DELIVERABLE

D.5.7 – Contributions to standardization
First year activities

Project Acronym: UNCAP

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Contents

Foreword

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Statement of originality

This deliverable contains original unpublished work except where clearly indicated otherwise. Acknowledgement of previously published material and of the work of others has been made through appropriate citation, quotation or both.

Introduction

UNCAP will create an ICT platform based on open standards, enabling monitoring, assisting, training and diagnosing health and psychological status of an ageing population. To ensure a successful uptake within this project, in line with Horizon 2020, this will be achieved by a robust and focussed Standardization plan.

The exploitation of UNCAP's results through the development of standards has been centred on key Technical Committees in CEN, Open Geospatial Consortium - OGC and ISO.

This report is the first of three deliverables on standardization activities and covers the first year of the project (Jan – Dec 2015). In particular, this report covers:

1) The usage of European certification for CE Marking (as in section 5) in light of future commercial exploitation of UNCAP.
2) The submissions to Open Geospatial Consortium - OGC for standardization (as from section 6). It should be noted that the text included in the section 6, describing the standard AHA-ML as it is proposed to OGC, has been used for an official "OGC Discussion Paper" and may led to the definition of a charter for a dedicated standard working group.
3) The standardisation activities carried on within ETSI.

An effective Standardization campaign showcasing successful technical activity will ensure maximum impact for the project. Software and hardware developers, including SME's, clinicians, researchers and other key stakeholders will be targeted in a variety of settings using a variety of methods, including conferences, journal articles and workshops. UNCAP aims to encourage the development of other technologies compatible with the UNCAP platform. Key actions include the development of relevant standards and the use of existing standards to support the innovative nature of the project.

This document provides a report on all standardization activities to date in the context of Task 5.6 "Standardization activities".

1. Table of acronyms and abbreviations

Acronym	Description
AHA	*Active and Healthy Ageing*
BMI	*Body Mass Index*
CE	*Conformité Européene (European Conformity)*
CEN	*Comité Européen de Normalisation*
CENELEC	*Comité Européen de Normalisation en Électronique et en Électrotechnique*
CityGML	*City Geographical Markup Language Profile*
DWG	*Domain Working Group*
ECG	*Electrocardiography*
EEG	*Electroencephalogram*
EN	*Norme Européenne, or in English, European Standard*
EP	*ETSI Project*
ETSI	*European Telecommunications Standards Institute*
GIS	*Geographical Information System*
GML	*Geographical Markup Language*
GTMC	*Geological and Topological Model Checker*
ICT	*Information and Communications Technology*
IEC	*International Electrotechnical Commission*
IndoorGML	*Indoor Geographical Markup Language Profile*
IoT	*Internet of Things*
ISG	*Industry Specification Group*
ISO	*International Organization for Standardization*
JSON	*JavaScript Object Notation*
LOINC	*Logical Observation Identifiers Names and Codes*

M2M	*Machine to Machine*
MeSH	*Medical Subject Headings*
MMSE	*Mini mental state examination score*
O&M	*Observations and Measurements*
OGC	*Open Geospatial Consortium*
SME	*Small and Medium Sized Enterprise*
SNOMED CT	*SNOMED Clinical Terms*
TC	*Technical Committee*
TC CYBER	*Technical Committee (TC) Cyber Security*
TETRA	*Terrestrial Trunked Radio*
TR	*Technical Report*
UMLS	*Unified Medical Language System*
UNCAP	*Ubiquitous iNteroperable Care for Ageing People*
VC	*Venture Capitalist*
XML	*eXtensible Markup Language*

2. Terms and Definitions

For the purposes of this report, the definition of Asset Management is specified in the document BS ISO 55000:2014.

For the purposes of this report, the definitions specified in Clause 4 of the OWS Common Implementation Standard [OGC 06-121r3] shall apply.

3. Bibliography

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[5] ISO 8601 on dates representation. Available online at: http://www.iso.org/iso/home/standards/iso8601.htm

[6] Guidelines for Successful OGC Interface Standards, OGC document 00-014r1.

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4. European Certification (CE)

4.1. Overview

Many Products that are sold within the European Economic Area (EEA) come with a 'CE' Mark. CE marking applies to products made in third countries which are sold in EEA and Turkey. CE Marking does not imply that a specific product was made in EEA, but it implies that it was assessed before placing in the market, and that it satisfies all relevant and essential requirements that need to be taken care of. The CE Marking is mandatory for a wide range of products as:

1. It shows that the manufacturer has made sure that his products meet the European Union (EU) Safety, Health and environmental regulations.
2. It is an indicator that the product complies with EU Legislation.
3. It encourages free movement of products within the European Market.

Not all products must bear the CE Mark. Only those product categories that are subject to specific directives in the CE Marking need to be CE Marked. But as CE marking covers a wide range of product types, very few products find themselves exempt from this.

A manufacturer has to make sure:

1. He/she completes the conformity test.
2. He/she prepares a technical file of the same.
3. He/she issues the EC Declaration of Conformity (DoC).
4. He/she places CE Mark on his product.

A distributor needs to check the existence of CE Mark on the product he is distributing and the necessary supporting documentation. If a product is being imported from a third country, relevant checks need to be implemented to confirm the manufacturer outside the European Union (EU) has taken necessary steps and the product is well documented.

4.2. Products that need CE marking

CE Marking applies to a wide variety of products ranging from electrical equipment to toys and from civil explosives to medical devices. A full list of these product categories is mentioned below:

- active implantable medical devices
- appliances burning gaseous fuels
- cableway installations designed to carry persons
- eco-design of energy related products
- electromagnetic compatibility
- equipment and protective systems intended for use in potentially explosive atmospheres
- explosives for civil uses
- hot-water boilers

- household refrigerators and freezers
- in vitro diagnostic medical devices
- lifts
- low voltage machinery
- measuring instruments
- medical devices
- noise emission in the environment
- non-automatic weighing instruments
- personal protective equipment
- pressure equipment
- pyrotechnics
- radio and telecommunications terminal equipment
- recreational craft
- safety of toys
- simple pressure vessels

The CE marking is not required for items like:

- chemicals
- pharmaceuticals
- cosmetics and foodstuffs

You can download the EC New Approach Directives guidance (PDF, 725KB) from the Europa website.

4.3. How to place a CE marking on a product

Before a CE mark is placed on a product, the manufacturer has to identify which directives apply to his/her product. The process to be followed for CE Marking depends on the directives you apply to your product.

1. Identify the directive(s) and harmonized standards applicable to the product.
2. Check the product specific requirements.
3. Identify whether an independent conformity assessment is required from a notified body. These bodies are authorised by national authorities and officially 'notified' to the European Commission and listed on the NANDO (New Approach Notified and Designated Organisations) database.
4. Test the product and check its conformity.
5. Draw up and keep available the required technical documentation.
6. Placing the CE Marking on your product and EC Declaration of Conformity.

4.4. Using the CE marking

The CE Marking should be attached to the product itself, but it can be additionally placed packaging, in manuals and on other supporting literature. EU Member states ensure the manufacturers implement the regime governing the CE marking. They can take appropriate action in the event of improper use of the marking and provide for penalties for infringements.

The general principles of the CE marking are contained within Regulation (EC) No 765/2008 which sets the requirements for accreditation and market surveillance relating to the marketing of products. You can read the CE marking regulations on the Europa website.

4.5. Keep documentation for CE marking

You must keep certain documentation in the form of a technical file once you have placed the CE marking onto your product. This information can be requested at any time by the Market Surveillance Authorities to check that a CE marking has been legitimately placed on a product.

4.6. The manufacturer's Declaration of Conformity

The EC DoC is a document which may be required to accompany a product. The DoC should:

- Indicate that the product meets all the necessary requirements of the directives applicable to the specific product.
- Make sure it has the name and address of the manufacturer together with information about the product, for example brand and serial number.

4.7. CE marking enforcement

There are many bodies that enforce CE marking legislation to prevent misuse of the CE marking and to ensure that product safety is maintained to a high standard.

Enforcement, or market surveillance, is undertaken by nominated public authorities (Market Surveillance Authorities) in each member state, and each state has separate ways of enforcing the legislation once it has been implemented into national law.

4.8. CE marking – Self Certification

Some manufacturers, depending on their product, can opt for CE Mark Self Certification of CE Certification Self Certification. CE marking by Self Certification can be performed in cases where harmonized standards cover all relevant safety aspects of a product.

The manufacturers need to initially decide whether their product needs CE Marking. But as CE Marking covers a wide range of product categories, very little percentage of products are exempt from the CE Marking. If the manufacturers decide to self-certify, they must:

1. If more than one directive is applicable to the product, it needs to comply with all of them.

2. The manufacturer has to choose the conformity assessment procedure from the modules called out by the directive for the product. There are several modules available for the Conformity Assessment Procedures as listed below:
    - Module A – Internal production control.
    - Module B – EC type-examination.
    - Module C – Conformity to type.
    - Module D – Production quality assurance.
    - Module E – Product quality assurance.
    - Module F – Product verification.
    - Module G – Unit verification.
    - Module H – Full quality assurance.

