# Chapter 1
# Introduction*

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## 1.1 Introduction

A standard can be understood as a rule, norm or requirement that is broadly established chiefly by authority, custom or consent. The American National Standards Institute (ANSI) classifies standards by function or origin into eight types: basic, product, design, process, specification, code, management system and personnel certification standard [1]. Historically, standards were developed in limited geographies in parallel with man's own technical development by common use and early custom.

Now, international standards are mostly developed by organized groups of stakeholders assembled from around the world and focus primarily on facilitating communication, promoting commercial trade and ensuring safety and health. Worldwide, there well may be more than 500,000 standards developed by more than 1,000 standard-setting bodies [1]. The number of standards, as well as the geographic and technical boundaries of their application, have been increasing as knowledge about societal risks, and the rapid communication of that knowledge, have grown. Standards development and standards application in governance have also been evolving to reflect changes in world trade, transportation, economics and politics. This chapter discusses the history of standards development in general, and the emerging area of standards development for nanotechnology in particular.

*The findings and conclusions in this report are those of the authors and do not necessarily represent the views of the National Institute for Occupational Safety and Health.

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## 1.2 History of Standards

The history of standards development can be broken into four phases, each characterized by distinct types of standards development, distribution modalities and governance mechanisms: (1) community standards development; (2) national standards development; (3) international standards development; (4) global standards development.

### *1.2.1 Community Standards Development*

The history of standards development can arguably be traced to the first use of time-unit standards by ice-age hunters in Europe over 20,000 years ago. These early standards developers scratched lines and gouged holes in sticks and bones for the purpose of counting the days between phases of the moon [2]. The first standards were aimed at harmonizing human activities with natural phenomena. The functions and applications of standards have been expanding ever since and have followed closely the increasing complexity of man's own technical and societal development.

The advent of agriculture as early as 10,000 years ago was a critical step in the development of human civilization and in the course of standards development. The production of excess food, made possible by agriculture, created a foundation for trade. In turn, trade required the introduction of unit standards to ensure that trade was fair, and to collect taxes on the goods that were traded. These early standards, such as unit standards for product value (or money) [3], length, and weights [4], were enforced by local authority or, in some cases, the state. Examples of commercial trading standards, such as measurement and exchange of goods can be found in the Babylonian Code of Hammurabi created in 1790 BCE.

Agriculture also facilitated the development and accumulation of technical knowledge and the standards that were associated with that knowledge. The need to transfer accumulated knowledge effectively to subsequent generations in the form of standards led to the development of writing. The first preserved writing was created 5,000 years ago in Egypt, Mesopotamia and China [5]. Writing was used to convey and distribute sophisticated standard practices for every activity. For example, the Horus Temple in Edfu, Egypt contains second century BCE carvings of practice standards specifying formulas for preparing incense and ointment for the divine statues [6].

Practice standards aimed at safety and health, such as building codes specifying the minimum acceptable level of safety for constructed objects and structures, appeared initially in agricultural societies. One of the first preserved building codes can be found in the Code of Hammurabi. Early food safety standards, another example of safety and health practice standards, were established primarily to prevent economic deception and adulteration of foods [7]. For example, the Romans



wrote civil law provisions to protect the populace against adulterated foods. In 200 BCE, the Roman statesman Cato described a method for determining whether merchants "watered down" their wine [7]. The English passed their first food law, the Assize of Bread, in 1266 to prevent the adulteration of bread with cheaper, inferior ingredients. The German "beer purity" law ("*Reinheitsgebot*") of 1516 was the oldest existing food safety regulatory standard in the world until it was struck down as a trade barrier by the European Court in 1987. The *Reinheitsgobot* gave the government the tools to regulate the ingredients (limiting them to barley malt, hops, and water), the processes and the quality of beer sold to the public [8]. In early colonial America, early food regulations were aimed at promoting export of quality food to Europe. For example, the Massachusetts Bay Colony's Meat and Fish Inspection Law of 1641 was developed to demonstrate that the colony produced and exported high-quality food products to the mother country, thereby gaining commercial advantage [7].

Artisanship and crafts flourished in agricultural societies. "Secrets of the craft" – a type of proprietary practice standard – was used by craftsmen and artisans from a wide range of trades such as masonry, glasswork and carpentry. These standards evolved with the sophistication of the particular craft and formed the basis of medieval guilds. Such practice standards, along with rules of professional conduct, were developed and practiced by craftsmen associations and passed from master to apprentice through many generations. Such practice standards were developed as early as 200 BCE in China where guilds, known as "*hanghui*," existed during the Han Dynasty. These guilds survived through the centuries and still exist in China for certain professions [9]. Gaining and protecting a particular guild's competitive advantage over less skilled market entrants was a prime function of such associations. Competitive advantage was facilitated by restricting knowledge of the practice standards to members of the association only. By the eighteenth century, these associations became obstacles to free trade and hindered technological innovation, technology transfer and business development [10]. As a result, they were replaced with national trade associations which developed transparent standards for all to see and use.

