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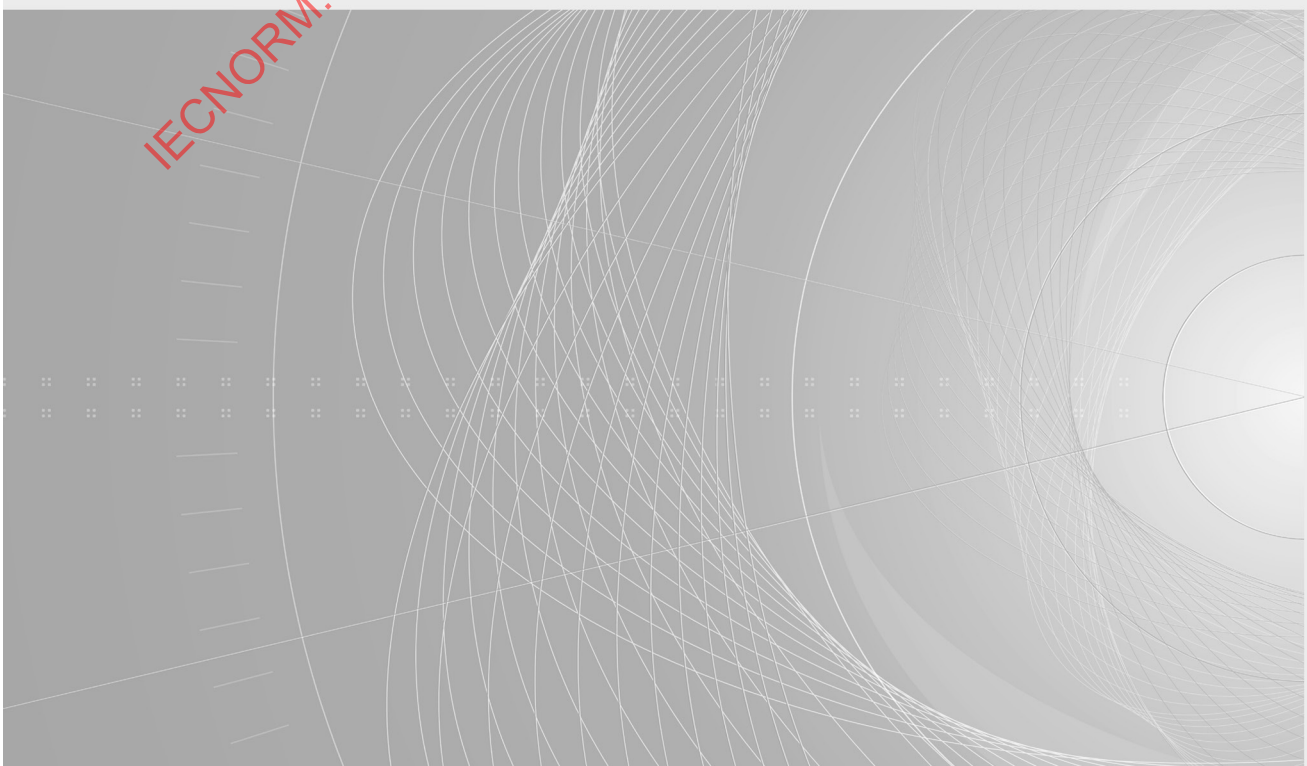
SYSTEMS REFERENCE DELIVERABLE

Active assisted living (AAL) system development guidance for AAL service providers



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Active assisted living (AAL) system development guidance for AAL service providers

INTERNATIONAL
ELECTROTECHNICAL
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ACTIVE ASSISTED LIVING (AAL) SYSTEM DEVELOPMENT GUIDANCE FOR AAL SERVICE PROVIDERS

FOREWORD

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IEC SRD 63219, which is a Systems Reference Deliverable, has been prepared by IEC systems committee Active Assisted Living.

The text of this Systems Reference Deliverable is based on the following documents:

Draft SRD	Report on voting
SyCAAL/247/DTS	SyCAAL/257/RVDTS

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

The language used for the development of this Systems Reference Deliverable is English.