CE Mark self-certifying eligible manufacturers still need to verify the standards by which their product must comply. All documentation should be filled in the Technical File.

Where compliance of a product with the applicable requirements has been demonstrated by that procedure, manufacturers need to draw up an EC declaration of conformity and a CE Mark is then affixed as referred to the applicable directive.

An application for an EC-type examination, performance of that examination and issue of the EC-type examination certificate is carried out by a Conformity assessment body (Notified body).

The following principles need to be carried out when CE Marking takes place by Self Certification:

- The manufacturer, his authorized representative or the importer (economic operator) must ensure and declare that the products meet the essential requirements of applicable directives.
- The economic operator shall establish the technical documentation (Technical File) and keep it for at least ten years after the last product is available for inspection by the competent national authorities.
- Based on the Technical File, the economic operator must be able to demonstrate whether the product complies with the essential requirements of the applicable directive(s). When applicable, the Technical File also covers the design, manufacture and operation of the product.
- The economic operator shall take all necessary measures, to ensure that the products are manufactured in accordance with manufacturing process as drawn up in the Technical File and with the essential requirements of the Directive(s) related to the product.

Manufacturers not permitted to CE Mark self-certify must work with a qualified testing lab to test and certify a product for the CE Mark.

Benefits of Self-certification:

1. CE Self certification helps the manufacturer to expand their scope which results in an in-depth knowledge regarding the procedures required for certifying their

product. This also helps the manufacturer with development of their future products in accordance with the necessary standards and directives.

2. With in-house self-certification, no third party Notifying Body is required. Based on the proven procedures developed by Certification Experts, this process is efficient and cost effective.
3. The benefits of CE Self Certification are important, particularly for manufacturers that they are updated and keep track on the latest developments in European product legislation.
4. If, based on your Technical File, you are able to demonstrate that the product complies with the essential requirements of the applicable directive(s) and all the necessary information, you as a manufacturer, can affix the CE marking on your products. And this results in free movement of goods in EEA.

Disadvantages of Self-certification:

1. The lack of knowledge regarding the applicable directives, selecting the standards which covers the essential requirements, the steps for CE marking, the essential requirements, safety assessment and the related consequences of its product(s) made.
2. This can result in a product re-call on the market, and can have a harmful effect to the corporate image of the manufacturer or additional costs for the manufacturer because all products must be modified.

The technical legal team of Certification Experts can help to ensure that the legal and technical requirements are in compliance, and this operates as a guide during the CE Self Certification process.

5. Active and Healthy Ageing Mark-up Language (AHA-ML) an O&M profile

5.1. Overview

This section provides a proposal for a new O&M (Observations and Measurements) profile focused on Active and Healthy Ageing, called AHA-ML (Active and Healthy Ageing Mark-up Language) an O&M profile - Discussion Paper). This section introduces the overall need for such a profile and it discusses the measures which have been identified.

5.2. AHA-ML an O&M profile

5.2.1. Introduction

Given the on-going demographic changes caused by ageing population, alternative approaches should be evaluated in order to overcome inevitably high healthcare costs, in terms of: pressure on pensions systems, ageing of the workforce and health and social care needs increase. UNCAP responds to this challenge through the development of an open ICT infrastructure that leverages on location and sensor-based technologies to create radically new paradigms for service care delivery,

UNCAP is delivering a suite of innovative ready-to-be-marketed ICT products and services, based on consumer-grade technologies, designed to help elderly people with cognitive impairments live a more independent life. The solution that will be developed is composed of a cloud platform used to collect, store and analyze data coming from a number of different devices and sensors. Those sensors, most of which are wearable or portable, provide a large variety of measurements that have to be shared with the server in order to being processed.

From a technical standpoint this is being done through fostering of:

- Openness, through release of open specifications and open software components.
- Scalability, through use of cloud-centric approaches.
- User friendliness, ensuring compliance with all most common usability standards.
- Privacy and security, through attention to all related privacy and security aspects.
- Interoperability and use of open standard, through support for a range of open standards from the Geospatial Consortium (OGC) and beyond (e.g. HL7, Open mHealth [3]) for all its key services (e.g. position, sensors, building automation systems, clinical assessment, storage of clinical data etc.) allowing for future extensions in terms of hardware and software.

Starting from this outlook, UNCAP is proposing the definition of a new profile to extend the O&M conceptual model to directly report data related to the Active and Healthy Aging domain, thus called AHA-ML. The conceptual model may then be used to define an XML (or JSON) schema to be used for the exchange of observations related to this specific domain.

5.2.2. Why a specific O&M profile for active and healthy aging is needed

The need for an Active and Healthy Ageing domain-specific profile emerges from the requirement to integrate data and information across multiple systems and sensors. There is a large variety of data and concepts acquired from bio-sensing technologies which are in most cases in a proprietary format. Therefore, it is necessary to identify the concepts shared in different applications and aggregate the semantics of commonly used features under a single definition.

The added value, with respect to other available standards (e.g. Open mHealth [3]), is the integration of the geographic information and the possibility – leveraging on SensorML – of aggregating the information about the specific sensor used and the description of the measurement procedure.

5.2.3. The overall approach

As part of the UNCAP project emerged the need to standardize the flow of measurements acquired from a large variety of sensors (both bio-sensors and not).

During the first year of the UNCAP project we have involved all technologies providers, those that are part of the consortium, in order to address and specifically identify the list of measures required by their technologies. To that list other measures were added in order to consider the possibility for future integration of new technologies.

Another input was collected from the pilot sites – addressing nursing homes and home care scenarios – by leveraging on the use cases collected during the preparation phase which involved clinical staff from 11 hospitals and nursing homes from different Counties. Clinicians and specialists described and highlighted a number of requirements to cover their specific needs. Those requirements were then translated into use cases and consequently in sensors to be adopted and relative measurements.

We have then identified for each entry a reference to some publicly available vocabularies in order to provide a well-defined description of the intended measure. Each vocabulary addresses different objectives. Some examples of those that have been selected as reference for this work:

- Logical Observation Identifiers Names and Codes (LOINC) is a publicly available database specialized on the identification of medical laboratory observations.
- Medical Subject Headings (MeSH) is a vocabulary that indexes biomedical scientific literature (books and articles).
- Unified Medical Language System (UMLS) is a collection of many biomedical vocabularies.

The resulting set of measurements is composed of 35 entries that are reported in the following sections. Each measure will be also related and associated with the geographic position where it was collected.

As per the O&M standard [1], an observation is "an act associated with a discrete time instant or period through which a number, term or other symbol is assigned to a phenomenon. The phenomenon is a property of an identifiable object, which is the feature of interest of the observation. The observation uses a procedure, which is often an instrument or sensor but may be a process chain, human observer, an algorithm, a computation or simulator. The key idea is that the observation result is an estimate of the value of some property of the feature of interest, and the other

observation properties provide context or metadata to support evaluation, interpretation and use of the result."

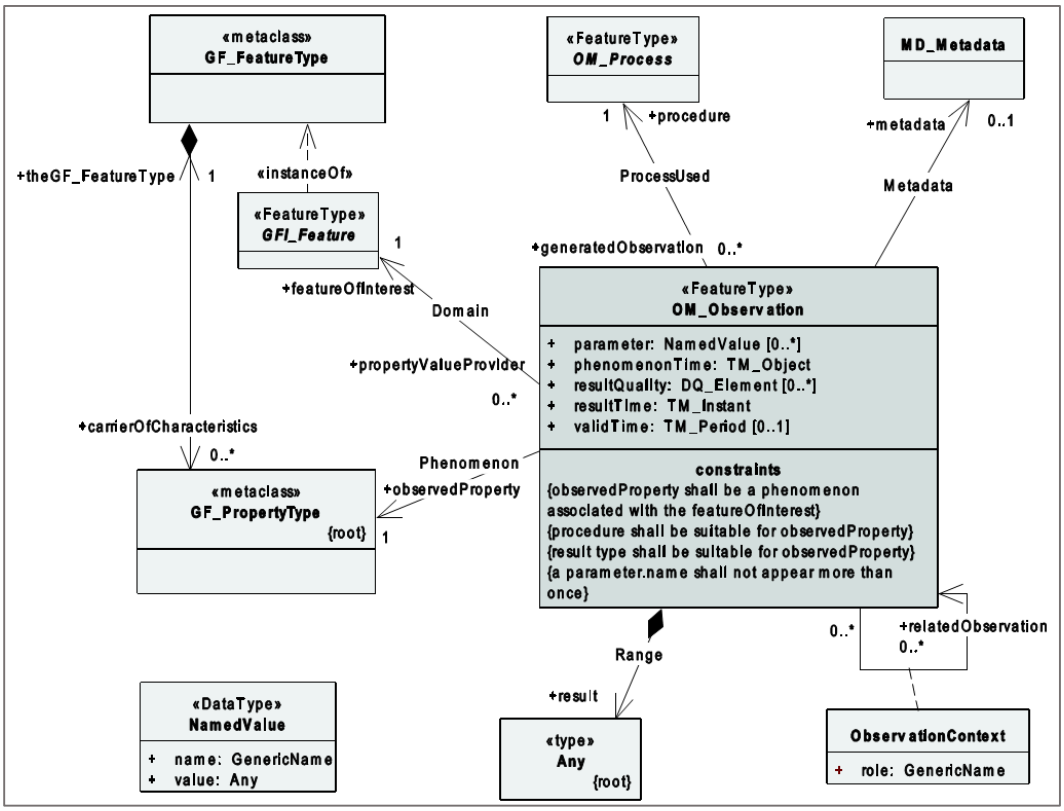

Figure 1: The basic Observation type.

