CHAPTER 6

Regulations and Standards: Considerations for Sensor Technologies

All sensor-based devices, particularly healthcare devices, require a degree of regulation to ensure that they are electrically, chemically, biologically, and physically safe for the end user. The degree of regulation required depends on the level of risk associated with the device. Implantable devices, such as pacemakers, require more stringent regulation than a noninvasive thermometer. When developing or using health, wellness, or environmental devices, it is important to be aware of the regulations that pertain to that device and ensure that your device is compliant. In fact, because of the potential risks posed by certain medical devices, it is illegal to market or sell a medical device without putting it through the appropriate regulatory processes. Geographical and domain-specific standards provide benchmarks against which the compatibility, interoperability, safety, or quality of a device can be measured. Given this broad scope, it would be impossible to describe, or even list, all the standards that pertain to health, wellness, and environmental sensors within a single chapter. Rather, this chapter will provide an example-based introduction to the topics of regulation and standards, referencing some of the most common standards and regulations applied in these domains.

Sensors are the key component of any medical device that has a measuring purpose. As discussed in Chapter 3, sensors can be stand-alone discrete devices (such as home testing kits) or can interface with devices such as smartphones. Most sensor-based medical devices operate by making physical contact with the user. It is therefore critical that the device does not harm the user physically, chemically, or electrically. Sensors generate medically sensitive data, which must be protected or shared in a secure manner. Sensor data also informs clinical and nonclinical decisions, making accuracy a key requirement. Given the risk associated with even the simplest sensor-based device, compliance with standards and regulations is essential.

The level of regulation differs depending on whether a device is for research or manufacture. For example, CE (Conformité Européene) marking is not required for investigational devices but is necessary for devices that are to be sold. Investigational devices must be labeled "Exclusively for Clinical Investigation." Ethical review should always be sought for a clinical investigation of a non-CE medical device, and informed consents should be obtained from end users.

Regulation of Medical Devices

Before discussing standards and regulations for medical devices, it is helpful to understand the differences between both terms. The International Organization for Standardization defines a *standard* as follows:

> *A document, established by consensus and approved by a recognized body, that provides, for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context.*

And a *regulation* is defined as follows:

> *A document providing binding legislative rules that is adopted by an authority*

In effect, a regulation has a legal status, but a standard does not. Therefore, medical devices must comply with the regulations in the geographical area in which they are sold.

The term *medical device* can be used to describe a broad range of items, ranging from a simple bandage to implantable pacemakers. Despite the broad scope of the term, medical devices are regulated by a single set of regulations. The process of medical device regulation is managed by national or international regulatory bodies, such as the United States Federal Food and Drug Administration (U.S. FDA) or a notified conformity assessment body in the European Union (EU). Although the regulatory requirements for medical device safety and manufacture are similar in most countries, they are not identical. Therefore, to market or sell a device in a specific jurisdiction, a device must undergo the regulatory process for that jurisdiction. This section will provide an overview to medical device regulation, using the U.S. FDA process and European Union Medical Device Directive as examples.

CE Marking

CE marking indicates that a product complies with EU legislation and can be sold within the European Economic Area (EEA), which are the 27 member countries of the EU plus Iceland, Norway, Liechtenstein, and Turkey. A CE mark is the manufacturer's declaration that the product meets the requirements of the applicable EU directives. It can be found on everything from toys to lightbulbs to PCs. CE marking does not indicate that the product is made in the EEA but simply that it has met all the requirements to be sold there. In the EU, all medical devices must be identified with the CE mark. To achieve a CE mark, the medical device must comply with one of the following directives:

- Directive 90/385/EEC regarding active implantable medical devices
- Directive 93/42/EEC regarding medical devices
- Directive 98/79/EC regarding in vitro diagnostic medical devices

The EU Medical Device Directive (also known as MDD or 93/42/EEC (EU 1993) is the most commonly applied directive for sensor-based devices. The MDD is a complex document, consisting of 23 articles, 12 annexes, and 18 classification rules. It is therefore highly recommended to work closely with your national "notified body" or regulatory agency to ensure all criteria of the directive are met. At a high level, obtaining CE certification for a medical device can be summarized as a six-step process (EC Enterprise and Industry):

1. ***Directives***: Verify that your device is a medical device, as defined in Article 1 of the MDD and that none of the exclusion criteria in this article applies. Ensure that your device is not an active medical device (in which case Directive 90/385/EEC applies) or an in vitro diagnostic medical device (in which case Directive 98/79/EC applies).

2. ***Verify requirements***: The essential requirements that the device must meet are listed in Annex I to the MDD. Compliance with these requirements must be demonstrated by a clinical evaluation in accordance with Annex X to the MDD. Note: it is possible that more than one directive applies to the same product (such as horizontal legislation on chemicals or environment); therefore, the requirements for these directives must also be met.

3. ***Need for notified body***: A notified body is required to certify a device's compliance if a device is classified as a Class II (medium risk) or higher or as a Class I (low risk) device, which is placed on the market in a sterile condition. Device classification is defined in Annex IX of the MDD. The role of the notified body is defined in Article 16 of the MDD.

4. ***Check conformity***: The conformity assessment procedure(s) depends on the class of the medical device. These procedures are listed in Annexes II to VII of the MDD, and the manufacturer can choose which procedure to apply. The conformity procedures address both the design and manufacture of the device. The manufacturer must provide objective evidence of how the design of the device meets with the essential requirements, described in Annex I of the MDD. A documented quality system must be in place to ensure that the devices continue to comply with the essential requirements. For Class IIa, IIb, and III devices, a notified body must verify and certify that the quality management of the manufacturer assesses the device's compliance with the essential requirements. Class I devices that are not placed on the market in a sterile condition can be self-certified. Regardless of the certification method, the manufacturer must declare its sole responsibility for the conformity to the MDD in a Declaration of Conformity (DoC).

5. ***Technical documentation***: Technical documentation (called a *design dossier*) must describe how the device conforms with the MDD requirements. This documentation must be provided by the manufacturer before submitting an application to the notified body or, at the latest, before placing the device on the market. The manufacturer must keep copies of the technical documentation for at least five years after the last product has been placed on the market.

6. ***Affix CE marking***: Once the necessary steps have been successfully completed, the CE marking must be visibly placed on the medical device. If this is not possible, it must be placed on the packaging and on the accompanying documentation. The identification number of the notified body must also be displayed if it was involved in the conformity assessment procedure.

Figure 6-1. *CE marking on a Shimmer device (reproduced with permission from Realtime Technologies Ltd)*

Obtaining CE certification is only part of the process. Once the device is on the market, the facilities in which the device will be manufactured will be subject to annual ISO 13485 audits by the national competent authorities. Any incident pertaining to the device must be reported to the competent authority, who will decide the appropriate action to take. This EU regulatory framework for the device lifetime is well illustrated by Eucomed in Figure 6-2.

