June 2012

Role of Standardisation in support of Emerging Technologies

A Study for the Department of Business, Innovation & Skills (BIS) and the British Standards Institution (BSI)

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Preface

This review of international approaches to standards development in support of emerging technologies has been commissioned by the UK Department of Business, Innovation and Skills (BIS) and by the British Standards Institution (BSI). It builds on previous research carried out by the Institute for Manufacturing, especially in the context of the EPSRC/IMRC funded Emerging Industries Programme, and is intended to present findings and observations of direct interest, relevance and utility to BIS and BSI.

In a context of intensified competition for industrial activity, new technologies have been earmarked by governments to drive national economies as they offer important prospects for growth. As technology emergence can be defined as a complex and dynamic phased journey, by which applied science ideas turn into workable technologies then viable applications and marketable products, fostering the right environment for each stage of this journey has become a priority for government. To this regard, there has been an increasing interest in advancing understanding of the effect of standards on emerging technologies but also of the appropriate roles for government and innovation system's actors in support of standardisation activities.

By exploring, through different and contrasting technology case studies, how key competitor nations have attempted to foster a supportive standards development environment, it is hoped that this report will contribute to broaden the evidence-base on how innovation system's actors may engage more effectively in standards development processes, support private sector innovation and what policies, programmes and practices could facilitate such engagement and support.

This study is based on desk research and a scoping literature review, with emphasis being put on standardisation landscapes in the US and Germany and on frameworks, support programmes and engagement practices. It is further informed by a number of interviews conducted with scientific experts, regulators, academic researchers and experts from standards development organisations.

1- Executive Summary

This study explores some international approaches to the support of standards development for emerging technologies of national importance. In particular, the report investigates the different approaches for standards development within national innovation systems of the United States and Germany. The study pays special attention to the different roles, practices and engagement models of standards development organisations at the earlier stages in the lifetime of a novel technology. In particular, we have tried to highlight those factors which may have implications for standards development “business models”.

The report includes both a review of existing analyses from standards development practitioners, policy makers and academics, as well as a number of emerging technology case studies selected to draw out variations in standards development dynamics and practices: regenerative medicine (tissue engineering), smart grid, additive manufacturing and synthetic biology. It is hoped that these analysis will offer practical insights which can inform BIS and BSI’s strategy, programmes and practices, as well as being of interest to other stakeholders within the UK innovation system. Some key themes identified during the study are listed below.

1.1 Key Themes

1. **Types of standards and phases of emergence** Standards are associated with the level of technology maturity and there seems to be general recognition that there are evolving levels of emphases on different types of standards depending on the phase of the technology’s lifecycle. Different types of standards will therefore be appropriate at different phases in the emergence of a new technology and this evolving character of standardisation raises issues in terms of timing and “standardisation readiness level”.

2. **National innovation system variations:** National innovation system actors engaged in standards development vary significantly in configuration, culture and mission, in the scale and scope of their activities, and in the quality and nature of their interconnectedness. US has a highly decentralized and private sector-dominated standardisation system, involving a large number of SDOs, industrial associations, and professional societies, although Federal mission agencies can play an important role and standards are sometimes accounted for in Federal initiatives related to technologies of critical national need. By contrast, Germany has a more centralized standardisation system, including emerging technology-related standards initiatives funded directly by the government and managed by a single national standards institute, although sometimes in collaboration with national professional engineering associations.

3. **Technology and industry sector variations:** There is a range of factors that influence the different trajectories of new technology emergence and associated evolving standards development needs. They include: multiplicity of stakeholders, societal infrastructure, degree of regulation, system complexity of application, multiplicity of competing technological approaches, multiplicity of application domains, interest and investment of Federal mission agencies (e.g. Departments of Defence, Energy, etc). These factors can have

a significant influence on which organisations are most appropriate to lead, fund and convene standards development activities at different phases in the life-cycle of an emerging technology.

4. **Government's modes of engagement variations:** Modes of engagement adopted by government in support of standards development can range from direct participation of governmental experts in standards-setting activities or funding of private standards-setting activities to undertaking an active role in both assessing standards needs and leading the standards development process in collaboration with the private sector. Identifying those instances where they should take a leadership, coordinating or convening role in standardisation activities is challenging for governments. To this regard, roadmapping-type and foresight exercises can be of assistance, by advancing understanding of the co-evolution and alignment issues arising between the different innovation system's dimensions during technology emergence.