The attributes associated with an observation are:

- phenomenonTime: describes the time that the result applies to the property of the feature-of-interest. This is often the time of interaction by a sampling procedure or observation procedure with a real-world feature. In our case it may refer to the time a blood sample was collected from the patient.
- resultTime: describes the time when the result became available, typically when the procedure associated with the observation was completed. For some observations, this is identical to the phenomenonTime. Following the previous example, it reports the time at which the blood sample was analyzed and the value of glucose was extracted.
- validTime: describes the time period during which the result is intended to be used. This is an optional attribute and since we have not yet envisioned an example in which this may be useful it will be probably not be provided.
- parameter: shall describe an arbitrary event-specific parameter. This might be an environmental parameter, an instrument setting or input, or an event-specific sampling parameter that is not tightly bound to either the feature-of-interest or to the observation procedure. In this specific scenario this attribute can be used to define the location where body temperature is measured (e.g. mouth).
- resultQuality: describes the quality of the result. This instance-specific description complements the description of the observation procedure, which

provides information concerning the quality of all observations using this procedure.

In the following figure are also depicted the possible interactions with other components/standards of OGC for the scenario envisioned:

- Sensor Observation Service (SOS) to manage and retrieve data and metadata from the registered devices by relaying on the O&M standard.
- Sensor Alert Service (SAS) to be used upon the detection of anomalies to send alerts to a specific user (e.g. a clinician or next of kin).
- Sensor Alert Service (SAS) to provide asynchronous notification of sensor events.
- SensorML to describe the sensor and the measurement process.

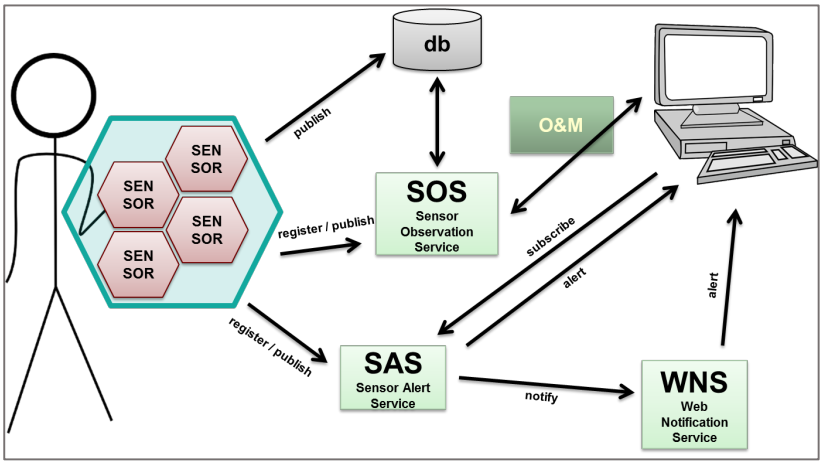

Figure 2: Possible integration with other OGC standards.

5.2.4. The measurements

This section reports the measures identified as relevant to comprehensively represent the psychophysical condition of an elderly person. In general terms, we focused on those measurements required by the sensors/devices that will be integrated in the UNCAP platform while considering also further measurements which could be relevant in general terms. The following list is therefore non exhaustive and many other may be added in the future.

Table 1: measurements proposed within the O&M profile.

Measurement	Vocabulary reference	Unit of Measure	Sensor
Affinity This relates to the emotional state related to a degree of affinity detected by the system in the performing of a given task (e.g. a cognitive game). There is not a specific normative data that could fit this value.	none	float between 0 and 1	portable EEG

Amount Extent of permanence at bed It represents the time spent at bed (ore, more in general, at rest) during a 24hrs interval.	none	hours/day	many sensors can produce such information including, but not limited to: accelerometers, smart sensing floor, pressure sensors, solutions based on the use of video cameras and in general any device able to detect the position of the user
Amount of physical exercise Represents the time-spent by the user doing physical exercise (i.e. not at rest).	none	hours/day	any sensor capable of monitoring the physical exercise (e.g. accelerometers, pedometers, indoor location based technology)
Attention This relates to the emotional state related to a degree of attention detected by the system in the performing of a given task (e.g. a cognitive game). There is not a specific normative data that could fit this value.	none	float between 0 and 1	portable EEG
Basal metabolic rate Represents the amount of energy (in calories) necessary to maintain the body functioning in normal healthy conditions (e.g. blood circulation, breathing, cell growth, etc.) when at rest.	none	kcal/day	usually basal metabolic rate is calculated manually, through the following formulas: for men: $BMR = 10 * weight\ (kg) + 6.25 * height(cm) - 5 * age(years) + 5$ for women: $BMR = 10 * weight\ (kg) + 6.25 * height(cm) - 5 * age(ye\square rs) - 161$ More precise measurements may be achieved through use of direct or indirect calorimetry in a laboratory

			environment.
Blood glucose Levels of glucose found in the blood. It should be related with the time (e.g. on waking) and relation with meal.	UMLS C0005802	mmol/L (millimole/liter) and mg/dl (normal range 70-110mg/dl)	glucometers
Blood Oxygen Saturation Represents the percentage of hemoglobin saturated with oxygen at the time of the measurement.	UMLS C0523807	Percentage time series (normal 95%-100%, low <90%, emergency <80%)	Pulse oximeter
Blood pressure It is the pressure exerted by circulating blood upon the walls of blood vessels. It is defined as diastolic and systolic pressure of the blood. It is a compound measure that should report both values.	UMLS C1271104	mm Hg (low <90/60), normal from 90/60 to 140/80, high >140/90)	blood pressure meter (sphygmomanometer)
Body fat percentage Body fat is the amount of fat in the body, compared to everything else.	UMLS C0518026	percentage	A smart scale is the simplest (yet less accurate) sensor that can be used. More accurate techniques are available but require a specialist and a laboratory environment.
Body height Represents the distance from the bottom of the feet to the top of the head.	UMLS C0005890	cm	self- reported
Body mass index Body Mass Index (BMI) is a measure of body fat based on height and weight that applies to adult men and women.	UMLS C0578022	kg/m^2	smart scale or self-reported
Body temperature Body temperature is a measure of the body's ability to generate and get rid of heat. It varies on the basis of the location where the measurement is taken (e.g. mouth, armpit, etc.). The location should	UMLS C0005903	°C (normal 36.5–37.5 °C)	thermometer

be taken into consideration and added as a parameter.			
Body weight Measurement of the body mass weight.	UMLS C0005910	Kg (normal values depend on many factors such as age, gender and height)	smart scale or self-reported
Bone density It represents the amount of mineral matter per square centimeter in bones.	UMLS C0005938	g/cm^2	Smart scale. More accurate techniques are available but require a specialist and a laboratory environment.
Calories burned Amount of calories burned.	LOINC 41981-2	kcal	it can be inferred from the type, duration and intensity of the physical activity
Electroencephalography (EEG) It is used to record electrical activity of the brain. A number (the number depends on the device) of – generally noninvasive – sensors is applied on the scalp to measure voltage variations generated by neurons' activity.	UMLS C0234550	voltage [V] time series. It is a time series of multiple measures depending on the number of electrodes applied.	EEG device
Engagement This relates to the emotional state related to a degree of engagement detected by the system in the performing of a given task (e.g. a cognitive game). There is not a specific normative data that could fit this value.	none	float between 0 and 1	portable EEG
Excitement This relates to the emotional state related to a degree of excitement detected by the system in the performing of a given task (e.g. a cognitive game). There is not a specific normative data that could fit this value.	none	float between 0 and 1	portable EEG
Fatigue	none	float between 0	portable EEG

