

Edition 1.0 2022-02

SYSTEMS REFERENCE DELIVERABLE



IEC SRD 63219:2022-02(en)



THIS PUBLICATION IS COPYRIGHT PROTECTED Copyright © 2022 IEC, Geneva, Switzerland

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from either IEC or IEC's member National Committee in the country of the requester. If you have any questions about IEC copyright or have an enquiry about obtaining additional rights to this publication, please contact the address below or your local IEC member National Committee for further information.

IEC Secretariat 3, rue de Varembé CH-1211 Geneva 20 Switzerland Tel.: +41 22 919 02 11 info@iec.ch www.iec.ch

About the IEC

The International Electrotechnical Commission (IEC) is the leading global organization that prepares and publishes International Standards for all electrical, electronic and related technologies.

About IEC publications

The technical content of IEC publications is kept under constant review by the IEC. Please make sure that you have the latest edition, a corrigendum or an amendment might have been published.

IEC publications search - webstore.iec.ch/advsearchform The advanced search enables to find IEC publications by a variety of criteria (reference number, text, technical committee, ...). It also gives information on projects, replaced and withdrawn publications.

IEC Just Published - webstore.iec.ch/justpublished Stay up to date on all new IEC publications. Just Published details all new publications released. Available online and once a month by email.

IEC Customer Service Centre - webstore.iec.ch/csc If you wish to give us your feedback on this publication or need further assistance, please contact the Customer Service CS.iteh.ai)

IEC Products & Services Portal - products.iec.ch

Discover our powerful search engine and read freely all the publications previews. With a subscription you will always have access to up to date content tailored to your needs.

Electropedia - www.electropedia.org

The world's leading online dictionary on electrotechnology, containing more than 22 300 terminological entries in English and French, with equivalent terms in 19 additional languages. Also known as the International Electrotechnical Vocabulary (IEV) online.

EC SRD 63219:2022

https://standards.iteh.ai/catalog/standards/sist/49ab846a-3e4b-4950-8cdf-a75799f89c07/iec-srd-63219-2022



Edition 1.0 2022-02

SYSTEMS REFERENCE DELIVERABLE

iTeh STANDARD

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

(standards.iteh.ai)

IEC SRD 63219:2022

https://standards.iteh.ai/catalog/standards/sist/49ab846a-3e4b-4950-8cdf-a75799f89c07/iec-srd-63219-2022

INTERNATIONAL ELECTROTECHNICAL COMMISSION

ICS 03.080; 11.180

ISBN 978-2-8322-1083-5

Warning! Make sure that you obtained this publication from an authorized distributor.

CONTENTS

FOREWORD	4
INTRODUCTION	6
1 Scope	7
2 Normative references	7
3 Terms and definitions	7
4 AAL service organization responsibilities	
5 AAL system development process	
5.1 General	
5.2 Use cases	
5.3 AAL reference architecture and architecture model	
5.4 Applicable standards	
5.5 Global/local regulatory requirements	
6 AAL system validation	
7 AAL system verification	11
7.1 Industry standards	
7.2 Regulations	11
8 AAL system evaluation i.Teh . STANDARD	12
8.1 Identifying gaps in the design of AAL technical component actors	12
8.2 Closing gaps	
9 AAL service organization recommendations	12
9.1 Policies and procedures and ards.iteh.ai)	12
9.1.1 General	
9.1.2 Internal to the AAL service organization 0.2.2.	13
9.1.3 Externational Strate And St	13
9.2 AAL service ofganization approvals 189c07/iec-srd-63219-2022	13
Annex A (informative) International Standards on usability, human factors, and risk	
management	
Annex B (informative) Standards/regulatory tracking	
Annex C (informative) AAL system development	16
C.1 General	
C.2 Determine the user and use environments	
C.2.1 User considerations when developing AAL systems	
C.2.2 Environmental considerations when developing AAL systems	
C.3 Determine AAL system components	
C.4 Develop usability/human factor evaluation	
C.5 AAL system validation	
C.6 AAL system verification C.7 Identify gaps in AAL system design	
C.7 Identify gaps in AAL system designC.8 Objective evidence (Certification)	
Bibliography	
ыынодгарну	19
Figure 1 AAL system design progression (inputs to system)	~
Figure 1 – AAL system design progression (inputs to output)	
Figure 2 – Example: Use case 1 from IEC TS 63134	
Figure 3 – AAL system validation/verification	11

