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Executive summary

This report summarizes the findings of the AALIANCE2 project with regard to the relevance of standards and interoperability to the field of Ambient Assisted Living (AAL). The vision and promise of AAL is to provide an intelligent environment surrounding the user, an environment that monitors and "understands" what the user is doing – or trying to do, an environment that offers support when needed, and remains largely invisible otherwise. The implementation of this vision requires many "building blocks": system components and human services need to integrate, to work together, in order to provide this desired ambient support for the user. This capability is called *"interoperability"*. Standards are arguably the most important "building block" for enabling interoperability among AAL systems and system components, and as such of high relevance for the development of *AAL products*. However, the availability of standards is not sufficient to really solve the challenge of an interoperable AAL product world – there are other important building blocks like integration profiles, certification programs, and more. Furthermore, it should be noted that a standards-based interoperable product range has implications on the business model, which may be positive or negative depending on the market structure.

In chapter 2, this document summarizes the results of three expert workshops organized by the AALIANCE project in order to discuss topics of key enabling technologies, standards and AAL software infrastructure (so-called middleware). Chapter 3 then condenses the "lessons learned" from the expert workshops as well as a number of further relevant topics that surfaced during the work of the AALIANCE2 project into a set of recommendations for activities that foster interoperability in integrated AAL applications, including European standardisation and certification activities and processes. These recommendations are intended as a contribution to the revised AALIANCE2 Strategic Research Agenda and Roadmap:

- the need for a European AAL Standardization Watch Initiative;
- a preparatory action towards a standardized AAL reference architecture;
- the set-up of an organisation for the development of Integration Profiles for AAL;
- a European certification programme for AAL products;
- a study group on the interactions between AAL and the Medical Device Directive;
- consultations on a modernised data protection law;
- more large scale AAL pilots;
- design for all and reconfigurable user interfaces as design principle for AAL products;
- the use, and freedom of choice, of AAL middleware for AAL projects;
- the lifting of the now starting national AAL standardisation work to an European level;
- recommendations on the standardisation needs of key enabling technologies.

Finally, the conclusion offers an outlook on the extended second version of this document that will be published in February 2014, which will add information e. g. on the current activities in this field in Japan and the USA.

The authors wish to stress that feedback – opinions, corrections, contributions – on this document are welcome. Contributions should be sent by mail to aaliance2@offis.de and will be taken into account for the revised second release of this document.

1 Introduction

This report summarizes the findings of the AALIANCE2 project with regard to the relevance of standards and interoperability to the field of Ambient Assisted Living (AAL). For this purpose it is helpful to first remember the comprehensive "vision" and promise of AAL as it was conceived when the research topic emerged. The following two paragraphs are cited from two publications (originally in German language) published in 2008:

"The forecasts about the social changes in our society are clear: We are living in a society where age and individualisation are increasing, while youth and community are decreasing. This means that the number of old and single people is continuously growing. This development will cause an increasing need for new offers of orientation, assistance and help for young and old people. We, therefore, have a need for technical systems that can take over or alleviate a – desired – part of daily life activities." [1]

"Ambient Assisted Living (AAL) denotes developments and assistive systems that create an intelligent environment. Through this technical support people are disburdened primarily in situations of exhaustion, excessive demands, and excessive complexity. The assistive systems should support the user in his or her daily activities as good as possible and almost invisibly, and take over control tasks. Particularly the mature person is enabled by technical assistance to mostly compensate age related limitations. From the perspective of information and communication technologies (ICT), AAL is characterised by the wide spectrum of solutions and the high level of interoperability required for a successful development of integrated solutions. Assistive systems are often personalised and offer reminder functions, e.g. for medication intake, they suggest activities, e.g. during a rehabilitation training programme, they train cognitive capabilities for the preservation of mental capacity, or they support mobility at home and outside. The various AAL applications often interact with sensors in an intelligent environment in order to capture input data for the assistive system. AAL is based on the use of ICT in devices of daily life. Highly integrated and at the same time distributed applications with a high communication capability are needed to provide the required environmental and processing intelligence for the user. Capturing of the required data (vital parameters, environmental data) takes place via sensors either close to the human body, or integrated into the environment. The variety of ICT technologies used ranges from intelligent data processing to automated decision support. The interaction of the user with the various applications should be as intuitive as possible. The system should adapt to the user context and the physiological and cognitive conditions of the user. The user can display and, if needed, interact with the data using ergonomic user interfaces and terminal devices, whereas older people, physicians or nurses and carers might be users of the system. Therefore, AAL applications always address interfaces to other systems within an eHealth based integrated healthcare sector. AAL should offer low-cost solutions that are relatively easy to install and at the same time almost maintenance free. These advantages make AAL interesting for the complete private sector." [2]

1.1 Interoperability

As the section above impressively shows, the vision and promise of AAL is more than "a device and a service" – the vision is to provide an intelligent environment surrounding the user, an environment that monitors and "understands" what the user is doing – or trying to do, an environment that offers support when needed, and remains largely invisible otherwise. It is clear that an implementation of this vision requires many "building blocks" need to integrate in order to provide the desired ambient support for the user and coordinated service delivery oriented on the user's needs: Components (e.g. sensors, actors, networks, reasoning components, user interfaces), services (e.g. concierge services, meals on wheels, mobility and autonomy support) and processes (e.g. health, care and

social services). This capability of working together seamlessly is denoted by the term *"interoperability"*. One (out of many) definitions of this term from a technical perspective can be found in the IEEE Standard Computer Dictionary [3]: "*Interoperability: the ability of two or more systems or components to exchange information and to use the information that has been exchanged.*"

It should be noted that interoperability can be addressed on several layers or levels. For example the ETSI report on interoperability and conformance testing [4] distinguishes four layers, the "protocol interoperability", i.e. the capability of exchanging bits and bytes (or packets) over the communication link, "service interoperability", i.e. the capability of exchanging well-formed messages implementing a service call (this is also called syntactic interoperability), "application interoperability", i.e. the correct interpretation of the data exchanged by all components of the application (also called semantic interoperability), and finally, "user perceived interoperability", i.e. the ability of the user to use the system as intended. It is clear that the layers are interdependent: user-perceived interoperability will only be possible if all components correctly interpret the data exchanged, which in turn requires an ability to exchange well-formed messages, which in turn requires the ability to exchange bits and bytes. It is also clear that a system that does not achieve all layers of interoperability is not acceptable from a user perspective, because in the end user perceived interoperability is what counts.

It can be argued that *interoperability* is a key requirement for the success of AAL systems on the market, for a number of reasons:

- *Variety of user requirements and preferences:* One characteristic property of older people as the main customer group for AAL systems is the very large variety of needs and preferences, compared to younger people. This is on one hand due to the large number of possible physical or cognitive limitations and chronic diseases that may or may not be present, and on the other hand due to the individual experience with, and acceptance of technical systems in general, and computers in particular. This means that a "one size fits all" product will hardly be accepted on the market. Successful solutions will have to be modular and adaptable to individual user needs and preferences.
- *Need for "future proof" systems:* As a user's health status and individual limitations change over time, an AAL system will have to be extended or complemented with additional modules whenever a new need arises. It is unlikely that users will accept that in each of these cases a system needs to be completely exchanged by a different one (with possibly different user interface).
- *Integration with existing infrastructure:* AAL systems that make use of sensors or actors embedded in the environment need to be adapted for the layout of each individual apartment. Depending on the number of rooms, doors, electrical appliances etc. the number and location of components will vary. Furthermore, in apartments where a home automation infrastructure (such as a KNX, LON or BACnet field bus) is already available, users will probably not accept that the complete network (including all cables in the walls) need to be exchanged only because the AAL system only supports a different home automation network. Again, this requires a significant amount of modularity in the product design.
- *Integration with local service providers:* AAL systems will most often have to integrate with local service providers delivering services such as nursing care, concierge services, meals on wheels, local transportation etc. Therefore, in each city or region the system will have to interact with different providers.
- *No comprehensive product programme:* Unlike markets such as the medical device market, where a few "big players" offer comprehensive product programmes covering all needs of a potential customer, the AAL sector is rather dominated by small and medium-sized enterprises (SMEs) offering innovative products. It is

unlikely that in this situation a single vendor will be able to offer a comprehensive product programme covering all needs of the customer base. This in turn makes it necessary to combine products from different vendors in order to address users' needs.

- *Freedom of choice:* From the user perspective, interoperability is very much desirable because it enables the user to choose over different products and services, and adapt a system according to the current needs, but also to the available financial and material means, which is especially important in times of economic crisis.

This is where standards come „into play": If the interfaces between systems and system components can be defined precisely through vendor-independent standards, then it might be possible to simply connect systems and system components and achieve a seamless interoperability, so that from the user perspective the system seems to be all of a piece – just like Lego™ building blocks can be combined many in different ways.

1.2 Standards

Standards play an important, although largely invisible, role in our daily lives. For example, this document, in printed form, is formatted in A4 (which is a standard), and if read in electronic form, the computer on which the document is read is most likely plugged into a 230V electrical outlet at least now and then (which is also a standard).