This relates to the emotional and physical state related to a degree of fatigue detected by the system in the performing of a given task (e.g. a cognitive game). There is not a specific normative data that could fit this value.		and 1	
Focus This relates to the emotional and physical state related to a degree of focus detected by the system in the performing of a given task (e.g. a cognitive game). There is not a specific normative data that could fit this value.	none	float between 0 and 1	portable EEG
Galvanic Skin Response Galvanic Skin Response is the variation in electricity conductance when external or internal stimuli occur to the user. It can be clearly related with sweat.	UMLS C0016989 - MESH D005712	mS (Siemens)	galvanic skin response meter
Heart rate It is the number of contractions of the hearth in a time span (the reference time is generally a minute). Should be considered the relation with the activity carried during the measurement (at rest, walking, etc.).	UMLS C0018810	bpm (beats per minute) and can be a single measurement or a time series (at rest the following conditions are commonly acknowledged: Tachycardia >100 and Bradycardia <60)	chest strap or pulse oximeter
Interest This relates to the emotional and physical state related to a degree of interest detected by the system in the performing of a given task (e.g. a cognitive game). There is	none	float between 0 and 1	portable EEG

not a specific normative data that could fit this value.			
Location Describes the position of the user/device when the measurement was collected. It should be considered as a parameter associated to any measure.	ISO 19141:2008 (moving features).	lat/lon	any sensor capable of recovering the geographic positions from different technologies (GPS, Wi-Fi, Bluetooth, etc.)
Mini mental state examination score (MMSE) The mini-mental state examination is a test used to evaluate cognitive impairments of a person. It is generally used to address dementia and assess the progression severity of the illness.	UMLS C1532985	integer between 0 and 30 (normal >25, moderate impairment 18-24, heavy impairment <18)	the score id defined upon the completion of a questionnaire
Falling condition Reports the event a user has fallen.	UMLS C0085639	boolean	wearable accelerometers, smart sensing floor, smart video based surveillance, location based system, caregiver reports
Relaxation This relates to the emotional and physical state related to a degree of relaxation detected by the system in the performing of a given task (e.g. a cognitive game). There is not a specific normative data that could fit this value.	none	float between 0 and 1	portable EEG
Respiratory rate The number of times an organism breathes with the lungs (respiration) per unit time, usually per minute.	MESH D056152	bpm time series	specialized chest strap
Sleep duration Time spent sleeping at bed per day. The time spent awake at bed should not be taken into consideration.	UMLS C0424574	minutes	self-reported or using applications extracting information from accelerometers, EEG and more
Sleep quality	SNOMED CT	float from 0 to	self-reported or using

Quality of the sleep detected using different sensors. It should be related with the duration of the sleep.	248254009	1	external sensors such as EEG monitors, accelerometers, bracelets, etc.
Step count Number of steps taken during a time span (generally a day).	LOINC 55423-8	integer	pedometer or similar devices based on the use of data collected from accelerometers and GPS receivers
Stress levels This relates to the emotional and physical state related to a degree of stress detected by the system in the performing of a given task (e.g. a cognitive game). There is not a specific normative data that could fit this value.	none	float between 0 and 1	portable EEG
Surprise This relates to the emotional and physical state related to a degree of surprise detected by the system in the performing of a given task (e.g. a cognitive game). There is not a specific normative data that could fit this value.	none	float between 0 and 1	portable EEG
Time spent alone Amount of time spent alone per day.	none	minutes	self-reported or acquired from smart location technologies
Total body water Amount of water content in the body.	UMLS C0429632	percentage	A smart scale is the simplest (yet less accurate) sensor that can be used. More accurate techniques are available but require a specialist and a laboratory environment.

5.2.5. Possible example of use

5.2.5.1. Scenario 1

Giulia, a 71 years old woman, was diagnosed a chronic cardiac disease. The treatment plan consists of periodical sampling of blood to determine drugs levels and ECG monitoring. Each analysis has to be shared with her family doctor and her cardiologist.

Moreover, her family doctor suggested her to periodically participate in Nordic walking sessions that the local gym is organizing. Giulia agrees to follow the suggestion and brings with her a smartphone which, connected to a chest strap, measures the heart rate continuously during the session. The information is complemented with the geographic information collected from the GPS module integrated in the smartphone. Giulia shares each session with her family doctor and instructor in order for them to monitor her progresses and react accordingly to adapt the treatment.

5.2.5.2. Scenario 2

Luca is a university researcher who is studying the evolution of aging population across Europe. He is trying to correlate the costs in the different health care systems with the lifestyle and health problems in each country. Out of the many parameters he is interested into, there are:

- Physical activity
- Weight
- Sleep quality and duration

Through his university he is able to connect to an exposed service from which he can gather those parameters in an anonymised and aggregated manner. Data are collected from a vast number of users all across Europe and are shared with Lein real time.

5.2.6. Conclusions and recommendations

This section presents the proposal for the definition of an O&M profile specifically designed to address Active and Healthy Aging scenarios and it explains the details of the envisioned profile. For each measure a definition is given together with a few examples of devices that are able to collect such measure. This profile is required to address specific scenarios that are otherwise not covered by other standards.

The current O&M profile will be submitted to the Health DWG (Domain Working Group) of the Open Geospatial Consortium (OGC) for further actions.

6. Geological and Topological Model Checker (GTMC)

6.1. Overview

This document identifies the list of validation controls that the GTMC service performs in order to validate a given IndoorGML file.

The set of checks are splitted into four main categories, each one contributing to generate a set of report messages, and each one has the power to stop further steps. The controls are performed in sequence since some may require a valid previous verification before proceeding.

6.2. GTMC

Maps are typically composed by a set of geographic data grouped into layers; each layer is connected to a specific dataset and data type, either on a remote database or local file. Usually mapping spaces are divided into two main categories; outdoor and indoor.

While outdoor maps have been covered widely during the last decades, indoor mapping has emerged relatively recently within the GIS domain and its degree of standardization is certainly not being mature as in the outdoor domain.

In i-locate, throughout each pilot 'lifecycle', indoor maps containing not only floor plans, but also the graphs used to represent their connectivity and/or adjacency (essential for indoor routing), will be created in a hybrid way. More specifically, background (floor plans) are uploaded as commonly used geographic files (e.g. Shapefiles) while indoor representations of the navigation graph can be either created by the user, through interactive drawing of the graphs on the map within the i-locate portal, or by uploading a specific file that follows a specific standard, more specifically the new standard (approved by OGC on September 2014) called IndoorGML.

The Geometrical and Topological Model Checker (GTMC) is a software component, deployed as a web-service that acts as a utility suite for the validation of the created/uploaded indoor data. In the context were it was initially developed, the geographical data that require validation are related to the indoor spaces and indoor navigation graph. Typically, each pilot site has its own floor plans and hence an associated indoor navigation map. The latter can be used to define if the indoor spaces will be partially of fully navigable, allowing users and services to search and find routes including indoor locations.

In order to provide a robust and standardized approach to indoor navigation as well as to avoid inconsistent paths, GTMC validates the indoor data provided and produces, as additional output, 'reports' with warnings and the errors (if any) related to the given data in case these are not fully compliant with the given standard.

The workflow of the portal (IndoorGML file creator) usage and GTMC validation can be simplified with the following diagram.

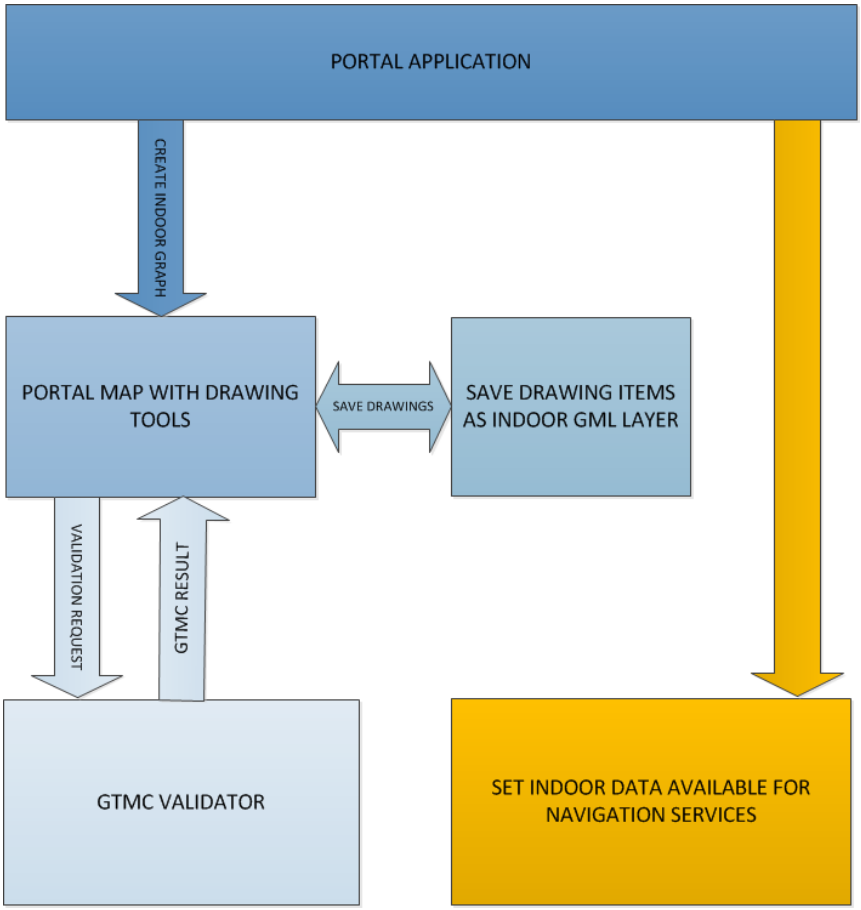

Figure 3: GTMC Workflow.

As illustrated in the previous figure, the GTMC service receives the indoor data, it validates it against a set of predefined rules and, in case of success, and it notifies the caller of the result. As a result, it will be possible for the user to save data within the data storage (the database) containing indoor navigation geographic data.