### *1.2.2 National Standards Development*

The advent of the steam engine and the industrial revolution of the mid-nineteenth century facilitated the emergence of powerful national states and decentralization of manufacturing and trade throughout those states. This created the need, for example, for nationally harmonized specification standards for transportation, such as a standard railroad gauge [11], and material specification standards, such as grades of steel used in rail construction [12]. These needs were addressed through voluntary standards development by national standards developing organizations (SDOs) and trades associations. Examples of such national standards development associations include the American Society for Testing and Materials (ASTM) and the Institute of Electrical and Electronics Engineers (IEEE). ASTM, which is presently known as ASTM International, was formed in 1898 in the United States of America (USA) by a group of engineers and scientists to address frequent rail breaks [13]. This ASTM work led to standardization of the steel used in rail construction across the USA. The IEEE, the world's largest technical professional society, was formed as the American Institute of Electrical Engineers in 1884 to support electrical professionals [14]. Both ASTM and IEEE later evolved to become private international consensus standards developing organizations without national body membership. Well over 600 SDOs currently exist in the US, some quite small with few standards while others are global in every sense.

Many national standards developing organizations, including those in United Kingdom (UK), in the USA and in the Russian Federation (Russia), were established at the end of the nineteenth century not only to harmonize and manage nationally-developed standards across nations, but also to represent national interests in international standards developing organizations.

The origin of the UK National Standardization Body (presently known as BSI British Standards) can be traced to the Engineering Standards Committee (ESC) which was founded by the Council of the Institution of Civil Engineers in 1901 [15]. The ESC extended its work to other fields, and was renamed to the British Standards Institution in 1931 after receiving its Royal Charter in 1929 [15].

The predecessor to ANSI, an administrator and coordinator of the United States private sector voluntary standardization system, was formed in 1916. ANSI was created when the American Institute of Electrical Engineers invited the American Society of Mechanical Engineers, the American Society of Civil Engineers, the American Institute of Mining and Metallurgical Engineers, and the American Society for Testing and Materials, to join together to establish a neutral national body to coordinate standards development, approve national consensus standards, and prevent user confusion on acceptability criteria [1].

In Russia, the Federal Agency on Technical Regulation and Metrology ("*Rostekhregulirovaniye*") serves as the National Standardization Body. It was formed by a Russian Presidential decree as a successor to the Union of Soviet Socialist Republics' State Standards agency upon disintegration of the USSR in 1991. In turn, the USSR State Standards agency originates from the Committee on Standardization established in the Soviet Council on Labor and Defense in 1925 [16].

Models for national standards development vary from country to country. In the USA, there is no official National Standardization Body in the sense of the UK and Russia as described above. Instead, standards development is voluntary, and overwhelmingly, private sector led. The National Technology Transfer and Advancement Act of 1995 (Section 12(d) of P.L. 104-113), and OMB Circular No. A-119 [17] directs Federal government agencies to use voluntary consensus standards in lieu of government-unique standards except where inconsistent with law or where otherwise impractical to implement. In addition, these documents also encourage Federal government agencies to actively participate in the development of voluntary consensus standards. For example, Occupational Safety and Health Administration (OSHA), a USA government regulator of occupational safety and health, and ANSI, have signed a Memorandum of Understanding which states in part that "ANSI will furnish assistance and support and continue to encourage the development of national consensus standards for occupational safety and health issues for the use of OSHA and others" [18].



The USA government permits participation in voluntary consensus standards development by government personnel, but does not provide dedicated funding to do so. For example, Public Law 107-101, National Defense Authorization Act for Fiscal Year 2002 (Public Law 107-101, Section 1115, entitled "Participation of Personnel in Technical Standards Development Activities") nullified language in USA Code Section 5946 which restricts the use of appropriated funds for payment of membership dues or expenses of an individual at meetings or conventions of members of a society or association. Yet, even though statutory permission exists for government experts to participate in voluntary standards development, government appropriations often do not provide the funding necessary for a government agency to send their experts to meetings. In addition, academic researchers receiving government grants and government personnel receiving salary and research support often do not have specific funding to participate in standards development committees. This approach is not supportive of the ANSI funding model, which is based on membership fees collected from volunteers participating in the development of standards. Nevertheless, as of January 2008, ANSI lists 267 entities accredited by ANSI as standards developers including: entities suggested by government regulators; entities prompted by industry; entities open to individual international membership, but without any established one-vote-per country membership structure; and entities with either long or short term missions. There is also a host of other US-based standards developers operating outside the ANSI accreditation, including some that produce standards in global use.

