 cm ² on face ≤ 50 cm ² on body	Major > 25 cm ² on face > 50 cm ² on body	Trachea Internal organs (minor) Heart Brain Lung, with blood or air in chest	Brain stem Spinal cord causing paralysis
Concussion	—	Very short unconsciousness (minutes)	Prolonged unconsciousness	Coma
Entrapment/ pinching	Minor pinching	—	(Use as appropriate the final outcomes of bruising, crushing, fracture, dislocation, amputation, as applicable.)	(Same outcome as for suffocation/ strangulation.)

Table A.1 (continued)

Type of injury	Severity of injury			
	1	2	3	4
Sprain, strain, musculoskeletal disorder	Extremities Joints Spine (no dislocation or fracture)	Knee ligaments strain	Ligament or tendon rupture/tear Muscle tear Whiplash	—
Dislocation	—	Extremities (finger, toe, hand, foot) Elbow Jaw Loosening of tooth	Ankle Wrist Shoulder Hip Knee Spine	Spinal column
Fracture	—	Extremities (finger, toe, hand, foot) Wrist Arm Rib Sternum Nose Tooth Jaw Bones around eye	Ankle Leg (femur and lower leg) Hip Thigh Skull Spine (minor compression fracture) Jaw (severe) Larynx Multiple rib fractures Blood or air in chest	Neck Spinal column
Crushing	—	—	Extremities (fingers, toe, hand, foot) Elbow Ankle Wrist Forearm Leg Shoulder Trachea Larynx Pelvis	Spinal cord Mid-low neck Chest (massive crushing) Brain stem
Amputation	—	—	Finger(s) Toe(s) Hand Foot (Part of) Arm Leg Eye	Both extremities

Table A.1 (continued)

Type of injury	Severity of injury			
	1	2	3	4
Piercing, puncturing	Limited depth, only skin involved	Deeper than skin Abdominal wall (no organ involvement)	Eye Internal organs Chest wall	Aorta Heart Bronchial tube Deep injuries in organs (liver, kidney, bowel, etc.)
Ingestion	—	—	Internal organ injury (Refer also to internal airway obstruction where the ingested object gets stuck high in the oesophagus.)	Permanent damage to internal organ
Internal air way obstruction	—	—	Oxygen flow to brain blocked without permanent consequences	Oxygen flow to brain blocked with permanent consequences
Suffocation/ Strangulation	—	—	Oxygen flow to brain blocked without permanent consequences	Fatal suffocation/ strangulation
Submersion/ Drowning	—	—	—	Fatal drowning
Burn/Scald (by heat, cold, or chemical substance)	1°, up to 100 % of body surface 2°, < 6 % of body surface	2°, 6 % to 15 % of body surface	2°, 16 % to 35 % of body surface, or 3°, up to 35 % of body surface Inhalation burn	2° or 3°, > 35 % of body surface Inhalation burn requiring respiratory assistance
Electric shock	(See also under burns as electric current can cause burns.)	Local effects (temporary cramp or muscle paralysis)	—	Electrocution
Neurological disorders	—	—	Triggered epileptic seizure	—
Eye injury, foreign body in eye	Temporary pain in eye without need for treatment	Temporary loss of sight	Partial loss of sight Permanent loss of sight (one eye)	Permanent loss of sight (both eyes)
Hearing injury, foreign body in ear	Temporary pain in ear without need for treatment	Temporary impairment of hearing	Partial loss of hearing Complete loss of hearing (one ear)	Complete loss of hearing (both ears)
Poisoning from substances (ingestion, inhalation, dermal)	Diarrhoea, vomiting, local symptoms	Reversible damage to internal organs, e.g. liver, kidney, slight haemolytic anaemia	Irreversible damage to internal organs, e.g. oesophagus, stomach, liver, kidney, haemolytic anaemia, reversible damage to nerve system	Irreversible damage to nerve system Fatality
Irritation, dermatitis, inflammation or corrosive effect of substances (inhalation, dermal)	Local slight irritation	Reversible eye damage Reversible systemic effects Inflammatory effects	Lungs, respiratory insufficiency, chemical pneumonia Irreversible systemic effects Partial loss of sight Corrosive effects	Lungs, requiring respiratory assistance Asphyxia

Table A.1 (continued)

Type of injury	Severity of injury			
	1	2	3	4
Allergic reaction or sensitisation	Mild or local allergic reaction	Allergic reaction, widespread allergic contact dermatitis	Strong sensitisation, provoking allergies to multiple substances	Anaphylactic reaction, shock Fatality
Long-term damage from contact with substances or from exposure to radiation	Diarrhoea, vomiting, local symptoms	Reversible damage to internal organs, e.g. liver, kidney, slight haemolytic anaemia	Damage to nervous system, e.g. organic psycho syndrome (OPS; also called chronic toxic encephalopathy, also known as 'painters' disease'). Irreversible damage to internal organs, e.g. oesophagus, stomach, liver, kidney, haemolytic anaemia, reversible damage to nervous system	Cancer (leukaemia) Effects on reproduction Effects on offspring CNS depression
Microbiological infection		Reversible damage	Irreversible effects	Infection requiring prolonged hospitalisation, antibiotics-resistant organisms Fatality

NOTE RAPEX criteria are normally applied to the evaluation of the safety of consumer goods^[6].

A.3 ISO/TR 14121-2 severity of injury

In ISO/TR 14121-2^[24], the severity levels used are:

- catastrophic – death or permanent disabling injury or illness (unable to return to work);
- serious – severe debilitating injury or illness (able to return to work at some point);
- moderate – significant injury or illness requiring more than first aid (able to return to same job);
- minor – no injury or slight injury requiring no more than first aid (little or no lost work time).

A.4 Abbreviated injury scale

The abbreviated injury scale (AIS) is a numerical rating system for quantifying the severity of injury to a human based on body region, anatomic structure, level of injury and injury severity that may be used in the scope of standards intended for safety or injury prevention, see [Table A.2](#). The range of severity is from 1 to 9. This scale was originally conceived as a tool for triaging injuries in hospital emergency departments, based on automotive accident injury data.

Table A.2 — Abbreviated injury scale

Injury severity	Abbreviated injury score
Minor injury	1
Moderate injury	2
Serious injury, but not life-threatening injury	3
Severe injury, potentially life-threatening injury, with survival probable	4