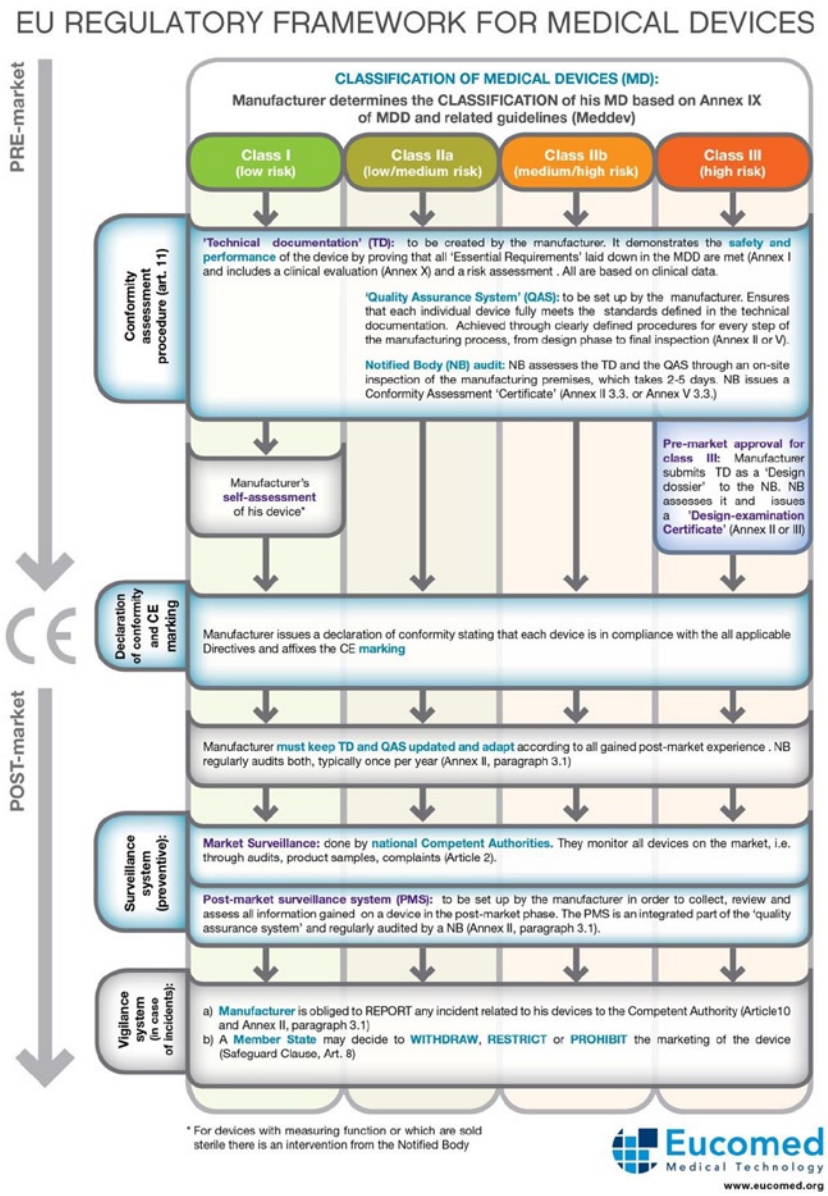

Figure 6-2. *EU regulatory framework for medical devices (reproduced with permission from Eucomed (www.eucomed.org/uploads/_key_themes/mdd/EUCOMED_infographie_03.jpg)*

U.S. FDA

The Food and Drug Administration's Center for Devices and Radiological Health (CDRH) is responsible for regulating firms that manufacture, repackage, relabel, and/or import medical devices sold in the United States (www.fda.gov/MedicalDevices/). It is also responsible for regulating medical (for example, X-ray systems) and non-medical (for example, color televisions) radiation-emitting electronic products. All medical devices are subject to the general controls of the Federal Food Drug & Cosmetic (FD&C) Act. These controls, which are contained in Title 21 Code of Federal Regulations Part 800-1200 (21 CFR Parts 800-1200) (FD&C Act, 2010), are the baseline requirements for marketing, labeling, and monitoring the postmarket performance of all medical devices. Technically, the U.S. FDA does not "approve" medical devices; it "clears" them for sale. The U.S. FDA marketing clearance process for medical devices can be described in three steps (U.S. FDA, 2013):

1. ***Ensure the product is a medical device***, as defined by section 201(h) of the FD&C Act. Products that do not meet this definition (for example, drugs) may be subject to different U.S. FDA regulations. Some medical devices (for example, radiation-emitting devices) may also require additional regulation.

2. ***Identify the risk-based device classification*** (see Table 6-1), as described in 21 CFR 860. The classification will determine the level of regulatory controls required to ensure the safety and effectiveness of the device. It will also determine the marketing process (premarket notification or premarket approval [PMA]) required for the device to obtain U.S. FDA clearance. A device for which there is no substantially equivalent device is automatically classified as a Class III (high risk) device, regardless of the risk it poses. A "de novo" petition may be submitted to the U.S. FDA to request a re-classification from Class III to a Class I or II, if appropriate.

Table 6-1. *FDA Device Classes*

Device Class	Description	Risk Level
Class I: General controls	Class I devices are subject to the least regulatory control. Class I devices are not intended to help support or sustain life or be substantially important in preventing impairment to human health and may not present an unreasonable risk of illness or injury.	Low
Class II: General controls with special controls	Devices in Class II are held to a higher level of assurance than Class I devices and are designed to perform as indicated without causing injury or harm to the patient or user. Examples of Class II devices include powered wheelchairs, infusion pumps, and surgical drapes.	Medium
Class III: General controls and premarket approval	Class III devices are usually those that support or sustain human life, are of substantial importance in preventing impairment of human health, or present a potential, unreasonable risk of illness or injury.	High

3. ***Develop data and/or information necessary to submit a marketing application***. The premarket notification process, which is also called the 510 (k) process, applies to most Class II (medium risk) and some Class I (low risk) and Class III devices (high risk). In this process, the device manufacturer must demonstrate that the device is safe and effective by proving "substantial equivalence" to a legally marketed "predicate device." The 510 (k) process rarely requires clinical trials. Premarket approval (PMA) is required to evaluate the safety and effectiveness of Class III (high risk) medical devices. PMA is the most stringent type of device marketing application required by U.S. FDA and is similar to the new drug approval process. Some 510(k) and most PMA applications require clinical trials to obtain clearance to market. Clinical trials must be performed in accordance with the U.S. FDA's Investigational Device Exemption (IDE) regulation.

The U.S. FDA reviews most 501(k) applications within 90 days and PMA applications within 180 days. If a 510(k) application is cleared, the U.S. FDA will mail the manufacturer a letter, with an assigned 510(k) number that says they "have determined that your device is substantially equivalent to legally marketed predicate devices." If a PMA device is cleared, the U.S. FDA audits the quality system regulation (QSR) of all major suppliers involved in the design, development, and manufacture of the device. If successful, a PMA approval letter is issued. On receipt of a 510(k) or PMA approval letter, the device is clear to sell, once the U.S. FDA device listing and establishment registration is completed on the U.S. FDA web site. The U.S. FDA will conduct random inspection to ensure compliance with the Quality Systems Regulation (QSR), 21 CFR Part 820.

Other Medical Device Regulators

According to the 2010 World Health Organization Baseline Country Survey on Medical Devices (World Health Organization, 2010), only 65 percent of 145 responding countries have a national authority responsible for implementing and enforcing medical device regulations. Many of those governments that have drafted regulations have made little progress in implementing them. The WHO is supporting countries that do not have regulations to develop and implement such regulations.

Medical device regulations differ among the 65 percent of countries that have implemented regulations. The WHO is an official observer of International Medical Devices Regulatory Forum (www.imdrf.org) and also supported its predecessor, the Global Harmonization Task Force (GHTF). The IMDRF is a voluntary group of medical device regulators (including the EU, U.S. FDA, and Australia) that have come together to "accelerate the international medical device regulatory harmonization and convergence." Their initial tasks include the following:

- Defining a path to implementing a globally harmonized approach to the uniform device identification system, previously defined by the GHTF
- Developing a standard set of requirements for auditing organizations that perform regulatory audits of medical device manufacturers' quality management systems
- Creating a list of international standards used for medical device regulatory purposes that are recognized by IMDRF Management Committee members

Standards for Medical Devices

Standards can serve different purposes. They can do all of the following:

- Provide reference criteria that a product, process, or service must meet
- Provide information that enhances safety, reliability, and performance of products, processes, and services
- Assure consumers about reliability or other characteristics of goods or services provided in the marketplace
- Give consumers more choice by allowing one firm's products to be substituted for, or combined with, those of another

Standards apply across many aspects of sensor-based devices, including radio standards (previously discussed in Chapter 3), industry standards, quality standards, and clinical standards. This section describes the standards and industry groupings most applicable to the health, wellness, and environmental domains.

Industry Standards and Certification

The healthcare industry, like many other industries, has developed a number of standards and guidelines where regulation does not exist. These standards were agreed upon by industry leaders to enable interoperability between devices and to ensure that a certain quality was maintained. Compliance with standards is voluntary, but compliant devices and software are more appealing to consumers because they are interoperable with other devices.