Being a specific service that validates indoor data, the input format needed to be defined beforehand. The decision made was to adopt as standards for indoor data, IndoorGML, the open standard by OGC that is very likely to become the reference format for indoor location based service. IndoorGML, which stands for Indoor Geographical Markup Language, allows the creation and description of complex indoor spaces by providing a set of items and attributes that can support a wide range of use cases typical of indoor location based services. The standard supports both real geographic data and dual (logical) representations of spaces. In addition, IndoorGML provides an extension for indoor navigation.

Through use of GTMC, data validation is carried on by reading an IndoorGML file (basically a graph made of nodes and edges) and by checking its content at the syntactic, semantic, geometrical and topological level.

6.2.1. IndoorGML overview

IndoorGML supports exchange of indoor maps and navigation graphs to simplify and standardize indoor navigation systems. It has been designed to cater for two different aspects: on the one hand, it allows representing the indoor spaces typical of the building and, on the other, it allows formalizing the "connections" between spaces, an

essential element to support navigation within indoor spaces. IndoorGML does not aim to replace the other available standards (CityGML, KML, GML and IFC); instead it has been engineered to act as a complement to these standards. For this reason, in IndoorGML is possible to define external references (inside the IndoorGML objects) linking to elements defined in the aforementioned standards. More specifically, IndoorGML allows the definition of the following information about indoor spaces:

- Navigation context and constraints.
- Space subdivisions and connectivity types between spaces.
- Geometric and semantic properties of spaces and connectivity.
- Navigation networks (logical and physical) and their relationships.

In a nutshell, it can be said that the scope of IndoorGML is to allow the representation of rooms, corridors and navigation constraints that are useful to users while finding a route inside a building. In order to create a robust representation of a building that allows the navigation graph to be created, it is worth introducing first a set of concepts and basic components, which have been defined by the standard specifications.

6.2.1.1. Indoor Space (Cell)

In IndoorGML, an indoor space is a navigable space made of a set of "cells" (one ore more) that may have common boundaries with other cells.

A "cell" can be a logic representation of a room (e.g. the check-in hall of an airport), or a subspace of a room (e.g. "check-in desk 32"). A cell can contain additional information detailing its semantics (classification and interpretation of the cell), geometry (3D or 2D representation of the space) and topology (adjacency or connectivity with other cells).

Cells can also be organized and aggregated (and then subdivided when required): a set of cells in a space can be aggregated to form a single cell for a different space (typical examples are various cells, each representing a different check-in desk, all of them forming the "check-in area").

The geometric information of a cell contains the description of the indoor space. The geometric information can be defined in IndoorGML in three ways:

- To use an external reference to an object defined in one of the supported standards such as GML, CityGML, IFC or KML.
- To include the geometric representation of the cell inside the IndoorGML cell object (3D solid or 2D surface)
- To omit the geometry and hence reduce the amount of available information for a cell

6.2.1.2. Transitions

IndoorGML transitions are the elements that enable navigation from state to state. Transition elements link two single cells at a time and provide a set of attributes useful for navigation purposes (weight, reference to real geometry, name and description).

There can be different types of transitions, whether if they are navigable or not and as for the states they contain the geometric information in one of the same three options.

6.2.1.3. Wall Model (Thin vs Thick)

In IndoorGML, the representation of the geometries of a cell can follow two different approaches:

- To draw the rooms as polygons so that walls representations are just a line (the polygon boundary); this approach is called thin model. With this approach the rooms are not connected via any other cell because they are touching one another. Instead, they are connected via a direct edge.
- The second approach follows a schema that is closer to the real world representation: walls and doors have a width and are represented as cells. This approach is called thick model.

Depending on which model is used for the representation, a different navigation graph is generated and different routing model has to be considered. The GTMC Validator can check both models, but is mainly focused on the thick model approach.

6.2.1.4. Anchor Nodes

The connection between indoor and outdoor is an important aspect for the indoor and navigation spaces description. In order to accomplish this, IndoorGML provides the concept of "anchor node", which is a special node that represents an entrance to the indoor space. The only difference between a "regular" node and an "anchor" node is that the latter may include additional information for the conversion between indoor and outdoor CRS (Coordinate Reference System). As illustrated in the previous figure, the anchor node contains a reference to the outdoor transportation network and it operates bidirectional (from indoor to outdoor and vice versa). In fact, the anchor node can be made accessible from an outdoor transportation network. This way, while in an outdoor scenario, it is possible to "connect" to the IndoorGML representation by using the anchor node. In addition, some conversion parameter could be made available through the anchor node; these parameters may be required to convert coordinates of each point within the indoor space to coordinates of the outdoor coordinate reference system. The available parameters that can be contained by an anchor node are:

- Rotation origin point.
- Rotation angle(s).
- Scaling factor.
- Translation vector.

By using the composition of the above parameters, all the indoor points can be converted to the outdoor CRS.

6.2.2. Validation Workflow

The validation of indoor data in the context of i-locate has been designed to be a standalone service that acts as a "Black Box", requiring only the data to be validated without any parameter or particular input type.

In particular, the GTMC service requires three Shapefiles (georeferenced vector data file) respectively containing the building floor plan, the walls representation of the floor and the "outline" (building perimeter), together with an additional IndoorGML file (formally an XML file). The input – for each floor plan - is hence formed by:

Three binary shapefiles which, in turn, are complemented by two files, respectively for indexes and for attributes;

The IndoorGML file containing the navigation graph drawn by the user for the given floor.

The validation service is available as a very simple REST service and it can be queried via a basic http POST request containing a zip file in its body. Being a simple REST service, it allows it to be available for everyone and to be extended easily. There is no need for login or security protection since the service does not save any data, or it accesses any protected/sensitive content or database. Instead the service acts only as a mere "in-memory" checking system.

As a consequence of this, all the warnings and errors resulting from the validation need to be stored in a persistent form. For the sake of simplicity, it has been decided to opt for a plain text format (formally a JSON object). In case of warnings or errors on specific nodes/edges, the message will contain the gml:id of the item so the caller can easily trace the source of the problem.

Input data accepted by the validator is sent within the body of the request (as a binary zip file). The zip file format is required because of the potentially high number of files to be sent by the caller. The file is read and processed by the GTMC and the content is checked against the minimum number of files (three shapefiles with additional two complementary files each -nine in total-, plus one IndoorGML file) and the file format extension (.shp for the shapefiles, and xml for IndoorGML).

If all these basic criteria are met, then the data regarding the floor plan are processed and their integrity checked. In case of success (correct binary geometry file), the shapefiles are read and the geometry types and data bounding boxes are retrieved. The geometry type of the floor plan is used, as previously explained, to derive the IndoorGML walls model to be used as reference for the model. In case of simple polygons, the validator will consider the thin model (using the polygons as rooms), while in case of multipolygons the validator will use the thick model (using single polygons as single walls representation). The model will be then used together with IndoorGML file. All of the above checks represent the basic and initial controls on floor plans, and are mandatory for the validator to precede to the last step, i.e. the evaluation of IndoorGML file.

In case of validation success of basic floor plan data, the GTMC will start processing the IndoorGML file. The first check, which is the prerequisite for the following validation stages, is the syntactical validation. At this stage, the IndoorGML file is read, evaluated and converted into in- memory representation of the corresponding objects. If this process fails, then it means that the IndoorGML file is not fully compliant to the standard, as the input file is validated against the official OGC xsd schema for IndoorGML. A fail at this validation stage is caused by a mistake within the IndoorGML structure.

The next step regards the semantic check of the provided file. The indoor data structure is processed and all the connections and references are checked against each other. Since the file contains edges and nodes only, the validation is carried on

by checking the cross references between cells (nodes) and transitions (edges). In case of wrong links (i.e. transition connected to transition), missing reference (i.e. an ID that does not have a correspondence) or wrong geometry type (a point representing a transition), a message is added to the response. With respect to the level of importance of the message, the result will be a "WARNING" or an "ERROR", or it could also be an "OK" if no mistakes are found.

Furthermore, the geometric validation stage performs checks related to the geometries of the items, ranging from boundaries check (general position inside the building) to the specific position of each cell and transition. This is the section of the GTMC that performs walls-check verification against the floor plan. In case of errors or warnings (non-blocking errors), the full list will be contained in the resulting response object.

The last set of checks performed on the IndoorGML data, are related to the topology of the generated graph, to assess the consistency of the graph. This is done by verifying the existence of non-linked edges/nodes (node with no transition or edge with one or two missing nodes) or the presence of standalone sub paths (paths not connected to the outside). This validation step will check the existence of the Anchor node too.

6.2.2.1. Syntax Validation

The syntax validation of the GTMC is the first of the four main steps that are performed on input data. The request is simplified and basic; there are no specific parameters and a small set of files to validate. This simplification has been ideated because the goal is to keep the validator as standalone as possible, and the removal of most of the input parameters allowed this by resulting in a single service that gets the request, validates it within an in memory computation and returns the validation result in the response. Reducing the input parameters lead to the direct reduction of syntax validation checks to perform: since the input data are the floor plan (a binary file) and an IndoorGML graph (a text file) the syntax validation is performed mainly on the second one.