This document was drafted in accordance with ISO/IEC Directives, Part 2, and developed in accordance with ISO/IEC Directives, Part 1 and ISO/IEC Directives, IEC Supplement, available at www.iec.ch/members_experts/refdocs. The main document types developed by IEC are described in greater detail at www.iec.ch/standardsdev/publications.

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

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- withdrawn,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

INTRODUCTION

AAL systems can comprise a compilation of components, systems, and services from multiple vendors and service providers. It is important that the parts of an AAL system are compatible in terms of safety, usability, accessibility, performance, and interoperability. It is also important that the security and privacy of the AAL user is protected.

This document provides guidelines for the design of AAL systems to ensure that the AAL systems are designed and developed to be compatible with and to meet the needs of the AAL user.

This document is intended for AAL service providers and AAL service organizations responsible for using, installing, and supporting AAL systems.

ACTIVE ASSISTED LIVING (AAL) SYSTEM DEVELOPMENT GUIDANCE FOR AAL SERVICE PROVIDERS

1 Scope

This document provides guidance for AAL service providers to design, procure, implement, and maintain AAL systems throughout their service life.

The objective is to ensure that AAL systems are designed, configured, and installed to meet the needs of the AAL user and the requirements from applicable industry standards and global regulations. Ultimately, however, users of this document are responsible for checking the applicable laws and regulations.

This document is intended for use by persons and organizations acting within an AAL service organization such as employees, contractors, and consultants and those working with external AAL technology vendors, as appropriate.

This document provides guidance on ensuring that AAL systems meet the needs of the AAL service user, in terms of safety, security, privacy, usability, accessibility, performance and interoperability.

This document provides guidance to supplement the AAL service organization's established policies and procedures.

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.

IEC TS 63134:2020, *Active assisted living (AAL) use cases*

3 Terms and definitions

For the purposes of this document, the terms and definitions in given in IEC TS 63134:2020 and the following apply.

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

- IEC Electropedia: available at http://www.electropedia.org/
- ISO Online browsing platform: available at http://www.iso.org/obp

3.1
AAL
active assisted living
concepts, products, services, and systems combining technologies and social environment with the aim of improving the quality of people's lives

[SOURCE: IEC 60050-871:2018, 871-01-02, modified – The deprecated term "ambient assisted living" has been omitted.]

3.2
AAL service organization
organization responsible for ensuring that the AAL system meets the needs of the AAL user

Note 1 to entry: An AAL service organization comprises AAL service provider employees, contractors, agents, and healthcare consultants responsible for using, installing, and supporting AAL systems.

3.3
residual risk
risk remaining after risk reduction measures have been implemented

[SOURCE: ISO/IEC Guide 51:2014, 3.8]

3.4
validation
confirmation, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled

[SOURCE: ISO 9000:2015, 3.8.13, modified – Notes to entry have been omitted.]

3.5
verification
confirmation, through the provision of objective evidence, that specified requirements have been fulfilled

[SOURCE: ISO 9000:2015, 3.8.12, modified – Notes to entry have been omitted.]

3.6
service life
the period from initial operation to final withdrawal from service of a structure, system, or component

[SOURCE: IEC 60737:2010, 3.6, modified – Note to entry has been omitted.]

4 AAL service organization responsibilities

The AAL service organization is responsible for:

a) developing or reviewing the AAL system specification based on the AAL system development process as described in Clause 5;

NOTE The AAL system can be designed by an entity that is not part of an AAL service organization.

b) designing/developing/implementing the AAL system;

c) validating that the system meets the needs of the AAL user as described in Clause 6;

d) verifying that the system meets the AAL system requirements as described in Clause 7;

e) developing policies and procedures and obtaining the applicable approvals specific to the implementation of an AAL system as described in Clause 9;

f) Maintain the AAL system throughout its service life.

5 AAL system development process

5.1 General

AAL systems are developed with consideration of representative use case analysis, AAL architecture, international and industry standards, and regulatory requirements as fundamental inputs together with consideration of AAL user needs and the environment of use as shown in Figure 1.