Continua

The Continua Health Alliance (www.continuaalliance.org/) is a nonprofit, open industry organization of more than 240 healthcare and technology companies collaborating to improve the quality of personal healthcare. Continua is not a standards body; rather, it identifies and resolves gaps in standards bodies so that personal telehealth solutions are interoperable and contribute toward improved health management. The alliance creates and updates design guidelines on standards to ensure interoperability between devices and manufacturers. Continua has created a product certification logo program with a consumer-recognizable logo signifying the promise of interoperability with other certified products. Continua is the only certification group in the personal connected healthcare domain.

Integrating the Healthcare Enterprise (IHE)

Like Continua, IHE (www.ihe.net) is a collaborative effort between healthcare professionals and the industry to promote the coordinated use of established standards, such as DICOM and HL7. The goal of the IHE is "to improve the quality, efficiency and safety of clinical care by making relevant health information conveniently accessible to patients and authorized care providers." To achieve this goal, every year the IHE brings together users and developers of healthcare information technology (HIT) to select and optimize established standards into "IHE Profiles" for HIT systems. The vendors can then test their systems against these profiles at "Connectathon" events to ensure they comply with the new profiles. The IHE focuses on total end-to-end interoperability of a system, not just one piece of it (as is the focus with most standards bodies). The IHE focus is primarily on medical imaging devices, radiology, cardiology, and HIT systems.

Happtique Health App Certification Program (HACP)

The Happtique Health App Certification Program (www.happtique.com/app-certification/) is a voluntary program developed to help healthcare providers and consumers easily identify medical, health, and fitness apps that do the following:

- Deliver credible content
- Contain safeguards for user data
- Function as described

Both federally regulated and unregulated medical, health, or fitness apps can be awarded a Happtique certification seal if they meet the operability, privacy, security, and content standards defined by HACP. The standards were developed under the direction of domain experts and relevant private organizations (for example, the American Medical Association). Federal agencies (for example, U.S. FDA, FCC) provided feedback during the development process. Compliance with the "technical standards" (Operability, Privacy, Security) is assessed by a third-party company (Inertek). Compliance with "content standards" is evaluated by the Association of Medical Colleges, CGFNS International, and appropriate clinical specialists. The HACP certification program, launched in February 2013, applies only to apps that are written in English and run natively on iOS, Android, BlackBerry, or Windows devices.

Quality Management System Standards

A quality management system (QMS) is a structured systematic approach to process and product quality management. It consists of organizational structure, responsibilities, processes and procedures, and resources. The most common QMS, the ISO 9001, is applicable to all business sectors. In many nonmedical device industries, creation and compliance with a QMS standard are simply methods to ensure quality and to promote continuous process and product improvement. A QMS standard can provide a competitive advantage over companies without QMS certification. In the medical device industry, demonstrating compliance with a QMS is a key part of the regulation process. The most common QMS for medical devices are ISO 13845 and 21 CFR 820. ISO 13845 and related standards.

ISO 13845 is an International Organization for Standardization (ISO) standard that defines the requirements for a comprehensive quality management system for the design and manufacture of medical devices. ISO 13845 is generally harmonized with ISO 9001, which sets out the requirements for a quality management system. They differ in one key area: ISO 9001 requires the organization to demonstrate continual improvement, whereas ISO 13485 requires only that a quality system is implemented and maintained. ISO 13485 is closely linked to the EU medical device directives, and demonstrating conformity with ISO 9001 and/or ISO 13485 and ISO 14971 is often seen as the first step in achieving compliance with European regulatory requirements. ISO 13485 is now considered to be an inline standard and requirement for medical devices. The International Medical Devices Regulatory Forum is currently working on the Medical Device Single Audit Program (MDSAP), which will align with the current ISO 13485 revision to achieve a harmonized standard among its members.

ISO 14971 is an ISO standard that establishes the requirements for risk management to determine the safety of a medical device during the product life cycle. This standard is required by higher-level regulations and other quality standards, including the ISO 13485 standard.

The U.S. FDA quality system requirements (21 CFR 820) were created many years before ISO 13485. As a result, they differ. The U.S. FDA does not recognize ISO 13485 certification, and the EU does not recognize 21 CFR 820. An integrated quality management system that meets the requirements of both the U.S. FDA and international regulatory bodies must be used if a medical device will be marketed within and outside of the United States. The differences between the EU and U.S. FDA QMS auditing processes are discussed later in this chapter.

Clinical Research Standards

Clinical research trials evaluate the efficacy of a clinical protocol, device, or drug. They are an essential part of the medical device approval process, and it is therefore essential that they are conducted safely and ethically and their results are reported accurately. Clinical research standards were developed to protect the patient and their data during clinical trials. The most commonly applied standards are the Declaration of Helsinki and Good Clinical Practice.

Declaration of Helsinki

The Declaration of Helsinki (WMA, 2013) is a set of ethical principles developed by the World Medical Association (WMA) to provide guidance to the medical community in research involving human subjects. This includes research on people, identifiable human material, or identifiable data. Although not a legally binding instrument in international law, it is considered a fundamental document in the ethics of healthcare research. As a result, the principles have been embodied in or have influenced national and regional legislation and regulations. The declaration was first adopted in 1964 in Helsinki, Finland, and has since undergone six revisions and two clarifications to accommodate advances in medical science and ethical problems. The declaration has 35 paragraphs, including principles on safeguarding research subjects, informed consent, minimizing risk, and adhering to an approved research plan/protocol.

The U.S. FDA rejected the 2000 and subsequent revisions of the declaration, and in 2006 announced it would eliminate all reference to it. In October 2008, the U.S. FDA replaced references to the Declaration of Helsinki with Good Clinical Practice.

Good Clinical Practice (GCP)

Good Clinical Practice (ICH, 2006) is a set of internationally recognized ethical and scientific quality requirements that must be observed for designing, conducting, recording, and reporting trials that involve the participation of human subjects. The GCP includes standards on how clinical trials should be conducted and defines the roles and responsibilities of clinical trial sponsors, clinical research investigators, and monitors. This standard ensures that the rights, safety, and well-being of trial subjects are protected and that the clinical trial data are credible. The unified clinical data standard provided by the ICH GCP guideline is accepted by the European Union, Japan, and the U.S. regulatory authorities. The guideline may also be applied to other nonregulatory clinical trials that involve human subjects.

Data Interoperability Standards

Data interoperability standards are essential to deliver better health and fitness data more quickly, safely, and at a lower cost. Without interoperability standards, data is either captured manually, captured using custom equipment, or not captured at all. Manual data capture is both labor-intensive and prone to errors. Custom equipment is invariably more expensive to run and maintain. The purchaser may be obliged to purchase all equipment from a single manufacturer to achieve end-to-end data connectivity rather than network the best (or cheaper) individual items to achieve the same goals. Lack of interoperability also hinders delivery of care. If individual devices are simultaneously capturing data from a single patient but cannot communicate with each other or with a centralized system, alarming trends or correlations may not be noticed.

CEN ISO/IEEE 11073

The CEN ISO/IEEE 11073 is an internationally adopted family of standards developed to enable complete connectivity between medical, healthcare, and wellness devices. These standards describe connectivity from the physical levels (cable or wireless connectivity) up to the abstract representation of data and the services to be exchanged with external computers. The standards are targeted at both personal health and fitness devices (including pulse oximeters, medication dispensers, and activity monitors) and hospital-based devices (including ventilators and infusion pumps). The goals of the standards are to do the following:

- Provide real-time plug-and-play interoperability for citizen-related medical, healthcare, and wellness devices
- Facilitate efficient exchange of care device data, acquired at the point of care, in all care environments

The ISO/IEEE 11073 Personal Health Device (PHD) standards are a subgroup of the ISO/IEEE 11073 family; they address the interoperability of personal health devices. These standards leverage existing IEEE11073 standards but apply a simpler communication model because they are designed for personal rather than hospital use.