5. **Convening the emerging technology stakeholder community:** Standards are, of course, only one aspect of complex emerging technology development agendas. Consequently, there can be significant value in endeavours that create awareness among all innovation system actors – industrial, technical, regulatory, and governmental – regarding standardisation issues, opportunities and challenges. This process can be enhanced by fully exploiting a range of initiatives and activities, including: satellite events to major technical conferences, wiki-style information-sharing and input-solicitation 'portals', and roadmapping-style exercises (see below).

6. **Standards development and 'roadmaps':** Throughout this study experts have pointed to the value of roadmapping-type exercises in supporting emerging technology development communities coalesce around needs, priorities and approaches for standards development. It is both important to fully acknowledge the standards dimension within any broader emerging technology-related 'roadmapping', 'foresight' or 'policy framework' architectures. There is, depending on the system-complexity and application diversity of the emerging technology, also value in standards-focused roadmapping initiatives. Such roadmapping-style exercises can not only have value in terms of integrating standardisation issues into private and public sector technology R&D agendas, but can also create awareness among stakeholders regarding technology development and standardisation sequencing issues, as well as competing technological approaches and trajectories, regulatory issues, etc.

7. **Government (emerging) technology procurement:** The emerging technology procurement practices of some international governmental agencies appear to offer potential stimulus (and sources of funding) for standards development. Because of the 'prudency of investment' imperative to procure emerging technology-based applications that are reliable, interoperable, repeatable, etc standardisation can play an important role in addressing these issues. The evaluation and investment criteria of (R&D-based) emerging technology procurement programmes offer an opportunity to encourage researchers and technology developers to engage in standards development in order to enhance the case for the reliability and repeatability of their outputs.

8. **Standards development and the national research base:** Public sector researchers can make significant contributions to standards development for emerging technologies, both at the earliest stages in a technology's maturity but also later in the industrial lifecycle. Under certain circumstances, academic researchers can play a useful 'honest broker' role in leading standards development efforts, especially for technologies relevant for a multiplicity of application domains and industrial sectors. Consequently, some international R&D agencies make particular efforts to facilitate the involvement of researchers, through funding mechanisms that can have implications for the 'business models' of particular standards development endeavours. There are also instances of initiatives specifically designed to ensure that major Federally-funded R&D initiatives in emerging technologies are sufficiently informed by and contributing to parallel standardisation efforts.

1.2 Report Outline

The key themes outlined above, together with an overview of policy analysis and discourse regarding standards and emerging technologies, are discussed in more detail in the remainder in this chapter and are further illustrated in the subsequent case study chapters.

Chapters 3 and 4 give overview of standardisation landscape within US and German national innovation systems respectively. Chapters 5, 6, 7 and 8 explore approaches to standards development in four technology domains: regenerative medicine, smart grid, additive manufacturing and synthetic biology. Chapter 9 looks into a number of practices accounting for standards development.

The final chapter reflects on some important emerging technology standardisation themes revealed in this study and points to areas for further exploration.

1.3 Selection of contrasting case studies

For the purpose of this study, we have tried to select four case studies which were strongly contrasting. Additive manufacturing, regenerative medicine-based tissue engineering, smart grid and synthetic biology were identified on the basis of:

- their UK national research & innovation strengths and/or industrial strategic importance
- their application characteristics in order to draw out potential variations in the issues, drivers and national (innovation system) context factors which influence standards development models, policies and practices:
    - variety of national and international, governmental, professional and industry-led organisations involved standards development
    - variety and number of industry participants in standards development processes
    - maturity of the industry into which the emerging technology would be deployed (size of market, number of firms, stability of value chains, etc)
    - variation in emphases on different types of standards (semantic, measurement, interoperability, quality, etc) relevant to each technology

    - technology characteristics which may influence importance of different standards types (e.g. technology maturity, system complexity, user sophistication, network infrastructure, level of regulation, complexity of production processes, etc)
- pragmatic considerations (e.g. accessibility of existing studies, existing contacts, technology familiarity of researchers, likelihood of access to authoritative interviewees, etc)

2- Introduction and Overview

In a context of intensified competition for industrial activity, with new industries emerging from science and technology being considered by governments as offering the best prospects for growth, the relationship between standards and innovation, and more specifically between standards and emerging technologies, has gathered a looming interest.