Standards define consistent interfaces enabling the interoperability and exchange-ability of different components; they define safety requirements or permit service offerings to be compared. They are developed by expert committees such that they solve certain tasks in a way that does not favour any specific party (individual or organisation) – this vendor-neutral nature is a mandatory requirement for all official standards published e.g. by standards bodies such as ISO, IEC, ITU, CEN, CENELEC or ETSI. Standard documents are voluntary, neutral recommendations that can be used by everyone – they become mandatory only if a law explicitly requires compliance with a certain standard or set of standards. An example for this is the medical device market, where the EU maintains an official list of "harmonized standards"[1] that must be complied with by every product placed on the EU market that falls within the scope of the Medical Device Directive 93/42/EEC [6].

International and European standards reduce national trade barriers and open the international market for products and innovations. Due to adoption agreements, all European standards (EN) must be adopted into identical national standards by all members of CEN and CENELEC, i.e. the national standards bodies of EU, EFTA and a few additional countries. Furthermore, all conflicting national standards must be retired whenever a European standard is published.

In addition to these official ("de jure") standards there are also "industry standards", also called "de-facto standards", "publicly available specifications" (PAS), "pre-standards" or "application guides". These documents are developed and published by a large variety of committees, including IEEE, IETF, OASIS, and HL7. Compared to official standards, industry standards can often be developed and published faster since the rules for public comment and voting may be simplified. Correspondingly, industry standards often play a major role in fields where technology changes very quickly, such as Information and Communication Technology (ICT). Table 1 (cited from [5]) shows the differences between official and industry standards.

[1] Summary list of titles and references harmonised standards under Directive 93/42/EEC for Medical devices: http://ec.europa.eu/enterprise/policies/european-standards/harmonised-standards/medical-devices/index_en.htm

Table 1. Principles of standards and industry standards in comparison

	Principle	Official Standard	Industry Standard
1	voluntariness	required	required
2	available publicly	required	*(optional)*
3	public comment	required	*(optional)*
4	unity and consistency	required	required
5	issue-related	required	required
6	consensus	required	*(optional)*
7	oriented on state of the art	required	required
8	oriented on economic conditions	required	required
9	oriented on public usefulness	required	required
10	internationality	required	*(optional)*

As can be seen in Table 1, industry standards are not always publicly available – in some cases they are only available to members of the organisation maintaining the standard – and correspondingly, the specifications may not have undergone a truly public comment phase, and may not be based on the consensus of all interested parties.

1.3 Relevance for AAL

Standards are obviously the most important "building block" for enabling interoperability among AAL systems and system components, and as such of high relevance for the development of *AAL products* (as opposed to *prototypes and feasibility studies*, where interoperability is of limited importance). However, standards also play an important role in other aspects related to AAL:

- *Usability & accessibility:* Usability refers to "the extent to which a product can be used by specified users to achieve specified goals with effectiveness, efficiency, and satisfaction in a specified context of use" (ISO 9241-11), in other words, usability describes the ease of use of a product. Accessibility on the other hand refers to the degree to which a product is available to as many people as possible, in particular people with disabilities or special needs. Both topics are important for AAL since AAL systems will be used by people with relatively limited experience with technology, and by people with various disabilities and special needs. It is, therefore, important to consider these factors at product design. A large number of standards exist that help system architects in improving the usability of a system and achieving a "design for all" that makes the system accessible to as many users as possible.
- *Safety & risk management:* The malfunction of an AAL system may pose a safety threat to the user. Therefore, both product safety (including electromagnetic compatibility) and risk management are relevant topics in AAL product design. Both topics are covered by standards, many of which (in the case of product safety) are legally required for all products brought to market in the EU (recognizable by the CE mark on the product).
- *Security & data protection:* AAL systems often acquire personal data (in particular, health data) that requires protection under the EU data protection directive 95/46/EC. Furthermore, unauthorized interference with the system (such as abusing system actors to facilitate burglary) may pose security and safety risks. In addition to the standards on risk management, there are also standards covering the topics of data protection and system security, which may help system designers to appropriately address these issues.

- *Process & service level:* In addition to the technical aspects, also the service level aspects and business processes of an AAL offering need to be well-designed. There is a number of specifications (in particular several German pre-standards) addressing requirements and quality criteria for AAL services.
- *Certification:* A certification or quality labelling programme is always based on a standard. A certificate is basically the confirmation of an independent third party that a product or service has been tested and found to be compliant with a certain set of requirements (standard), or, more precisely, that no deviations from the standard have been found during the test.

1.4 Risks and Challenges

While there are many advantages of standards-based solutions with open, well-defined interfaces, it needs to be clearly stated that the use of standards also poses a number of risks and challenges that may cause vendors to prefer closed, proprietary solutions over open standards-based ones:

- *Complexity:* Communication standards are often designed to support a wide range of possible use cases. This comes at a price, which is the greatly increased complexity of the specification. As an example, a blood pressure monitor is a device that essentially measures two or three values: the systolic and diastolic blood pressure, and optionally the mean arterial pressure. Designing a proprietary communication protocol that delivers these three values over a communication link such as a serial cable or a Bluetooth emulation thereof is fairly trivial. However, the standard way of communicating such a measurement would be ISO/IEEE 11073-10407 “Health informatics — Personal health device communication — Part 10407: Device specialization — Blood pressure monitor”, which in turn is based on ISO/IEEE 11073-20601 “Health informatics — Point-of-care medical device communication — Part 20601: Application profile — Optimized exchange protocol”. Together these two standards have a volume of about 260 pages (!), and they define a highly complex communication protocol. It is understandable that many implementers will shy away from implementing such complexity, unless the additional flexibility of the standard based interface (i.e. the possibility to simply exchange one blood pressure monitor by another one with the same interface) is absolutely needed.
- *Implementation cost:* Since implementing a standard is expensive, the final product may be more expensive than a comparable product with a simple, proprietary interface. This problem is increased if an expensive external certification of the standards compliance of the interface is needed – this may be one of the factors limiting the market uptake of Continua based products.
- *Competition:* Vendor-independent, standard interfaces are a double-edged sword from the perspective of a vendor. On one hand it may create new markets where a product can now be combined with components of other vendors, on the other hand it may permit the competition to produce compatible, but perhaps cheaper, alternatives that may threaten the market position of a product. This may be a danger especially for small enterprises producing high-quality, high-priced products, who fear of being overwhelmed by cheap competitor products mass-produced e.g. in eastern Asia if they open their devices by standardising the interfaces. In such cases, “vendor lock-in”, while in general undesirable from the end-user perspective, is an integral part of the business model.
- *Interoperability problems:* Different developers may well read the same standard differently and produce incompatible implementations. Opening a product’s interface to the competition makes it much more difficult for a vendor to guarantee to the customer that the product will always work as intended when combined with other

products offering the same interface. Having a product portfolio that just "causes no trouble" may well be a reason for customers to prefer a proprietary product family.

- *Stifling innovation:* The preparation and publication of a standard takes time, in the case of international standards often 3-5 years. This means that a standard, once published, by definition will be somewhat outdated in technical fields that see a rapid technological development. Furthermore, doing things "the standard way" may prevent implementation of innovative ideas not (yet) supported by the standard. Innovative ideas such as the "EnOcean" low-power wireless communication protocol that is optimized for energy harvesting necessarily start as incompatible alternatives to established standards (like wireless KNX in this example), although they may become standardised later (in this case, as ISO/IEC 14543-3-10).
- *Access:* One final, very simple reason not to use standards is a lack of knowledge about, and access to standards. Especially in the research community there seems to be a significant lack of knowledge about available standards, and the standardisation processes as such. Furthermore, most official standards are sold by the standards bodies, i.e. unlike the IETF recommendations that govern the Internet are not freely available. While the costs of purchasing a standard will be negligible compared to the costs of implementing a standard, even the task of identifying which standard(s) are of relevance for a certain task is difficult if the standard cannot be browsed – the abstract alone is often not sufficient. Furthermore, the costs of purchasing a number of standards (like the complete family of ISO/IEEE 11073 specifications) can be an issue, especially for researchers with limited budgets.