Health Level 7 (HL7)

Health Level 7 (www.hl7.org/) describes both a nonprofit international standards organization and the interoperability standards it creates. HL7 specifies a number of flexible standards, guidelines, and methodologies that enable the different computer systems in hospitals and other healthcare organizations to communicate with each other. Specifically, HL7 develops the following standards:

Messaging standards: The HL7 v2.x and v3.0 messaging standards define how data is packaged and transferred from one party to another.

Conceptual standards: The HL7 Reference Information Model (RIM) standards represent the HL7 clinical data and life cycle of the message(s).

Document standards: The HL7 Clinical Document Architecture (CDA) standard specifies the XML-based encoding, structure, and semantics of clinical documents for the purposes of exchange.

Application standards: The HL7 Clinical Context Object Workgroup (CCOW) standard allows a clinical user to access a single patient's data across multiple applications using a single username and password.

Regulation of Environmental Sensors

As we become increasingly aware of our health and our environment, we become increasingly interested in quantifying the interactions between them. Environmental monitoring allows us to measure the quality of the air we breathe, the water we drink, any changes in weather, and the noise around us. These parameters can be measured using highly calibrated specialized devices or using off-the-shelf hobbyist devices. These devices report parameters that can have a serious impact on our lives; thus, it is vitally important that the sensors we rely on to warn us about unsafe water or dangerously high levels of carbon monoxide report accurately, consistently, and in a timely manner. A number of standards and regulations have been developed to quantify what parameters should be measured, how they should be measured, and how these data should be reported. Understanding both the standards and the ability of the sensors to meet these standards is a key part of application design: there is no point having a low-cost carbon dioxide sensor in an office environment if it cannot accurately measure carbon dioxide levels in the range set down by the indoor air quality standards. In many cases, low-cost sensors cannot perform to the specification required by the standards, but there is a research interest in understanding if a number of less accurate sensors can compensate for each other and collectively provide as much useful information as a single regulated sensor. This research question has yet to be answered, and until it is answered, it is best to comply with existing standards and regulations for critical applications or to indicate from the outset that the device has limitations.

Regulations for environmental noise, air quality, water, and weather have many subregulations—typically one regulation per parameter to be regulated. It is outside of the scope of this section to describe, or even list, every subregulation pertaining to these topics. However, this section will describe the overarching regulation covering each topic and the body responsible for regulating these environmental parameters.

Environmental Noise

Environmental noise pollution is the term used to describe excessive, unwanted, or disturbing outdoor sounds levels that affect the quality of life of people or animals. Unwanted noise can cause annoyance and aggression, increase stress levels, disturb sleep, and in severe cases damage hearing. Traffic, construction, industrial, and some recreational activities are the most common sources of outdoor environmental noise. Noise pollution can also occur indoors, but the sources of indoor noise are different (house alarms, music, home appliances, animals, and family conflict). Indoor noise pollution may also be subject to different regulations, depending on the use of that indoor location (for example, occupational health and safety). Noise regulations restrict the amount of noise, the duration of noise, and the source of noise. The permitted noise level can also be dependent on the time of day and the location of the noise: at nighttime or in very quiet locations the permitted noise levels are much lower than during the daytime in other areas.

Sound level meters are used to measure noise. These devices sense changes in pressure because of sound and amplify and filter this signal to provide a decibel reading. These devices must be calibrated in the field before every series of reading using a calibrator. Both the sound level meter and calibrator must comply with ISO standards and must be calibrated in a laboratory annually. The key standards describing the measurement of environmental noise are ISO 1996-2 and ISO 9613. Both these standards describe how to quantify noise from various sources. The most common measures used to describe noise are the equivalent continuous sound level ($L_{Aeq,T}$), which describes fluctuating noise from all sources in terms of a single noise level over the sample period (T); and the rated noise level ($L_{Ar,T}$), which adds a penalty to the $L_{Aeq,T}$ for more annoying tonal and impulsive noise. These levels can be measured continuously throughout the sample period or can be calculated by taking a number of representative samples for

a prescribed duration during the sample period. Modern sound meters are capable of measuring other relevant statistical, maxima/minima, and 1/3 octave band data, which are also relevant to the assessment of noise. Information on these measures can be found in the ISO standards referred to earlier. As with many environmental measures, it is important not to overlook the time aspect of these measures. These standards describe an average value over a period of time, which can range from a few seconds to a day. Single samples of a pollutant, taken intermittently, may be interesting to an individual but is not comparable to the legislated values.

In Europe, the Environmental Noise Directive (2002/49/E, 2002) was created to map areas affected by noise pollution levels and to act upon it both at the member state and EU level. It defines a common approach to avoiding, reducing, and preventing the harmful effects due to exposure to long-term environmental noise. The directive deals mainly with noise due to major roads, railways, airports, and agglomerations. The World Health Organization recently published the Night Noise Guidelines for Europe (WHO, 2009), which presents details on the impact of nighttime noise on health. These guidelines recommend that the annual average outdoor noise at night should not exceed 40 decibel (dB). The WHO Guidelines for Community Noise (WHO, 2010) provides guideline exposure levels for community scenarios (Table 6-2). In the United States, individual states and local governments are responsible for addressing noise issues. However, the Environmental Protection Agency (EPA) investigates and studies noise and its effect, disseminates information to the public regarding noise pollution, responds to inquiries relating to noise, and evaluates the effectiveness of existing regulations for protecting the public health and welfare.

Table 6-2. *WHO Community Noise Guidance (Source: WHO Guidelines for Community Noise)*

Environment	Critical Health Effect	Sound Level dB(A)*	Time (Hours)
Outdoor living areas	Annoyance	50 to 55	16
Inside bedrooms	Sleep disturbance	30	8
School classrooms	Disturbance of communication	35	During class
Industrial, commercial, and traffic areas	Hearing impairment	70	24
Music through earphones	Hearing impairment	85	1
Ceremonies and entertainment	Hearing impairment	100	4

Ambient Air Quality

Humans can be adversely affected by exposure to solid particles, liquid droplets, or gases in the air. There is a wide range of air pollutants, which can occur naturally (radon gas) or be man-made (carbon monoxide from a vehicle exhaust). These pollutants come from stationary sources, such as manufacturing facilities, refineries, and power plants; and mobile sources, such as cars, heavy goods vehicles, and airplanes. Many regulations exist to manage all these sources. For example, in Europe there are regulations for paint emissions (the Paints Directive), Industrial Emissions (the IPPC Directive), and Emissions from Maritime transport (Directive 1999/32/EC), among many others (EU, 2013). The Clean Air For Europe (CAFE) Directive (2008/50/EC) is the most relevant European regulation for this book. This directive provides both limits (Table 6-3) and target values for air quality pollutants. Like noise pollution, these limits and targets apply over differing periods of time. This is because the health impacts associated with each pollutant can occur over different exposure times. The individual member states in the EU are responsible for implementing this directive in their own countries. They must assess air pollution levels in zones across their country, prepare an air quality plan for when a limit is exceeded, and disseminate air quality information to the public.

Table 6-3. *Limit Values of CAFE Directive (Source: http://ec.europa.eu/environment/air/quality/standards.htm)*

Pollutant	Concentration	Averaging Period	Permitted Exceedences Each Year
Fine particles (PM2.5)	25 μg/m^3	1 year	n/a
Sulfur dioxide (SO_2)	350 μg/m^3	1 hour	24
	125 μg/m^3	24 hours	3
Nitrogen dioxide (NO_2)	200 μg/m^3	1 hour	18
	40 μg/m^3	1 year	n/a
PM10	50 μg/m^3	24 hours	35
	40 μg/m^3	1 year	n/a
Lead (Pb)	0.5 μg/m^3	1 year	n/a
Carbon monoxide (CO)	10 mg/m^3	Maximum daily 8 hour mean	n/a
Benzene	5 μg/m^3	1 year	n/a
Ozone	120 μg/m^3	Maximum daily 8 hour mean	25 days averaged over 3 years
Arsenic (As)	6 ng/m^3	1 year	n/a
Cadmium (Cd)	5 ng/m^3	1 year	n/a
Nickel (Ni)	20 ng/m^3	1 year	n/a
Polycyclic Aromatic Hydrocarbons	1 ng/m^3 (expressed as concentration of Benzo(a)pyrene)	1 year	n/a

The Clean Air Act was introduced in 1970 to protect the health and environment in the United States from air pollution. This act gives the EPA the authority to set and revise national ambient air quality standards (NAAQS), based on the latest science. The Clean Air Act refers to two standards: primary standards are the standards for public health, and secondary standards are for the protection of crops, the environment, and property. The EPA currently regulates six "criteria pollutants": sulfur dioxide, carbon monoxide, particles, nitrogen dioxide, ozone, and lead (Table 6-4). These pollutants can damage health, the environment, and property. Each of these pollutants is regulated by a different code of federal regulation (CFR). Each U.S. state is responsible for implementing its own air pollution regulations, programs, and policies, but they cannot have weaker limits than those set by the EPA. Each state can also grant and enforce operating permits to major pollution sources that contain emission standards and limitations.