2.1 Policy Analysis: Standards and Emerging Technologies

A number of academics have explored this topic, focusing on the different supportive functions standards can perform to foster the growth of emerging technologies. The balance of evidence they have presented points towards a positive impact of standards on emerging technologies, with standards establishing common vocabularies and agreed definitions of terms, increasing the confidence of investors and consumers, increasing the speed at which companies can bring their products to market and reducing the technical barriers to trade, they can provide a competitive advantage (Allen & Sriram, 2000; van Merkerk & Robinson, 2006; Swann, 2010). A technology journey approach has been adopted by other authors and has led to interesting thinking in terms of appropriate degrees and types of standardisation depending on the stage of the technology emergence (Tassey, 2000; Blind & Gauch, 2009).

At the policy level, strategies have been developed by governments to support the development of standards to enhance countries' competitiveness (German Federal Government, 2009; USSS, 2010). Key objectives include the use of standardisation to support the implementation and dissemination of innovation and research results, to reduce the volume of legislation and to increase awareness and education about standards. The greater use of standards in public procurement, especially with a view to promoting innovation has been also stressed upon. Interestingly, a high level of attention has been paid by both governments in Germany and in the US to the ways in which the standards development process could be made more efficient. In the US, a study has been conducted by a Federal agency to explore how the Government could improve its engagement in standardisation activities (NIST, 2011). In Germany, a number of reports have looked into how the research community could be better integrated in the standards development process and how translational research could be developed (BMBF, 2010; DKE-DIN, 2007; DIN, 2010). The economics of standardisation have also been addressed with reports highlighting the positive impact of standards on economic growth (DIN, 2010).

However, the academic literature, policy papers and strategy documents have left largely unexplored issues around the development of standards in support of an emerging technology at the early stages of its life cycle and the alignment/coordination of standardisation activities. Moreover, the better integration of research and standardisation activities has been only touched upon in a very fragmented way. Likewise, very few studies have looked into international practices associated with the co-evolution of emerging technologies and standards development processes. This report offers an initial attempt to explore these issues in more detail through examination of contrasting practices in leading national innovation systems and case studies of key emerging technologies. It has revealed a number of concepts and themes, among which:

- Technology lifecycle stage
- Industry lifecycle stage
- Technological innovation system elements affected
- Function of type of standard
- Role and interests of standard development participants

Variations in terminology and some conceptual frameworks used to structure analysis of the standardisation development dynamics of emerging technologies are discussed in Appendix A1. More information about dimensions and dynamics of standards from a practitioner perspective, based on a study conducted for the Department for Business, Innovation and Skills, can be found in Appendix A2.

The remainder of this introductory chapter summarises the main observations from this analysis. The national 'standardisation landscapes' and emerging technology case studies are explored in more detail in the subsequent chapters.

2.3 Standards development 'business models'

Although challenging for SDOs to make a business case for supporting standards development at the very earliest stages in the emergence of novel technology, with early stage standards types (terminology, etc) developed at a loss, there is some evidence such investment helps establish the SDO as the natural home for developing later stage technical standards which have potential to generate more substantial returns through publishing model (as industry emerges).

Early convening can be made more cost effective where opportunities to leverage technology R&D activities, e.g. technology procurement, technology conferences, research grants, other activities of professional and academic associations

2.4 National innovation system variations

National innovation and standardisation systems can vary significantly in configuration and culture, in the scale and scope of stakeholder activities, and in the quality and nature of their interconnectedness. These variations reflect particular national industrial strengths, the historical evolution of national funding agencies, professional societies and technology development institutions. This systems perspective is crucial in understanding the effectiveness of particular approaches to manufacturing R&D and in considering the relevance and transferability of particular practices, programmes or institutional structures for the UK. The innovation and standardisation systems context of the United States and Germany are discussed in more detail in Sections 3 and 4.

Characteristics which distinguish the US emerging technology innovation & standardisation landscape include:

- **Decentralized, diverse and private sector-led** nature of technology-related standards development organisations;
- **The central convening and accreditation role of ANSI** (the American National Standards Institute), including the activities of its 'standards development panels' for emerging technologies in areas of critical national need

- **The coordination role of NIST** (National Institute for Standards and Technology). Not only measurement and test activities that underpin standards in the early stages of an emerging technology, but also its coordination role
- **Federal mission agency activities** related to emerging technology standards development, notably the Departments of Energy and Defense.