Table A.1 – Examples of International Standards on usability, human factors, and risk	
management	14
Table B.1 – Example of standards/regulatory tracking (device)	15
Table B.2 – Example of standards/regulatory tracking (system)	15

iTeh STANDARD PREVIEW (standards.iteh.ai)

IEC SRD 63219:2022 https://standards.iteh.ai/catalog/standards/sist/49ab846a-3e4b-4950-8cdf-a75799f89c07/iec-srd-63219-2022 - 4 -

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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

FOREWORD

- 1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
- The formal decisions or agreements of IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested IEC National Committees.
- 3) IEC Publications have the form of recommendations for international use and are accepted by IEC National Committees in that sense. While all reasonable efforts are made to ensure that the technical content of IEC Publications is accurate, IEC cannot be held responsible for the way in misinterpretation by any end user.
- 4) In order to promote international uniformity, IEC National Committees undertake to apply IEC Publications transparently to the maximum extent possible in their national and regional publications. Any divergence between any IEC Publication and the corresponding national or regional publication shall be clearly indicated in the latter.
- 5) IEC itself does not provide any attestation of conformity. Independent certification bodies provide conformity assessment services and, in some areas, access to IEC marks of conformity. IEC is not responsible for any services carried out by independent certification bodies.
- 6) All users should ensure that they have the latest edition of this publication.
- 7) No liability shall attach to IEC or its directors, employees, servants or agents including individual experts and members of its technical committees and IEC National Committees for any personal injury, property damage or other damage of any nature whatsoever, whether direct or indirect, or for costs (including legal fees) and expenses arising out of the publication, use of, or reliance upon, this IEC Publication or any other IEC Publications.
- 8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.
- 9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

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.

iTeh STANDARD PREVIEW (standards.iteh.ai)

IEC SRD 63219:2022 https://standards.iteh.ai/catalog/standards/sist/49ab846a-3e4b-4950-8cdf-a75799f89c07/iec-srd-63219-2022

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.

iTeh STANDARD PREVIEW (standards.iteh.ai)

IEC SRD 63219:2022 https://standards.iteh.ai/catalog/standards/sist/49ab846a-3e4b-4950-8cdf-a75799f89c07/iec-srd-63219-2022

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.

(standards.iteh.ai)

2 Normative references

IEC SRD 63219:2022

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.

- 8 -

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

service life

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

(standards.iteh.ai)

the period from initial operation to final withdrawal from service of a structure, system, or component <u>IEC SRD 63219:2022</u>

https://standards.iteh.ai/catalog/standards/sist/49ab846a-

[SOURCE: IEC 60737320104356, modified 79Note to rentry 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;

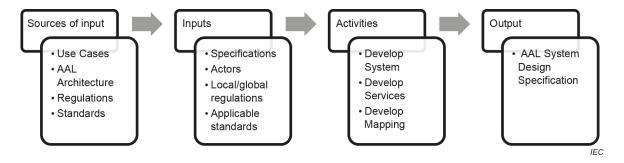
NOTE The AAL system can be designed by an entity that is not part of an AAL service organization.

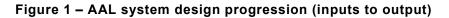
- b) designing/developing/implementing the AAL system;
- c) validating that the system meets the needs of the AAL user as described in Clause 6;
- d) verifying that the system meets the AAL system requirements as described in Clause 7;
- e) developing policies and procedures and obtaining the applicable 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.





5.2 Use cases

iTeh STANDARD

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;

IEC SRD 63219:2022

- Mobility; https://standards.iteh.ai/catalog/standards/sist/49ab846a-
- Health and wellness:4b-4950-8cdf-a75799f89c07/iec-srd-63219-2022
- 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.