The check to be performed on the floor plan (shapefile) is the verification of the attributes attached to the plan. Each shapefile is composed by the geometric part (in this use case the rooms geometry) and by an alphanumeric part (a table with text, numeric and other database like attributes type). The first one is contained in the .shp file while the second is placed in the .dbf file. The attributes part follows a specific schema like a table, each "row" is directly correlated to a specific geometry and have a list of "columns", one for each attribute. The syntax validation on the shapefile parses this table and verifies that the input file follows a specific schema, i.e. contains all the required attributes and each one is of the expected type (text, numeric, Boolean or date time). In case of negative result, the next steps of the validation are not done and the result is immediately given as error. The message of the error will explicitly contain "Wrong floor plan attribute schema".

The IndoorGML syntax validation follows a different approach. Since the indoor data is contained in a plain text file following the XML format, the validation can be done using xsd schemas. Xsd schema is another plain text file that contains all the "rules" for the XML composition. The validation consists on scanning the XML file and for each "tag" found, check if it is valid by checking the tag name, the provided attributes and the item position against the xsd schema. As an example, the xsd schema for IndoorGML core (version 1.0) requires that the root tag is "IndoorFeatures" which can

contain at most one "MultiLayeredGraph" and both derive from the already existent schema "gml:AbstractFeature" from the GML 3.2 xsd. If the syntax validation over IndoorGML file fails, the GTMC service will give back an error response with a message describing the "Wrong IndoorGML Syntax".

In case of syntax validation correct, the GTMC will proceed with semantic validation of the given data.

6.2.2.2. Semantic Validation

The second core validation group that the GTMC performs is related to the semantics of the data passed as input. It is worth noting that at this level such "semantic" check ensures that "the input file does not contain data that can change the behavior and meaning of the navigation with respect to the real world".

In relation to the above definition, a set of checks is performed on the shapefiles, and others are done to the IndoorGML file. As in the previous validation phase, the controls are done to each file type alone, this means that, at this step, no cross validation between shapefiles and IndoorGML file is carried on.

Since geometries and binary file processing is easier and faster, the first controls are performed over the shapefiles. Given the outline file that contains the boundaries (perimeter) of the building and the floor plan that contains the rooms, each room is processed in order to check that it is fully contained in the building perimeter. In case of error within this iteration, one or more messages are added to the response. In this case the final result will be considered as error, but the validation will complete this phase in order to provide a full semantic validation report, providing to the caller all the potential errors of the floor plan.

```
<stateMember>
    <State gml:id="WAS1">
        <gml:description xlink:type="simple">Stairwell</gml:description>
        <gml:name>Stairwell</gml:name>
        <connects xlink:href="#WAT010" xlink:type="simple" />
        <connects xlink:href="#WAT001" xlink:type="simple" />
        <geometry xlink:type="simple">
            <gml:Point srsName="EPSG:4326" gml:id="WAP1">
                <gml:pos>23.556150930059 46.071584048012 0.0</gml:pos>
            </gml:Point>
        </geometry>
    </State>
</stateMember>
```

Figure 4: State Item.

The second phase of semantic validation is carried on at the IndoorGML file level. The indoor navigation graph is processed node-by-node and edge-by-edge. Each node is parsed; its transition members are read and checked for existence. In case this exists, the transition is checked and the start or the end tag must reference the node just parsed. If one of the above checks fails, the final result of the validation will be an "error" state and there will be a message specifying the error. A similar check is done for edges: each edge is parsed, its start and end tags are checked against node list and if one or both are missing or non-existing, a blocking message is added.

```
<Transition xlink:type="simple" gml:id="WAT010">
    <gml:description xlink:type="simple">WAT010</gml:description>
    <gml:name>WAT010</gml:name>
    <weight>1.0</weight>
    <connects xlink:href="#WAS1" xlink:type="simple" />
    <connects xlink:href="#WAS501" xlink:type="simple" />
    <geometry xlink:type="simple">
        <gml:LineString srsName="EPSG:4326" gml:id="WALS010">
            <gml:pos>23.556150930059 46.071584048012 0.0</gml:pos>
            <gml:pos>23.556169705523 46.071571978071 0.0</gml:pos>
        </gml:LineString>
    </geometry>
    <transitionType>NORMAL</transitionType>
</Transition>
```

Figure 5: Transition Item.

While performing the above procedure a set of second-order checks are also performed, namely:

- Wrong transition nodes: a Transition references another transition as start or end tag. If this occurs the validation state will be set as Error.
- Incorrect transition member: a State (node) references another node as a transitionMember.
- Missing reference node: the node referenced in a Transition as start or end tag, must be present in the nodes list.
- Missing reference transition: the transition referenced as transitionMember for a State must be present in the edges list.
- Unexpected State geometry type: the geometry type for State (node) must be a gml:point. In case of different geometry type, the validation will fail with an error message.
- Unexpected Transition geometry type: the geometry type for a Transition (edge) must be a gml:LineString. In case of different geometry type, the validation will fail with an error message.

Despite the geometry type check could seem to be a part of the geometric validation, it is part of the semantic validation, because this regards the case a different geometry type than the expected is found. The IndoorGML standard accepts different types of geometries (and of course, the parameter is optional for the standard).

If all the semantic checks are passed, the validation will proceed to validate the geometric part of the input data, otherwise it will stop the process and return the error log together with all the collected messages.

6.2.2.3. Geometrical Validation

The third core step of GTMC is actually the first stage that requires checking shapefiles and the IndoorGML data at the same time. At this stage, the four inputs (Outline, Floor Plan, Walls and IndoorGML) are used to "geometrically" validate the indoor graph.

The first check regards the outline shapefile and the IndoorGML data. Each item of the IndoorGML graph is processed; if one or more of the nodes and transitions reside outside of the perimeter, then the validator will end up with a negative result (indoor navigation must be inside of the building). With this first check the system ensures that IndoorGML data are referring to the same context/building of the outline.

After the first check, the floor plan shapefile substitutes the outline and a node-room validation is performed. More specifically, since for each node contained in the IndoorGML graph there should be a corresponding room in the floor plan, the system will check exactly the inclusion of the State geometry inside the room polygon. In case of negative result, the validation will not be set as error, but only as a warning because there could be the case where a non-room space can be considered as a state.

The last geometrical check is again carried on taking into account the wall model and the IndoorGML data. In this case the walls are used as base for the verification, while the transitions are the active part of the check. For each transition, the validator verifies if it crosses the walls of the rooms or go through open spaces. If the model in use is the thin model and the transition is crossing the walls, the result will be given as a warning, because if the transition is drawn as a logic connection between two states and not as a geometric connection, the issue cannot be fixed.

If otherwise the model in use is considering thick walls, then each door and navigable gate must be a state itself and hence, there should not be transitions crossing the walls; in this case the result of the validation will be set as error.

6.2.2.4. Topological Valdation

The topologic validation in the GTMC acts at a very low level. The topologic controls performed over the IndoorGML graph should be dependent on each pilot (building) rule and use case, and hence cannot be easily included in a generic validator. However, it is possible to run a set of verification based on some general assumptions that each indoor graph should follow.

The first requirement for an indoor graph is to be a consistent graph. This means that there must not be any non-linked edges or nodes. It is possible to check this use case by visiting the whole graph and the whole list of edges/nodes. The system will verify that each node is connected to other nodes via at least one transition and, if this is not the case, it will return a warning. The expected result is to have a navigable graph that can reach every navigable space.

If the IndoorGML file contains "dead nodes" this means that the node is not reachable and hence unuseful to the navigation graph description. However, there could be the case that the state is not temporarily navigable, but will be in the future, and the user wants to keep it in the graph (provisionally).

The same idea can be extended to standalone paths. If instead of a single state there is a set of cells interconnected (albeit not connected to the rest of the graph) then that part would be considered as a dead path and, again, the system would set the result of the validation stage as a warning.

The last topologic validation is relative to the presence of the Anchor node (refer to section 6.1.4). In order to connect the outdoor and indoor space, there should be an anchor node that is designed to link the external navigation graph to the indoor counterpart. Even if the anchor node is required, it could not be set as mandatory in

the GTMC because since the validator is called floor by floor, there will be some floors not connected directly to the outdoor space.

6.2.2.5. Request and response format

As mentioned in the previous chapters, the GTMC validator has been designed to be as simple as possible for the caller. The final implementation has implemented a very simple and basic call procedure, as detailed in the reminder of this section.

The service is available as a RESTful HTTP request. The request must provide in the body a ZIP file; hence the request method must be POST. There are no query parameters and the URL of the call is as simple as the normal endpoint:

http://IPADDRESS/gtmc/validate

The user needs to add, in the payload of the request, a zip file and call it "zipFile", by setting the "Content-Type" of the request as "multipart/form-data".

When the validator receives the request it starts processing the data. The result will be a *Content- Type* "application/json" containing the following structure:

```
{
   "result":"OK/WARNINGS/ERRORS",
   "messages":[
      {
         "messageType":"ERROR/WARNING",
         "messageTitle":"Invalid Input File",
         "messageDetail":"The given file is not a zip file."
      },
      ...
   ]
}
```

The list of messages can be an empty list or a verbose list depending on the validation steps result. This response format is kept even if the provided data is not compliant with the requirements (e.g. in case of missing files, wrong input, no input etc.).