Some high level characteristics which help define the German emerging technology standards development system include:

- **Role of Central Government:** The Federal Ministry of Economics and Technology plays a key role in funding standards development and initiatives to connect these activities to Federally funded R&D
- **Emphasis on German manufacturing competitiveness:** There is more direct emphasis within the German policy discourse on emerging technology development (and standardisation) on supporting the competitiveness of German firms operating in relevant industrial sectors
- **Role of Professional Societies:** The German Standards Institute (DIN) works closely with German professional societies – most notably the leading engineering societies, the Association for Electrical, Electronic and Information Technologies (VDE) and the Association of German Engineers (VDI)

2.5 Technology and industry sector variations

A range of factors can influence the different trajectories of particular emerging technologies and their associated evolving standards development needs. In particular, these factors can have a significant influence on the most appropriate roles for different stakeholder organisations, including which actors are most appropriate to lead, fund and convene standards development activities at different phases in the life-cycle of an emerging technology. Factors which account for some of the variations in standards development models and practices for the emerging technology case studies explored in this report are identified below.

Additive manufacturing: Features which influence variations in additive manufacturing standards development include:

- Potential impact on a multiplicity of sectors (e.g. aerospace, automotive, machine tools, medical devices)
- Multiplicity of technical approaches with the potential to implement the AM processes (e.g. stereo-lithography, selective laser sintering, fused-deposition, etc) modeling
- Potential impact of additive manufacturing for missions of federal mission agencies (e.g. agencies of departments of defense, health, etc)

Regenerative medicine (tissue engineering): Features which influence variations in approaches and models for standards development for (regenerative medicine-enabled) tissue engineering include:

- High level of regulation
- Current emphasis on measurement standards
- Multiple application areas
- Important scale-up issues

Smart grid: Features and characteristics which influence variations in actor roles and practices for Smart Grid standards development include:

- Emphasis on interoperability standards (due to technological system-complexity)
- The large number of actors involved in smart grid development and operation
- Interoperability challenges across regional and national network and infrastructure
- high level of regulation (related energy and cyber infrastructure, environmental impact, etc)

Synthetic Biotechnology: Features which influence variations in synthetic biology standards development include:

- Emphasis on interface standards
- Multiple application areas (biofuels, drug synthesis, food, new materials, environmental technology…)
- Production technology
- Very early stage and not completely defined character of the field

2.6 Convening the entire stakeholder community

Standardisation is only one factor in the emergence of new technologies and systems. The journey from promising emerging technology to full industrialization is a complex process involving a range of innovation activities, including research, systems engineering, manufacturing, marketing, business models, regulation, value chain development, etc, as well as standards development. Standards can have different functions throughout this journey and, consequently, can involve different innovation systems actors performing different roles at different stages in the technologies development lifecycle.

Because of the complex, dynamic, multi-actor nature of the process of technological emergence, there can be significant value in endeavours that create ongoing awareness and alignment among all innovation system actors – industrial, technical, regulatory, and governmental – regarding standardisation needs, issues, opportunities and challenges. This process can be enabled by a range of exercises and initiatives. In addition to technology roadmapping-style exercises discussed in more detail below, other stakeholder community exercises include:

- **Conferences:** satellite events to major technical conferences

- There appears to be significant added value in convening standards development workshops which are “woven” into larger emerging technology conferences. These large meetings are typically attended by a broader range of technical, regulatory and governmental actors and provide a forum to engage the broader stakeholder community in the standards development agenda. This approach is considered to have a number of potential advantages. In particular, both the technical meetings and ‘satellite’ standards workshops benefit in terms of increased attendance with technical experts more likely to prioritize attending a standards meeting if they can also participate in a conference of their peers, similarly standards developers can take advantage of the gathering to engage broader spectrum of stakeholder input. Furthermore, technical conferences are likely to have greater international involvement with benefits to the standardisation workshops in terms of increasing international inclusivity, helping ensure community is paying more than lip-service to international consensus and awareness.