At the other end of the spectrum are countries where standards development is completely a government function. In Russia, the Federal Agency on Technical Regulation and Metrology ("*Rostekhregulirovaniye*") provides funds for the development of *GOsudarstvennyi STandart-Rossii* (GOST-R) standards, which are the national standards of the Russian Federation. The Russian Federal Agency on Technical Regulation and Metrology also administers a GOST-R certification program for products and acts as a national member body in international standards organizations such as International Organization for Standardization (ISO). Similarly, the Standardization Administration of China (SAC) is authorized by the State Council to exercise administrative responsibilities for standardization work in China and serves as a national standardization body in international standards organizations, such as ISO [19]. SAC is responsible for funding and managing the development of national standards including research in support of national standards development and maintenance.

Standards development in the UK represents an intermediate case with the standards development enjoying some level of government support. The UK National Standards Body, British Standards Institution (BSI), can act on behalf of the UK government in some instances [20]. It is a non-profit organization which markets for sale the various standards it develops. BSI British Standards develops standards through committees including representatives from government, testing laboratories, suppliers, customers, academic institutions, business, manufacturers, regulators, consumers and trade unions. It also provides testing and certification services.

Regardless of how national standards developing organizations function, they have facilitated the emergence of standards which provide consistency across divergent commercial entities operating within national boundaries. But, with the increasing volume of international trade, differing national standards have created significant obstacles to global trade [21]. The drive to harmonize national standards between countries has prompted establishment in the early twentieth century of international standards developing organizations with national body membership.

### *1.2.3 International Standards Development*

International standards often provide technical foundation for international agreements or treaties. They are based on the voluntary participation of all national commercial market interests which are affected by the particular standard. Establishment of international standards, such as international codes of conduct, was catalyzed by international trade in the late nineteenth and early twentieth centuries. Early international governance standards can be traced to the emergence of seafaring as a valuable way to trade goods.

The earliest known examples of sailing instructions – the Greek *periploi*, which became the basis for cartography standards in the medieval period – date from the fourth to third centuries BCE [22]. Modern practice standards governing conduct at sea originate from a 1609 work of Grotius, a Dutch lawyer, titled *Mare Liberum* ("Free Seas"). Grotius articulated the principle of the "freedom of the seas." This principle held that the sea is not owned by any particular nation, but should be available for use by all nations. In 1884, another milestone in establishing maritime standards occurred when the International Meridian Conference, a public government-level organization, adopted the Greenwich meridian as the universal prime meridian or zero point of longitude, undoubtedly the historically most important example of a maritime reference standard.

The twentieth century achievements in commercial aviation, and the post-WWII rapid economic growth spurt, further accelerated the development of international standards. As trade and transport between countries increased, so did the need for international standards and international standards developing organizations. Specifically, multinational enterprises and other transnational actors sought to harmonize national legal standards applicable to international transactions (such as safety and health testing standards) to reduce the transaction costs of doing business across nations [23].

A wide range of international standards developing organizations emerged in mid-twentieth century targeting specific gaps in standards. International standards incorporated into national laws and international agreements are often developed by only a limited number of public organizations with national body memberships such as the Organization for Economic Cooperation and Development (OECD), the International Labour Office (ILO) and the World Health Organization (WHO), and a number of private organizations such as the International Organization for Standardization (ISO) and the International Electro-technical Commission (IEC). However, there also exists a large body of voluntary international standards which are often developed by private organizations without national body memberships, such as ASTM International and IEEE. Nevertheless these standards can be globally accepted and used by industrial interests. With the wide range of standards development models, the governance model where a public standards developing organization identifies essential requirements, considers voluntary standards which were developed by private standards developing organizations, and sets technical specifications to meet essential requirements, has become more prominent in the late twentieth century and early twenty-first century [23].



Inter-governmental organizations have been involved in international standards development since the League of Nations was established in 1919 under the Treaty of Versailles "to promote international cooperation and to achieve peace and security" [24].

Founded in 1945, the United Nations (UN) can be considered the largest public international organization developing standards. The UN Charter contains a broad mandate "to achieve international co-operation in solving international problems of an economic, social, cultural, or humanitarian character" and "to be a center for harmonizing the actions of nations in the attainment of these common ends" [25]. Some UN specialized agencies were even established before 1945 and subsequently incorporated into the UN. For example, the International Telecommunication Union was founded in 1865 as the International Telegraph Union to facilitate communication between nations, and the ILO was founded in 1919 to promote social justice and international human and labor rights.