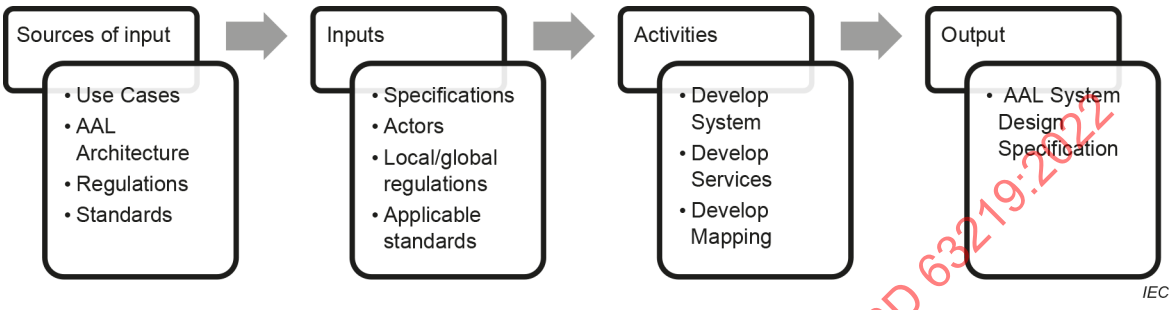

Figure 1 – AAL system design progression (inputs to output)

5.2 Use cases

AAL use cases are based on real-world applications. The use case development process is described in detail in IEC TS 63134. To summarize the process described in IEC TS 63134, use cases are developed based on the needs of an AAL user considering levels of criticality (major, moderate, minor) and required levels of assistance (level 0 to level 3) in the areas of:

– Prevention and management of chronic long-term conditions;
– Social interaction;
– Mobility;
– Health and wellness;
– Management of daily life activities.

Use cases specify AAL user requirements and identify the elements of an AAL system. User requirements include:

– Context (environment) of use – global, public buildings, personal mobile phone, personal vehicle, home, body and personal, workspace;
– System component level – AAL devices, (platform) backend system, applications, services, and AAL information systems;
– Actors – person, technical component, or organization.

NOTE 1 Refer to IEC 60050-871 for context of use definitions.

NOTE 2 Refer to IEC TS 63134 for more detailed information of the user requirements in the dashed list above.

A use case example is shown in Figure 2.