- **The Additive Manufacturing Conference in Loughborough, UK** hosts one of the ASTM International F42 (Additive Manufacturing) committee's annual workshops
- Federally-convened initiatives related to smart grid standards development are active participants in major stakeholder gatherings such as: '**GridWeek**', '**ConnectivityWeek**', and '**Grid Interop**'

- **'Wikis':** wiki-style information-sharing and input-solicitation 'portals'

  - **NIST Smart Grid Collaboration Wiki:** As part of its Smart Grid initiative on interoperability standards, NIST hosts a 'Smart Grid Wiki' – a website for the extended smart grid community to enable stakeholders to work with NIST and contribute content towards the development of a standardisation framework. The NIST wiki also acts a webportal giving access to technical documents created by working groups and committees under the guidance of the Smart Grid Interoperability Panel.
  - **Smart Grid Information Clearing House** Wiki: In 2009 the US Department of Energy invested in a 'Smart Grid Information Clearing House' – a website portal website designed to provide information to the public and firms regarding the entire range of smart grid initiatives occurring nationwide [SGIC, 2011]. The 'Clearing House' is managed by and run from the Virginia Tech Advanced Research Institute in collaboration with the IEEE Power & Energy Society and the EnerNex Corporation. The website contains a range of information including a searchable database of SG-related standards, but also information about demonstration projects and case studies (including lessons learned and best practices), as well as information about policies and regulations, and advanced topics covering emerging technology R&D breakthroughs

2.7 Standards development and 'technology roadmaps':

'Technology roadmapping'-style exercises are often perceived as complementary processes to standards development. Both reflect phases in the emergence of new technologies, indicating that uncertainties associated with technologies potential have been reduced to the point where stakeholders perceive a value in coming together as a community, whether it should be to jointly map future technology R&D priorities or to coordinate around consensus standards.

Such roadmapping-style exercises can not only have value in terms of integrating standardisation issues into private and public sector technology R&D agendas, but can also create awareness among stakeholders regarding technology development and standardisation sequencing issues, as well as competing technological approaches and trajectories, regulatory issues, etc. Roadmapping exercises are also effective in enhancing the networking of leading emerging technology experts, standards development professionals along with other stakeholders from industry, academia, regulators and government.

Such roadmapping exercises can take a variety of forms with different levels of emphasis on standards and the other emerging technology system functions. For example:

- The US government-funded '**Roadmap for Additive Manufacturing'** (RAM) workshop in 2009, although mainly focused on identifying areas of high priority R&D, the workshop produced greater awareness, clarity and consensus around the critical role of internationally recognized product, process and material standards in driving the adoption of AM technologies. This roadmapping exercise is discussed in more detail in Sections 5 and 9.
- By contrast, NIST's '**Roadmap for Smart Grid Interoperability Standards'** is a standards-focused exercise, but still involved engagement with a broad spectrum of stakeholders within the US smart grid innovation system, soliciting information hundreds of stakeholders through public workshops, as well as input from dedicated working groups. See Sections 7 and 9.
- The German '**E-Energy / Smart Grid Standardisation Roadmap'** was standards-focused, but was specifically developed in consultation with the researchers involved in the Federal E-Energy R&D programme. See Sections 7 and 9.

2.8 Federal 'mission agencies' and government procurement:

The emerging technology procurement practices of some international governmental agencies appear to offer potential stimulus (and sources of funding) for standards development. Because of the 'prudency of investment' imperative to procure emerging technology-based applications that are reliable, interoperable, repeatable, etc standardisation can play an important role in addressing these issues. The evaluation and investment criteria of (R&D-based) emerging technology procurement programmes offer an opportunity to encourage researchers and technology developers to engage in standards development in order to enhance the case for the reliability and repeatability of their outputs.

For example, the technology development and associated procurement activities of the US Department of Defense were a significant stimulus to Additive Manufacturing (AM) standards development in the United States, including participation levels in the main SDO initiative related to AM – the activities of committee F42 of the ASTM International. Given the potential impact of additive manufacturing to the rapid production of parts for a range of military applications, the Department of Defense (DOD) makes significant investments in emerging technologies with the potential to advance the equipment and infrastructure supporting US warfighters. Both the DOD's requirements for repeatability and usability, along with the interests of many participating firms' in ultimately deploy the technologies within mature value chains, increase private sector motivation to engage in standards development.