The General Assembly occupies a central position as the UN's chief deliberative, policymaking, and representative body. It comprises all 192 member nation and plays a significant role in the process of standards development and the codification of international law [25]. The General Assembly is empowered to make non-binding recommendations to member nations on international issues within its competence. Each member nation in the Assembly has one vote. Votes taken on designated important issues, such as recommendations on peace and security and the election of Security Council members, require a two-thirds majority of member nation, but other questions are decided by simple majority. In recent years, a special effort has been made to achieve consensus on issues, rather than deciding by a formal vote, thus strengthening support for the General Assembly's decisions.

Technical standards in UN are commonly developed at committee or task group levels by experts nominated by participating member nations. The development process varies for different standards areas covered by UN organizations. For example, the Codex Alimentarius Commission was created in 1963 by Food and Agriculture Organization (FAO) and WHO to develop food standards including guidelines and related texts such as codes of practice under the Joint FAO/WHO Food Standards Programme [26]. The main purposes of this Programme are protecting health of the consumers, ensuring fair trade practices in the food trade, and promoting coordination of all food standards work undertaken by international governmental and non-governmental organizations. Decisions are taken by a majority of the votes cast at annual meetings of the Commission with each member nation of the Commission having one vote [27].

Another example is standards development process in the World Health Organization. The WHO functions according to its constitution include development of health-related standards [28]. Although major regulatory standards are adopted at the World Health Assemblies by member nations, in the development of most technical standards WHO historically has relied on expert opinions obtained through Expert Advisory Panels and Committees [29]. These panels are convened to make technical recommendations on a subject of interest to WHO. Advisory panel members are appointed by the WHO Director General and these members contribute technical information and offer advice on scientific developments in the expert's field. However, the WHO process has been criticized as promoting poor quality standards. In 2003, WHO improved the process with the publication of WHO Cabinet Guidance [30, 31]. WHO emphasized the use of an evidence-based and transparent approach to the development of standards and implementing standards [32]. Once the draft standards are prepared, they are approved in most cases by the Director-General Office [28].

In contrast, ILO is the only tripartite UN agency. To carry out its responsibilities for drawing up and overseeing international labor standards, ILO gathers representatives of government, employers and workers to develop its policies and conventions jointly.

The OECD is a treaty organization which can be also considered a public sector transparent international standards developing organization. OECD is both a user of international standards and a developer of standards (technical regulations) to address needs of OECD member governments. OECD was formed as the Organization for European Economic Co-operation in 1947 to administer US and Canadian post-World War II aid under a specific reconstruction plan [33]. In 1961, the Organization for European Economic Co-operation became OECD with a mission to help member countries achieve sustainable economic growth, robust employment, and high standard of living. Today, OECD is composed of 34 member countries committed to democracy and a market economy. OECD shares its member countries' expertise with more than 70 other countries. In addition, OECD invited Russia to engage in membership talks and offered enhanced engagement to Brazil, China, India, Indonesia and South Africa. Industry and labor have also been engaged with the OECD since its creation, notably through the Business and Industry Advisory Committee to the OECD and the Trade Union Advisory Committee to the OECD.

OECD has established an effective standards development process consisting of data collection, data analysis, and collective policy discussions, followed by collaborative decisions-making and implementation. Technical work in OECD is conducted through committees and working parties by representatives of member countries and by invited non-member experts. Discussions at the OECD committee



level can culminate in formal agreements with countries to produce specific standards or model recommendations or guidelines such as Good Laboratory Practices [34]. According to the Convention on the OECD, which established a legal framework for OECD operations, decisions made by the OECD are binding on all OECD Members (Article 5(a), [35]). Decisions and recommendations are made by consensus defined as "mutual agreement of all the Members" (Article 6(1), [35]) with each member holding one vote during the adoption process.

The first private sector international standards developing organizations with national body memberships, the International Electro-technical Commission, held its inaugural meeting in June 1906, following the recommendation of the 1904 International Electrical Congress. IEC prepares and publishes international standards for electrical, electronic and related technologies and manages conformity assessment systems. In 2008, the IEC listed 72 members and 83 affiliate country members developing standards by means of 174 technical committees and subcommittees.

The ISO is perhaps the most well-known private sector international standards developing organizations with national body memberships. The ISO arose out of the International Federation of the National Standardizing Associations (ISA) which was established in New York City in 1926. The ISA focused heavily on mechanical engineering and was disbanded in 1942. In 1944, the UN established the United Nations Standards Coordinating Committee (UNSCC). In 1946, ISA was re-established and then was merged with UNSCC in 1947 to create ISO [36, 37]. Today, the ISO has a membership of 160 national standards institutes with about 680 international standards developing organizations as partners, including most UN agencies.