1.5 Why Standards are not Enough

While the use of standards is a prerequisite for achieving interoperability, the use of standards in itself is not sufficient to guarantee interoperability, due to the following reasons:

- *Incompatible options:* As mentioned in section 1.4, communication standards are often designed to support a wide range of possible use cases. For this reason, standards often contain a multitude of options, because not every bit of information that can be transmitted with the standard is known or needed in every use case, and because it is possible to use the same standard in quite different ways. That means that two products implementing the same standard may still be incompatible if they implement incompatible options.
- *Incompatible or incorrect implementations:* It is very difficult to write a standard so unambiguously that all implementers correctly understand all clauses as they were intended. Little ambiguities are often found only later, when two implementations of the standard provide to be incompatible, and the reason is that the developers of the products interpreted the same standard differently. Furthermore, the implementation of any complex communication protocol may well contain errors (bugs), just like any other complex piece of software. Such bugs may also render devices incompatible.
- *Protocol stacks:* For each interface between devices, typically multiple standards need to be combined into a "protocol stack" to cover all layers of the communication link, from the physical layer (connector and cable or radio link), over the network and transport layers defining how packets and bit-streams are exchanged over the link, up to the application layer protocol defining messages, fields, and their meaning (semantics). In most cases it is necessary to combine several standards in order to define one protocol stack. Only if two products implement the same selection of standards, they will be interoperable without the use of an intermediate gateway ("translator").
- *Mapping of data between standards:* In more complex application scenarios there will be more than one interface, and often one piece of information will be transmitted

using one standard on the first interface, and using another standard on the second interface. A good example is the monitoring of vital parameters for patients with chronic diseases: The sensor itself may transmit its measurements like blood pressure or the patient's weight using the ISO/IEEE 11073 standard to a gateway computer located in the patient's home, for example a set-top box, tablet computer or smart phone. This device will then forward the information over a long-distance connection in encrypted form to a telemedicine service centre. However, this transmission will not be ISO/IEEE 11073, which is not intended for this purpose, but perhaps another standard like HL7. In this situation it needs to be defined which field of an 11073 message must be copied or translated to which field in the HL7 message. Such information cannot be found in either of these two standards, but still, it is a necessity in order to achieve interoperability for the overall use case.

A number of approaches have been devised over time to deal with these issues. It should be noted that all of these approaches only *complement* the use standards – they do not try to replace standards.

- *Application and integration profiles:* Many standards define so-called "application profiles" that reduce the complexity and optionality of the standard by defining more precise requirements for a specific use case ("application"). Here the goal is to ensure that two devices are interoperable if they implement the same application profile. Integration profiles go a step further by looking at complete use cases (application scenarios) and defining the complete protocol stack for each interface between systems or system components needed in that use case, plus a mapping between standards where needed. Integration profiles are defined by organisations such as Integrating the Healthcare Enterprise (IHE), the Continua Health Alliance, or the Digital Living Network Alliance (DLNA) and complement the specifications of the standards themselves.
- *Conformance statements:* Some standards require that a vendor implementing the standard publishes a document for each product that describes which options of the standard are implemented, and how. Such conformance statements are intended to help customers select products that are interoperable. One problem with this approach, however, is that these document can be very complex (typically 50-60 pages in the case of the DICOM standard for medical imaging) and require an intimate understanding of the standard's details, which cannot (and perhaps should not) be expected from a customer.
- *Conformance testing:* This term denotes procedures that actively test whether a product is really compliant with a standard by performing a number of tests between the product ("system under test") and specific test software or hardware. Such conformance testing, when performed by an independent body, is most often the basis for certification programmes.
- *Cross-vendor testing:* This term denotes tests, where two or more products are connected, and tests are performed in order to validate whether or not the products are really interoperable. The advantage of cross-vendor testing is that complex use cases such as "integration profiles" can be tested, and that the test result is directly related to the customer's expectation of a user-perceived interoperability. However, the problem of combinatorial explosion prevents each possible combination of devices from being thoroughly tested in this manner, so that both conformance and cross-vendor testing complement each other in practice.

2 Preliminary Findings

This chapter briefly summarizes the results of the expert workshops carried out by the project that are of relevance to the topic of this document. This summary provides the basis for the discussion and derivation of recommendations in the following chapter. A comprehensive documentation of the workshops can be found in the Deliverables D2.2 "Second Stakeholder Workshop 'Technologies for Ambient Assisted Living Solutions: Enabling Technologies'" [7], D4.2 "1st Workshop on Standards and Certifications in AAL" [8] and D4.3 "2nd Workshop on Reference Designs for Integrated Applications" [9].

2.1 Workshop on Enabling Technologies

On September 27th 2012, the AALIANCE2 workshop on enabling technologies took place in Eindhoven, Netherlands as a satellite event of the 2012 AAl Forum. 31 experts discussed in four interactive sessions with two main goals:

- The goal of the "Mapping" session was to identify relevant technical developments in the field of enabling technologies for AAL solutions and to map them on a timeline indicating when the workshop participants believe the results of these developments would be available. The timeline was divided into four parts: now (2012), soon (2014), mid-term (2017), and long-term (2020+).
- The goal of the "Prioritising" session was to identify possible interventions (measures) that would allow the current state of technology to be "pushed" by R&D or strategic research. For each "what if" scenario, the main effects for people and society and the prerequisites needed to make the scenario come true were discussed. Finally, the timeline from the Mapping session was reviewed and participants discussed how the interventions would affect the developments laid out there.

Mapping Session

Beside the identification and assignment of standards to the timeline, some overlapping findings were discussed. First of all, four different stages of development need to be distinguished:

- the availability of a technology as a working prototype;
- the availability on the market as product;
- standardisation of the technology and
- widespread adoption on the market.

These four stages may be reached at quite different points in time and not always in the same order (for example, IEEE 801.11n compliant products were on the market before the standard was actually finalized while the market uptake of IEEE 1173 and its successor standard ISO/IEEE 11073 took many years.). This is quite important for AAL, because in this domain on the one hand standards from other fields are used for AAL and on the other side, AAL-specific standards need to be developed. This leads to the next topic, an increasing level of cooperation and interoperability between AAL and other domains and technologies, for example a cooperation between AAL and Smart Metering developments or between AAL and Internet of Things developments. Various technological approaches and communication protocols are used in different domains for similar tasks like measuring and transmission of a temperature. Gateways or converters are needed to enable the communication between sub-systems. For this purpose, the development and harmonization of data models is needed to enable the reasoning on data from different domains. Data

models and ontologies for semantic interoperability are one of the big challenges that need to be addressed by the AAL community.

Prioritising Session

Two "interventions" related to standards and interoperability were discussed in this session: a "Continua Alliance for AAL" and a new European-wide unified data protection law.

A "Continua Alliance for AAL" similar to the Continua Health Alliance could develop implementation guidelines for plug-and-play interoperability between system components from different vendors. The end-users would benefit because this would enable a reduction of installation effort, a wider range of products to select from and the availability of "future-proof" systems. Vendors would benefit from decreased R&D costs, shorter time to market, and the possibility of reusability of system components like sensors for different applications (the latter argument also applies to the end-user). Possible disadvantages are market barriers for innovative products not suitable for established systems and potentially an inappropriate reduction of the interoperability challenge to the syntactic factor, neglecting the semantic aspects. For a successful implementation the timing is crucial. Beginning too early there might be a lack of participation from industry and use-cases, starting too late would result in trying to bring standardisation to an established market with a large incompatible installed base. Relevant industries, like the home automation, medical device and consumer electronics industry, should be integrated right from start. In the end, a reference architecture for AAL might be useful for this issue.

The data protection laws in EU member states, based on Directive 95/46/EC, basically reflect 1970s technology, when governments were seen as the primary risk to citizens' privacy, and "processing of personal data" meant mainframe computers. New technologies like Internet, Social Media or smart appliances were not considered. In addition, the data protection laws in the EU are very fragmented among the member states and, in certain member states, even on a regional level. Having a modernized and unified data protection law in all EU member states would help to legalize modern Ambient Assisted Living scenarios and increase the acceptance, resp. decrease rejection.

2.2 Repository on Standards

The repository of standards is an inventory of standards and specifications of relevance to AAL [10]. It is intended to be a knowledge base for AAL researchers and system developers and gives a brief overview of the manifold standards landscape.

The overall feedback gathered on the repository was predominantly positive. Workshop participants and users stated that the repository is very useful and the amount of standards and specifications available is very impressive. However, to be useful in the future the repository needs to be updated continuously.

An further lesson learned is that AAL specific standards are only in their very beginning, and where they exist they are mostly national pre-standards (like the various German DIN SPECs and VDE-ARs).

2.3 Workshop on Standards

On February 12th 2013, the AALIANCE2 workshop on standards and certifications in AAL took place in Frankfurt/Main, Germany, with 28 experts attending. In ten discussion groups on enabling technologies and cross-cutting topics, the standards landscape and future development were discussed. The basis for this workshop was the online repository of standards.

Apart from information that was user to update the repository of standards, such as existing standards not yet listed, or incomplete descriptions in the repository, several gaps in the standardisation landscape were also identified, in particular:

- a measurement standard for radio interference in the home,
- a standard for indoor localization,
- a standard for privacy policies in residential gateways,
- a standard for the handling of access rights to personal data in emergency cases ("break-the-glass policy"),
- a standard for quality assurance and calibration of medical devices in the home environment,
- a standard on the use of data from the home environment for medical purposes,
- a standard AAL ontology that can be used in the reasoning components of AAL devices,
- a standard high-level architecture to describe use-cases, interfaces, system components etc. in a way that promotes an understanding across projects, products and communities and,
- a standardized reference architecture for AAL middleware (including APIs).