7. Standardisation activity in privacy, security and eHealth domains at ETSI

ETSI (see http://www.etsi.org) is one of the 3 European Standards Organisations (ESOs) formally recognised and supported by the EU with a focus on ICT and the home of key global standards in cellular radio (e.g. GSM, TETRA, 3G, LTE), of euro-ISDN, and of many other key areas in the domain.

One of the overall goals of standardisation is to achieve interoperability and the aims in the eHEALTH work is to address each of the following domains:

- Syntactic interoperability
    - Syntax derives from the Greek word meaning ordering and arrangement. The sentence structure of subject-verb-object is a simple example of syntax, and generally in formal language syntax is the set of rules that allows a well formed expression to be formed from a fundamental set of symbols. In computing science syntax refers to the normative structure of data. In order to achieve syntactic interoperability there has to be a shared understanding of the symbol set and of the ordering of symbols. In any language the dictionary of symbols is restricted, thus in general a verb should not be misconstrued as a noun for example (although there are particularly glaring examples of misuse that have become normal use, e.g. the use of "medal" as a verb wherein the conventional text "He won a medal" has now been abused as "He medalled").
- Semantic interoperability
    - Syntax cannot convey meaning and this is where semantics is introduced. Semantics derives meaning from syntactically correct statements. Semantic understanding itself is dependent on both pragmatics and context. There are a number of ways of exchanging semantic information although the success is dependent on structuring data to optimise the availability of semantic content and the transfer of contextual knowledge (although the transfer of pragmatics is less clear). Semantic interoperability is very difficult to add to a system that has not been initialised with it as
    - The problem that semantic interoperability attempts to solve is that of given an identifier what deterministic action should be taken (given the system's present state and any inputs, there should be only one possible action that the system takes). Semantic interoperability also provides greater richness and thus accuracy of identity of any object in the wider eHealth environment.
- Electrical and mechanical interoperability
    - Quite simply a device with a power connector using, for example, a Type-IEC 60906-2 connection cannot accept power from anything other than a IEC 60906-2. Similarly, for example, a serial port complying to USB-Type-A will not be able to connect with a USB-Type-C lead. In addition to simple mechanical compatibility there is a requirement to ensure electrical interoperability covering amongst others the voltage level, amperage level, DC or AC, frequency if AC, variation levels and so forth.

The positioning of UNCAP with regards to ETSI is fairly wide and takes in a number of technical bodies with ETSI to achieve a large body of standards work that taken together will present developers and procurement bodies with the potential to fulfil the market requirement for standards based eHealth ICT equipment. The overall strategy is to develop use cases in EP eHEALTH with considerable input from those developed in UNCAP but suitably sanitised and generalised for further development of standards. These use cases will themselves drive further development of standards in smartM2M and oneM2M (and by reference in 3GPP) on extension of the machine to machine ontology to include eHealth devices. In general support to this work supporting work in CYBER will be undertaken to address the particular security models for the privacy protection and long term data protection requirements of eHealth. In CYBER this work is complemented by work planned and being undertaken in the ISGs of NFV and QSC, in oneM2M and with oversight from the regulators in LI. An outline of the work items that have been started and where work is planned is given below.

It has to be recognised that UNCAP has no status in ETSI (or indeed in CEN/CENELEC) as UNCAP is not a legal body in its own right. In order to take work from UNCAP (or any other project in a similar state) to ETSI it has to be introduced by an ETSI member. For UNCAP this role is taken by partner C3L. When standards are published they are necessarily anonymous with respect to the contributors (although the rapporteur and supporting members is known and visible on the ETSI work programme management tool). This means that whilst contributions may be made by C3L on behalf of UNCAP and in response to requirements coming from UNCAP this is not made public in the final ETSI publication. There is one exception in the Industry Specification Groups (ISG) where a Group Specification may indicate in an annex the names and affiliations (including acknowledging funding sources such as UNCAP) of the contributors. Where C3L is involved in the development of GSs this acknowledgement shall be given.

7.1. EP eHEALTH

A first work item has been raised in early 2015 (details below) and is in development across the meeting calendar of the group. Unfortunately, the overall meeting attendance of EP eHEALTH has been somewhat disappointing and due to changes in circumstances a few meetings have had to be moved to later dates with an overall review expected in early 2016 with the ETSI Board.

Details of 'DTR/eHEALTH-007' Work Item

Work Item Reference	Type	STF	Technical Body in Charge	Standard Not Ready For Download
DTR/eHEALTH-007	TR		eHEALTH	
Current Status (Click to View Full Schedule)	**Latest Version**	**Cover Date**	**Standstill**	**Creation Date**
Early draft (2015-11-19)	0.0.2	2015-10-01	View Standstill Information	2014-11-12
Rapporteur	**Technical Officer**		**Harmonized Standard**	
Scott Cadzow	Patrick Guillemin		No	

Title	eHEALTH Standardisation use cases for eHealth eHealth use cases
Scope and Field of Application	To present a number of typical use cases in the eHealth domain and from their analysis to identify gaps in standardisation. The analysis should cover aspects of link connectivity, network interconnectivity, semantic and syntactic interoperability, security (risks and provisions), and the existence of standards to meet each aspect. Furthermore the analysis should clearly identify actors and their roles, for each of primary, secondary and tertiary involvement in the use case. Examples will be sought from industry, from existing and completed FP7 and H2020 projects and from current eHealth and Health industry practices.
Supporting Organizations	Cadzow Communications, CSEM, ITT RAEN, Cybernetic Medical Systems Ltd

	Keywords	Projects	Clusters	Frequencies	Mandates	Directives
	HEALTH interconnection INTEROPERABILITY INTERWORKING privacy SECURITY usability use case USER		Connecting Things Interoperability			
Official Journal	2015-5--20					
Remarks	2015-11-19 cadzow Draft contributed - V 0.0.2 contributed for Discussion in eHEALTH(15)000009 as Early draft 2015-11-19 cadzow A new draft is uploaded - V 0.0.2 with status: Early draft - with comment: Intended for review in the November workshop 2015-04-05 cadzow Draft contributed - V 0.0.1 contributed for Discussion in eHEALTH(15)026003 as Early draft 2015-04-05 cadzow A new draft is uploaded - V 0.0.1 with status: Early draft - with comment: First draft for review at eHealth meeting in April 2014-12-11 MINAEV TB adoption of WI eHEALTH, see contribution eHEALTH(14)025003r1 2014-12-11 MINAEV WI proposed to TB eHEALTH, see contribution eHEALTH(14)025003r1 2014-11-12 CADZOW WI proposed to TB eHEALTH, see contribution eHEALTH(14)025003					

	Work Item Aspects
Security aspects	Deals with the identification of security risks in the eHealth and telemedicine contexts

Figure 6: details of DTR/eHealth-007 work item.

When this work item is close to completion (assuming that EP eHEALTH will continue in its current form) at least one extension work item will be proposed that identifies the semantic interoperability requirements for eHEALTH across a range of connected equipment and protocols.

7.2. TC CYBER

The work in TC CYBER addresses all aspects of security in ICT, thus it acts as a horizontal point of reference where detail or explicit specialisation is not required (e.g. as would be necessary for the very specific needs of 3G). For UNCAP work has been raised in a number of areas that are key to the long-term success of eHEALTH solutions based on UNCAP thus addressing identity management and privacy verification. This is further supported by complimentary work in the areas of protection requirements for Critical Infrastructure (see definition below for its relevance to UNCAP and eHealth in general), and for examination of methods to achieve crypto-agility for long term protection of data from threats arising from Quantum Computing specifically and advances in attack capability over the lifetime of data. Data lifetimes in eHealth may be of the order of 10s of decades whereas cryptographic algorithms are considered "safe" for periods that rarely exceed 20 years.

Details of 'DTS/CYBER-0013' Work Item

Work Item Reference	ETSI Doc. Number	STF	Technical Body in Charge	Standard Not Ready For Download
DTS/CYBER-0013	TS 103 485		CYBER	
Current Status (Click to View Full Schedule)	**Latest Version**	**Cover Date**	**Standstill**	**Creation Date**
Start of work (2015-10-15)		2015-10-01	View Standstill Information	2015-09-16
Rapporteur	**Technical Officer**		**Harmonized Standard**	
Scott Cadzow	Carmine Rizzo		No	

Title	CYBER; Mechanisms for privacy assurance and verification Privacy assurance and verification
Scope and Field of Application	To provide technical means, building on ongoing work in TC CYBER, that enable assurance of privacy and verification of said assurance. The document shall address Identity Management with respect to privacy, naming structures with respect to PII and objects that may be associated as proxies to entities requiring PII protection, protocols and policy mechanisms to give assurance and the verification of assurance for PII
Supporting Organizations	Cadzow Communications; Telecom Italia S.p.A.; CESG; Intellinium

Keywords	Projects	Clusters	Frequencies	Mandates	Directives
assurance CONFIDENTIALITY identification privacy		Security		M/530	

Official Journal	2015-5--20
Remarks	2015-10-15 CADZOW TB adoption of WI CYBER, see contribution CYBER(15)005011r2 2015-09-16 CADZOW WI proposed to TB CYBER, see contribution CYBER(15)005011

Figure 7: details of DTS/CYBER-0013 work item.