Table 6-4. *U.S. National Ambient Air Quality Standards (Source: http://epa.gov/air/criteria.html)*

Pollutant	Primary/Secondary	Averaging Time	Level	Form
Carbon monoxide	Primary	8-hour	9 ppm	Not to be exceeded more than once per year
		1-hour	35 ppm	
Lead	Primary and secondary	Rolling 3-month average	0.15 μg/m^3	Not to be exceeded

(*continued*)

Table 6-4. (*continued*)

Pollutant		Primary/Secondary	Averaging Time	Level	Form
Nitrogen dioxide		Primary	1-hour	100 ppb	98th percentile, averaged over 3 years
		Primary and secondary	Annual	53 ppb	Annual mean
Ozone		Primary and secondary	8-hour	0.075 ppm	Annual fourth-highest daily maximum 8-hour concentration, averaged over 3 years
Particle pollution	PM2.5	Primary	Annual	12 μg/m^3	Annual mean, averaged over 3 years
		Secondary	Annual	15 μg/m^3	Annual mean, averaged over 3 years
		Primary and secondary	24-hour	35 μg/m^3	98th percentile, averaged over 3 years
	PM10	primary and secondary	24-hour	150 μg/m^3	Not to be exceeded more than once per year on average over 3 years
Sulphur dioxide		Primary	1-hour	75 ppb	99th percentile of 1-hour daily maximum concentrations, averaged over 3 years
		secondary	3-hour	0.5 ppm	Not to be exceeded more than once per year

An air quality index is a simple method to represent air quality status as a single value on a scale. Different countries have created different scales by weighting the inputs differently. The EU air quality index, the Common Air Quality Index (CAQI), is a 5-level scale, ranging from 0 (very low) to >100 (very high). This scale (Elshout et al., 2012) is based on 3 pollutants (PM10, NO_2, O_3) and is applied to provide air quality status in the previous hour, the last day, and the last year. This scale is applied by several EU countries and allows nonexperts to quickly compare air quality between locations without understanding the underlying data. The EPA implemented a 6-level AQI (U.S. EPA, 2009) based on 5 of the "criteria pollutants." This data is gathered from around the United States and is represented using color-coded levels on the live AirNow air quality website (www.airnow.gov/).

Indoor Air Quality

While outdoor air quality and industrial air quality are well regulated at a federal level, there are few regulations for indoor air quality. This is surprising considering how much time we spend indoors, sleeping, working, traveling, or engaging in indoor sporting or leisure activities. Indoor air quality (IAQ) is the term used to describe the concentrations of air pollutants that are known or suspected to affect people's comfort, health, or performance at work or school. In serious cases, poor IAQ can spread airborne infections, such as Legionnaire's disease; cause cancers, such as lung cancer from radon exposure; or cause death due to severe acute respiratory syndrome (SARS) or carbon monoxide (CO) poisoning. There as several sources of air pollution, with corresponding standards and regulations.

Most indoor air pollutants come from topical chemical sources, such as cleaning products, air fresheners, and pesticides; or emissions from construction materials, heating, and cooking. The impact of these pollutants can be overcome by adequate ventilation. Ventilation is increasingly becoming an issue in Western countries. As we strive to achieve airtight energy-efficient homes and workplaces, we overlook the importance of natural or mechanical air flow

in and out of a building. Global warming also has a part to play; extreme weather encourages us to shut all the windows and sources of natural ventilation, thus leading to a buildup of chemicals, pathogens, and allergens. Good building and ventilation design are therefore essential factors in ensuring IAQ. The American Society of Heating, Refrigerating, and Air-conditioning Engineers (ASHRAE) publishes a well-recognized series of standards and guidelines relating to HVAC systems and issues, such as ASHRAE Standard 62-2001, "Ventilation for Acceptable Indoor Air Quality" (ANSI/ASHRAE). These standards are widely applied in industry but are not legally enforceable. However, the EPA has adopted some of these recommendations in its regulations. Poor thermal conditions and inadequate ventilation can encourage the growth of microorganisms on building surfaces and the survival of airborne infectious pathogens and dust mites. Outdoor sources of air pollution can also impact indoor air quality.

From a sensing perspective, the ISO/TC 146 Air Quality Technical Committee (ISO/TC 146, 2013) is responsible for standardization of tools for air quality characterization of emissions, workspace air, ambient air, and indoor air and for meteorological parameters. It describes measurement methods for air pollutants (particles, gases, odors, and micro-organisms), measurement planning, procedures for Quality Assurance/Quality Control (QA/QC), and methods for the evaluation of results including the determination of uncertainty. This technical committee is responsible for a total of 140 ISO standards in the IAQ sensing domain. The WHO Guidelines for Indoor Air Quality Selected Pollutants (WHO, 2010) provides scientific-based guidelines for a number of chemicals commonly present in indoor air. The chemicals described in this guideline are commonly found indoors and are demonstrated to be hazardous to health. These chemicals are benzene, carbon monoxide, formaldehyde, naphthalene, nitrogen dioxide, polycyclic aromatic hydrocarbons, radon, trichloroethylene, and tetrachloroethylene. The guideline describes the scientific evidence, which demonstrates the risk posed by each of these chemicals. As with outdoor air quality regulations, the exposure limits of each chemical is described according to an average exposure time.

The most commonly sensed chemicals, from a consumer perspective, are carbon monoxide and radon. Carbon monoxide (CO) is a byproduct of heating, cooking, and combustion engines and is therefore often found at low levels in both indoor and outdoor environments. Inadequate ventilation or damaged appliances can cause a lethal buildup of this tasteless, colorless, odorless gas. It is therefore recommended that all homes install and maintain a CO alarm. In Europe, in-home CO sensors must comply with the European Standard EN50291, which states that an alarm should be triggered at the following levels:

- Not before 120 minutes for a concentration of 30 ppm
- Between 60 and 90 minutes at a concentration of 50 ppm
- Between 10 and 40 minutes at a concentration of 100 ppm
- Before 3 minutes at a concentration of 300 ppm

These standards are safer than the U.S. standards for CO (Underwriters Laboratories, 2005). It should be noted that CO alarms are designed to prevent acute poisoning (one-time accidental poisoning). They are not designed to prevent chronic poisoning (multiple low-level poisonings), which also poses a health risk.

Radon is a naturally occurring radioactive gas that results from the decay of uranium in rocks and soils. Like CO, it is colorless, odorless, and tasteless and can be measured only using special equipment. It is the leading risk factor for lung cancer in nonsmokers. In open air, radon is quickly diluted to harmless concentrations. However, in enclosed spaces, such as a house, radon levels can build up to dangerous concentrations. National radiological monitoring agencies map locations of high radon risk. Building regulations state that mitigation methods should be employed to protect the building from radon from the ground during the construction phase of a building. These measures include fully sealed, low permeability membranes, or radon sumps. However, these membranes can be damaged, and radon may still leak into the building. Radon sensors can be purchased from national radiological agencies levels for a nominal fee. These sensors measured radon over a three-month period to allow for temporal fluxations in radon levels. Radon levels are described by regulation agencies in terms of action level and reference levels. As the name implies, an action level is the level at which action should be taken to mitigate against radon exposure, whereas a reference level is a warning of unacceptable levels. The WHO (WHO, 2010) recommends a maximum acceptable annual average level of 100 Bq/m^3 for radon in dwellings. European countries (EU, 2009) have references levels between 200 and 400 Bq/m^3; the EPA recommends action be taken at levels of 74 Bq/m^3 (US EPA, 2013).