The majority opinion on the contents of the repository was that this should only be a first step. Users of the repository might need more information than just the mere existence and availability of a certain specification or standard. Further information would include

- the development of guideline documents and tutorials on how to select the appropriate set of standards for a certain project or product;
- guidelines on the design of dependable AAL systems;
- a "smart database" on standards that could support system designers and developers in choosing the appropriate set of standards (or requirements derived thereof) for a certain development;
- for a better retrieval of specifications, a separate "AAL" category in the ICS (International Classification of Standards) was proposed.

Furthermore some recommendations were discussed and described in the workshop report (Deliverable D4.2):

- *International standardization:* In general, standardization for the AAL sector should take place on European or international level, not on a national level.
- *Better integration of research communities:* Many activities that may be important also for the AAL community are currently taking place in other fields, such as the "Internet of Things" community, where the oneM2M initiative develops generic middleware solutions for the integration of sensors and actors, and the Smart Metering community, where for example security profiles are being developed that could also be applicable to AAL. The impression of the workshop participants is that the different research communities often have insufficient knowledge of the activities of other sectors and communities, which may lead to fragmented/incompatible developments.
- *Better access to and better knowledge about standards and standardization:* Workshop participants noted a significant lack of knowledge in the research community about standards, their relevance, and the standardization processes. One problem is the limited access to standards that many researchers perceive due to the expenses. Workshop participants expressed the need for a push for open and publicly available specifications that are available at most at moderate cost. Furthermore, standards bodies and industry standard organizations such as the

Continua Health Alliance need to be more open for participation by researchers – often the organizational structure, required annual payments or simply travel cost make it very difficult for researchers to participate and collaborate. Finally, a separate "AAL" category in the ICS (International Classification of Standards) should be implemented.

- *Integration profiles:* One solution (and perhaps *the* solution) to the interoperability challenge is the development of use-case based integration profiles similar to the works of IHE, Continua, HITSP and DLNA. Such integration profiles need to be developed as part of a consensus process involving industry, researchers and users, published and established on the market. This will require an appropriate organisational structure. Discussions will be needed in particular with the Continua Health Alliance to see if they are able and willing to extend their scope to "cater" for the needs of the AAL community, or if instead a dedicated body for AAL needs to be founded.
- *Quality labelling and certification:* Participants agreed that a quality labelling programme for AAL systems should be established (perhaps based on the concept of integration profiles as discussed above). This would provide a better market acceptance, visibility and enhance interoperability. Participants disagreed on whether this quality labelling should actually be implemented as a certification programme (i. e. independent validation of products by a third party) as opposed to a self-declaration by system vendors. In any case, participants noted that such a process should not be established on national level, but on European or international level.
- *Large scale pilots* will be needed to assess the maturity of the various middleware solutions and runtime environments for AAL systems such as universAAL, Persona, Embassi etc. The "REAAL" project, which aims at equipping 7,000 apartments in Europe with universAAL-based technology, is certainly a good example.
- *Reconfigurable user interfaces:* AAL systems need to support reconfigurable user interfaces to satisfy the specific needs of different groups of users (e. g. with reduced eye-sight, hearing or fine motor skills). This requires a separation of the application layer from the presentation layer in the AAL system architecture. This separation needs to included into user interaction standards, into AAL middleware solutions (Universal Remote Console is a good example), and of course into the AAL systems being developed.

Several activities with regard to AAL standardisation on international/European level are in progress at this time and have not yet been discussed in the workshop report:

- CEN has meanwhile submitted a proposal for the creation of a new Technical Committee to work on standards for the Service Chain for Social Care Alarms (based on SCAIP) – see AAL2 D4.2 section 3.1.2.
- CENELEC TC100X (Audio, video and multimedia equipment and systems) has started a "stage 0 project" on AAL. The tasks are a collection of use cases from their field, contributing to IEC SG 5 and defining new work items in the scope of TC100 and AAL.
- Since 2011 IEC runs a strategic group on AAL called SG 5 "Ambient Assisted Living". This group conducted several actions like summarizing the status of standardisation, making an inventory of standards already existing and in progress, and liaison activities to other standardisation bodies. Writing new standards is not in the scope of this group. By end of 2013 this group will be converted into a so-called Systems Committee that has the permission to write standards.
- The AAL Joint Programme started an action on standards and interoperability titled "Negotiated Procedure for an Action Aimed at Promoting Standards and

Interoperability in the Field of AAL". This action includes a collection of use cases, formalization of use cases and a mapping of existing standards to the use cases.

- ITU-T Study Group 16 (Q28/16) is working on transposing Continua Health Alliance Guidelines into an ITU-T Recommendation as well as on developing a new Recommendation on e-health data exchange services. Approval of both standards is expected before 1st quarter 2014.

2.4 Workshop on Middleware

On June 11th 2013, the AALIANCE2 4th Stakeholder Workshop on Reference Designs for Integrated Applications in AAL took place in Frankfurt/Main, Germany, with 24 experts attending. 9 invited representatives from industrial and academic organisations active in the field of AAL middleware introduced their projects or products. Afterwards a structured discussion involving all participants was conducted along guiding questions. The guiding questions were:

- *Important features*: What are the most important features in terms of services and interfaces (network protocols) that AAL middleware should support "out of the box"?
- *Need for a standardised reference model*: Do we need a standardized reference model for an AAL system to facilitate discussion between users, developers and system architects? How could such a model "look like"?
- *Role of semantic technology*: How do you see the role of semantic technology (i.e., self-description, discover, binding and calling of services based on ontologies and reasoning) in AAL systems? Is this something that AAL middleware should be based on?
- *Need for standardisation on API level*: Do you think it would be possible and useful to standardize AAL middleware on an API level (think of "Posix for AAL")?
- *Market demand on AAL middleware solutions*: How many alternative AAL middleware solutions does the market need, and how do you think "winners" and "losers" will be determined? Do you foresee collaboration between middleware projects, or rather a competition?
- *Sustainable business model*: What are the requirements of sustainable business model for long-term maintenance and further development of AAL middleware solutions? How do we avoid more "abandonware" projects?

Important features

AAL systems and AAL middleware should provide modularity/expandability to meet the need of changing a system's capabilities with the change of the user's needs and the development and improvement of technology over time. AAL middleware should support a core set of standards like

- Core Network Protocols (e.g. TCP/IP, Bluetooth, WLAN)
- Home Automation Protocols
- ISO/IEEE 11073 (medical device connectivity)
- OSGi (runtime with software lifecycle management capabilities)

If possible, open standards should be preferred. Other features discussed were

- *Intelligence*: The development of "intelligent" AAL solutions should be strengthened; the focus is still on technical solutions. This "intelligence" could be a context management for the aggregation of data, reasoning, or recognizing new situations leading to fully-automatic functionality in the background.

- *User Interface Design*: The UI is the central component of an AAL system the user perceives. Customizing the UI to meet the end users needs (on both customer and service provider side) is one of the key factors in this context. Furthermore, it should be possible to design an UI exactly as it appears later to the user ("pixel-by-pixel").
- *Human Service Integration*: Besides technical services in AAL scenarios there are many projects including human services offered by external service providers. Human services could be call centres, taxi or shopping services, and health-related services like care. Interfaces to ordering/managing such human services are of critical importance.
- *Open Intellectual Property*: Not only the wire protocol should be open, but also the IP on the higher-level protocols should be open (e.g. implementing EnOcean is impossible unless you are member of the EnOcean alliance). Today, many medical sensors combine the Bluetooth protocol (e. g. the serial port profile, which emulates a serial cable connection) with negotiation on application layer, which prevents successful connection from a Bluetooth implementation not implementing the same application layer, which is often proprietary.
- *Data Security*: Since a large number of sensitive and personal data is used in AAL scenarios, an AAL middleware should support at least basic functions on data security and privacy.
- *Remote Maintenance*: Remote maintenance and secure backup are important points that have been recognized in the UniversAAL project – they are called "AAL space management".
- *Reliability*: Reliability is one of the core features for any kind of medical assistance and integration of medical devices. Medical systems cannot be certified in the EU unless they have a certain level of reliability and being trustworthy.
- *Alarm Systems*: The discussion on alarm systems did not led to a consensus. On the one hand reliable alarm systems should be a core feature, since an AAL system is to support people with special needs. On the other hand an alarm system was said to be a core feature only for certain use cases, which means that it is not a general "must have". The discussion on alarm systems is a good example that there is not always an agreement on core features an AAL middleware should support.

Need for a standardised reference model

Reference architectures, reference models, and layer models are useful models for understanding a certain domain. Most participants agreed that having such a standardised reference model would be very good, but immediately declared this as unrealistic or "a dream". The majority opinion was that, due to the variety of projects, implementations and scenarios, it will not be possible to find a consensus here and simultaneously being still useful instead of being over-generic. Some ideas to tackle with this problem are

- *Reference requirements/Use cases*: It maybe useful to have reference requirements or use cases rather than a reference model. This would match the variety of scenarios better than a generic reference model.
- *Domain understanding*: a reference model should help to understand the domain rather than providing a technical solution. It may be useful not to call this approach "Reference Model" but "Definition of Terms".
- *AAL systems as socio-technical systems*: In the majority of models the human factors are often neglected and AAL systems mainly occur as technical systems. But AAL systems are socio-technical systems with end users and human service providers. This should be strongly taken into account for future work.

