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Hydra

Networked Embedded System middleware for
Heterogeneous physical devices in a distributed architecture

D2.3 Initial regulatory-standards watch

Integrated Project
SO 2.5.3 Embedded systems

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Index:

1. Introduction

1.1 Purpose and context of this deliverable

This document is the initial report for the regulatory standards watch task in Hydra. This ongoing activity forms part of the iterative user requirements engineering work of WP2. The regulatory standards watch activity is described in the DoW as follows:

> *"Maintain a continuous study of the … regulatory-standards … affecting the HYDRA middleware and their impacts on project requirements."*

The purpose of this work is to support the user requirements by searching for and collating relevant regulatory factors and trends that could impact the requirements over and above the specific explicit needs expressed by end-users in the development of the Hydra scenarios. Again, the DoW states:

> *"Defining societal and business user requirements specifications will be done by correlating socio-economic, regulatory and policy issues with aspects of e.g. social acceptance, economic performance, regulatory frameworks for monitoring and control of private citizens, privacy of data, governmental policies for health and safety, etc. will be addressed and integrated with the functional, security and infrastructure requirement."*

This initial report feeds into the Initial Requirements Phase of the project and provides input into the Functional Requirements, Security and Trust Requirements, Infrastructure and Deployability Requirements, and Social and Business Requirements.

1.2 Scope of this deliverable

The regulatory standards watch activity feeds into the iterative requirements engineering process. The scope of this document is to present the initial findings of the regulatory standards watch activity for the early requirements iterations. As the project progresses, updates to this document will be produced as necessary.

The document contains a general overview of regulatory standards that impact network embedded systems in the broad sense, then focuses on the three applications domains addressed by Hydra:

- Intelligent buildings;
- Healthcare; and
- Agriculture.

Each chapter looks at the policy-level regulatory trends as well as lower-level standards compliance issues.

Rather than reproduce the vast quantity of material, the scope of this report is to highlight the existence and relevance of regulations and standards, then to direct the reader via references to further material.

The report draws from European legislation and standards, along with international standards.

2. Executive summary

The purpose of this document is to inform the user requirements by identifying regulatory factors and trends that could impact the requirements over and above the specific needs expressed by end-users.

European regulatory standards are identified that could have a potential impact on Hydra, in terms of factors that affect general applications involving networked embedded systems and factors specific to the three Hydra application domains (intelligent buildings, healthcare and agriculture). In each case, the possible impact on Hydra is assessed in terms of whether regulations pose a threat, opportunity, or simply a requirement on the project.

The majority of implications for Hydra at the more detailed technical level are found to be requirements, for example the need for compliance with data privacy laws in terms of network security, data retention and user consent.

Some important design inputs are identified, for instance the need to factor in health and safety issues and thereby reduce/eliminate potential future risks where components of Hydra are likely to be deployed in the workplace.

Regulations at the higher policy level are included for the three application domains – construction sector, healthcare and agriculture – and these tend to provide opportunities for Hydra to contribute significantly towards regulatory compliance at reduced cost.

Existing and emerging international standards, in particular from ISO, such as building automation protocols also offer an opportunity to Hydra to enable communication with third party devices but could also pose a threat if the Hydra consortium choose not to comply where such a standard were to become mandatory, or even *de facto*.

Over the course of the project, the Hydra consortium will continue to monitor regulatory developments in the areas addressed, in particular assessing adoption of standards and ensuring compliance with evolving regulations.

3. General overview

3.1 Key areas

European legislation can be broadly broken down into a number of areas, the most relevant to Hydra concerning protection and support of:

- Citizens – both in terms of consumers and as employees;
- Society – in terms of planning, public health and security;
- Environment – in terms of sustainability, energy conservation and animal welfare; and
- Economy and industry – in terms of the *Information Society*, standards promotion and the encouragement of interoperability.

Clearly there are many other areas of policy which are less relevant for this project, such as foreign relations and trade, monetary policy, enlargement, etc. which have been assessed for relevance but excluded at this stage of the project in order to focus on the factors which have the highest potential impact. Therefore the regulations and standards addressed by this document are drawn from the above four areas.

3.2 Assessing impact on Hydra

The potential impact upon Hydra of each regulatory issue has been assessed in terms of opportunities and threats. Strengths and weaknesses do not apply as clearly Hydra-derived solutions do not exist in the present so we are taking a future view.

The main implications for Hydra concern whether or not Hydra might help to reduce or increase:

- The time and cost to achieve compliance;
- The risk of failing to achieve compliance; and
- The cost of maintaining compliance in terms of processes, procedures, materials, tools used and labour effort.

3.3 Areas of relevance

The next part of this document is organised into 4 chapters, addressing in turn:

- General regulatory issues that could relate to all Hydra applications;
- Regulatory issues specific to the intelligent buildings domain;
- Regulatory issues specific to the healthcare domain; and
- Regulatory issues specific to the agriculture domain.

4. Regulatory standards for all Hydra ES applications

4.1 Key areas

Embedded systems, by their nature, have a wide range of potential applications and therefore could be impacted by an even wider array of legislation and regulatory standards. In order to focus this report on relevant areas for Hydra, this section looks at regulatory standards that cover more than one of the three Hydra application domains. The key areas of European legislation listed in the previous section for which general regulatory standards apply are presented below along with the specific areas of relevant regulation.

4.2 Protection of Citizens

Privacy and electronic communications

Perhaps one of the most critical of areas in relation to Hydra is data privacy. This is addressed by Directive 2002/58/EC of the European Parliament and of the Council of 12 July 2002 concerning the processing of personal data and the protection of privacy in the electronic communications sector[1].

This Directive tackles a number of issues of varying degrees of sensitivity, such as the retention of connection data by the Member States for police surveillance purposes (data retention), the sending of unsolicited electronic messages, the use of cookies and the inclusion of personal data in public directories. The table below summarises the directive along with specific implications for Hydra.

Aspect	Summary	Implications for Hydra
Confidentiality of communications	The Directive reiterates the basic principle that Member States must, through national legislation, ensure the confidentiality of communications made over a public electronic communications network. They must in particular prohibit the listening into, tapping and storage of communications by persons other than users without the consent of the users concerned.	Hydra must employ the most appropriate network security technologies to ensure confidentiality of transmitted personal data.
Data retention	On the sensitive issue of data retention, the Directive stipulates that Member States may withdraw the protection of data only to allow criminal investigations or to safeguard national security, defence and public security. Such action may be taken only where it constitutes a "necessary, appropriate and proportionate measure within a democratic society".	Hydra as a potential repository of person-identifiable data (especially within the health domain), will need flexible and secure archival and retrieval mechanisms.
Unsolicited electronic messages ("spamming")	The Directive takes an "opt-in" approach to unsolicited commercial electronic communications, i.e. users must have given their prior consent before such messages are addressed to them. This opt-in system also covers SMS text messages and other electronic messages received on any fixed or mobile terminal.	Hydra software must provide the end-user with opt-in facilities for the receipt of any mass communications in any message form.

Aspect	Summary	Implications for Hydra
Cookies	Cookies are hidden information exchanged between an Internet user and a web server, and are stored in a file on the user's hard disk. Their original purpose was to retain information between sessions. They are also a useful and much decried tool for monitoring a net surfer's activity. The Directive stipulates that users should have the opportunity to refuse to have a cookie or similar device stored on their terminal equipment. To that end, users must also be provided with clear and precise information on the purposes and role of cookies.	If Hydra supports a browser-interface to end-user, the use of cookies must be optional.
Public directories	European citizens will have to give prior consent in order for their telephone numbers (landline or mobile), e-mail addresses and postal addresses to appear in public directories.	In particular in the health domain, end-users must be allowed to give consent before their personal data is stored on any publicly accessible directory.

4.2.1 Directive 2006/24/EC

In March 2006 the European Parliament and the Council adopted a Directive [2] on the retention of data generated or processed in connection with the provision of publicly available electronic communications services or of public communications networks services and amending Directive 2002/58/EC. The Directive seeks to harmonise the provisions of the Member States concerning obligations on the providers of electronic communications services with respect to data retention. The aim is to ensure the availability of these data for the purpose of investigating, detecting and prosecuting infringements. In particular, the new Directive defines the following:

- the categories of data to be retained;
- the shelf-life;
- the storage requirements for retained data; and
- the principles to be observed in the area of data security.

As with the existing legislation, this further directive emphasises the need for Hydra to offer flexible and secure management of archived personal data.