In ISO and IEC, each national member body has one vote as in the UN. Standards are based on two levels of consensus: (1) consensus between national stakeholders to put forward as a national position and (2) consensus across nations. As a reflection of the diverse nature of the support from national standards development bodies, some ISO and IEC national members are either part of the governmental structure in their countries or have a mandate from their governments to engage in international standardization, while others are private sector standards development bodies originating in industrial associations. Participation of developing countries in ISO and IEC is facilitated by pro-rating membership fees on the basis of the each nation's Gross Domestic Product.

Two major private international standards developing organizations without national body memberships are ASTM International, and IEEE Standards Association. Both follow the principles of transparency and consensus in developing international standards similar to ISO and IEC except for the "one-country-one-vote" principle. Membership in these organizations is open to any individual, company, governmental agency, academia, or similar entity, upon payment of annual fees. Every individual member or entity has one vote. Therefore, both organizations benefit from international membership from a wide spectrum of technical experts. For example, in ASTM International, a diverse range of standards is developed by over 30,000 members, representing producers, users, consumers, government and academia from over 120 countries [38]. IEEE Standards Association has over 20,000 members participating in standards development for electro- and information technologies and sciences [39].

The main objective of developing consensus-based international standards through diverse public and private organizations is to facilitate global trade and to protect human health and the environment. As such, they are widely used to support the regulatory work of global intergovernmental organizations such as the World Trade Organization (WTO) and the OECD.

Specifically, when it comes to international trade, the WTO Agreement on Technical Barriers to Trade explicitly recognizes the importance of international consensus standards. For instance, an importing nation's requirement that imported goods trade must conform to an international standard does not constitute a basis under WTO rules for an exporting nation to claim that the importing country is erecting a "trade barrier" [40]. Similarly, at the OECD Ministerial meeting in 1997, the role of international standards received a big boost from the policy recommendation to "develop and use, wherever possible, internationally harmonized standards as a basis for domestic regulations, while collaborating with other countries to review and improve international standards to assure that they continue to achieve intended policy goals efficiently and effectively" [41].

Economic forces unleashed by globalization in knowledge generation, trade, manufacturing and safety oversight have led to promoting the role of international standards development. As twenty-first century international politics move towards more globally distributed technological power, the worldwide acceptance of US national standards produced outside the more formal international standards framework as de facto international standards – common in the twentieth century when the US economy dominated the world – has been diminishing [42].

In the early phase of twenty-first century standards development, international organizations are providing increased opportunities for negotiations between representatives of divergent national economic interests. This process, though time-consuming, has worked well in the twentieth century. However, the revolution in communication created by new digital information technologies which have expanded social networks to a global scale and facilitated further globalization of commerce and production has put new pressures on traditional international standards developing organizations and created new opportunities for emergence of global standards developing frameworks.

### 1.2.4 Global Standards Development

The emergence of the global phase of standards development is marked by a revolution in information technology which is leading to a radical shift in the standards development process.

On September 2, 1969 engineers at the University of California at Los Angeles transferred data from one computer to another, which signified the beginning of the internet [43]. By the 1990s, the World Wide Web brought the internet from the academic environment to mainstream users. Instant access to the data, information and knowledge, real-time exchange of ideas, and creation of documents by a specialized groups of experts located in different countries, became not only possible, but commonplace. "Cloud" computing and "data farming" are revolutionizing how new knowledge is generated, analyzed and disseminated [44].



Information technology has also become a tool to facilitate the standards development process in several different ways. In the early twenty-first century, electronic balloting, which increases participation by reducing travel costs, was adopted by most standards developing organizations. Knowledge management systems were introduced to facilitate the connection between the generation of new knowledge and the development of standards dependent for their relevance on new knowledge. This connection was facilitated by the emergence of novel information technology capabilities. Knowledge management systems are revolutionizing the standards developing process by democratizing it and reducing time-lag between knowledge generation and standards adoption. Using the knowledge management approach, websites have been established for the development of consensus-based dynamic global standards. For example, in October 2009, ISO launched the ISO Concept Database to provide an environment for ISO committees to store and develop structured content including terms and definitions, graphical symbols, codes, data dictionaries, product properties, and reference data used in their standards [45]. The database is available to the public and allows the public to obtain terms and definitions, graphical symbols, codes, data dictionaries, product properties, and reference data free of charge without buying the standards containing them.