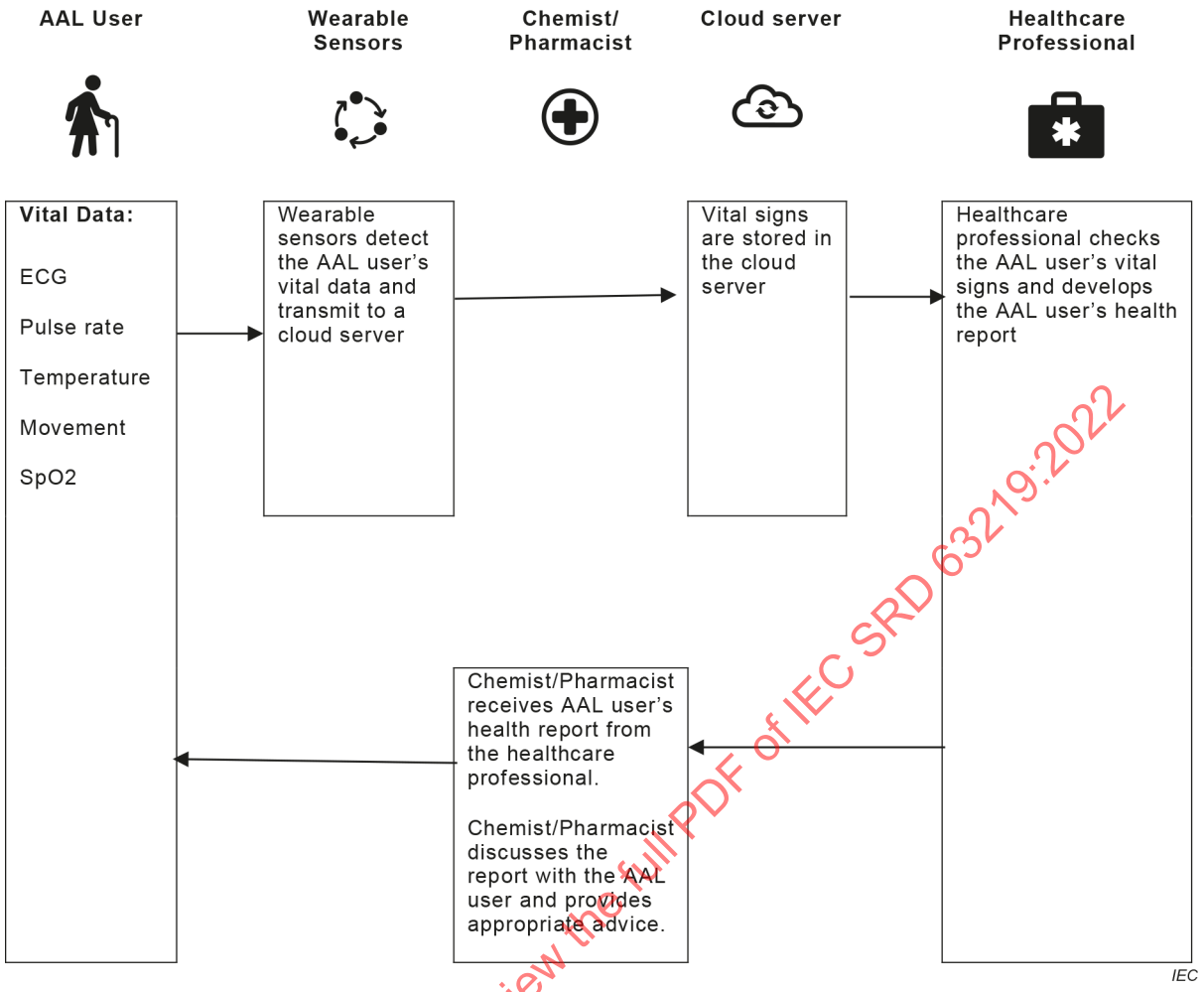

Figure 2 – Example: Use case 1 from IEC TS 63134

5.3 AAL reference architecture and architecture model

Information to guide the development and implementation of AAL systems and services can be found in the IEC 63240 series, published under the general title Active assisted living (AAL) reference architecture and architecture model. IEC 63240-1 describes the generic concepts and terminology of the reference architecture and provides rules of design for the development of AAL systems and services with an emphasis on interoperability.

IEC 63240-2 provides details of the architecture model and its relationship to the use case structure described in 5.2 of this document. IEC 63240-2 also describes AAL systems architecture and interoperability and provides information for designers to account for usability, accessibility, security, privacy, and trustworthiness.

5.4 Applicable standards

Applicable industry standards for AAL systems and AAL technical components, including electrical safety, electromagnetic compatibility (EMC), risk management, usability, sustainability, and assistive products should be considered.

NOTE The IEC SYC AAL Standards Inventory containing a list and description of applicable standards is publicly available at https://www.iec.ch/dyn/www/f?p=103:252:0::::FSP_ORG_ID:11827

5.5 Global/local regulatory requirements

Regulatory requirements for data security, privacy, e-Health, ethics, medical device registrations, and training and education should be considered.

NOTE The IEC SYC AAL Regulatory Inventory containing a list of applicable regulations is publicly available at https://www.iec.ch/dyn/www/f?p=103:252:0::::FSP_ORG_ID:11827

6 AAL system validation

The AAL service organization is responsible for validation to ensure that the AAL system meets the needs of the AAL user in terms of functionality, ease of use and residual risk. Usability engineering (human factors engineering) techniques should be implemented to ensure that the AAL system meets its intended purpose to meet the needs of the AAL user based on the specific use case. System validation can be carried out by another entity, but the AAL service organization is responsible for ensuring that the validation is completed, and that the results are reviewed and accepted. See Annex A for examples of standards and guidance related to usability/human factors/risk engineering.

7 AAL system verification

7.1 Industry standards

The AAL service organization is responsible for verification to ensure that the technical components actors comprised within the AAL system have the applicable certifications and meet the requirements of the applicable industry standards. Such standards include but are not limited to international standards for electrical and mechanical safety, electromagnetic compatibility (EMC), risk, usability, sustainability, and assistive products. System verification can be carried out by another entity, but the AAL service organization is responsible for ensuring that the verification is completed, and that the results are reviewed. See Figure 3 for steps in AAL system verification/validation.