2.9 Engagement with the national research base:

Public sector researchers can make significant contributions to standards development for emerging technologies, both at the earliest stages in a technology's maturity but also later in the industrial lifecycle. Not only can academic researchers inform standards development activities with insights into relevant emerging scientific and engineering breakthroughs, but under certain circumstances, academic researchers can play a useful 'honest broker' role in actually leading standards development efforts, especially for technologies relevant for a multiplicity of application domains and industrial sectors.

Consequently, some international R&D agencies make particular efforts to facilitate the involvement of researchers, through funding mechanisms that can have implications for the 'business models' of particular standards development endeavours. For example, the US National Institute of Biomedical Imaging and Bioengineering (one of the National Institutes of Health) has held regular competitions for **grant supplements to participate in standards development** in particular fields of bioengineering, including participation in technical subcommittees (e.g. under ASTM Committee F04) associated with emerging technology-related domains such as regenerative medicine/tissue engineering. During the course of this study, several experts pointed to the potential value of technology R&D funding agencies more explicitly allowing (or even, where appropriate, encouraging) costs associated with standards development activities as eligible items within grant applications, for example: SDO membership, purchasing published standards, additional travel to participate standards development workshops, supplements to workshop grants to incorporate standards development-related sessions, etc.

There are also instances of initiatives specifically designed to ensure that major Federally-funded R&D initiatives in emerging technologies are sufficiently informed by and contributing to parallel standardisation efforts. For example, the **E-Energy Expertise Centre** run by the German Commission for Electrical, Electronic & Information Technologies (DKE) acts the interface between the Federal smart grid-related E-Energy R&D projects and the German smart grid standardisation system.

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3. The Standardisation Landscape of the United States

By contrast with the UK, Germany and many other leading economies, the standardisation landscape in the United States is more diverse, decentralised and specialized. At the same time, as in most EU countries, standard setting and standardisation of emerging technologies in the US are a voluntary market-led and private sector-driven activity. For certain emerging technologies of critical national need, however, the Federal Government may play an important role as participant or convener, especially at the early stages in the lifetime of a novel technology and/or where there are significant regulatory challenges.

3.1 Overview

In this chapter, we highlight some important aspects of the US standardisation system. In particular we explore some key actors and initiatives which help characterize the national industrial-innovation systems-context within which emerging technologies standards are developed in the US. These include:

- The **decentralization and diversity** of technology-related standards development organisations; and the potential for specialized, market-driven associations and consortia to respond effectively to standardisation needs of emerging technologies
- The central role of the American National Standards Institute (ANSI), in particular its **convening** function, including the activities of its 'standards development panels' for emerging technologies in areas of critical national need
- The important role of the National Institute for Standards and Technology (NIST). Not only measurement and test activities that underpin standards in the early stages of an emerging technology, but also its **coordination** role
- The standards development-related activities of Federal government mission agencies. In particular, the impact of R&D-intensive mission agencies (e,g. Depts of Energy and Defence) own standards development and **procurement** activities.
- The contribution of US-based national and international professional and learned societies (e.g. IEEE, ASME) whose membership is made up of **technical experts**
- The extent to which standardisation issues are addressed within Federal initiatives related to **technologies of critical national need** (e.g. MATES, NNI, Smart Grid)

These themes, as well as other distinguishing features and variations within the US standardisation landscape, are illustrated and explored in more detail within the individual emerging technology case studies later in this report.

3.2 Actors in the US Standardisation System

Perhaps the most striking feature of standardisation landscape in the United States is the sheer number and diversity of standards development-related organisations. There are over 600 non-governmental standards development organisations. These bodies are overwhelmingly demand-driven – standards are developed in response to particular needs or issues indentified by industry stakeholders, government (including Federal mission agencies and regulatory bodies) or consumers.