A "wiki," from the Hawaiian word for "fast," is a website that connects interlinked Web pages to aid in collaboration among geographically separated parties. Wikis are powered by wiki software. A wiki-software platform for the generation and maintenance of consensus documents, including standards, is one novel approach made possible by internet-based knowledge management systems. The most well-known example of using this approach is *Wikipedia*. Wikipedia's predecessor, *Nupedia*, was created in 2000 as a platform for expert-written, peer-reviewed content [46]. However, *Nupedia* failed as it was based on the traditional model for content generation and quality assurance. A new model that did not have a formal editorial review process, www.wikipedia.org, went "live" on the internet in January 2001. In the new model, the quality of the content was assured by volunteer editors who checked their own and others' contributions to content against Wikipedia rules [47]. As the project matured, vandalizing or diluting its content became rare, while the accuracy significantly improved and approached that of the Encyclopedia Britannica [48]. By 2009, Wikipedia has grown to a massive global enterprise containing more than 13 million articles in 271 different languages with a budget of $6 million US per year [46]. The success of web-based platforms did not go unnoticed by the traditional standards developing organizations. In 2008, ANSI started utilizing a "wiki-platform" to facilitate its own standards development processes [49].

Advancements in information technology have also democratized the standards development process by significantly reducing entry and participation costs and have enabled new standards development entities to emerge. In September 2008, a consortium of stakeholders launched the *GoodNanoGuide* project based on a wiki software platform [50]. The *GoodNanoGuide* is described as a "collaboration platform designed to enhance the ability of experts to exchange ideas on how best to handle nanomaterials in an occupational setting. *GoodNanoGuide* meant to be an interactive forum that fills the need for up-to-date information about current good workplace practices, highlighting new practices as they develop" in a fast-moving area of technology [50]. New entities like the *GoodNanoGuide* could prove to be viable alternatives to the traditional standards developing organizations provided that issues of transparency, credibility, funding, and quality assurance can be resolved.

The *wiki*-based model for standards development can be further enhanced through addition of automatic programs for annotation and embedding media files such as sound files, videos and charts and, more importantly, for automatic update as linked data is changed [51]. Such new tools, characterized by real-time authoring, date-stamped recording of contributions, and automatically updated live content, could prove to be a useful method for the development and maintenance of dynamic standards. It would also prompt the further evolution of the process for creating and maintaining global standards.

Progress in information technology has also contributed to the emergence of a global community with access to standards development. At the beginning of the twenty-first century, the influence of the public over national and international safety and health regulation increased significantly. Economic globalization and the involvement of formerly national grassroots interests participating in international standards development has put pressure on national and international standards developing organizations to use the standards development process to guide technological innovation to ensure a safe and healthy outcome for workers, consumers and for the environment. For example, as a reflection of this shift, ISO's 2011–2015 Strategic Plan states that its activities aim to address five global challenges:

1. "Facilitation of global trade in products and services in a way that does not compromise the level of safety and quality of life to which the citizens of the global village aspire, in the context of an overall increasing, but also, in some regions, aging world population;
2. Financial crisis which started in 2008, and which affects financial markets and impacts on economies at large, has shown the need to restore confidence, to promote good business and governance practice, and to better anticipate and manage risk and business continuity;
3. Interrelated challenges of responding to climate change, ensuring a sustainable energy future, optimizing the use of, and access to, water and providing the world's growing population with adequate food supplies in a safe and sustainable way;
4. Pervasiveness and rapid growth of information and communication technologies, which revolutionize daily life as well as production processes and business practice; and
5. UN Millennium Goals of eradicating poverty and hunger and granting access to education and better health conditions to all the people of the world" [52].



Addressing the challenges that ISO points out in its Strategic Plan requires a more "proactive" approach to standards development. The "reactive" approach does not look down the road to see future stumbling blocks to the commercialization of a new technology and only reacts to information suggesting a risk from the new technology, product or service – often in a time frame too late to prevent harm to workers, consumers or to the environment.

Proactive standards development brings new challenges and opportunities. Proactive development of international interoperability standards (such as specification standards for material requirements) avoids elevating local standards developed by a single company to the regional level or national level. This would prevent expenditures on the subsequent costs of conversion to another standard and possible loss of economic leadership [23]. There is risk that with rapidly evolving technology, early lock-in on any overly specification-oriented standard can inhibit transition to superior performance standards in the future. Under these conditions, technological progress should be constantly monitored and standards adjusted to accommodate changes. Disproportionate influence by a single interest on the standards development process may lead to a suboptimal standard. Hence, balanced representation across all interest groups is critical.

The example of Genetically Modified Organisms (GMO) highlights the increasing influence of consumers over the market and promotes the shift from reactive to proactive risk management in the development of safety and health standards. GMO introduction into the food for human consumption initially occurred without identification of significant benefits to the consumer and without transparency about the safety of the new genetically-modified products to the consumer and the environment. The result of this lack of a proactive approach in looking down the risk road was public rejection of the technology which significantly hindered the development of an otherwise promising technology [53–56].