Drinking Water

Drinking water is essential to sustain life, and access to an adequate, safe, and accessible supply is a basic human right. However, drinking water may contain microbial, chemical, or radiological constituents that are unsafe. Drinking water standards are defined and implemented on a national or regional level. The WHO publishes guidelines (WHO, 2011) on the minimum standards that should be achieved, and these standards are applied in countries in which there are no existing standards. The WHO guidelines contain guideline levels for chemical and microbial pollutants, as well as describing how to apply these guidelines. However, these standards are not legally enforceable. In Europe, drinking water is regulated by the European Drinking Water Directive (98/83/EC). In the United States, the EPA regulates drinking water according to the Safe Drinking Water Act (42 U.S.C. 300f). Both the EU and U.S. regulations are legally enforceable. These standards and regulations describe the parameters of a substance in terms of a concentration (30 mg/l of iron) or a population count for microbial contamination. The maximum accepted concentration for each parameter varies according to the regulation body. For example, the maximum contaminant levels (MCL) for cyanide in the EU is 0.05 mg/l, but the MCL for cyanide is 0.2 mg/l in the United States(SWDF). Drinking water standards and regulations not only describe the MCLs but also the context (sampling location, sampling methods, and sampling frequency) of the sample acquisition and the interpretation of the sample (analytical methods, and laboratory accreditation). This context is important if an individual wants to personally monitor water quality using a sensing device. It is also important to be aware of the parametric range at which pollutants are unlikely to have any impact on health.

Regulation and Allocation of Radio Spectrum

Radio spectrum is the term used to describe the part of the electromagnetic spectrum used for radio frequencies (the full frequency range from 3 kHz to 300 GHz). The radio spectrum is used for a wide range of applications, including government communications (defense, public safety, transport); commercial services for the public (voice, data, TV and radio broadcasting); and industrial, scientific, and medical use (cordless telephone, baby monitors, Wi-Fi). This wide variety of applications requires careful management to ensure the spectrum is best used for the benefit of all. Radio spectrum management is the role of government authorities in each nation, although it is closely aligned with regional and global authorities. The radio spectrum is broken into different nonoverlapping frequency ranges, called *bands*, to prevent interference and allow for efficient use of the radio spectrum. Similar services are grouped in the same bands, and these bands are described according to their frequency (for example, Very High Frequency [VHF]) or their application (for example, marine). Each band has a basic set of usage rules, which ensures compatibility between receivers and transmitters and avoid interference between different sources.

Radio spectrum is a valuable commodity, which is typically owned by the government of a country. The government-appointed regulators can license parts of the spectrum for exclusive use by radio, television, and cellular phone companies in a given geographical area. A broadcasting license gives the commercial entity exclusive rights to broadcast their services in the band(s) that they were allocated. Entities that broadcast their services in the licensed spectrum without a license are called *unlicensed* broadcasters and are breaking the law. Fortunately, there are also bands of the spectrum that have been allocated for individuals to use for local communications. The most common of these bands are located at 900 MHz and 2.4 GHz and are called the industrial, scientific, and medical (ISM) bands. These bands are unlicensed; therefore, the user is free to use them without having to register or to pay for an individual license from the telecommunication regulatory authorities. The ISM radio bands were originally reserved for electromagnetic radiation produced by ISM equipment. However, in recent years these bands have also been used by license-free, error-tolerant, communications applications such as cordless phones, Bluetooth devices, near field communication (NFC) devices, and wireless computer networks. Low-power communication devices operating in this band must accept interference from licensed users of the frequency band and must not cause interference to licensed users.

The term *unlicensed* ISM radio devices does not imply they are unregulated; the device itself must usually meet strict regulations and be certified by the appropriate regulatory authorities. In the United States, the Federal Communications Commission is responsible for ensuring that low-power communication devices comply with Title 47 of the United States Code of Federal Regulations Part 15 (47 CFR Part 15). This regulation applies to most electronic

equipment because it describes the regulations under which intentional, unintentional, or incidental radiators that can operate without an individual license. 47 CFR Part 15 requires that most electronic devices are either verified to not cause harmful emissions or certified to not cause harmful emissions. The verification process is typically used for receivers and unintentional transmitters and involves the creation of a declaration of conformity, which states that the emissions limits are within the FCC Part 15 rules. An accredited test laboratory must test a sample device and produce a test report and Declaration of Conformity for the manufacturer to submit to the FCC. All intentional transmitters must receive FCC certification. To obtain certification, an accredited test laboratory must request a FCC Grantee Code, test the device, and submit a detailed test report to the FCC. If the FCC deems that the device meets with its regulation, it will certify the device and issue an FCC identification number for the device. The vendor must attach this FCC identification number and the FCC logo to each transmitter device it sells.

In Europe, ISM band devices are referred to as *short-range devices* (SRD). These devices are low-power wireless devices, which have low capability of causing interference to other radio equipment. In Europe, the regulations governing low-power wireless devices are defined by two separate bodies:

- The European Conference of Postal and Telecommunication Administration (CEPT) defines the frequency, allocation, and use of short-range radio device (SRD) frequency bands in document ERC/REC 70-03 (CEPT, 2013)
- The European Telecommunications Standards Institute (ETSI) defines the procedure required to bring SRD wireless equipment to the EU market in the Radio and Telecommunications Terminal Equipment Directive (1999/5/EC)

The European process for achieving radio compliance is similar to the FCC process, in that receivers can simply create a declaration of conformity and establish technical documentation to support their application, whereas transmitters must undergo radio testing to establish compliance with harmonized standards. If harmonized standards are not applicable, the radio device must also be assessed by a notified body. A number of harmonized standards may apply to any given radio. Therefore, it is best to seek the advice of a qualified laboratory when developing and applying for certification.

The FCC and EU bodies perform a number of other vital nonregulatory roles, which are outside of the scope of this chapter. These include advancing the introduction of new wireless technologies, rationalizing and optimizing the use of RF spectrum, and collaborating with other governmental bodies for the good of citizens. The FCC, for example, formed a mobile health (mHealth) task force in 2011, which investigates methods in which the FCC can facilitate adoption of mHealth technologies to improve health outcomes and lower healthcare costs. As a spectrum regulator, it was able to define and allocate spectrum for a new class of devices, called medical body area networks (MBANs); investigate and plan for improved rural broadband healthcare networks; and provide input to the FDA on its mHealth regulations.

Challenges

There are a number of challenges in the standards and regulation space; the most pressing of which is the limited regulation of mobile phone applications. Developing standards and regulations can be a slow process requiring consensus across many parties. The difficulty in achieving consensus for mHealth regulation is further exacerbated by the lack of consensus in international regulatory processes. Yet again, there is widespread agreement that an international standard for medical device regulation would be beneficial for both device manufacturers and consumers, but progress toward achieving this goal has been slow. The lack of international guidelines for data privacy and data sharing could have a significant impact on the development of personalized health solutions. Large quantities of data are required to investigate and develop personalized health solutions; for particularly rare diseases, it may not be possible to gather a statistically significant dataset within the geographical region controlled by an individual regulatory body. Finally, the ability for citizen scientists to generate, store, and report data from their own experiments is an exciting prospect. However, it may also be risky if people place faith in lower-quality sensors from nonrigorous experiments. As low-cost sensors become more readily available, there may be a requirement for light-touch regulation or disclaimers for such data.

Country-Specific Regulatory Processes

Safety, quality, performance, equitable access, and cost effectiveness of medical devices are common goals of all device regulators. However, it can be argued that the variety of regulatory agencies and differing regulatory requirements (see Table 6-5) can impede these goals.