4.2.2 Product Safety

The safety of products sold in Europe is guaranteed by Directive 2001/95/EC of the European Parliament and the Council of December 2001 [4] which ensures a consistent level of protection for the health and safety of consumers. The EU has introduced a rapid alert system for products which pose a serious risk (RAPEX), and provisions for products to be withdrawn from the market if they are likely to put the health and safety of consumers at risk. This is relevant to Hydra in the case of Hydra-enabled appliances or premises where consumers come into contact with the device(s), and emphasises the need for stringent product testing prior to any product release. It also emphasises the value chain, in that Hydra as a middleware component could still carry liability (dependent on contract negotiation) should a final customer be injured in some way as direct result of a failure in Hydra middleware.

4.2.3 Economic – warranty provision

The *Sale of consumer goods* directive [5] and associated Member State legislation is intended to protect consumers with sufficient and fair warranty provisions. This is relevant to Hydra in the context of any Hydra-enabled appliances which may be purchased directly by consumers, and emphasises the importance of reliability and longevity of both hardware platform and middleware to avoid expensive product recalls.

4.3 Health and safety at work

For the citizen as an employee, Health and Safety at work represents today one of the most important most advanced fields of the social policy of the EU. The EU action in health and safety at work has its legal basis in Article 137 of the EU Treaty. The improvement of health and safety of the workers already started from 1952 under the European Coal and Steel Community. Since then a solid corpus of legislation has been adopted covering a wide number of risks.

The Commission also works in partnership with the European Agency for health and safety at work and the European Foundation for the Improvement of Living and Working Conditions to provide guidance and promotion, in particular to SMEs, of a healthy working environment.

The Commission communication "Adapting to change in work and society: a new Community strategy on health and safety at work 2002-2006" [6] outlines the options for further action to make workplaces across Europe safer and healthier.

A fundamental aspect of Health and Safety legislation is the need for risk assessment and risk management. The introduction of new technology has the potential to reduce or mitigate risks, provided that employee safety is taken into account in the design phases.

4.4 Protection of the Environment

The electronics sector contains a large spectrum of mass produced products, which pose a considerably environmental load from production, use and disposal of these products.

The electronics sector is rapidly increasing, due to emerging new products such as mobile phones, Internet modems, DVD players, etc. The advances in embedded technologies and in miniaturization and cost effectiveness of electronic systems have further spurred the proliferation of electrical and electronics products.

Electrical and electronics products have traditionally been produced using a wide variety of materials and chemical substances with specific thermal, electrical, weight and cost properties. However, the environmental dimension was not as carefully regarded by the industry's designers as the other properties, which were used to competitive advantage. A series of international initiatives have been instigated to address this issue and to ensure that future electronic products meet raising environmental criteria.

When looking at the environmental aspects of electronics, there are four main areas of interest:

- Use of Materials
- Use of Energy
- Chemical Substances
- Waste deposit/incineration

Some of the major reasons for being concerned about them are seen in the table below:

Environmental Aspect	Environmental Impact
Use of Materials	Pollution and energy use from mining and refining of raw materials, use of non-renewable resources, destroying beautiful scenery etc.
Use of Energy	Pollution from power plants (acid rain, NOx-gases, radioactive and other waste etc.), use of non-renewable fossil fuels
Chemical Substances	Potentially toxic to humans and eco-systems. Emissions can occur during the whole life-cycle (mining and refining of raw materials, production, in the use- and end-of-life phases)
Waste deposit/ incineration	Pollution of soil and ground water by leakage from waste deposits or ashes and slag, removal of non-renewable resources from circulation

The key areas of environmental regulations that impact the products are:

- Energy use: The EuP Directive ("E*nergy using Products*" [7]);
- Material type and usage: The RoHS Directive ("*the Restriction of the use of certain Hazardous Substances in electrical and electronic equipment*" [8]); and
- Waste minimisation: The WEEE Directive ("*Waste Electrical and Electronic Equipment*" [9]).

4.4.1 Energy use

Fossil fuels for energy production are limited resources. Energy prices will most likely continue to rise in the coming years, and for electrical and electronic equipment this means that Cost-of-Ownership will become an important parameter for the customer. So both from an economic and an environmental point of view it is important to design energy efficient equipment.

The stand-by consumption of electronic equipment in private households is about 10% of the total electricity consumption. The problem is illustrated with the following data for Set-top boxes (e.g. for cable-, satellite- and Internet access): Data from the American Council for an Energy-Efficient Economy (ACEEE) and Lawrence Berkeley National Laboratory (LBNL) has indicated that the amount of energy used when "off" is nearly equal to the amount needed to operate set-top boxes in their primary function or active mode. Cable, satellite, and Internet access set-top boxes, as well as video game consoles, consume an estimated 7 billion kWh per year, producing pollution roughly equivalent to that of over 1 million cars. Americans spend over $618 million on utility bills to power these electronic devices. Set-top boxes consume much of this energy while consumers are not watching television or using these products.

In a life-cycle sense, the total energy consumption includes the energy used in manufacturing products from raw material extraction to refinement, manufacturing and transport to its final destination. EuP-related research shows that this can be as much as 25 percent of the total energy used by consumer electronics products such as TVs and PCs throughout their entire life cycle, offset by what is recovered during incineration [10].

4.4.2 Material type and amount

The authorities focus on chemical substances in electrical and electronic equipment. This is partly because of experience with substances used in older equipment and now seen as a problem in waste disposal (e.g. mercury, PCB). But also in today's equipment, new substances are suspected of having toxicological impacts on environment.

Life-cycle assessments (LCA) consider how much material is used and of what type. The type assessment examines environmental attributes like toxicity and ecotoxicity, which can be broken down into further properties that can then be compared for optimal environmental impact. The following substances are of particular concern in electronic products:

- ***Lead*** is used for solder, in batteries, and in Cathode-Ray-Tube glass. Processing of metallic lead may give rise to lead compounds, which are all classified as dangerous substances. In humans, lead e.g. affects the central nervous system and the kidneys. Environmental toxicity has been reported in several organisms.
- ***Cadmium*** is used in batteries and pigments. The health and environmental effects of cadmium have been widely studied since the detection of adverse human health effects in Japan in the 1950s and 1960s (Itai Itai disease). In addition, small amounts of dissolved cadmium may be toxic to aquatic and terrestrial organisms.
- ***Mercury*** is used in switches, relays, fluorescent lamps for flat panel displays. Elemental mercury is classified as a dangerous substance: toxic by inhalation with danger of cumulative effects. Toxicity in humans is mainly effects on the central nervous system effects (CNS) and the kidney. Mercury is also classified as very toxic to aquatic organisms and may cause long-term effects in the aquatic environment.

Other harmful substances in electrical and electronic equipment include PCB (Poly-Chlorinated Biphenyls), mercury, beryllium and brominated flame retardants.

The RoHS Directive bans the placing on the EU market of new electrical and electronic equipment containing lead, cadmium, mercury, hexavalent chromium, polybrominated biphenyl (PBB) and polybrominated diphenyl ether (PBDE) flame retardants.

4.4.3 Waste minimization

The waste amount from electrical and electronic equipment is rapidly increasing, partly because of the growing demand, and partly because of the still shorter life-cycle of this type of equipment.

Landfill is not a solution to this problem, both because of lack of landfill-sites, and because this constitute a risk for pollution from leakage of harmful substances.

Incineration is not a solution either. It causes pollution from gases, heavy metals and formation of poisonous substances in the slag, and also because valuable resources are lost in this way.

To minimise waste the solutions are:

1. Extended life of equipment (repair/upgrade)
2. Re-use
3. Recycling.

This issue is addressed by WEEE, but needs to be built into the process of product development and manufacturing, and by industry itself.

Increased recycling of electrical and electronic equipment will limit the total quantity of waste going to final disposal. According to the WEEE Directive, producers will be responsible for taking back and recycling electrical and electronic equipment. This will provide incentives to design electrical and electronic equipment in an environmentally more efficient way, which takes waste management aspects fully into account.

4.5 Other Product Legislation

There are a range of other directives influencing the production of electrical and electronic devices, which has to be taken into consideration by the developers. These directives are listed here for reference.

The ***Batteries Directive*** aims to make businesses that produce and sell batteries responsible for collecting and recycling spent batteries. It will require the collection and recycling of all batteries placed on the market. It applies (with limited exception) to all batteries and accumulators regardless of their chemical composition. It replaces earlier directives which only apply to batteries containing certain quantities of lead, mercury or cadmium. The primary objective of this directive is to minimise

the negative impact on the environment of batteries and accumulators and waste batteries and accumulators and it takes effect from 26 September 2008.