Under the conditions of proactive standards development, assuring the information quality of standards becomes critically important. A limited scientific basis for standards increases the role of expert opinions and makes standards development processes more vulnerable to influences of special interests. Tapping into the global pool of experts would make this process more robust and would ensure a more representative science-based consensus.

Proactive standards development also means that standards would be developed in parallel with standards validations. For example, a revision to an ASTM nanotechnology standard, ASTM E2490, Guide for Measurement of Particle Size Distribution of Nanomaterials in Suspension by Photon Correlation Spectroscopy, incorporates a large-scale inter-laboratory study that took place in 2008. The inter-laboratory study involved 26 laboratories conducting a total of 7,700 measurements of particle size distribution in three NIST Standard Reference Materials™ [57] and two solutions of dendrimers using several corroborative techniques including photon correlation spectroscopy. The results were factored into precision and bias tables that are now a part of the ASTM standard. As a reflection of the emerging nature of the field, the ASTM E2490 document is a practice guide rather than a prescriptive standard [58].

### 1.2.5 *Emerging Development of Nanotechnology Standards*

Standards development for nanotechnology reflects the new economic and political realities of the twenty-first century. The desire to guide the development of an emerging technology, and to proactively assess and manage any risks arising from that technology at the earliest opportunity highlights the challenging conditions under which nanotechnology standards are being developed. While the electronics industry has been at the forefront of proactive approach to standards development and IEEE coined the term "anticipatory" standards to describe standards produced well before the products they concern are commercialized, nanotechnology standards development has brought proactive standards development into the main stream and has become a testing ground for this approach.

Nanotechnology builds on achievements in a broad range of scientific and technological research since Richard Feynman first promoted the concept of working at the nanoscale [59]. Thus, a host of standards was rapidly developed for nanoscale objects, phenomena and techniques prior to the launch of nanotechnology-specific initiatives across the world. Some existing standards relevant to nanoscale measurement were established by "pre-nanotech" standards developing committees and include surface chemical analysis, sample preparation, microbeam analysis, material characterization and workplace air quality (for a more detailed list of existing and planned nanotechnology-related standards please refer to Annex C and D of Ref. [60]).

The launch of national nanotechnology programs in the first 5 years of the twenty-first century was followed by establishing nanotechnology technical committees and working groups in major standards developing organizations. Unlike the traditional structure of standards development around specific application areas, umbrella committees were formed to cover nanotechnology as a whole, which reflects the nascent nature of nanotechnology and the desire to guide its development.

A brief account of major milestones in national standards development starts in December of 2003 when China established a United Working Group for nanomaterials standardization and published the first Chinese industry nanotechnology standards in 2004. In May of 2004, the UK established NTI/1 national committee on nanotechnology. In the USA, ANSI at the request of the Office of Science and Technology Policy in the Executive Office of the President established in August, 2004 an ANSI Nanotechnology Standards Panel to coordinate nanotechnology standards development in the USA [61]. In November, 2004 Japan established a study group for nanotech standardization. And in November, 2005, the European regional standardization body, European Committee for Standardization (CEN), established CEN TC 352 Nanotechnologies.

Private standards developing organizations without national body membership on the international level were first to establish nanotechnology committees. In 2002, the IEEE Nanotechnology Council was formed as a multidisciplinary group to advance and coordinate the many nanotechnology scientific, literary and educational endeavors within the IEEE. The Council supports nanotechnology-related lectures, symposia and workshops, publishes the "IEEE Transactions on Nanotechnology" and other periodicals, and sponsors nanotechnology standards [62, 63]. The IEEE Nanotechnology Council focuses on creating standards to aid commercialization, technology transfer and diffusion into the market including standards in nanoelectronics device design and characterization and quality and yield in high volume manufacturing.



The ASTM International Technical Committee E 56 on Nanotechnology was formed in 2005 [64]. Its work is organized into four technical subcommittees: "Informatics and Terminology," "Characterization: Physical, Chemical, and Toxicological Properties," "Environment, Health, and Safety," and "International Law and Intellectual Property."

Private international standards developing organizations with national body membership soon followed. ISO established a technical committee for nanotechnologies, TC 229, in June, 2005. The technical committee is structured around four working groups on "Terminology and Nomenclature," "Measurements and Characterization", "Health, Safety and the Environment", and "Material Specification". This technical committee also established several task groups aimed at exploring nanotechnology standards development and consumer and societal dimensions and sustainability. As of the eighth meeting held in June, 2009, ISO TC 229 brought together 32 participating member countries and eight observer countries, and the membership keeps growing.