Details of 'DTS/CYBER-0014' Work Item

Work Item Reference	ETSI Doc. Number	STF	Technical Body in Charge	Standard Not Ready For Download
DTS/CYBER-0014	TS 103 486		CYBER	
Current Status (Click to View Full Schedule)	**Latest Version**	**Cover Date**	**Standstill**	**Creation Date**
Start of work (2015-10-15)		2015-10-01	View Standstill Information	2015-09-16
Rapporteur	**Technical Officer**		**Harmonized Standard**	
Scott Cadzow	Carmine Rizzo		No	

Title	CYBER; Identity management and naming schema protection mechanisms Identity management and naming schema protection mechanisms
Scope and Field of Application	The intent of this work item is to identify means to protect identity (as distinct from privacy) in order to alleviate some of the resultant threats. The structure of identity and the means to build associations between identifiers and other data is a source of data leakage in many systems that when abused may lead to identity theft, loss of privacy, as the bootstrap to crime, and many other societal and technical ills. The work item shall detail the mechanisms to protect such data in the general case and link to specific use cases in NFV, the PLMN domain, and the wider Internet of Things domain to ensure the widest scope of protection can be defined
Supporting Organizations	Cadzow Communications; Telecom Italia S.p.A.; CESG; Intellinium

Keywords	Projects	Clusters	Frequencies	Mandates	Directives
authentication authorization CONFIDENTIALITY identification trust services		Security		M/530	

Official Journal	2015-5--20
Remarks	2015-10-15 CADZOW TB adoption of WI CYBER, see contribution CYBER(15)005012r2 2015-09-16 CADZOW WI proposed to TB CYBER, see contribution CYBER(15)005012

Figure 8: details of DTS/CYBER-0014 work item.

Details of 'DTR/CYBER-0002' Work Item

Work Item Reference	ETSI Doc. Number	STF	Technical Body in Charge	Standard Not Ready For Download
DTR/CYBER-0002	TR 103 304		CYBER	
Current Status (Click to View Full Schedule)	**Latest Version**	**Cover Date**	**Standstill**	**Creation Date**
Early draft (2015-10-26)	0.0.4	2015-08-01	View Standstill Information	2014-10-02
Rapporteur	**Technical Officer**		**Harmonized Standard**	
Giovanni Bartolomeo	Carmine Rizzo		No	

Title	CYBER; PII Protection and Retention
Scope and Field of Application	Essentially different than any previous telco scenario where user data was accessible from network functional elements only, today even sensitive PII is directly accessible from terminals. Server-based data access control technologies are becoming less effective for PII protection. This new WI is intended to describe novel access control technologies that enable 1) data protection, based on policy rules, as soon as data leaves the boundary of terminal's OS and 2) portability of protection settings when data moves from one service provider to another.
Supporting Organizations	Cadzow Communications, HUAWEI TECHNOLOGIES Co. Ltd., CNIT, ISMB

Keywords	Projects	Clusters	Frequencies	Mandates	Directives
access control privacy		Security		M/530	

Official Journal	2015-5--20
Remarks	2015-10-26 bartolomeog Draft contributed - V 0.0.4 contributed for Discussion in CYBER(15)000007 as Early draft 2015-10-26 bartolomeog A new draft is uploaded - V 0.0.4 with status: Early draft 2015-10-10 bartolomeog Draft contributed - V 0.0.3 contributed for Discussion in CYBER(15)005027 as Early draft 2015-10-10 bartolomeog A new draft is uploaded - V 0.0.3 with status: Early draft 2015-10-08 bartolomeog A new draft is uploaded - V 0.0.2 with status: Early draft 2015-01-25 bartolomeog Draft contributed - V 0.0.1 contributed for Discussion in CYBER(15)003016 as Early draft 2015-01-25 bartolomeog A new draft is uploaded - V 0.0.1 with status: Early draft 2014-10-15 RIZZOC TB adoption of WI CYBER, see contribution CYBER(14)002013r1 2014-10-15 RIZZOC WI proposed to TB CYBER, see contribution CYBER(14)002013r1 2014-10-02 BARTOLOM WI proposed to TB CYBER, see contribution CYBER(14)002013

	Work Item Aspects
Key requirements	Privacy
Security aspects	

Figure 9: details of DTR/CYBER-0002 work item.

Details of 'DTR/CYBER-0001' Work Item

Work Item Reference	ETSI Doc. Number	STF	Technical Body in Charge	Standard Not Ready For Download
DTR/CYBER-0001	TR 103 303		CYBER	
Current Status (Click to View Full Schedule)	**Latest Version**	**Cover Date**	**Standstill**	**Creation Date**
Early draft (2015-10-07)	0.0.3	2015-08-01	View Standstill Information	2014-08-18
Rapporteur	**Technical Officer**		**Harmonized Standard**	
Scott Cadzow	Carmine Rizzo		No	

Title	CYBER; Protection measures for ICT in the context of Critical Infrastructure Security of ICT in CI
Scope and Field of Application	The critical infrastructure protection addressed in the EU's published directive is essentially Power and Transport. It is clear to most casual observers that the global economic infrastructure is now composed of a huge set of ICT networks and services. It would not be a stretch to say that ICT capabilities now underpin all of the other critical infrastructures. This means food security, economic activity security, citizen safety and just about everything else. The purpose of the TR to be delivered by this work item is to identify the role of ICT protections through the deployment of security technologies and security management to deliver effective Critical Infrastructures that are reliant on ICT technology. The topics to be addressed by the work item include: Resilience (taking as input the ENISA reports on this topic and work from related national programmes); M2M communications (in close liaison with oneM2M and smartM2M); eHealth (in order to give assurance of access to ICT enabled eHealth systems). The report is intended to highlight aspects of CI and ICT that have to be addressed to ensure that CI maintains its infrastructure role.
Supporting Organizations	BIS, Cadzow Communications, TeleTrusT Bundesverband, CESG

	Keywords	Projects	Clusters	Frequencies	Mandates	Directives
	Critical Infrastructure Cyber Security		Security			
Official Journal	2015-5--20					
Remarks	2015-10-07 cadzow Draft contributed - V 0.0.3 contributed for Discussion in CYBER(15)005023 as Early draft 2015-10-07 cadzow A new draft is uploaded - V 0.0.3 with status: Early draft 2015-01-25 cadzow Draft contributed - V 0.0.2 contributed for Discussion in CYBER(15)003015 as Early draft 2015-01-25 cadzow A new draft is uploaded - V 0.0.2 with status: Early draft - with comment: Updated taking into account the contribution from Yaana 2014-12-12 cadzow A new draft is uploaded - V 0.0.1 with status: Early draft - with comment: Table of Contents and some initial references 2014-10-16 CADZOW TB adoption of WI CYBER, see contribution CYBER(14)002008r2 2014-10-16 CADZOW WI proposed to TB CYBER, see contribution CYBER(14)002008r2 2014-10-16 CADZOW WI proposed to TB CYBER, see contribution CYBER(14)002008r1 2014-08-18 CADZOW WI proposed to TB CYBER, see contribution CYBER(14)002008					

Figure 10: details of DTR/CYBER-0001 work item.

It is noted that some of these work items were proposed in anticipation of UNCAP and therefore were added to the work programme in advance of UNCAP, however their relevance is essential.

7.3. TC LI

There is no direct work for UNCAP being done in the LI group whose remit is to ensure that law enforcement is able, with appropriate authorisation, to view data held in, or transmitted through, ICT systems. There is a challenge raised by M2M and IoT that encompasses the domain of UNCAP that needs to be made visible to this group and to ensure that each side of the divide (law enforcement on one side and the M2M/IoT community on the other).

7.4. ISG NFV

In like manner to the LI group there is no active UNCAP work being done here but the remit of this group is to address the management of virtualised functions across networks. This is an extension of the middleware model of UNCAP and is the model of choice of almost all network providers for future evolution and is also the model of choice that is redefining the "cloud" and many of the aaS technologies (where aaS is an acronym of "as a service" and this could be "Network function aaS", "Storage aaS", "Processing aaS", and so on).

7.5. smartM2M and oneM2M

smartM2M is the ETSI face of the global partnership project oneM2M whose scope includes the IoT and M2M aspects of eHealth. The primary role for UNCAP here is to assist in the development of a scripting language for privacy protection policy exchange. This is being addressed by development of Change Requests to a number of developing standards and is being integrated to the development of the home appliances ontology (a development of the SAREF ontology developed for smartM2M).

7.6. Summary of ETSI activity

There is close interaction between all of the activities at ETSI. As stated above the root is the work in EP eHEALTH on use cases and this is extended through the work in each of the increasingly specialised bodies as it comes closer to a set of standards that are normative (as opposed to establishing boundaries and requirements for detail work).