- *Environmental information*: It would be helpful to have information on the domestic environment integrated into such a model. This may include room layout, location of sensors and other relevant information.
- *Orientation on other reference models*: Instead of starting from scratch for an AAL reference model, already existing reference models should be taken into account. The reference model for the smart home is a good example; maybe it just needs to be enhanced by AAL features and the human service level.

Role of semantic technology

The discussion on semantics was very controversial with pros and cons. Pro arguments are that semantics are able to provide the missing intelligence to an AAL system as already demanded in the earlier discussion. With reasoning, semantics provide one of the key enabling technologies identified in the first AALIANCE roadmap. Furthermore, semantics can provide context awareness for the correct interpretation of events. Contra arguments are that customers might expect and appreciate reproducibility. Customers would be over-challenged working with semantics, because they would expect the same results under the same circumstances. At the moment semantics are difficult to place to the end-user and even more difficult to charge at a premium. More aspects of semantics are:

- *Reliability in the context of medical devices*: medical devices are legally required to act deterministically. If they don't, there will be legal and liability consequence. Semantics are difficult to integrate here, i.e. to make AAL systems with semantics reliable.
- *Research orientation:* Semantics are still a research topic, although they could be very useful. Compared to other fields where technology and markets are much more developed like the Internet, only a minor amount of websites offer semantics, in this specific case RDF support, which in some way is crucial for the semantic web. This demonstrates how difficult the implementation of semantics to a market is. Given the wide scope of AAL, the effort for describing nearly the whole world through ontologies might also be too big.
- *Integration effort on semantics:* the integration of semantics makes systems more difficult to develop. At the moment AAL systems are already very complex with components from home automation, communication protocols, gateways, cross-sectoral communication and external providers. The integration of semantics would increase the effort on building these systems.
- *Lean version of semantics:* semantics could be used for very specific areas of an AAL system, not as an overall approach. This would decrease the development and integration effort.
- *Rule based algorithms:* Instead of using semantics, statistics or rule-based algorithms might work quite as well. Other fields like translation services this already work quite fine. Another solution could be to keep the systems open to semantics and implement them as an additional service.
- *Interoperability between semantics:* the exchange between developers already implementing semantics should be strengthened. This may ensure future interoperability between semantics developed separately.

Need for standardisation on API level (POSIX for AAL)

Participants stressed that this topic cannot be solved yet because no agreement about reference functionality is available. The complexity of this topic is so high that standardisation will have to follow real-world experience of which approach proves its worth in practice, and which one does not. Experts disagreed on whether such a standardisation

would be useful at all – while some believed that a standard API would be desirable, others noted that a "least common denominator" between the different AAL middleware approaches might be too high-level to be of any practical use, and expressed doubt whether there is actually any practical need to port applications between different middleware systems.

- *Low-level specification*: Furthermore, it was noted that POSIX may not be the perfect role model for an AAL API standard, since it is a very low-level specification containing operating system APIs specific to the C programming language. One core question for any such work would be the environment of the API: specific to one programming language (such as C or Java), runtime environment (such as OSGi), or based on inter-process communication (such as a REST web service API), which is operating system and programming language independent, but much less efficient.
- *ISO/IEC 24752 (Universal Remote Console, URC)*: URC focuses on the user interface, and its "user interface socket" is a different layer of abstraction than APIs for back-end services. It is an abstract user interface description consisting of variables, actions etc., which are then mapped to user interface concepts. The socket interface makes life easier for application (user interface) developers at the expense of an increased effort for the implementation of the back-end.
- *Standardisation*: Finally it was noted that even though a standardisation of a complete "operating system for AAL" might not yet be feasible, the standardisation of individual elements might very well be desirable and possible. One particular example is access to sensors and actors, where it should be possible to define a standard protocol (based for example on Universal Plug and Play, UPnP, or the Devices Profile for Web Services, DPWS) with device classes like "presence detector", "thermostat", etc. This would allow applications to connect to devices without knowledge of the underlying protocol, if there were software components available in the system translating from the common format to the respective proprietary protocol. Again, the role of semantic technology (for describing device classes and device properties) would need to be clarified.
- *IPv6*: Participants stated that in their perspective, the transport protocol of the future will be IPv6, so one step in solving the challenge of device access would be a mapping of the various non-IP networks (e.g. Bluetooth, Zigbee) to IPv6, including an address translation scheme that permits devices on non-IP-networks to be accessed from an IPv6 network. A gateway between networks would have to be fast enough to allow working with protocols that require peer-to-peer negotiation and have short timeouts (e.g. ISO/IEEE 11073 for medical devices). It was noted that in the case of Zigbee, a specification for "Zigbee over IP" is currently under development, and this will enable communication with Zigbee devices over IP networks. As a final remark, it was noted that on the long term it would be desirable to push vendors to move from proprietary protocols to well-document open protocols (based on IPv6), which would solve many of the problems experienced today.

Market demand on AAL middleware solutions

The common agreement was to let the market decide. This has been a good principle for several years and competition has always been a driver for innovation. Of course participants understood that this may not led to the best solution or allocation. Nevertheless some recommendations and expectations for the market development were pointed out:

- *Different solutions for different requirements*: the span of available products and products under development is very wide. This may cause a stronger diversification of available middleware and not "one big solution".

- *Collaboration*: The challenge of developing an AAL middleware that matches nearly all requirements is too big for a single organization. This may led to some kind of collaboration. One form of collaboration could be the exchange of reusable software components on a lower level to combine them to a (general or specific) middleware.
- *Open Standard*: It might be useful to agree on an open standard and use this as a basis for independent developments. The market of web browsers is a good example: HTML is the standard here and, based on this, four big competing Browser products (plus several smaller developments) are available.
- *Co-opetition*: Another way could be the co-opetition declared in the AALOA manifesto[2]. There should be one open source reference implementation and upon this, several forks could be developed. The overall aim should be to a translation from research to industry to achieve stable versions for the market.
- *Collaboration with other markets*: As already suggested in the Lecce declaration[3] collaboration between the AAL market and other markets might be suitable. The activities inside the M2M branch are very active in terms of middleware and the challenges are very similar (except that the human factor is missing there). Standardisation activities have very much progressed with OneM2M and ETSI M2M.
- *New market actors*: Beside the M2M market there might be some other actors stepping into the AAL market like telecommunication providers, electricity providers, medical and smart home device manufacturers. At least, the AAL market could be completely changed if some international big player would enter the market, like Google or Apple. In this case there would be one big solution because these actors have such a strong market power that they can shape a rather unstructured and undeveloped market, like the AAL market is at the moment, to their needs.
- *Market overview*: Collaboration, co-opetition, other branches and new actor lead to a strongly diversified and confusing market situation in a technological and economic manner. But it was suggested that a good market overview is essential for developers and end-users. Developers could derive a better overview on available system components which makes the development and integration of AAL middleware much easier.

Sustainable business model

The comparison between open source and industrial/licensed (maybe based on open source) business models was the main topic of discussion. The advantage of an open source approach would be a freely available middleware and a bigger development community. An industrial model would provide legal certainty in terms of reliability and medical devices, and continuity in funding (i. e., maintenance). Beside these two general concepts, there were some more points stressed:

- *Maintenance*: Software needs to be maintained. This general statement is crucial for AAL middleware, because the software is used in a critical environment, maybe for emergency detection or medical applications. Security updates, bug fixes and other updates need to be published. Regulatory requirements, which are also changing over the years, need to be taken into account. Another factor is the size of the code base. The developers should try to limit this factor, because the effort of maintenance correlates with the number of lines of code.
- *Liability/Risk Management*: One of the biggest challenges is the question of liability and risk management. AAL middleware might be used in some scenarios where emergency messages and other high-risk data are processed. Several problems and

[2] AAL Open Association (2010): The AALOA Manifest (version 0.14)
[3] Lecce declaration

damages might occur, like an emergency call that is not delivered on-time or a wrong decision that was made by the "intelligent system". In case of any damages suffered by humans, who is responsible? This problem has to be solved before open source AAL middleware is brought to the market and combined with emergency or medical scenarios.

- *Future support*: AAL systems are designed for long-term usage, probably over many years. This will not only require a continuous maintenance of the software (see above) but also a continuous support of end-users and business users. The question is how this can be handled with an open source approach.
- *Funding policy*: From research side there were some postulations towards funding authorities. The main point is on funding for the usage of already existing software. The funding authorities should appreciate projects that are willing to use already existing middleware instead of "re-inventing the wheel" over and over again. For this purpose a small amount of the funding for the research project could be used to pay the maintaining community of the middleware. This would help the researchers to focus on their research work and simultaneously support software developers maintaining AAL middleware. Furthermore this would limit the number of "abandonware" and reward good software solutions.

3 Discussion and Recommendations

This chapter condenses the "lessons learned" from the expert workshops as well as a number of further relevant topics that surfaced during the work of the AALIANCE2 project into a set of recommendations for activities that foster interoperability in integrated AAL applications, including European standardisation and certification activities and processes. These recommendations are intended as a contribution to the revised AALIANCE2 Strategic Research Agenda and Roadmap (Deliverable D2.7).