The ***Medical Devices Directive*** covers the regulatory requirements of the European Union for Medical Devices. Active implantable devices (e.g. pacemakers, implantable infusion pump) are covered by a separate directive, the Active Implantable Medical Devices Directive. The routes to compliance depend on the classification of the product. Class I devices are low risk. Examples are stethoscopes, scalpels, hospital beds, wheelchairs. The manufacturer has to produce a technical file, including product test results to relevant standards. In addition, manufacturers of sterile products and devices with a measuring function must apply to a Notified Body for certification of the aspects of manufacture relating to sterility or metrology. Class IIa are low-medium risk devices, with examples such as hearing aids, electrocardiographs, ultrasonic diagnostic equipment. As for Class I, the manufacturer produces a technical file, but in addition a conformity assessment must be carried out by a Notified Body. Class IIb are medium-high risk devices, with examples such are surgical lasers, infusion pumps (non-implantable), ventilators, intensive care monitoring equipment. Routes to compliance are the same as for Class IIa, with the addition of Type Examination of the product by the Notified Body, except for the full quality assurance route (EN 46001), where Type Approval is not necessary. Class III devices are high risk. Examples are balloon catheters, prosthetic heart valves. Routes to compliance are audit of the full quality assurance system (EN 46001) and examination of the design dossier by the Notified Body plus Type Examination of the product. For all Classes a Technical File must be prepared, demonstrating compliance of the device with the directive's essential requirements. Compliance can be assumed by showing conformity to the appropriate standards listed by the European Union as Harmonised Standards for the Medical Devices Directive.

The ***EMC Directive*** states that most electrical and electronic products made or sold in Europe must be so constructed that they do not cause excessive electromagnetic interference and are not duly affected by electromagnetic interference. It remains the responsibility of the manufacturer to verify that the goals as defined in the EMC directive (essential requirements) are being met.

All devices and embedded systems using the Hydra middleware will need to be in conformity with several or all of the above environmental Directives. It is thus important that the Hydra middleware will support the developers in developing products that comply with the detailed requirements of the Directives.

4.6 Economy and Industry – Information Society Regulations

There are two main areas of regulation under the European Commission's Information Society programme: *Transmission*, including issues concerning *Radio Spectrum Policy*, and *Content*.

4.6.1 Transmission

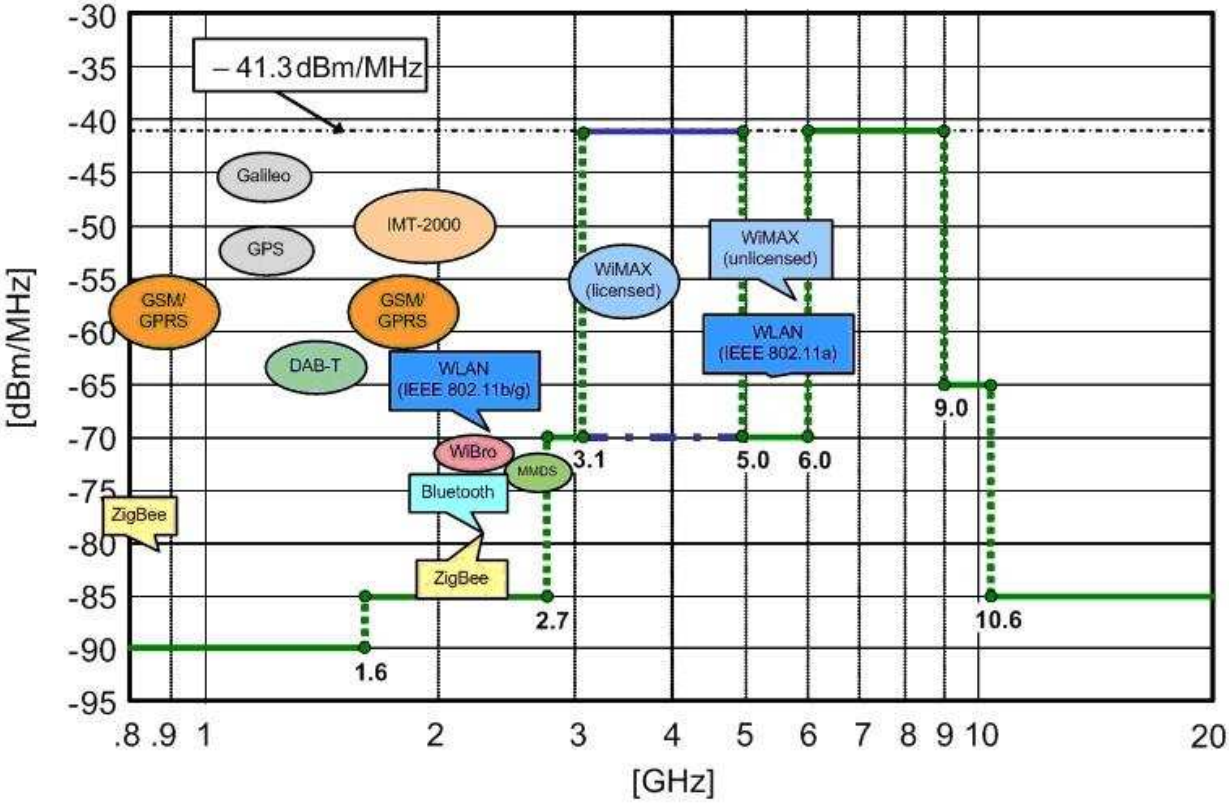
Regarding transmission, an electronic communications regulatory framework, launched in July 2003 provides a legal framework for continuing the development of the industry, stimulating competition, creating growth and safeguarding public and user interests.

The new Framework covers, among other things, the management of scarce resources essential to communications. One particularly important resource is radio spectrum, through which all wireless communications travel, so the EU's new radio spectrum policy was launched as part of the new framework. However, while the Framework focuses on communications networks and services, radio spectrum policy covers all areas where spectrum is an issue, and is addressed in more detail below.

These regulatory areas are also coordinated with the Radio Equipment and Telecommunications Terminal Equipment (RTTE) Directive, which regulates the telecommunications equipment market. By replacing over 1000 national approval regulations, the Directive has created a framework for regulating what is now a European single market worth 30 billion euros.

4.6.2 EU Radio Spectrum Policy

Radio spectrum is fast becoming the lifeblood of the Information Society, whether you use a mobile phone or watch a TV broadcast. Moreover, the direct economic contribution of industries using the radio spectrum is already considerable, between 1 and 2% of national GDP in the EU, but could be greatly increased if national regulators and all stakeholders can identify common approaches at EU level to create a single market for equipment and services using radio spectrum. All wireless equipment receives information transmitted in a different part of the radio spectrum which includes radio waves in frequencies between 9 kHz and 3000 GHz. For instance, radio stations are on the 'FM band' (around 100 MHz), while GSM phones operate at either 900 or 1800 MHz. Next figure shows which part of the spectrum are using some of these communication technologies.



If equipment and services did occupy the same frequency band they would potentially interfere with each other, impacting quality of service and potentially safety and/or security, therefore regulating the use of radio spectrum is essential. And in a European single market, this coordination must sometimes happen on a European scale.

The Radio Spectrum is shared between a number of communication technologies (UWB, GSM, FWA, Bluetooth, DECT, RMR, DVB, Galileo, DAB, TT&C, PMR, RADAR, Wi-Fi, 3G, Wireless sensors, etc.) used in a number of environments (military, astronomy, broadcasting, cars, TLC operators, ships, hospital, planes, civil protection, etc.). Therefore, the spectrum "bottleneck" has to be regulated by the EU even though the European Commission has no spectrum of its own to manage.

At the moment, radio spectrum usage is still fragmented among the 25 Member States, which prevents this important economic resource from being efficiently exploited across Europe. This is why the Commission proposes to develop common EU rules for a number of promising new mass-market applications, including Ultra Wideband and Broadband Wireless Access technologies as well as "wireless barcodes" for Radio Frequency Identification Tags (RFIDs). A greater flexibility in access to spectrum will give market players more freedom to use radio resources as they choose. This is an essential condition for achieving the full potential of radio spectrum resources and for keeping pace with technological advances and convergence both of technology platforms and of services.

As part of its spectrum reform strategy, the Commission also proposes that by 2010 the exclusive usage rights for significant parts of the radio spectrum ought to be made tradable according to common EU rules. As a de-regulated access to spectrum can encourage the development and use of innovative technologies, the Commission's new strategy finally foresees investigating further the opportunities to make available licence-free radio frequencies to allow different users to share bands as already the case for WiFi radio access. This will ultimately widen the choice of the wireless applications for the consumer. In this line, the Radio Spectrum Decision (676/2002/EC) adopted by

the European Parliament and the Council on 7 March 2002 has laid the foundation for a general Community radio spectrum policy.

The objectives of radio spectrum policy are to:

- ensure co-ordination of radio spectrum policy approaches
- provision of relevant information on spectrum usage
- co-ordination of Community interest in international negotiations in relation to existing EU policies such as in electronic communications, transport, R&D or broadcasting
- contribute to a modern approach to spectrum management in Europe.