Table 6-5. *Selected International Medical Device Regulatory Authorities*

Geographical Location	Regulatory Authority
Australia	Therapeutic Goods Administration (TGA)
Brazil	Agência Nacional de Vigilância Sanitária (ANVISA)
Canada	Health Canada
China	State Food and Drug Administration (SFDA)
India	Central Drugs Standard Control Organization (CDSCO)
Japan	Pharmaceuticals and Medical Devices Agency, Japan (PMDA)
Russia	Roszdravnadzor

The most obvious example of this is the lack of compatibility between U.S. FDA and EU medical device regulations, which differ in three significant ways (COCIR/MITA, 2013):

- ***Auditing of medical technology manufacturer quality management systems***: The EU conformity assessment bodies and U.S. FDA do not mutually accept reports of each other's audits of QMS. As a result, manufacturers must be audited by both bodies, despite having similar requirements. Both authorities are members of the IMDRF and could resolve this issue by implementing a common audit process or single quality system.
- ***Marketing application format***: Although a common dataset is accepted by both authorities, the submission methods and application formats differ greatly. This leads to further regulatory burden for manufacturers, which could be eliminated by adopting the harmonized premarket submission format developed by the GHTD.
- ***Unique device identification (UDI)***: Development of a UDI database is an international objective to facilitate traceability and interoperability. However, a UDI or common labeling requirements have yet to be implemented in Europe, and the FDA is in the process of developing a database.

The members of the IMDRF, overseen by the WHO, are collaborating to create regulatory harmonization and convergence. However, despite years of harmonization talks, the debate continues on which is the best regulatory model. The U.S. FDA applies a centralized model, in which it is responsible for all aspects of premarket and postmarket regulation of medical devices. The EU applies a decentralized model, in which national "notified bodies" review the safety and performance of new medical devices. Critics of the centralized model (`www.dontlosethe3.eu`) complain that it is slow and bureaucratic and delays patient access to devices by three to five years (see Figure 6-4). Those who advocate a centralized model cite the PIP breast implant incident as an example of the failure of the distributed model. Research (BCG 2011) has demonstrated that both systems are equally safe. The members of the IMDRF will continue to align various aspects of medical device regulation. Whether they will ever be able to answer the centralized versus decentralized model debate remains to be seen.

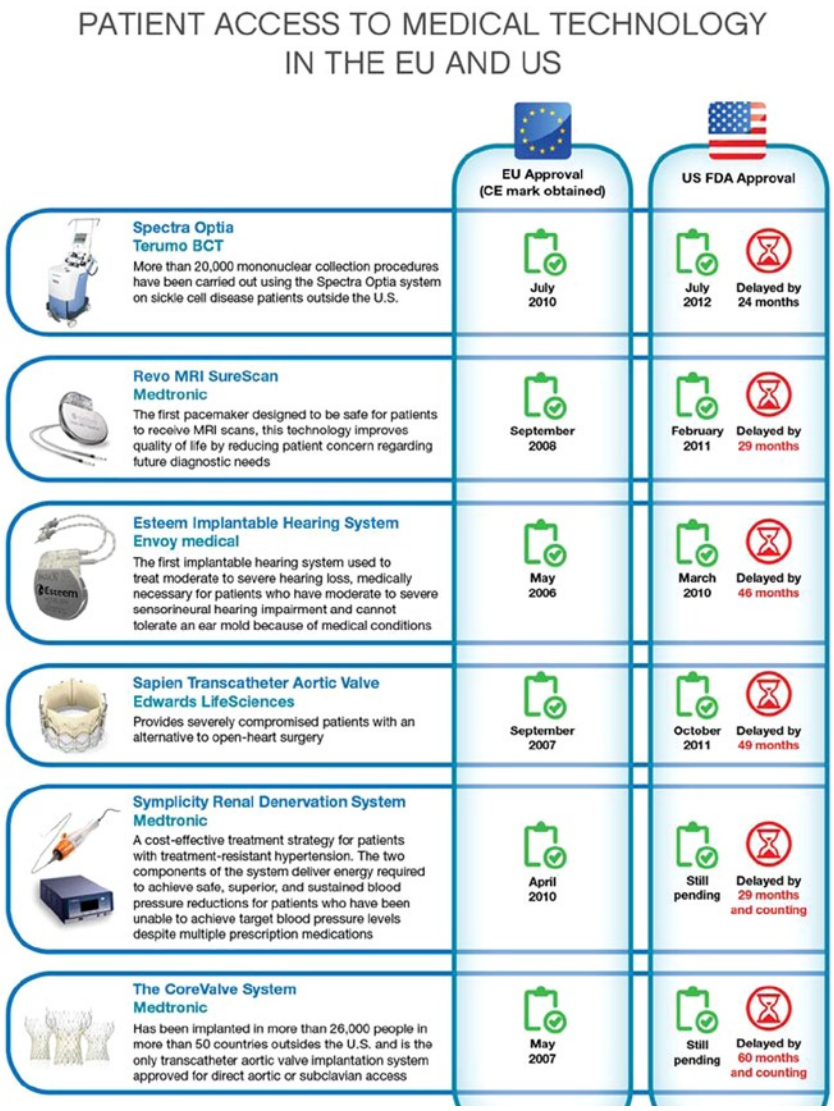

Figure 6-3. *Patient access to medical technology in the EU and United States (reproduced with permission from Eucomed* `www.eucomed.org/uploads/images/_key_themes/mdd/visuals/patient_access.jpg`*)*

Mobile Health Applications

Mobile medical applications (mHealth apps) are a rapidly increasing market, with more than 38,000 apps categorized as healthcare and fitness apps and 24,000 apps categorized as medical apps in the iOS app store in 2013. In an era in which doctors are increasingly prescribing health apps, it is extraordinary that the mHealth app market is still largely unregulated. Although the majority of apps are wellness or health monitoring apps, a small but increasing number of apps claim to diagnose or recognize disease. Developers of apps that made unsubstantiated claims were recently fined by the Federal Trade Commission, but a proactive rather than a reactive approach is urgently required.

In 2012, in the absence of clear guidelines as to how current regulations apply to mHealth, a private company, Happtique, developed a certification system (HACP, 2012) for mHealth apps. The HACP, described earlier in this chapter, uses independent third parties to assess compliance with content, privacy, performance, and operability guidelines.

Regulating for mHealth applications is a complex task. New regulations must allow for rapid innovation while ensuring safety, and they must consider the end-to-end application rather than a single device or module. In the United States, the U.S. FDA issued guidelines on mobile medical applications in 2013 (U.S. Food and Drug Administration, 2013). In these guidelines, a mobile medical app is defined as follows:

> *a mobile app that meets the definition of "device" in section 201(h) of the Federal Food, Drug, and Cosmetic Act (FD&C Act); and either: is used as an accessory to a regulated medical device; or transforms a mobile platform into a regulated medical device. The intended use of a mobile app determines whether it meets the definition of a "device."*

According to these guidelines, the FDA will focus its regulatory oversight on a subset of mobile medical apps that present a greater risk to patients if they do not work as intended. Therefore, the majority of mHealth applications, which are low-risk applications, will not be subject to regulation. The Federal Communications Commission has set up an mHealth taskforce to consider the implications of mHealth on the communications industry. In 2010, the U.S. FDA and FCC signed a memorandum of understanding on regulation, which is indicative of the cross-disciplinary nature of mHealth.

Personalized Medicine

The emergence of personalized medicine will have significant implications for regulatory and standards bodies. Personalized medicine promises to move healthcare from the "one size fits all" medical approach to a "right intervention to the right person at the right time" approach. However, to achieve this goal, patients must be subdivided into groups according to their biological makeup, lifestyle, and environmental factors. By stratifying patients into groups, interventions can be identified that are most effective for individual groups. Each person's unique genetic disposition, lifestyle, and environment factors must be understood, and integrated data profiles must be created and maintained for large populations. As diseases are reclassified into smaller and smaller subtypes, transborder sharing of data will be necessary to achieve sufficient numbers in each study group. Transborder sharing will pose several challenges to the regulatory bodies. A consistent, international, regulated approach to data capture, data protection, data use and reuse, and data lifetime must be developed that balances citizens' rights and public good will be required.