3.1 Standardization Watch Initiative

One topic that was intensively discussed during the workshops was the lack of information in the AAL community about applicable standards. This is in part due to the difficulties, especially for researchers, in accessing the available body of standards, and in part due to the complex standards landscape that is indeed difficult to have an overview of, in particular in a field like AAL where many traditional industry domains come together. Several tasks are, therefore, needed to address the awareness about, and the development of standards and specifications in the context of AAL.

- *Origin of standards*: First of all, standards and specifications relevant to AAL are available from various sources. Sources are electrical engineering and information technology related standardisation bodies like CENELEC and IEC, non-electrical standardisation bodies like CEN and ISO and numerous industrial consortiums like W3C, EnOcean, IEEE and many more. In addition there are national bodies, European bodies (CEN, CENELEC, ETSI) and international bodies (ISO, IEC, IEEE, W3C). Furthermore, relevant standards and specifications are from very different kinds of branches like home automation, information technology, service robotics, medical devices and many more. Each branch has several subtopics relevant and which have to be tracked for AAL. This requires a continuous coordination with all of these actors and branches.
- *Objectivity*: The different sources of standards and specifications have another topic to take care of. It is important to have a neutral and objective view on standards and specifications. It is in the nature of things that organisation have first of all a view for their stakeholders' view and problems. For this, it is important to have an institution independent from the established structures.
- *Future developments*: During the work in AALIANCE2 an online repository listing the standards of relevance for AAL was set up and is continuously maintained with current developments like new standards, updated standards and other changes. First feedback from the community approved the utility of this source. To keep the repository up-to-date and useful to the community it is necessary to ensure maintenance after the end of AALIANCE2.
- *Promotion of standards*: Incompatible system components, reduced/missing interoperability between different systems and re-inventing the wheel over and over again are three negative outcomes of disregarding available standards and specification. Therefore it is essential to promote the usage of standards along the AAL community. This comprises the maintenance of the online repository, the organisation of thematic-related workshops for dissemination and gathering feedback, and the publication of results through newsletters and other sources.

Therefore the authors recommend the **installation of a neutral and independent future-orientated standardisation watch initiative for AAL**. This initiative could be integrated into the envisaged ETP AAL to provide the initiative with the necessary impact power to enforce European leadership in this field. The epSOS project is good example for a successful implementation being based in many European countries [11].

3.2 Standardized Reference Architecture

Standardisation in an emerging field of technology requires a common understanding among the stakeholders involved about the concepts and terms used. Ideally this common understanding is formed into a generally accepted *reference model* that serves as a basis for conceptual discussion, standardisation, development and deployment. A standardised reference model for AAL systems does not yet exist. The question whether or not a standardised reference model for AAL systems is needed, and is possible today, was discussed during both the AALIANCE workshop on standards and the workshop on middleware. The consensus of the participants was that the maturity of the field is insufficient at this time to permit the development of a generally accepted reference model. At this time, the approaches and architectures used in this research dominated field vary too much to allow for a common reference model, unless that model would be extremely generic and thus not really useful. However, participants agreed that having such a reference model would be very helpful in promoting standards and interoperability in the field of AAL, and that certain preliminary steps are possible today.

The recommendation, therefore, is to **support a preparatory action working towards a common understanding of the AAL domain, which may ultimately result in a commonly accepted reference model.** In detail, this preparatory action should develop a dictionary with definitions of terms for the AAL sector and harmonise it with the various existing developments (e. g. IEC electrotechnical vocabulary, ISO/IEEE 11073 medical device nomenclature, and the German pre-standard VDE-AR-E 2757-1 “Ambient Assisted Living (AAL) – Terms and definitions”). Furthermore, the action should collect use cases (AAL application scenarios) and derive reference requirements. Again, on-going work (IEC SG 5, IEC TC 100, AAL-JP Action on Standards and Interoperability) should be taken into account. Finally, the action should analyse existing reference models from related domains (e. g. internet of things, smart home) for their applicability and adaptability for the AAL domain. This work should take into account the human service level, since AAL systems are socio-technical systems combining technology with human service providers.

3.3 Development of Integration Profiles for AAL

As described in section 1.5 “Why standards are not enough”, the use of standards is a prerequisite for achieving interoperability among AAL systems and system components, and interoperability is a key requirement for a long-term success of AAL solutions on the market, due to customer needs. However, the use of standards in itself is not sufficient to guarantee interoperability. This goal can be reached, however, by making use of *Integration Profiles*, which are standards-based specifications that define all interfaces needed for all systems and system components for one specific use case or application scenario. Integration profiles have very successfully been developed and deployed in the field of healthcare IT by the Integrating the Healthcare Enterprise (IHE) initiative, in the field of telemonitoring by the Continua Health Alliance, and in the field of consumer electronics by the Digital Living Network Alliance (DLNA). The authors believe that the **development of standards-based integration profiles for the most common AAL application scenarios** are a key for achieving interoperability in the AAL sector, if these integration profiles are really accepted by the market and find their way into wide-scale product implementation and deployment.

The topic of integration profiles has surfaced in each of the AALIANCE2 workshops discussed in chapter 2, and several groups outside the project have also taken up this topic:

- The German project RAALI (“Roadmap AAL Interoperability”) has in 2013 proposed a format for describing such AAL integration profiles. This specification will be converted into a VDE application rule (i. e., a German pre-standard) [12][13].

- IEC TC 100 (Multimedia) and IEC SG 5 (Strategic Group AAL) have both started a collection of use cases / scenarios for AAL, which can be seen as preparatory work for integration profile development.
- The recently started CIP-PSP ANTILOPE project ("Advancing eHealth Interoperability") plans to develop integration profiles for 10 different use cases, two of which are related to telemonitoring and have close relationship with AAL.
- The AAL Joint Programme has started a small project entitled "Action Aimed at Promoting Standards and Interoperability in the Field of AAL". This action includes a collection of use cases, formalization of use cases and a mapping of existing standards to the use cases.
- The eHealth European Interoperability Framework (eHealth EIF) [14] recently published by the European Commission extensively discusses "high level use-cases" and related "profiles" (i. e., integration profiles), and proposes the implementation of 10 such profiles, three of which are linked to AAL topics: involvement of the patient in documentation of his/her specific chronic disease and making it available either via PC or web based applications, or via mobile monitoring devices and mobile phones to healthcare provider (e.g., diabetes, cardiac diseases, COPD, hypertension); for ever-present care outside conventional care facilities, involving the interoperability necessary from sensor devices to monitor activity, e.g. of elderly people.

While it may seem as if the topic of "integration profiles for AAL" has really taken off with all the activities taking place at the moment, it should be noted that the maintenance of such profiles following the development of the overall information technology and IT standards, the development of test tools and the organisation of cross-vendor-testing opportunities requires time and a proper organisation. IHE, which has published more than 130 integration profiles for the eHealth sector, has needed about 15 years and several committees of domain experts to do so, and a similar timeframe must be expected for the AAL sector. The question whether any existing organisation is well-suited for this task, or whether a new organisation is needed, cannot be clearly answered today. Candidates for this task could be either existing standards bodies (e. g., IEC, CENELEC, ETSI), the Continua Health Alliance (which is very interested in the AAL topic, but has certain issues with transparency, openness and consensus, as discussed on the eHealth EIF), or another body still to be founded. Long-term funding of such a body is a key issue, and both IHE and Continua demonstrate that such organisations can be sustainable without continued public funding.

In summary, the recommendation is to **establish a European or international forum where all actors interested in AAL integration profiles can collaborate towards the establishment or commissioning of an organisation taking over the long-term responsibility for developing and maintaining integration profiles for AAL**, together with the required accompanying measures such as the development of test tools and cross-vendor testing. Note that it suggests itself to couple a certification programme to such integration profiles, therefore, the discussion in section 3.4 should be seen in conjunction with this topic.

3.4 Certification in AAL

In general, certificates give guidance to customers by informing about specific product attributes, manufacturing conditions, compatibility with other products and compliance with legislation. An AAL certificate would facilitate the market penetration because customers would be much more informed about AAL products. AAL vendors and service providers could promote their products and services with more success.

During the workshop on standards certification issues have been discussed. First of all different AAL certificates with specific scopes are possible. In particular these are:

- *Technical certification*: A technical certificate testifies the ability of connecting a certain AAL device to an existing AAL infrastructure (similar to Universal Plug and Play, or the Continua Health Alliance certification programme).
- *Data privacy label*: Since AAL usually is implemented in the private environment and very private data is processed (medical data, activity monitoring), compliance with legal data protection regulations is essential. In terms of confidence building it is recommended to implement future-oriented data protection regulations like Privacy by Design or Security by Design. Finally, these data protection policies should be bundled to a data privacy label (similar to the Privacy Seal available in Germany[4]).
- *Label for buildings*: Similar to the energy performance certificate for houses now legally required in Germany, an AAL label for buildings and housing could inform the potential lodger and/or home buyer about AAL specific attributes, such as the availability of a home automation infrastructure, basic accessibility features of the apartment, the availability of broad-band internet, etc. A three-staged certification could be a possible with stages like low-medium-high, bronze-silver-gold, comfort-living-caring.