The Challenges of the policy are to:

- reconcile national competence with EU coherence
- balance the competing spectrum needs of different EU/EC policies
- improve allocation harmonisation while providing for more usage flexibility
- find the right mix of spectrum management approaches.

EU radio spectrum policy is conceptually developed in dialogue with Member States, the European Parliament and spectrum users in order to ensure co-ordinated use of radio spectrum, modernisation in the regulation of radio spectrum in the Community and to contribute to horizontal policy objectives such as the completion of the internal market and development of competition.

The EU Radio Spectrum Policies can be classified according to the sector they belong and thus they have special regulations:

- Information Society
    - Broadband mobile/wireless: GSM, 3G, FWA, RLAN, PMR, UWB, etc.
    - Audiovisual: DVB, DAB, DRM, etc.
    - Convergent systems: IP datacasting
- European Space
    - Communication Satellites: mobile-fixed-broadcasting
    - Environment Satellites: GMES, EESS, Meteosat, etc.
    - Galileo
    - Space Science
- Transport Policy
    - Single European Sky: ATM (GBAS)
    - Maritime Safety: GMDSS
    - Road Safety & Vehicle Control: automotive SRRs, EFC, etc.
    - Railways Interoperability: GSM-R
- Civil Protection Cooperation: PPDR, avalanche beacons, etc.
- e-Health: medical telemetry, inductive devices, etc.
- Social Inclusion: wireless hearing aids, social alarms, etc.
- Scientific Research: radio astronomy, radar imaging, etc.

Moreover, there are a number a groups and committees in the scope of the EU deciding over the radio spectrum:

- Radio Spectrum Committee (RSC), created by the Spectrum Decision (767/2002/EC), decides on spectrum allocation harmonization which is legally binding to member states of the EU (commission decisions). The members of this committee are national administration delegates (EEA, accession countries, ECC and ETSI as observers) and Commission chairs.
- Radio Spectrum Policy Group (RSPG), created by Commission RSPG Decision (2002/622/EC), which delivers advice, which means that it has to decision power. The members of the group are high-level member state administration representatives with "consolidated national view" and commission representatives.

The conclusions are that the radio spectrum is a key resource for many essential services in society: mobile, wireless and satellite communications, TV and radio broadcasting, transport, radio location (GPS/Galileo), and many other applications (alarms, remote controls, hearing aids, microphones, medical equipment, etc.). Radio technology also supports public services such as defence, security/safety and scientific activities (e.g. meteorology, Earth observation, radio astronomy and space research). Spectrum management has a strong cross-border dimension, given the European and global markets dependent on radio-based services, as well as the need to avoid harmful interference between countries. A coordinated spectrum policy in the EU aims to enhance a genuine single market for radio services and equipment. In this respect, the Commission intends to take concrete actions to:

- Lower barriers to access to spectrum, improving efficiency, promoting innovation, greater flexibility for users and more choice for consumers.
- Allow convergence to become a reality, by removing artificial restrictions, notably between broadcasting and mobile communications.

The Commission's strategy for a coherent EU radio spectrum policy is part of the i2010 initiative, which seeks to encourage the development of the digital economy. In particular, the need for a gradual but systematic liberalisation of radio spectrum use is essential. While bearing in mind national interests in this matter, common action at EU level will give a critical contribution to the coherence and final success of this task.

4.6.3 Content

In the field of content, European audiovisual regulation aims to ensure the free provision of services and to fulfil objectives of public interest such as access to information and protection of users in areas such as commercial communication, protection of minors and human dignity. Two EC papers relate to this:

- The "*Television Without Frontiers*" Directive [11], which promotes the European broadcasting industry by ensuring the free movement of television broadcasting services throughout the EU; and
- the Council Recommendation on the Protection of Minors and Human Dignity, which provides guidelines for national legislation in combating illegal and harmful content transmitted over electronic media.

The transmission directive is more relevant to the majority of likely Hydra applications however, as any use of content will be specific to the application and unlikely to be the responsibility of the Hydra consortium. This can be contractually covered by appropriate wording of an acceptable use policy or terms of use.

5. Intelligent buildings domain regulatory standards

5.1 Emphasis on regional and national regulations

Under European Law, individual countries and regions are responsible for ensuring that buildings within their territory are designed and constructed in a way that does not endanger the safety of citizens, animals and neighbouring property. European member states have provisions, including requirements relating not only to building safety, but also to health, durability, energy efficiency, protection of the environment, aspects of economy, and other aspects important in the public interest.

It will therefore be essential that any practical demonstration of Hydra Intelligent Building scenarios is also validated against the relevant regional and national planning and construction laws.

5.2 Common factors

All of the general regulatory factors outlined in the previous section apply to the intelligent buildings domain:

- Privacy of users' personal data;
- Product safety where consumers use or are at risk from Hydra-enabled products;
- Warranty issues in the case of Hydra-enabled consumer products networked with the intelligent building;
- Health and safety factors for workers installing and using Hydra components;
- Environmental factors concerning the electronic hardware used with Hydra middleware; and
- Information society transmission regulations in the use of wireless networks.

The remainder of this section outlines the regulations and policies that are specific to this application domain.

5.3 Trends

The major trends in construction-related regulations at the European level concern the harmonisation of building materials and the energy performance of buildings.

5.3.1 Harmonisation of building materials and components

The "*Construction Products Directive*" (CPD [1]) from 1989 has had wide implications for the harmonisation of technical standards used in the construction industry and its implementing measures, follow-on work and Member State adoption continues to reduce the complexity of producing components used for buildings across Europe.

5.3.2 Energy performance of buildings

The buildings sector accounts for 40% of the EU's energy requirements. It offers the largest single potential for energy efficiency. Research shows that more than one-fifth of the present energy consumption and up to 30-45 MT of CO_2/Year could be saved by 2010 by applying more ambitious standards to new and when refurbishing buildings – which represents a considerable contribution to meeting the Kyoto targets. The following statistics emphasise the need for change [2]:

- Two thirds of energy used in European buildings is accounted for by households; their consumption is growing every year as rising living standards are reflected in greater use of air conditioning and heating systems.
- 10 million boilers in European homes are more than 20 years old; their replacement would save 5% of energy used for heating.
- 30-50% of lighting energy could be saved in offices, commercial buildings and leisure facilities by using the most efficient systems and technologies.
- Half of the projected increase in energy needed for air conditioning– expected to double by 2020 – could be saved through higher standards for equipment.

The key Directive addressing these issues is the "*Energy Performance Of Buildings Directive*" [3] which became law in 2003. The four main aspects of its framework are:

- a common methodology for calculating the integrated energy performance of buildings;
- minimum standards on the energy performance of new buildings and existing buildings that are subject to major renovation;
- systems for the energy certification of new and existing buildings and, for public buildings, prominent display of this certification and other relevant information. Certificates must be less than five years old; and
- regular inspection of boilers and central air-conditioning systems in buildings and in addition an assessment of heating installations in which the boilers are more than 15 years old.

Member States will be responsible for defining minimum standards, so again compliance with this regulation will require assessment at the national level before deployment.

5.4 International technical standards for Building Automation and Control Systems (BACS)

The International Standards Organisation (ISO) has a set of projects developing standards for BACS which could be highly relevant to Hydra work in the intelligent building domain. These fall under TC205, Building Environment Design which is concerned with:

"Standardization in the design of new buildings and retrofit of existing buildings for acceptable indoor environment and practicable energy conservation and efficiency. Indoor environment includes air quality, and thermal, acoustic, and visual factors." [4].

In particular, working group 3 TC205/WG3 is addressing Building Control System Design. The table below lists the guidelines available from ISO relating to home and building automation (see references for more details).

ISO Number	Title	Summary
ISO 16484-2:2004[5]	Building automation and control systems (BACS) -- Part 2: Hardware	Specifies the requirements for the hardware to perform the tasks within a BACS
ISO 16484-3:2005 [6]	Building automation and control systems (BACS) -- Part 3: Functions	Specifies the requirements for the overall functionality and engineering services to achieve building automation and control systems.
ISO 16484-5:2003 [7]	Building automation and control systems (BACS) -- Part 5: Data communication protocol	Defines data communication services and protocols for computer equipment used for monitoring and control of heating, ventilation, air-conditioning and refrigeration and other building systems. It defines, in addition, an abstract, object-oriented representation of information communicated between such equipment, thereby facilitating the application and use of digital control technology in buildings.
ISO 16484-6:2005 [8]	Building automation and control systems (BACS) -- Part 6: Data communication conformance testing	Defines a standard method for verifying that an implementation of the BACnet protocol provides each capability claimed in its Protocol Implementation Conformance Statement
ISO/IEC 18012-1:200 [9]	Information technology -- Home Electronic System -- Guidelines for product interoperability	Specifies requirements for product interoperability in the area of home and building automation systems, with sufficient detail needed to design interoperable Home Electronic System products.