The AAL service organization should identify any gaps in the industry standards.

7.2 Regulations

The AAL service organization is responsible for ensuring that AAL systems meet the requirements of any regulatory laws and directives. Such laws and directives can include those related to privacy, security, sustainability, and medical device registration, if applicable.

Annex B contains an example of International Standards and regulation tracking.

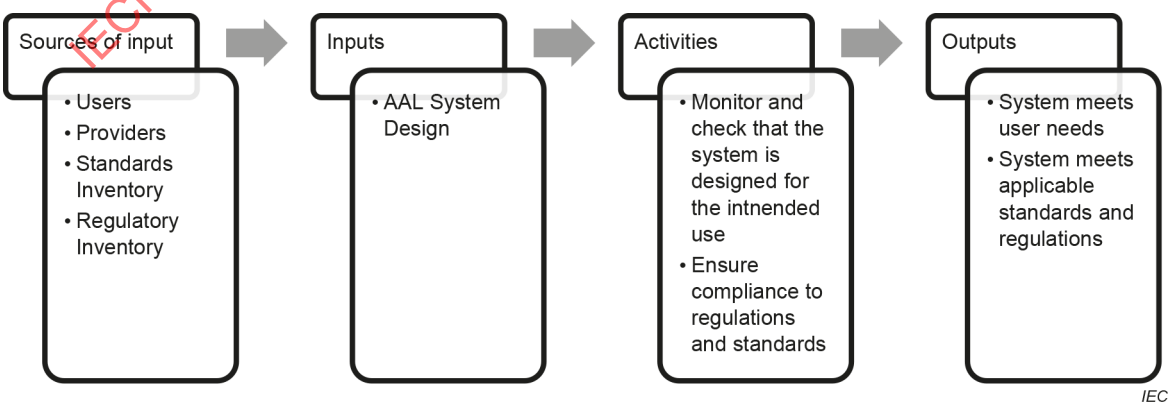

Figure 3 – AAL system validation/verification

8 AAL system evaluation

8.1 Identifying gaps in the design of AAL technical component actors

Technical component actors in an AAL system can be commercially available off-the-shelf devices that meet the relevant industry standards. However, it is possible that these devices will not be designed or evaluated to be used by a typical AAL user or operator with cognitive or physical limitations.

EXAMPLE 1 A mobile phone designed with too small a touchscreen and user interface would be difficult to operate for a user with vision or dexterity limitations.

EXAMPLE 2 Alert system with too low an audio volume would not be recognized by a user with hearing limitations.

Technical component actors operating within the AAL system should be reviewed against relevant human factors and accessibility standards to ensure that gaps are minimized in meeting the needs and considering the limitations of the intended AAL user and operator. AAL users are typically of an older age or disabled with related issues such as lack of mobility, vison and/or hearing problems, lack of muscle strength, memory, and cognitive issues. AAL operators are usually family member care givers who could be under stress with this added responsibility. AAL users and operators may have a limited education or not be a native speaker of the language used. As a result, devices and systems should be designed with easy-to-understand instructions and user interfaces.

The AAL system environment is uncontrolled in terms of temperature, humidity, altitude, ambient lighting, noise, unreliable AC mains connection and can be susceptible to power outages. Therefore, devices and systems should be designed to consider the limitations of operation in an uncontrolled environment of use.

8.2 Closing gaps

A mechanism should be in place for AAL service organizations to provide feedback to suppliers of AAL services and AAL components identifying the potential design gaps as noted in 8.1 and a method for ensuring that the gaps are closed or minimized before the AAL system is used. Closing the gaps could include redesigning in such a way that would result in the application of additional industry standards.

Annex C provides an example of the development and verification and validations processes.

9 AAL service organization recommendations

9.1 Policies and procedures

9.1.1 General

AAL service organizations should have written policies and procedures in place to ensure that AAL systems are developed following defined and established processes to meet the needs of the AAL user, ensure that technical components meet the applicable industry standards, and ensure that the applicable regulatory requirements are followed.

These policies and procedures can be part of an established quality management system.

These policies and procedures should be applicable for the implementation of an AAL system.