Within this diverse set of organisations, there are about 19 standardisation bodies which produce the majority of new standards; and about half of these are active in developing standards for emerging technologies. These organisations can be broadly classified within the following groups:

- **Professional technical societies**, for example: the American Society of Mechanical Engineers (ASME), the Society of Automotive Engineers (SAE), the Institute of Electrical and Electronics Engineers (IEEE)
- **Industry and trade associations**, for example: the Electronics Industries Association (EIA), Telecommunications Industry Association (TIA), the Aerospace Industries Association (AIA), National Electrical Manufacturers Association (NEMA)
- **Membership-based Standards Development Organisations**, for example ASTM International
- **Consortia** for example: the Internet Engineering Task Force (IETC). Such consortia are often in emerging industrial sectors or sectors with fast technology lifecycles or 'clockspeeds'

Private sector-led and voluntary

Another main feature of the US standardisation system is its relatively decentralized nature and, as for most EU member states, its emphasis on private sector leadership and *voluntary* standards. In its overview of the US standardisation system, the American National Standards Institute (ANSI) points to the this system as a 'reflection of American values' – "a national belief that society will benefit and innovation and creativity will flourish in a system that is free from government control but strengthened through essential governmental participation" [ANSI, 2007]

Government engagement: Emerging technologies of 'critical national need'

Despite the market-driven emphasis of US standardisation landscape, the Federal government does play a variety of roles in supporting standards development, not least for emerging technologies of critical national need. In particular, the government participates at the earlier phases of technology development where uncertainties (in technology platforms, application, market, regulation, interoperability, etc) inhibit private sector involvement.

In January 2012, a Memorandum entitled Principles for Federal Engagement in Standards Activities to Address National Priorities was issued by the Office of Science and Technology Policy (OSTP), the Office of Management and Budget (OMB) and the Office of the United States Trade Representative (USTR). This Memorandum was for the heads of executive departments and agencies. While recognizing that the private sector leadership in standards development remains a primary strategy for government engagement in this development, it also stresses upon those policy areas of national priority where the Federal Government may need to intervene in order to facilitate and accelerate the setting and adoption of standards to foster technological advances that support national priorities. The Memorandum is a practical document, outlining engagement aspects and strategic objectives to guide departments' and agencies' involvement in standardisation activities.

Another distinguishing feature of the US standardisation landscape for emerging technologies is the importance of Federal mission agencies which invest heavily in emerging technology R&D (e.g. the Department of Defence, Department of Energy, National Institutes of Health, etc). Whether through their own standards development programmes, mechanisms to facilitate researcher engagement in the standards development process, or investment criteria for emerging technology procurement; governmental agencies in the US can play an important role in the emerging of new technologies and industries.

3.3 American National Standards Institute (ANSI)

The American National Standards Institute has formal responsibility for overseeing the development of voluntary consensus standards in the United States – 'American National Standards' (ANS). Founded in 1918 by three engineering societies in cooperation with federal government agencies, ANSI is a non-for-profit membership-based organisation which counts firms, government agencies, learned societies and individuals among its members. Although ANSI does not develop standards itself, it does provide an 'honest broker' role – offering US organisations and individuals a forum to come together and work towards consensus-based agreements for new standards. One of ANSI's main roles is accrediting US-based standards development organisations, validating that they follow principles and guidelines that ensure appropriate fairness, equitability.

In the context of emerging technologies, not only does ANSI offer a forum for emerging technology standards development and accredits a range of technology-focused SDOs, ANSI also convenes a small number of 'Standards Panels' which act as national cross-sector coordinating bodies which identify and align standards relevant to areas of critical national need. These panels engage in a range of coordination and alignment exercises that accelerate the development of emerging technologies and industries, often including the development of standardisation roadmaps.

Recent emerging technology-related ANSI 'Standards Panels' include:

- **The ANSI Nanotechnology Standards Panel (ANSI-NSP)** is the national coordinating body for nanotechnology-related standards development with particular emphasis on those standards types most relevant at the earliest phases of a new technology: semantics and terminology; materials properties; and testing, measurement and characterization
- **The ANSI Biofuels Standards Coordination Panel (ANSI-BSP)** focuses on standards development and conformity assessment underpinning the scale-up and commoditization of biofuels
- **The ANSI Electric Vehicles Standards Panel (EVSP)** addresses standardisation coordination and collaboration among public and private sector stakeholders to support the mass deployment of electric vehicles (and associated infrastructure) in the US, as well as engaging with international coordination efforts

The establishment of 'Standards Panels' can be initiated by ANSI itself or following a request by the Federal Government (or its agencies). For example, the Nanotechnology Standards Panel was established after ANSI was approached by the White House Office of Science and Technology Policy (OSTP). The OSTP believed that support and coordination of standardisation for nanotechnologies would enable a range of stakeholders – academic researchers, firms, private sector investors, government mission agencies (that invest in nanotechnology R&D or utilize nanotechnologies directly) – to advance their endeavours to develop nanotechnologies of economic and social value to the United States.