5.5 Potential impact on Hydra

- **Requirement** to ensure compliance with CPD should Hydra be embedded within products sold for use in construction.
- **Opportunity** from the CPD of a larger marketplace for Hydra-enabled products used in construction thanks to harmonisation of technical building standards.
- **Opportunity** to directly contribute towards the energy performance of buildings, both through the management of electrical devices but also through increased reliability, reduced fault-finding costs and increased intelligence of energy management systems.
- **Opportunity** to exploit emerging ISO building automation protocols to enable communication with third party systems and devices, automation stations and controllers.

6. Healthcare domain regulatory standards

6.1 Common factors

All of the general regulatory factors outlined in section 4 apply to healthcare domain:

- Privacy of patients' personal data;
- Product safety where patients or health professionals use or are at risk from Hydra-enabled products;
- Warranty issues in the case of Hydra-enabled consumer products networked with the Hydra health applications;
- Health and safety factors for workers installing Hydra components and for healthcare professionals;
- Environmental factors concerning the electronic hardware used with Hydra middleware; and
- Information society transmission regulations in the use of wireless networks.

The remainder of this section outlines the regulations and policies that are specific to this application domain.

6.2 Key regulations and trends

6.2.1 Public Health policy

The key policy area from the EC for health is the proposed European Health Strategy [1] which was first drafted in 2005 and is expected to be adopted in June 2007.

The majority of health policy is defined and legislated at European Member State level, but the EU has responsibility to undertake actions which complement the work done by Member States. This includes: reducing health inequalities and cross border health threats and promoting patient mobility. The European Health Strategy aims to provide an overall strategic framework spanning core issues in health as well as health factors in all policies and global health issues. The Strategy aims to set clear objectives to guide future work on health at the European level.

The main objective of the strategy will be to create coherence between the many health-related policies and activities at European level. Key issues addressed will include:

- promoting public health and reducing health inequalities;
- work on health determinants, for example the strategies on alcohol and mental health;
- improving health systems cooperation at European level;
- the new Health Services Initiative (developing an internal market in health services); and
- supporting technological innovation with a focus on increasing efficiency, in particular e-Health.

For a useful set of links and overview of European Health Policy, see [2].

6.2.2 eHealth policy

The Commission adopted its Action Plan for eHealth [3] in April 2004. This action plan focuses on three priority areas:

- creating a common framework to support eHealth, including interoperability of health information systems and of electronic health records, patient identifiers and mobility of patients and health professionals;

- accelerating deployment by improving information on health education and disease prevention and promoting the use of cards in health care; and
- working together and monitoring best practice.

The Action Plan sets out a number of key targets for member states, impacting both the healthcare ICT industry and health providers. It also specifically calls for new regulation and legislation to be introduced by Member States by the end of 2009 that will:

- Set a baseline for a standardised European qualification for e-Health services in clinical and administrative settings.
- Provide framework for greater legal certainty of e-Health products and services liability within the context of existing product liability legislation.
- Improve information for patients, health insurance schemes and providers regarding the rules applying to the assumption of the costs of e-Health services.
- Promote e-Health with a view to reducing occupational accidents and illnesses as well as supporting preventive actions in the face of the emergence of new workplace risks.

The Action Plan also includes a number of detailed specific targets for member states. Those which have possible implications Hydra are summarised in the table below.

Action	Timescale	Implication for Hydra
Each member state to produce a national roadmap for eHealth	end-2005	Need to assess timescales of member state's implementation in order to maximise exploitation potential (ie. identify the early adopters and target those countries for Hydra-derived products).
Agree common approach to patient identifiers	End 2006	Need to monitor this work to ensure compliance.
Identify and outline interoperability standards for health data messages and electronic health records, taking into account best practices and relevant standardisation efforts.	End 2006	Need to monitor this work and the corresponding standards (see ISO section below).
Member States should adopt conformity testing and accreditation schemes following successful best practices	End 2007	Need to be aware of emerging accreditation criteria and ensure compliance.
Member States should support deployment of health information networks for eHealth based on fixed and wireless broadband and mobile infrastructures and Grid technologies.	2004- 2008	Confirms adoption of networking models, encouraging future widespread deployment of wireless and fixed networks.
Adoption of implementation of an electronic health insurance card.	2008	Opportunity for applications that access data from standard ehi cards.
By end 2008, the majority of European health organisations and health regions (communities, counties, districts) should be able to provide online services such as teleconsultation (second medical opinion), e-prescription, e-referral, telemonitoring and telecare.	End 2008	Availability of online services increases potential applications for Hydra-enabled devices in interfacing with such services.

6.2.3 Updated Health strategy and i2010

In June 2006, the Commission's ICT for Health Unit adopted an updated strategy, "Transforming the European healthcare landscape" [4], in line with the Commission's new policy framework i2010. This strategy builds upon the Action Plan for eHealth with the vision of building a "*new healthcare delivery model, based on preventive and person-centred health systems, which can only be achieved through proper use of ICT*". It provides greater emphasis on interoperability, the shift to preventative healthcare and more effective management of health risks, and also aligns eHealth under the EC's broader i2010 policy framework.

6.3 Interoperability requirements

Both the Action Plan and updated Strategy for eHealth emphasise interoperability between health systems, services and technologies. This is clearly of great importance to Hydra, but there is little yet in the way of clear guidance and regulation. eHealth interoperability is a complex issue, involving more than simply technical factors. It also has legal, ethical, economical and organizational implications which need to be resolved.

A useful paper, "Connected Health: Quality and Safety for European Citizens", has been produced by the Commission in September 2006 which provides an overview of activities in this area [5]. This paper emphasizes the importance of compliance with emerging international technical standards for healthcare, including HL7 (see ISO section below).

6.3.1 eHealth standardization

The World Health Assembly in May 2005 adopted resolution WHA58.28[6], recognising that a WHO eHealth strategy could serve as a basis for WHO's activities in eHealth as well as encouraging Member States to consider creating their own long-term strategic plans for developing and deploying eHealth services. It also requests WHO to provide technical support to Member States and facilitate integration of eHealth in health systems and services, including in training. This strategy from WHO should be positive for Hydra as it encourages convergence of international adoption of eHealth technologies and associated standards compliance.

6.3.2 Medical devices regulation

Another aspect of regulation which may apply to Hydra-enabled products is the area of medical devices. Strict rules govern the safety of medical devices as issues of patient safety as well as employee safety apply. The key European regulation in this area is the Medical Device Directive (MDD) Directive 93/42/EEC[7]. The MDD covers the placing on the market and putting into service of Medical Devices that do not require invasive procedures with the patient (other directives cover these products). The MDD nonetheless covers an extremely wide range of products, including, for example:

- first aid bandages;
- tongue depressors;
- hip prostheses;
- X-ray equipment;
- ECG;
- heart valves;
- spectacles; and
- dental materials.

However, the relevance at present of this legislation to Hydra would be limited to any devices requiring direct connection to the patient, and it is likely that such sensors would be developed by experienced medical equipment suppliers.

6.3.3 Emerging regulations for software development for medical devices

ISO TC 215 is preparing two new documents on "Risk evaluation and management in the deployment and use of health software"[8] and "Application of risk management to the manufacture of health software"[9].

Through these new papers, ISO is proposing a new product category called "health software" defined as software which has a "possible influence" on patient health. Under this definition, software with influence on patient health may either be software classified as a medical device (either as part of a medical device, controlling a medical device, or software which by itself is a medical device), or software not classified as a medical device.

If mandated, software developers may have to follow medical device standards and regulations including IEC 60601 (Medical electrical equipment – General requirements for basic safety and essential performance)[10], ISO 14971 (medical devices: application or risk management to medical devices)[11], and in the future IEC 62304 (medical device software: software lifecycle processes) [12]. This IEC standard specifies a life cycle framework for medical device software in terms of processes, activities and tasks to be adopted for medical device software development.

6.4 International eHealth standards

The table below summarises the key international standards relating to eHealth and potentially to Hydra in the healthcare domain. This has been collected in a database, which includes links where available, and will be maintained during the project as an internal reference source. The most significant categories of standards to Hydra are "Infrastructure Architecture" and Security.