For all these kinds of certificates an organisation is needed to define criteria, testing procedures, term of validity and the designation of auditing authorities. The authors strongly recommend i**mplementing an independent certification initiative** at least at an European level, better yet at a worldwide level. Whether or not an existing organisation (such as the Continua Health Alliance or Integrating the Healthcare Enterprise) could take over this role, or whether a new organisation is needed, still requires further study.

3.5 AAL and the Medical Device Directive

In the EU member states, specific laws apply to "medical devices", i. e. products intended for diagnostic or therapeutic purposes.

The regulatory requirements for medical devices in the European Union are described in the "Council Directive 93/42/EEC of 14 June 1993 concerning medical devices" (in brief: Medical Device Directive, MDD), which has been amended several times, the most important amendment being directive 2007/47/EC. This directive has been harmonised and adapted into national law in all EU member states. According to the MDD, article 1.2, the "intended use" of a product (as determined by the product's manufacturer) decides whether or not a product is a medical device:

> *'Medical device' means any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:*
>
> - *diagnosis, prevention, monitoring, treatment or alleviation of disease, diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,*
> - *investigation, replacement or modification of the anatomy or of a physiological process,*
> - *control of conception,*
>
> *and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means;*

[4] https://www.datenschutzzentrum.de/faq/guetesiegel_engl.htm

When in doubt, a manufacturer can consult with a notified body or a supervisory authority to determine whether or not a product falls into the scope of the MDD. This has far-reaching legally binding consequences for the manufacturer, the operator and the user. The intention of the MDD is to minimise risks for the patient, the user and third parties caused by the use of the medical device through mandatory requirements concerning the production processes, documentation, certification, distribution channels, training, limitation of use, operation, incident reporting and maintenance. Depending on the degree of exposure, a medical device is classified into risk class I, IIa, IIb or III. Depending on the classification, quality management systems, risk management and post-market surveillance processes have to be established by the organisation placing the device on the market, and verified in a regulatory compliance audit.

In particular, all "harmonized standards" need to be taken into account for the design, production and quality management of the medical device. The current list of harmonized standards can be found in the "Commission communication in the framework of the implementation of the Council Directive 93/42/EEC of 14 June 1993 concerning medical devices" (last amended 2011) [15]. At this time, the list is comprised of 284 standards (plus amendments), and it is the responsibility of the manufacturer to make sure that all applicable standards are applied. Depending on the nature of the medical device, the list of applicable standards can of course be much smaller. For example, for software-only medical devices (a type that was introduced in 2007/47/EC), only six standards apply: EN 60601-1-66 and EN 62366 on usability, EN 62304, EN 60601-1-4 and EN 60601-1-8 on lifecycle processes and safety, and EN 14971 on risk management. Nevertheless, compliance with all harmonized standards can be a significant burden, especially for small manufacturers.

Today, the provision of health care most often depends on medical devices that are integrated into IT networks, i.e. connected to devices such as LAN switches, routers or file servers that are not medical devices. Such a combination of medical devices and non-medical devices comprises a "Medical IT Network" that needs to be handled in accordance with EN 80001-1 "Application of risk management for IT Networks incorporating medical devices — Part 1: Roles, responsibilities and activities". Formally, the medical IT network is a new, unique medical device ("custom-made device") produced by the operator (hospital or system integrator), which needs to follow the MDD rules for regulatory conformity. Therefore, the operator needs to formulate a new "intended use" and perform risk management (risk analysis and residual risk analysis) in accordance with EN 14971 "Medical devices — Application of risk management to medical devices". For example, the operator must assess the damage that could be caused by non-transmission of an alarm message generated by the medical device, due to network failure, and how this risk is minimized and managed.

Many AAL systems implement functionality that is related to the management of the user's health in the widest sense, and often these systems combine medical and non-medical devices, or use non-medical devices (such as home automation sensors) for medical purposes, i.e. in order to derive diagnostically relevant information. Therefore, many AAL systems comprise a "Medical IT Network" as defined by EN 80001-1, and the above mentioned rules apply.

Furthermore, the approval of new types of medical devices requires a "clinical investigation" according to Article 15 and Annex X of the MDD – a rule that will apply to most AAL systems that fall into the scope of the MDD. A clinical investigation is basically a clinical study performed on a sufficiently large patient base that the performance of the device, its effect on patients, and its safety can be adequately assessed:

> *Clinical investigations must be performed on the basis of an appropriate plan of investigation reflecting the latest scientific and technical knowledge and defined in such a way as to confirm or refute the manufacturer's claims for the device; these investigations must include an adequate number of observations to guarantee the*

scientific validity of the conclusions. […] Clinical investigations must be performed in circumstances similar to the normal conditions of use of the device. All the appropriate features, including those involving the safety and performances of the device, and its effect on patients must be examined. […]The investigations must be performed under the responsibility of a medical practitioner or another authorized qualified person in an appropriate environment.

Since the costs of the clinical investigation need to be borne by the manufacturer of the device, this is a significant financial and organisational burden especially for small and medium-sized enterprises (SME) with innovative products.

Many vendors in the AAL field are concerned that the effort required to approve AAL systems as medical devices will increase the costs of the device such that a sustainable business case does not exist anymore. Whether or not this concern is justified, it is clear that the additional burden/effort caused by the classification as a medical device is significant, and that the medical device legislation was never conceived with "devices at the patient's home" in mind. Furthermore, the organisational and regulatory effects of combining medical devices with non-medical devices in a complex AAL service setting are not well understood today – it has taken almost 20 years to reach European-wide consensus about the classification of typical hospital IT products such as hospital information systems, image archives, diagnostic workstations etc., and similarly it will take many years until the interactions between assistive technology at home and the MDD will be fully understood. This may very well be an important obstacle for the success of AAL on the market.

Therefore, we recommend that **a study group be established involving experts from the AAL domain and representatives of the MDD regulatory system** (e. g., DG Health and Consumer, Directorate B, Unit B2 "Health Technology and Cosmetics"; The European Association Medical devices of Notified Bodies - TEAM-NB - and the International Medical Device Regulators Forum, IMDRF). The task of this study group should be two-fold: 1. to examine how the service model of AAL systems can be mapped to the MDD regulatory system, and which modifications to the MDD may be required; 2. to provide guidance to AAL system developers on the classification of AAL systems according to the MDD, and on the risk management for complex systems combining medical device components and non-medical components into a Medical IT Network, or using non-medical ambient sensors to derive diagnostically relevant information.

3.6 AAL and Data Protection Law

AAL systems that monitor vital parameters or activities of daily living produce very sensitive data showing intimate details of the health and lifestyle of the monitored subject. Therefore, it is of great importance that data protection and privacy protection are taken into account already during the system design phase of such systems, since data protection often cannot be "retro-fitted" into an existing system [16]. The authors, therefore, recommend that **AAL system architects and system designers take into account guidelines such as the "Privacy by Design" concept during requirements analysis, system architecture and implementation** [17]. Particular care needs to be taken whenever sensitive data leaves the home environment of the patient, i. e. is transmitted to or stored on servers that are not under physical control of the user (e. g. Cloud computing).

Secondly, it was noted during the workshop on enabling technologies (see section 2.1) that data protection laws in EU member states, based on Directive 95/46/EC, basically reflects 1970s technology, when governments were seen as the primary risk to citizens' privacy, and "processing of personal data" meant mainframe computers. New technologies like Internet, Social Media or smart appliances did not exist when today's data protection laws were conceived. Furthermore, despite the common underlying directive 95/46/EC, the data protection laws in the EU are very fragmented among the member states and, in certain member states, even on a regional level (e. g. in Germany the applicable data protection

law in a hospital depends both on the federal state the hospital is located in, and the hospital ownership). The authors, therefore, recommend that the **European Commission initiates consultations with the member states about a renewed data protection law that is adapted to the technology challenges and opportunities of the 21st century** – an activity that certainly would require many years to complete, but could and should be started now.

3.7 Large scale pilots

Despite the multitude of AAL R&D projects, AAL must still be considered an experimental technology, since the proof that large-scale AAL solutions are both manageable technically and viable economically is still missing. The "ReAAL" project, which aims at equipping 7,000 apartments in Europe with universAAL-based technology, is arguably the first real large-scale pilot of AAL in Europe. While the authors clearly welcome this ambitious project, we believe that there will be a need for **more large-scale pilots** than this first one. Such large-scale pilots are important not only from an economic perspective, but also from the perspective of standards and interoperability, because certain important technical issues such as failure of system component (maintainability), the relevance of remote maintenance across all system components, the need to adapt a system to changing needs of the user, etc. only surface in large-scale installations over a longer time. Therefore, such pilots are of critical importance to better understand these aspects of AAL.