Data literacy will become increasingly important. Patients must understand the choices available to them so that they can make informed decisions about their health. Data privacy laws will have to change from a "data protection" to a "data sharing with controls" mentality. Commercial use of genetic/genomic data must be closely monitored and regulated to prevent discrimination between patients. From a sensing perspective, electronic health records will have to be amended to allow for lifelong data capture from personal health and wellness devices, as well as traditional medical records. The context and quality of personal health and wellness device data will require careful consideration if it is to be associated with clinical data.

Citizen Science

Easy access to health, wellness, and environmental sensors and aggregation platforms has enabled a generation of citizen scientists to capture, interpret, and disseminate data. Crowd-sourced data can provide a level of geographical granularity that more expensive regulated devices cannot provide. The Asthmapolis mHealth application (http://asthmapolis.com) is a good example of crowd-sourced data. This app is synchronized with an asthmatic's inhaler, and every location where the inhaler is used is geotagged. This data can be shared with the wider community to identify asthma "hotspots" where inhaler use is high. Similarly, the Air Quality Egg (http://airqualityegg.com/) allows anyone to collect readings of NO_2 and CO concentrations outside of their home and share this data with the wider community. These are just two examples of Internet of Things (IoT) applications, which contribute to public knowledge and well-being.

However, there are limitations to data captured by citizen scientists: the sensor resolution of the devices may not be comparable to regulated devices. The data may be unintentionally biased by untrained volunteers applying incorrect data capture protocols. Further, data may be incorrectly interpreted by nonexperts. In personal health, incorrect application of regulated devices such home blood pressure monitors also leads to invalid data. Highly accurate weather and pollution stations can give misleading data if they are placed in the shade or too close to a road. Trusting citizen data gathered using a highly accurate regulated device without considering context may cause unnecessary alarm, which could have serious implications in crowded locations such as subways. Regulations apply to ensure the safe use of the device, but should there be guidelines pertaining to the safe use and interpretation of data? Should data be curated, according to a lightweight hobbyist standard? Or is it safe to assume that invalid data will simply be an outlier within a larger grouping of data sources? Would education on research methods and existing standards ensure more accurate data? Or should the data consumer simply be willing to accept the risks of using data from unregulated sources? In the next chapter, we will examine the social relationships that create opportunities and barriers for widespread, consumer-based biosensing. Citizen-led science is driving a shift from sensor technologies of "should" to sensor technologies of "could." These technologies facilitate new understandings of the body and its environment and drive new methods and practices of personal data sharing. For this reason, citizen science will be an area of significant focus in the EU Horizon 2020 research program (EU, 2013).

Summary

This chapter introduced the topics of standards and regulations as they apply to sensor-based health, wellness, and environmental domains. The complex medical device regulation process was described, using the U.S. FDA and EU MDD as examples. The topic of standards was introduced, using a representative sample of the most common standards that apply to sensor applications in the domains of concern. The regulations and standards bodies that regulate environmental sensors and radio spectrum were also introduced. Finally, the challenges facing regulatory and standards bodies, in an era of rapidly evolving science, technology, and user demands, were discussed.

References

European Standards, "Council Directive 93/42/EEC of 14 June 1993 concerning medical devices," 1993.

European Commission Enterprise and Industry. "*CE marking for professionals: 6 steps for manufacturers*", Last Update: November 2013, http://ec.europa.eu/enterprise/policies/single-market-goods/cemarking/professionals/manufacturers/directives/index_en.htm

Underwriters Laboratories, "Single and Multiple Station Carbon Monoxide Alarms," vol. UL 2034, ed 2, 2005.

United States, "Federal Food Drug & Cosmetic (FD&C) Act," in *Title 21 Code of Federal Regulations Part 800-1200*, 2010.

U.S. Food and Drug Administration. "*Medical Devices: How to Market Your Device*", Last Update: November 2013, http://www.fda.gov/medicaldevices/deviceregulationandguidance/howtomarketyourdevice/default.htm

World Health Organization, "Baseline country survey on medical devices", http://whqlibdoc.who.int/hq/2011/WHO_HSS_EHT_DIM_11.01_eng.pdf, 2010.

World Medical Association. "*Declaration of Helsinki*", Last Update: November 2013, http://www.wma.net/en/30publications/10policies/b3/

International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), "ICH Harmonised Tripartite Guideline. Guideline for Good Clinical Practice E6(R1)," 1996.

European Standards, "Directive 2002/49/EC of the European Parliament and of the Council of 25 June 2002 relating to the assessment and management of environmental noise," 2002.

World Health Organization, "Night Noise Guidelines for Europe", 2009.

World Health Organization, "WHO guidelines for indoor air quality: selected pollutants", 2010.

European Commission. "*Air Quality Legislation*", Last Update: November 2013, http://ec.europa.eu/environment/air/legis.htm

European Standards, "Directive 2008/50/EC of the European Parliament and of the Council of 21 May 2008 on ambient air quality and cleaner air for Europe," 2008.

Elshout, Sef van den, Hans Bartelds, Hermann Heich, and Karine Léger, "CAQI Air quality index. Comparing Urban Air Quality across Borders", http://www.airqualitynow.eu/download/CITEAIR-Comparing_Urban_Air_Quality_across_Borders.pdf, 2012.

U.S. Environmental Protection Agency Office of Air Quality Planning and Standards Outreach and Information Division, "A Guide to Air Quality and Your Health," 2009.

American Society of Heating Refrigerating and Air-Conditioning Engineers, "Ventilation for Acceptable Indoor Air Quality," vol. ANSI/ASHRAE 62-2001, 2003.

ISO/TC 146 Air quality Technical Committee. Last Update: November 2013, http://www.iso.org/iso/home/standards_development/list_of_iso_technical_committees/iso_technical_committee.htm?commid=52702

European Environment and Health Information System, "Radon Levels in Dwellings: Fact Sheet 4.6," in http://www.euro.who.int/__data/assets/pdf_file/0006/97053/4.6_-RPG4_Rad_Ex1-ed2010_editedViv_layouted.pdf, ed, 2009.

United States Environmental Protection Agency, "Basic Radon Facts," in http://www.epa.gov/radon/pdfs/basic_radon_facts.pdf vol. EPA 402/F-12/005, 2013.

World Health Organization, "Guidelines for drinking-water quality - 4th ed.", http://www.who.int/water_sanitation_health/publications/2011/dwq_chapters/en/index.html, 2011.

European Standards, "Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption," vol. 98/83/EC, 1998.

"Safe Drinking Water Act," in *Title 42 - The Public Health and Welfare. Chapter 6a - Public Health Service. Subchapter XII - Safety of Public Water Systems* vol. 42 U.S.C. 300f, 1996.

Safe Drinking Water Foundation. "*Comparison Chart of Drinking Water Standards from around the World*", Last Update: November 2013, http://www.safewater.org/PDFS/resourceswaterqualityinfo/RegulationsGuidelinesComparisons.pdf

Code of Federal Regulations, "Title 47-Telecommunication Chapter I--Federal Communications Commisions Subchapter A--General Part 15--Radio Frequency Devices," vol. Title 47 CFR Part 15.

European Conference of Postal and Telecommunication Administration, "ERC Recommendation 70-03 (Tromsø 1997 and subsequent amendments) relating to the use of Short Range Devices (SRD)," in *ERC/REC 70-03*, 2013.

European Standards, "Directive 1999/5/EC of the European Parliment and of the Council of 9 March 1999 on radio equipment and telecommunications terminal equipment and the mutual recognition of their conformity," vol. 1999/5/EC, 1999.

COCIR/MITA Joint Contribution, "EU and US call for input on regulatory issues for possible future trade agreement," 2013.

Boston Consulting Group, "EU Medical Device Approval Safety Assessment. A comparative analysis of medical device recalls 2005-2009", 2011.

U.S. Food and Drug Administration, "Guidance for Industry and Food and Drug Administration Staff - Mobile Medical Applications," 2013.

European Union. "*Horizon 2020 Funding Programme*", Last Update: November 2013, http://ec.europa.eu/research/horizon2020/index_en.cfm