Name	Short name	Org.	Description	Category	Comments
Digital Imaging and Communications in Medicine	DICOM	NEMA	DICOM (Digital Imaging and Communications in Medicine) defines the coding of medical images, the protocols of interchange between both sides and a security policy to hide information from third parties.	Imaging	For Computer tomography, image archives, telediagnostic, EEG, ECG. DICOM 3.0 has added waveform support to allow EEG and ECG interchanges. Refer to: www.dclunie.com
MEDICOM	EN 12052	CEN	This standard is the European contribution to the well-known DICOM.	Imaging	For Imaging comms (see DICOM). EN 12052 superseded the former ENV 12052, ENV12623 and ENV12922-1.
Computer-assisted electro-cardiography	ENV 1064	CEN	This standard has been taken up worldwide, not only by European countries	Medical Device Communications	SCP-ECG (Standard Communication Protocol Computer Assisted Electro-cardiography)
Interoperability of healthcare multimedia report systems	CR 14300	CEN	Provides interoperability of healthcare multimedia report systems	Knowledge manage-ment	It is not mandatory. It is a recommendation only

Name	Short name	Org.	Description	Category	Comments
HL7 Version 2.5	HL7 v2.XML	ANSI	Old HL7 standards were focused on medical information exchange. With the addition of XML support, multimedia capabilities are now reliable	Messages	Improved support for imaging has been introduced in version 2.5.
Profiles for medical image interchange	CR 12069	CEN	Provides the set of profiles for a given user scenario. Defines greyscale, colour, volumetric and time sequences.	Imaging	CR 12069 is not a mandatory standard, it is a report.
Algorithm for Digital Signature Services in Health Care	ENV 12388	CEN	Defines the algorithm used for digital signatures in medicine information exchange.	Security	It is required to achieve legal acceptability of the information exchange. SEMRIC: Secure Medical Record Information Communication.
Safety and Security Related Software Quality Standards for Healthcare (SSQS)	UNE-CR 13694	AENOR	Proposes several quality norms related to security and protection in e-Health software.	Security	It associates the system type with the appropiate security measures.
Security for healthcare communication	ENV 13608	CEN	Defines concepts for secure systems, secure data objects and secure data channels.	Security	
Management and security of authentication by passwords	ENV 12251	CEN	It addresses the management and security of authentication by passwords.	Security	Sometimes is mandatory to fulfill legal issues.
Standard Practice for Healthcare Certificate Policy	E2212-02a	ASTM	Addresses the policy for digital certificates that support the authentication, authorization, confidentiality, integrity, and nonrepudiation requirements of persons and organizations that electronically create or transact health information.	Security	There are 3 types of certificate: one for computerized entities, one for individual person and the last one for clinical individuals.

Name	Short name	Org.	Description	Category	Comments
Standard Specification for Healthcare Document Formats	E2184-02	ASTM	Defines requirements for the headings, arrangement, and appearance of sections and subsections when used within healthcare documents.	Standards Method-ology	Use of this specification in conjunction with XML DTDs and the EHR (Electronic Health Records) would further enhance efficiency in time and cost.
Standard Guide for Properties of Electronic Health Records and Record Systems	E1762-95 (2003)	ASTM	The standard defines a document structure for use by electronic signature mechanisms and the characteristics of the electronic signature itself.	Security	
Interoperability of Telehealth Systems and Networks	DTR 16056	ISO	Adresses the interoperability of telehealth systems and networks.	Infra-structure architecture	Part 2 of the standard is related to real-time e-Health systems.
Medical Data Interchange: HIS/RIS-PACS and HIS/RIS	ENV 13939	CEN	Describes the interchange of sanitary data. HIS/RIS-PACS and HIS/RIS.	Medical Device Commun-ications	
Interoperability of patient connected medical devices	ENV 13735	CEN	The standard sets up the basis of interoperability among patient connected devices taking account of VITAL standard to achive device and signal interoperability.	Medical Device Commun-ication	This standard and VITAL standard are designed to work together. Each one specifies a level of interoperability.
Messages for the exchange of information on medicine prescriptions	ENV 13607	CEN	Specifies a message, called prescription dispensing report message, containing information about prescription items that is sent from the dispensing agent to any other party that is legally permitted to receive such message.	Messages	Also available at: http://www.cenorm.be/catweb/35.240.80.htm
Electronic healthcare record communication	ENV 13606	CEN	Proposes a scheme to define a healthcare record in order the information is recognizable and understandable in	Knowledge manage-ment	It is divided in four parts: Part 1: Extended architecture, Part 2: Domain term list, Part 3: Distribution

Name	Short name	Org.	Description	Category	Comments
			different applications.		rules, Part 4: Messages for the exchange of information
Healthcare Information System Architecture (HISA)	ENV 12967	CEN	Describes the Healthcare Information System Architecture (HISA), which is a description of the middleware layer used in healthcare.	Infra-structure architecture	It is described with diagrams.
Messages for the exchange of healthcare administrative information	ENV 12612	CEN	Specifies messages for the exchange of healthcare administrative information to provide safe, efficient and effective healthcare delivery within hospitals and in primary care.	Messages	The messages do not cover the reimbursement nor the admission, discharge and transfer processes themselves, but make such processes much easier because of the overall availability of registration and identification data. More Info at: http://www.ramit.be/
Registration of information objects used for EDI in healthcare	ENV 12537	CEN	Defines the registration of information objects used for EDI in healthcare for the purpose of information interchange related to healthcare.	Termin-ology	It has two parts: Part 1: The Register, Part 2: Procedures for the registration of information objects used for electronic data interchange (EDI) in healthcare
Healthcare Information Framework (HIF)	ENV 12443	CEN	Creates a basic framework to guide healthcare informatics developers. It is a first step in standardising the architectures that will support the latest approaches to the delivery of computer systems such as are required to provide the global information.	Infra-structure architecture	

Name	Short name	Org.	Description	Category	Comments
Identification, administrative, and common clinical data structure for ICDs	ENV 12018	CEN	This standard proposes a standardised framework for data structures used with respect to Intermittently Connected Devices (ICDs).	Infra-structure architecture	An ICD is a device that stores and transmits person related data in such a fashion that the originator of the information may not receive confirmation of receipt by the recipient. Overview info available at: http://www.ramit.be/scripts/imiawg16/1standard
Medical Informatics Vocabulary (MIVoc)	ENV 12017	CEN	Defines the Medical Informatics Vocabulary, which is a foundation for the development of a vocabulary of terms used in Medical Informatics.	Termin-ology	
Messages for exchange of laboratory information	ENV 1613	CEN	Provides a complete implementable specification of the laboratory messages by implementation guidelines to supplement the message difinitions. It also provides comprehensive data and structured tables.	Messages	These coding schemes are commonly used to provide precise and unambiguous representation of the data
Point-of-care medical device communication	IEEE 1073.5.x	IEEE	Efforts are underway to add standards for enabling internetworking of medical devices across a LAN/WAN.	Medical Device Commun-ication	It is not a standard, it is a series of standards that will be published soon. More info available at: http://www.ieee1073.org/standards/standards-at-a-glance/standardsataglance.html
Point-of-care medical device communication – Application profile – Optional package, remote control	ISO 11073-20301	ISO	Describes an optional application profile optional packages for remote control.	Medical Device Commun-ication	Some functions are similar or complement the european standard ENV13735.

Name	Short name	Org.	Description	Category	Comments
Point-of-care medical device communication – Application Profiles – MIB Elements	IEEE 1073.2.1.2	IEEE	MIB Element definitions from the revised DIM standard	Medical Device Commun-ication	More information at: http://www.ieee1073.org/standards/standards-at-a-glance/standardsataglance.html
Medical Device Communications – Transport Profile – IrDA Based – Cable Connected	IEEE 1073.3.2	IEEE	Describes the IrDA-based, RS-232, cable connected transport beetwen devices connectivity. It also set up the basis for firmware upgrades for medical devices.	Medical Device Commun-ication	This new transport profile offers a key advantage in fostering implementation and adoption of the IEEE 1073 Medical Information Bus Standards. More info at: http://www.ieee1073.org/standards/11073-30200/11073-30200.html
Categorical structures of systems of concepts - Model for representation of semantics	ENV 12264	CEN	The standard provides the vocabulary and the guidelines to describe the categorial structure of a concept system: the structure consists in practice of a list of involved categories with reference to the available authoritative sources for a detailed value.	Termin-ology	Medical Informatics deals with a great number of large, overlapping coding systems that are facing each other and conflicting in the coming Integrated Healthcare Information Environment. This standard tries to solve these conflicts.
Time Standards for Healthcare Specific Problems	ENV 12381	CEN	Provides a set of basic entities, with precisely defined properties and interrelationships among them, that is sufficient to allow an unambiguous representation of time-related expressions.	Termin-ology	
Messages for Patient Referral and Discharge	ENV 12538	CEN	It refers to referral and discharge but also covers the request for specialist services and the reports by the specialist service provider, including clinic letters and	Messages	Graphical or image information that forms part of a request for or report of a specialist healthcare service is excluded.