In 2006, IEC established TC 113 in the field of nanotechnologies. This technical committee has three working groups: two joint with ISO TC 229 on "Terminology and Nomenclature" and "Measurements and Characterization" and the third on "Performance Assessment." As of August 14, 2009 the committee has 15 participating countries and 15 observers.

OECD was one of the first major international treaty organizations to establish nanotechnology groups. In 2006, OECD's Council established the Working Party on Manufactured Nanomaterials (WPMN) as a subsidiary body of OECD's Chemicals Committee [65]. The WPMN, in its turn, established nine steering groups to undertake specific tasks including development of guidance on toxicity testing and on exposure measurements and mitigation. In 2007, the OECD Committee on Science and Technology Policy established a Working Party on Nanotechnology (WPN) to look at economic and policy issues. WPN organized its activities into six project areas including policy dialogue, statistical framework for nanotechnology, and monitoring and benchmarking nanotechnology developments [66]. OECD has been especially active in the area of exposure assessment and mitigation for the nanotechnology workplace [65].

Although a number of agencies within the UN family of agencies have indicated their interest in nanotechnology, only a few exploratory and information-exchange activities have been initiated. Examples of early UN activity include: (1) a joint WHO/FAO expert meeting exploring safety of implications of applications of nanotechnologies in food and agriculture held in June 2009 [67]; (2) a UNESCO conference exploring ethical and social aspects of nanotechnology held in June 2007 [59]; and (3) series of workshops on risks of nanomaterials organized by United Nations Institute for Training and Research (UNITAR) [68]. Since 2006, the WHO Global Network of Collaborating Centers in Occupational Health has included nanotechnology projects in the WHO Network Workplan aimed at advancing the Network's Global Plan of Action [69].

Since nanotechnology covers a very broad range of applications, and an increasing number of international standards developing organizations are initiating activities in this field, there is a need for close coordination both within and between standards developing organizations. For example, as of June 2009 ISO TC 229 established 25 internal liaisons including liaison with REMCO, IEC TC 113 and CEN TC 352. There are also six external liaisons with outside organizations (OECD, EC Joint Research Center, Versailles Project on Advanced Materials and Standards, Asia Nano Forum, Bureau International des Poids et Mesures, European Environmental Citizens Organization for Standardization). Similarly, OECD WPMN recognized the importance of coordination with other standards developing organizations and outlined coordination activities in its roadmap for 2009 and 2010 [70].

In addition to bilateral agreements, a multi-stakeholder forum was convened by the USA government's National Institute of Standards and Technology, in February 2008 to further promote a dialogue among the standards developing organizations active in nanotechnologies standardization to identify standards needs related to nanotechnology [60]. At the 2008 meeting, participants agreed to develop: (1) a discussion forum to align information and developments from the different standards developing organizations; (2) a centrally maintained, searchable and freely accessible repository of information on existing standards and standardization projects in the field; (3) a database of existing measurement tools and new tools needed; (4) a searchable database covering definitions and terminology from all sources [60].

The structure of nanotechnology standards development committees follows broad application areas and was adopted in this book. Thus, eight chapters provide state-of-the-art review articles on progress in major standards developing areas: *Nomenclature & Terminology, Reference materials, Metrology, Performance standards, Application measurements, Implication measurements, Biological activity testing, and Health and safety*. Each chapter summarizes active areas of national and international standards development, together with its supporting knowledge base and emerging issues. The book also puts standards development in the context of legal international requirements and application of international standards to national governance structures in a dedicated chapter on *Legal considerations*. Specifically, this chapter discusses how nanotechnology standardization provides a common platform for addressing environmental, occupational and consumer implication issues and enables trade across differing national regulatory frameworks.

## 1.3 Conclusion

Throughout human history, standards have been crafted to enhance man's relationship to the laws of nature, to facilitate commerce, to promote technological innovation, to ensure the safety and health of workers, consumers and the environment, and to advance the standard of living for all mankind.



As the means of communication have improved, the range of stakeholder experts who develop standards, as well as the national and international reach of standards, has grown from localities, to regions, to nations and to the world, and from small trade groups to the global economy. The informational foundation for standards development has changed, which permits standards development to mature from a reactive mode, where well-established knowledge is used to set a standard, to a proactive mode, where the knowledge is generated in parallel with standards development, where the standards development guides and promotes the advance of technological innovations, and where precautionary approaches are put into place when risk information has yet to be definitely generated. Lastly, a global risk governance process is emerging where the pace of national governmental mandatory standards is being eclipsed by international, private sector, voluntary standards development.

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