3.8 Reconfigurable user interfaces

One specific requirement of the user group of AAL system, predominantly older adults and people with chronic diseases, is the large variety in capabilities, resources, experience with technology, and limitations due to function loss (e.g. reduced eyesight, hearing loss, or reduced fine motor skills). Furthermore, as a user's health status and individual limitations change over time, an AAL system will have to be extended or complemented with additional modules whenever a new need arises. It is unlikely that users will accept that in each of these cases a system needs to be completely exchanged by a different one (with possibly different user interface).

The authors, therefore, recommend that AAL system designers on one hand **consider the principles of "design for all",** and on the other hand **equip systems with a reconfigurable user interface**. Technically, this requires a separation of the application layer from the presentation layer in the AAL system architecture. This separation needs to included into user interaction standards, into AAL middleware solutions, and of course into the AAL systems being developed. One important standard in this field is ISO/IEC 24752 "Universal Remote Console".

3.9 Middleware

AAL software infrastructure (middleware) was the main topic of the "workshop on middleware" (see section 2.4). The discussions during the workshop clearly showed that several feature-rich middleware systems are available to AAL system developers today, often even under an open-source licence. One obvious conclusion is that **future AAL system developments should be based on AAL middleware**, and not be developed from scratch. The middleware offers solutions for many typical "low-level" tasks such as persistently storing sensor data, connecting to home automation networks, communicating between system components etc. and thus simplify system development and improve the interoperability of developments based on the same middleware.

On the other hand, the workshop also showed that multiple AAL middleware approaches exist, each with their own merits and deficits, and that it would be premature to recommend one specific middleware solution as "the only one" that should be used by all future projects. We, therefore, recommend that **future AAL projects receiving public funding**

(e. g. Horizon 2020 or the AAL Joint Programme) **should be required to use an AAL middleware, but have the freedom of choosing the most appropriate one** for their specific project.

3.10 Standards and Business Models

The authors identified several standards and specifications related to AAL. First of all, there are the general standards like the standards series ISO 9000 or environmental management systems like ISO 14000 and EMAS. In addition there is a number of standards from the healthcare sector that also might be applicable. These standards have specific requirements for health care organizations and, due to the diversity of national health care systems, a national colouring. Furthermore there are first beginnings in Germany to develop AAL specific standards. DIN (mirror organisation to CEN and ISO) and VDE (mirror organisation to CENELEC and IEC) have announced first specifications on AAL. The specifications by DIN focus on requirements for AAL services whereas the work of VDE on components and technical systems. The authors strongly recommend **lifting this standardisation work on a European and international level**. This would strengthen Europe's competence on AAL and would make components and services exchangeable over national borders. Having European-wide standards would help to establish a large European-wide AAL market instead of having small national separated markets. Of course, national applications are necessary due to the diversity of national health systems.

Another point the authors want to stress is the interoperability of AAL components and services. The authors strongly believe that a successful AAL market is only possible if components of different providers can be combined to a running system. The customer won't accept to have 2 or more set-top boxes from different providers each having the own sensors while the sensors only differ in their provider origin but not in their functionality. An example could be an emergency system based on motion detectors from provider A and a automated lightning control also based on motion sensors. Due to the lack of interoperability of both systems it is necessary to have motion sensors from both providers in each room. This is, in the opinion of the authors, how the market should not develop. On the other hand, a standards-based and interoperable product family could be the foundation of a sustainable business model for AAL system vendors, in particular in a market where many relatively small companies (SMEs) offer a limited product range – here the ability to combine products and components from multiple vendors into a single offering could be significant. In this context, also the discussions about certification programs (section 3.4), but also on the risks and challenges of a standards-based product range (section 1.4) should be taken into account.

3.11 Standardisation needs of Key Enabling Technologies

The work on Key Enabling Technologies (KETs) already started in the predecessor project AALIANCE (2008 to 2010). In AALIANCE2 the KETs are covered by the Strategic Research Agenda (see deliverable D2.5 for more details)[18]. In addition the authors here introduce some standardisation aspects to selected KETs, the complete list of which is also included in D2.5.

Sensing

- *Smart Sensors*: Compared with current sensors, which are able to collect data, in the future smart sensors will be able to perfom tasks currently processed by AAL middleware. The authors strongly recommend **implementing current standards like EnOcean or ZigBee** and also consider future developments in the middleware context like **standardisation of remote maintenance**.
- *Lab on Chip*: These compact systems will be able to perform laboratory functions autonomously. The authors recommend **following the recommendations for**

Smart Sensors and furthermore to **adopt standards and specifications for a laboratory diagnostic data set** like **CDA** and **medical terminologies** like **UCUM (Unified Cod for Units of Measure)**. At least **ISO/IEEE 11073** offers already communication standards for health devices and should be taken into account.

- *Biosensors*: These kinds of sensors will be wearable and/or ingestible and have an energy harvesting approach. For data transmission the authors recommend **implementing interfaces for human body communication**, currently developed by the IEC (**IEC 62799**).
- *Environmental sensing/pervasive sensing*: These developments will enable users to connect/interact with sensors in a mobile context. For this it is strongly recommended to **consider terminologies for the environmental/urban context like CityGML** and force the development of a **self-description language for sensors**, but at least **use semantic technologies** to support **basic self-description** on a interim basis.
- *In- and On-Body Sensors*: Like biosensors these sensors should support **human body communication**.

Reasoning

- *Sensor Fusion*: In the future data from multiple sensors will be used to solve AAL issues. To enable self-regulated sensor fusion it is important to force the development of **self-description language for sensors.**
- *Semantics:* This topic was covered in the second workshop, detailed recommendations for semantics are listed in section 2.4. It is recommended to ensure **interoperability between semantics**. In transition **lean version of semantics** or instead **rule based algorithms** can be used.
- *Maintainability:* A standard for **remote maintenance** was already postulated during the workshop on standards. Furthermore this standard still to develop should also focus on **self-maintenance issues**.

Acting

- *Service Robotics*: A key function in the future will be mobile assisting functions outside the home. For this reason we recommend to early adopt **terminologies for building information modelling** like **CityGML, IFC, ISO 19000** and **ISO 29481**. There are also many standards available for **indoor** and **outdoor localization**. This are well established standards like **GPS** for outdoor navigation or novel approaches **ultra-wideband technology (UWB)** for indoor localization.
- *Smart Mobility:* Smart Mobility also demands **indoor and outdoor localization techniques**. In addition the authors recommend the adoption of **terminologies for building information modelling** (see above).
- *Wearable Robotics:* Beside wireless communication like **Bluetooth** other novel approaches like **human body communication** (**IEC 62799**) might be useful for controlling wearable robotics.

Interacting

- *General usability*: The authors strongly recommend following the current standards on usability, ergonomics and design for all, especially **ISO 9241**. This standard is maintained by **ISO/TC 159/SC 4 "Ergonomics of human-system interaction"** and continuously updated with new interaction techniques like **tactile and haptic**

interfaces (ISO/CD 9241-940) and **gesture interaction (ISO/AWI 9241-960)**.

Communicating

- *Data protection regulations*: Beside the future **General Data Protection Regulation** which is still under negotiation the authors strongly recommend to cosnider design principles already features like **Privacy by Design** and **Security by Design**. They will be part of the new regulation but are already available.
- *Roaming of Body/Personal Area Networks*: Body Area Networks (BANs) and Personal Area Networks (PANs) should be able to connect to different environments in private or public settings. For this a **self-description language for BANs/PANs** similar to the sensor area is needed.

Conclusions

The aim of this document was to summarize the findings of the AALIANCE2 project with regard to the relevance of standards and interoperability to the field of Ambient Assisted Living (AAL). While the AAL sector is clearly moving, albeit slowly, from research towards large-scale pilots and commercial implementation, the topics associated with standards & interoperability have arguably so far not received the attention they deserve, but at this time many initiatives and working groups are becoming active, perhaps most notably the IEC, which is aiming to initiate an AAL systems committee before the end of this year.

Due to the heterogeneous structure of both the AAL sector and the standardisation landscape, it is very difficult to achieve a comprehensive overview of what is happening where at this time, and certainly this report is missing some important development. This is just another reason why a more permanent "standardisation watch initiative" for the AAL community, as described in section 3.1, would be a major benefit.

It should be noted that this report does not constitute the end of the work of the AALIANCE2 project in the field of standards and interoperability for AAL. A second, extended edition of this report will be published in February 2014 and used as a contribution towards the final AALIANCE2 Strategic Research Agenda and AAL Roadmap. The authors, therefore, wish to stress that feedback – opinions, corrections, contributions – on this document are welcome. Contributions should be sent by mail to aaliance2@offis.de and will be taken into account for the revised second release of this document. Beyond corrections and extensions based on user feedback, the following additional topics will be covered in the second release of this report:

- Ethical aspects,
- Considerations from an end-user perspective,
- Results of further literature analysis and discussions,
- Results from consultations with Japanese and American experts,
- Feedback from wiki users,
- Changes in the repository of standards since the D4.1 snapshot.

The AALIANCE2 WP4 project team,
September 2013.

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