Name	Short name	Org.	Description	Category	Comments
			discharge summaries.		
Request and Report Messages for Diagnostic Services Departments	ENV 12539	CEN	It provides the description of the scope of the messages and its functionality and implementation guidelines for different scenarios.	Messages	The scope is limited to character-based messages, but includes: X-rays, CAT, NMR, ultrasound scans, ECGs, lung-function tests, anatomic pathology and nuclear medicine
Standard guide for description of reservation/registration-admission, discharge, transfer systems for Electronic Health Record (EHR) systems	E1239-00	ASTM	This guide identifies the minimum information capabilities needed by an ambulatory care system or a resident facility R-ADT system.	Electronic Health Record	
Standard guide for content and structure of the Electronic Health Record (EHR)	E1384-02a	ASTM	This guide covers all types of healthcare services, including those given in acute care hospitals, nursing homes, skilled nursing facilities, home healthcare, and specialty care environments as well as ambulatory care.	Electronic Health Record	They apply both to short term contacts (for example, emergency rooms and emergency medical service units) and long term contacts (primary care physicians with long term patients).
Standard guide for view of emergency medical care in the computerized-based patient record	E1744-98	ASTM	It addresses the identification of the information that is necessary to document emergency medical care in a computerized patient record that is part of a paperless patient record system.	Electronic Health Record	

Name	Short name	Org.	Description	Category	Comments
An object-oriented model for registration, admitting, discharge, and transfer functions in computer-based patient record systems	E1715-01	ASTM	Details the objects that make up the reservation, registration, admitting, discharge, and transfer functional domain of the computer-based record of care.	Electronic Health Record	It is intended to amplify guide E1239 with an object-oriented focus.
Specification for management of the confidentiality and security of dictation, transcription, and transcribed health records	E1902-02	ASTM	It describes certain steps that shall be taken by those involved in the processes of dictation and transcription of healthcare documentation.	Security	It also seeks to identify certain dictation and transcription practices that may increase the risks of infringing on privacy and violating security of healthcare documentation.
Standard specification for clinical XML DTDs in healthcare	E2185-02	ASTM	This guide provides a compendium of information for the use of E2183 XML DTDs within health care. This guide describes design considerations, the architecture of the DTDs, and implementing systems using the E2183 DTDs.	Standards Method-ology	
Standard guide on security framework for healthcare information	E2085-00a	ASTM	Describes a framework for the protection of healthcare information. It addresses both storage and transmission of information.	Security	It makes use of well-known security algorithms such as SHA-1, triple-DES and others.
Standard guide for information access privileges to health information	E1986-98	ASTM	This guide covers the process of granting and maintaining access privileges to health information. It directly addresses the maintenance of confidentiality of personal, provider, and organizational data in the healthcare domain.	Security	

Name	Short name	Org.	Description	Category	Comments
Standard guide for individual rights regarding health information	E1987-98	ASTM	This guide outlines the rights of individuals, both patients and providers, regarding health information and recommends procedures for the exercise of those rights.	Knowledge manage-ment and Security	This guide is intended to amplify Guide E1869.
Standard Specification for Authentication of Healthcare Information Using Digital Signatures	E2084-00	ASTM	This specification covers the use of digital signatures to provide authentication of healthcare information, as described in Guide E 1762. It describes how the components of a digital signature system meet the requirements specified in Guide E 1762.	Security	This includes specification of allowable signature and hash algorithms, management of public and private keys, and specific formats for keys, certificates, and signed healthcare documents.
Interoperability and compatibility in messaging and communication standards -- Key characteristics	ISO/TR 18307	ISO	Describes a set of key characteristics to achieve interoperability and compatibility in trusted health information interchange between communicant application systems.	Messages	The key characteristics describe inter-application interoperability needs of the healthcare community, in particular the subject of care, the healthcare professional/caregiver, the healthcare provider organization, its business units and the integrated data
Clinical Context Object Workgroup Version 1.5	CCOW V1.5	HL7	CCOW V1.0 defined the overall technology-neutral context management architecture (CMA), a core set of data definitions, rules for application user interfaces, and the translation of the CMA to Microsoft's COM/ActiveX technology.	User Interfaces/ web services	This version also support technology mapping to SOAP.

Name	Short name	Org.	Description	Category	Comments
Clinical analyser interfaces to laboratory information systems	ISO 18812	ISO	Specifies general messages for electronic information exchange between analytical instruments and laboratory information systems within a clinical laboratory.	Messages and Medical Device Commun-ication	Covers the specification of messages used by communicating parties and the syntax in which they are communicated. It does not cover the transport mechanisms used for the message interchange.
Standard guide for identification and establishment of a quality assurance program for medical transcription	E2117-00	AST M	It establishes a quality assurance program for dictation, medical transcription, and related processes. Quality assurance is necessary to ensure the accuracy of healthcare documentation.	Standards Method-ology	This guide establishes essential and desirable elements for quality healthcare documentation, but it is not purported to be an exhaustive list.

6.5 ISO Projects in Healthcare ICT

A significant number of ISO projects relate to the development of standards for health informatics. These will need to be assessed for relevance to Hydra prototypes and eventual products. These are listed below and can be reviewed at the ISO Health Informatics website [13].

ISO Project reference	Title
ISO/DIS 11073-90101	Health informatics -- Point-of-care medical device communication -- Part 90101: Analytical instruments -- Point of care test
ISO/CD TS 11073-90201	Health informatics -- Medical waveform format -- Part 90201: Encoding rules
ISO/DIS 13606-1	Health informatics -- Electronic health record communication -- Part 1: Reference model
ISO/DIS 17090-1	Health informatics -- Public key infrastructure -- Part 1: Overview of digital certificate services
ISO/DIS 17090-2	Health informatics -- Public key infrastructure -- Part 2: Certificate profile
ISO/DIS 17090-3	Health informatics -- Public key infrastructure -- Part 3: Policy management of certification authority
ISO/DIS 17113.2	Health informatics -- Exchange of information between healthcare information systems -- Method for development of messages
ISO/FDIS 17115	Health informatics -- Vocabulary for terminological systems
ISO/NP TS 17117	Health informatics -- Controlled health terminology -- Structure and high-level indicators
ISO/CD TS 21298	Health informatics -- Functional and structural roles
ISO/DIS 21549-5	Health informatics -- Patient healthcard data -- Part 5: Identification data
ISO/DIS 21549-6	Health informatics -- Patient healthcard data -- Part 6: Administrative data
ISO/FDIS 21549-7	Health informatics -- Patient healthcard data -- Part 7: Medication data
ISO/TR 21730	Health informatics -- Use of mobile wireless communication and computing technology in healthcare facilities -- Recommendations for electromagnetic compatibility (management of unintentional electromagnetic interference) with medical devices
ISO/CD TS 22220	Health Informatics -- Identification of subjects of health care
ISO/NP TS 22600-3	Health informatics -- Privilege management and access control -- Part 3: Implementations
ISO/CD TS 22789	Conceptual framework for patient findings and problems in terminologies
ISO/NP TR 22790	Functional characteristics of prescriber support systems
ISO/NP TS 25237	Health informatics -- Pseudonymisation
ISO/PRF TS 25238	Health informatics -- Classification of safety risks from health software
ISO/CD 25720	Genomic sequence variation markup language
ISO/NP TS 27527	Health Informatics -- Provider Identification
ISO/DIS 27799	Health informatics -- Security management in health using ISO/IEC 17799
ISO/HL7 NP 27931	Health Informatics -- HL7 Messaging Standard Version 2.5 -- An application protocol for electronic data exchange in healthcare environments
ISO/HL7 NP 27932	Health Informatics -- Clinical document architecture, release 2
ISO/HL7 NP 27951	Health informatics -- Common terminology services, release 1

7. Agriculture domain regulatory standards

7.1 Common factors

Many of the general regulatory factors outlined in section 4 apply to the agriculture domain, including:

- Privacy of users' personal data;
- Health and safety factors for workers installing and using Hydra components;
- Environmental factors concerning the electronic hardware used with Hydra middleware; and
- Information society transmission regulations in the use of wireless networks.

The remainder of this section outlines the regulations and policies that are specific to this application domain.

7.2 Key regulations

The European agriculture industry is affected by a wide range of legislation as it encompasses:

- Consumer food safety;
- Animal welfare and nutrition; and
- The environment.

These are covered in the following sections.

7.3 Trends – General Food Law

Many of the issues listed above have been integrated over the past few years under the umbrella of the "General Food Law" [1], introduced in response to the food supply scares of the 1990s. This integrated strategy has four elements:

- rules on the safety of food and animal feed;
- independent and publicly available scientific advice;
- action to enforce the rules and control the processes; and
- recognition of the consumers' right to make choices based on complete information about where food has come from and its ingredients.