9.1.2 Internal to the AAL service organization

Policies and procedures internal to the AAL service organization should include but are not limited to the following areas:

- Organization structure and leadership;
- Quality management and improvement;
- Process management;
- Documentation and information management;
- Training and education of staff.

9.1.3 External to the AAL service organization

Policies and procedures external to the AAL service organization should include but are not limited to the following areas:

- Customer focus to monitor the needs of the AAL user;
- Monitoring for changes in the AAL environment;
- Monitoring for changes in regulatory requirements or applicable standards.

9.2 AAL service organization approvals

Authorities at the regional, country, and local levels can have requirements as to the appropriate approvals needed, which AAL service providers are responsible for checking and putting in place.

NOTE Examples are Care Quality Commission (CQC) in UK, individual state requirements in the US, and individual province and territory requirements in Canada.

The IEC SYC AAL Regulatory Inventory contains additional country approval information.

Annex A
(informative)

International Standards on usability, human factors, and risk management

Table A.1 provides examples of usability, human factors, and risk management standards and the associated technical committees.

Table A.1 – Examples of International Standards on usability, human factors, and risk management

Reference	Standard	Title	Technical Committee
Usability	IEC 60601-1-6	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability	IEC SC 62A
Risk management	IEC 62366-1	Medical devices – Part 1: Application of usability engineering to medical devices	IEC SC 62A/ISO TC 210
Human factors	ISO 9241-210	Ergonomics of human-system interaction – Part 210: Human-centred design for interactive systems	ISO TC 159
Risk management	ISO 14971	Medical devices – Application of risk management to medical devices	ISO TC 210/IEC SC 62A
Risk management	ISO 31000	Risk management – Guidelines	ISO TC 262

Annex B
(informative)

Standards/regulatory tracking

Table B.1 and Table B.2 give examples of standards and regulatory tracking.

Table B.1 – Example of standards/regulatory tracking (device)

Actor (hardware)	Aspect	Standard/ Regulation	Does the standard provide 100 % coverage?	Entity responsible for performing the verification/ validation activities	Type of conformance required
Wellness monitor	Safety	IEC 62368-1	Yes	AAL service organization	CB report
	EMC	EMC Directive Directive 2014/30/EU	Yes	Third party test laboratory	IEC report
	Hazardous Substance Management	RoHS Directive 2011/65/EU	Yes	Supplier	Technical file
	Battery	IEC 62133-2	Yes	Supplier	IEC report
	Accessibility	ISO/IEC Guide 71	No	AAL service organization	Further evaluation necessary

Table B.2 – Example of standards/regulatory tracking (system)

Aspect	Does the regulation provide 100 % coverage?	Entity responsible for performing verification/validation	Type of conformance required
Usability/Human factors	Yes	AAL service organization	Usability report
Privacy/security	Yes	Third-party contractor	System evaluation report
Interoperability	Yes	Third-party contractor	Technical file

Annex C
(informative)