The General Food Law covers the whole of the food chain, including animal feed production, and clearly attributes primary responsibility for safe food production to industry, producers and suppliers.

7.4 Food Safety

7.4.1 Traceability

The General Food Law also introduced stringent traceability to the food industry. Animal feed producers, food producers, processors and importers must ensure that all foodstuffs, animal feed and feed components are traceable throughout the food chain, from "farm to fork" [2]. Each actor in the value chain must be able to identify its supplier and customers. This is known as the 'one-step-backward, one-step-forward' approach.

The European rapid alert system used for food and feed scares was also reinforced, and the European Food Safety Authority (EFSA – see [3]) was established.

Adequate procedures to facilitate such traceability must be introduced. These include the obligation for feed and food businesses to ensure that adequate procedures are in place to withdraw feed and food from the market where a risk to the health of the consumer is posed, which clearly requires accurate information and effective systems to support this. Operators should also keep adequate records of suppliers of raw materials and ingredients so that the source of a problem can be identified. Unambiguous tracing of feed and food and their ingredients is a complex issue, however, and must take into account the specificity of different sectors and commodities, so a "one-size-fits-all" solution is not appropriate to this problem.

Such traceability poses security and privacy challenges to technology providers, as food manufacturers' precise recipes, production processes and supply chains are clearly commercially sensitive, yet potentially, competitors who share common stages of the supply chain (possibly common suppliers as well as common distributors) could analyse the traceability data and deduce the details of competitors' recipes, processes and suppliers.

7.4.2 Animal welfare

The Commission's objective is to protect and raise the health status and condition of animals in the Community, in particular food-producing animals, whilst permitting intra-Community trade and imports of animals and animal products in accordance with the appropriate health standards and international obligations.

EC legislation now covers farm animal welfare throughout its lifecycle, including all aspects of transportation and slaughter or killing. This includes:

- veterinary checks, animal health rules and hygiene of food;
- the hygiene package, intra-community trade, production and placing on the market;
- animal nutrition covering official controls, additives, genetically modified feeding stuffs, animal waste and pathogenic agents;
- animal welfare (including livestock farming, transportation, slaughter); and
- animal health (including issues such as BSE, foot and mouth disease, swine fevers and avian influenza).

Again this legislation adds to the need for transparency and traceability in terms of the monitoring and audit of animal welfare. The "Community Action Plan on the Protection and Welfare of Animals 2006-2010" [4] provides a framework policy for the coming 5 years.

7.4.3 Product Labelling And Packaging

Consumers have the right to expect information on food quality and constituents that is helpful and clearly presented, so that informed choices can be made. The legislation aims to promote the importance of a balanced diet, and its impact on health, to consumers. The EC states that:

> *"Consumers are to be provided with essential and accurate information so that they can make informed choices."* [5]

On this basis, the Directive 2001/12/EC on the labelling presentation and advertising of foodstuffs [6] requires that labelling of food products must include precise data on ingredients and potential allergens which again links back to the food value chain and the need for integrated information. Such "*Full ingredient labelling*" not only ensures optimal consumer information as to the composition of a food product but at the same time ensures the necessary information for those consumers who for health or ethical reasons have to, or want to, avoid certain ingredients.

7.5 The environment

Sustainable agriculture [7] is closely linked to the environment and as such farmers have to follow CAP (Common Agriculture Policy) and other EC legislation in addition to national laws to manage the

level of intensity of farming. This presents another constraint on farm efficiency, increasing the need for effective management systems and technologies to assist productive farming while preserving eco-systems and biodiversity.

The growth in popularity of organic food further challenges the factory farming business models of the last century.

7.6 Technical standards

A number of international standards are under development specifically for messaging and control of agricultural machinery, which could greatly enhance the interoperability between Hydra-embedded systems within the agriculture domain. These are listed below and can be reviewed at the ISO Agricultural electronics website [8]

ISO Project reference	Title
ISO 11783-2:2002	Tractors and machinery for agriculture and forestry -- Serial control and communications data network -- Part 2: Physical layer
ISO 11783-3:1998	Tractors and machinery for agriculture and forestry -- Serial control and communications data network -- Part 3: Data link layer
ISO 11783-4:2001	Tractors and machinery for agriculture and forestry -- Serial control and communications data network -- Part 4: Network layer
ISO 11783-5:2001, ISO 11783-5:2001/Cor 1:2002	Tractors and machinery for agriculture and forestry -- Serial control and communications data network -- Part 5: Network management
ISO 11783-6:2004, ISO 11783-6:2004/Cor 1:2005	Tractors and machinery for agriculture and forestry -- Serial control and communications data network -- Part 6: Virtual terminal
ISO 11783-7:2002, ISO 11783-7:2002/Cor 1:2004	Tractors and machinery for agriculture and forestry -- Serial control and communications data network -- Part 7: Implement messages application layer
ISO 11783-8:2006	Tractors and machinery for agriculture and forestry -- Serial control and communications data network -- Part 8: Power train messages
ISO 11783-9:2002	Tractors and machinery for agriculture and forestry -- Serial control and communications data network -- Part 9: Tractor ECU
ISO 11784:1996, ISO 11784:1996/Amd 1:2004	Radio frequency identification of animals -- Code structure
ISO 11785:1996	Radio frequency identification of animals -- Technical concept
ISO 11786:1995	Agricultural tractors and machinery -- Tractor-mounted sensor interface -- Specifications
ISO 11787:1995	Machinery for agriculture and forestry -- Data interchange between management computer and process computers -- Data interchange syntax
ISO 11788-1:1997	Electronic data interchange between information systems in agriculture -- Agricultural data element dictionary -- Part 1: General description
ISO 11788-2:2000	Electronic data interchange between information systems in agriculture -- Agricultural data element dictionary -- Part 2: Dairy farming
ISO 11788-3:2000	Electronic data interchange between information systems in agriculture -- Agricultural data element dictionary -- Part 3: Pig farming
ISO 14223-1:2003	Radiofrequency identification of animals -- Advanced transponders -- Part 1: Air interface
ISO 15003:2006	Agricultural engineering -- Electrical and electronic equipment -- Testing resistance to environmental conditions

8. Conclusions

8.1 General regulatory standards affecting embedded systems

The majority of implications for Hydra at the cross-application level are requirements, including compliance with:

- data privacy laws in terms of network security, data retention and user consent
- product safety requirements for any devices with which consumers will have contact
- environmental regulations unless Hydra middleware is sufficiently efficient to run on low energy-efficient hardware which meets RoHS and WEE material use requirements
- information society transmission regulations.

Health and safety issues should be anticipated at the scenario and requirements specification stage to ensure that these do not pose any risks in a final Hydra product.

Warranty liability risks can also be mitigated through careful design and sufficient testing of Hydra components.

8.2 Intelligent buildings

The construction products directive presents both requirements for compliance at the Hydra product level, and opportunities at the application level thanks to harmonisation of building standards.

Energy performance of buildings presents opportunities to Hydra to offer a solution that improves energy performance through the management of electrical devices, increased intelligence and reliability of boilers and air-conditioning systems.

Emerging ISO building automation protocols also offer an opportunity to Hydra to support communication with third party field devices, automation stations and controllers.

8.3 Health

The eHealth initiative presents an important opportunity to Hydra, which is closely aligned to its aims of interoperability of health information systems and of electronic records, and mobility of patients and health professionals. The widespread adoption of eHealth and its associated initiatives across European states can also leverage the adoption of Hydra, provided that Hydra monitors and adheres to relevant standards.

Compliance with future eHealth systems and services accreditation criteria may become mandatory, as will be the requirement to support medical equipment regulations where relevant, in particular in terms of the ISO "Health Software" proposals.

International standards relating to eHealth from IEEE, CEN, HL7, ASTM and ISO present both an opportunity (for wider interoperability) and a threat (of reduced market for health products) in the case of non-compliance.

8.4 Agriculture

The combination of consumer food safety, animal welfare, traceability, product labelling and environmental regulations place a substantial burden on the food producer value chain. Hydra has the potential to assist the industry with compliance (in particular with traceability) at reduced cost and improved efficiency by means of enabling improved interoperability, communications and security between systems and devices throughout the supply chain.

At the same time, Hydra products must not have a detrimental environmental impact, and must also not harm animal welfare.

Compliance with ISO agricultural electronics standards has the potential to enable wider interoperability for Hydra agricultural products.

8.5 Next steps

The Hydra project will continue to monitor regulatory developments in the areas addressed, in particular assessing adoption of standards and ensuring compliance with evolving regulations.

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