AAL system development

C.1 General

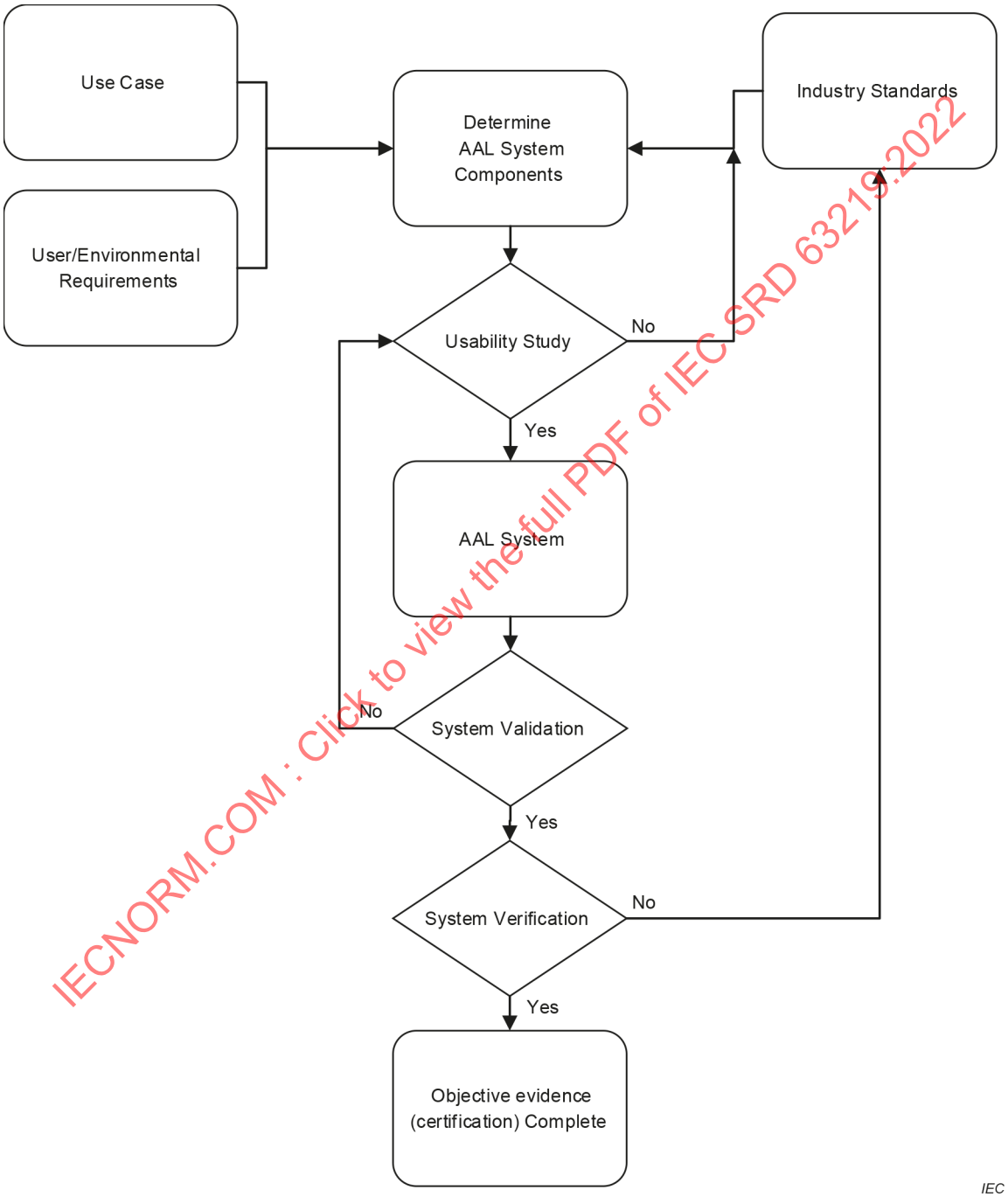

Figure C.1 − AAL system development

Figure C.1 shows the flow of AAL system development.

C.2 Determine the user and use environments

C.2.1 User considerations when developing AAL systems

- Vision: acuity, colour vision, contrast
- Hearing: limitations in pitch, vocal variety; volume of alerts/alarms
- Speech – for speech recognition systems
- Language – non-native speakers
- Sensory processing
- Mobility
- Stability
- Ability to respond: simple, intuitive, easy-to-understand information regardless of user knowledge, language, and/or ability to concentrate
- Ability to process information
- Ability to understand written and verbal instructions
- Cognitive abilities: short- and long-term memory, decision making
- Unintended use

C.2.2 Environmental considerations when developing AAL systems

- Environment of use – home, outdoor, automobile, wheelchair
- AC mains power – stability, reliability
- Back-up power/emergency generator – availability, reliability
- Temperature and humidity
- Altitude
- Acoustic noise
- Lighting
- Contaminants
- Pets: guide animals, or companion animals
- Identify care giver
- Other members of household
- Unintended use

C.3 Determine AAL system components

Annex E of each use case will provide an overview of the AAL system composition as it relates to the y-axis of the AAL architecture model shown in Figure 1 of IEC 63240-2:2020.

C.4 Develop usability/human factor evaluation

A usability study will determine if an AAL user can safely and effectively use the AAL system components as determined in the user considerations of C.2.1.

C.5 AAL system validation

Validation will determine if the AAL system meets the needs of the AAL user and the intended environment as determined by C.2.1 and C.2.2. See also Clause C.7.