ANSI is representative body for the United States participating in the main international standards development organisations – the International Standards Organisation (ISO) and the International Electrotechnical Commission (IEC). As part of ANSI's role representing US interests in ISO and IEC, it also accredits the so-called 'Technical Advisory Groups' that establish and communicate a US position on particular standards development needs to ISO and IEC working groups.

3.4 The Federal Government

The standards development landscape in the United States - and its market-driven, consensus-based emphasis – is reflected in the key piece of legislation impacting standards development, the National Technology Transfer and Advancement Act (NTTAA). This 1995 law directs all federal agencies, where feasible, to use standards (and conformity assessment solutions) developed by standards bodies rather than developing agency-specific standards. The act also encourages government agencies, where appropriate to the agency's mission, to participate in stakeholder-led standards development activities.

The importance of incorporating standards developed by the private sector into regulation has been further enhanced by the Administrative Conference of the United States (ACUS). ACUS is an independent federal agency which was set up in 1968 and is composed of experts from the public and private sector (Federal government officials, lawyers, academics and experts in administrative law). Working as an advisory committee, ACUS studies administrative processes and promotes improvements of federal agency procedures. In a recommendation issued in December 2011, it pointed out the importance for federal agencies *to draw on the expertise and resources of private sector standard developers* and advised on some issues faced by these agencies when incorporating standards in their requirements.

Most governmental standard-setting activities focus on performance standards, without reference to specific technologies. This approach is designed to ensure that private sector technology developers have maximum flexibility to meet particular standards requirements.

Some Federal regulatory agencies (e.g. the Environmental Protection Agency or the Food & Drug Administration) may establish health and safety or environmental standards requirements, some of which may have consequences for emerging health or environmental technologies. These agencies will, however, typically use voluntary consensus-based standards-development processes, where possible, to achieve their regulatory objectives to protect the well-being of US citizens.

Occasionally, in cases of emerging technologies of critical national interest the government will initiate standards development coordination efforts addressing particular technologies, typically through the auspices of ANSI (e.g. the Nanotechnology Standards Panel) or the National Institute of Standards and Technology (e.g. Smart Grid interoperability standards – see section 7).

The NTTAA specifically assigns NIST the responsibility for coordinating standards policy among different federal agencies. NIST works in close cooperation with ANSI. The role of NIST within the US standards development landscape is discussed in more detail below.

Standardisation can be directly referred to in US government legislation related to areas of critical national need, for example the *Energy Independence and Security Act* (EISA). The Energy Independence and Security Act charged NIST with "primary responsibility to coordinate development of a framework that includes protocols and model standards for information management to achieve interoperability of smart grid devices and systems." NIST's role in convening key 'smart grid' stakeholders - including equipment manufacturers, consumers, energy providers, and regulators— to develop 'Interoperable standards' is discussed in more detail in Section XXX.

3.5 Federal agencies

Despite the highly decentralized and private sector-led nature of the standards development in the US, the Federal government can still be an important player in the American standardisation system. Over three thousand governmental agency representatives participate in private sector-led standards development processes. There is a strong view that government participation can help ensure that governmental users (and government procurement practices) fully account for the intent and content of stakeholder-developed standards.

The National Institute for Standards & Technology (NIST)

The National Institute for Standards & Technology is an agency of the Department of Commerce. It has a broad mission to:

> *'Promote U.S. innovation and industrial competitiveness by advancing measurement science, standards, and technology in ways that enhance economic security and improve our quality of life.'*

As part of the standards-related aspects of this mission, NIST supplies firms, academic researchers, other government agencies with 'Standard Reference Materials' – i.e. materials certified as having specific characteristics or component content, used as calibration standards for measuring equipment and procedures, quality control benchmarks for industrial processes, and experimental control samples. Furthermore, many members of its large scientific and technical staff are active participants in a range of technology-related standardisation processes led by independent standards development organisations. NIST has particular expertise in a range of measurement and testing standards which can be especially important in the early stages of (materials-based) emerging technologies.

As mentioned above, the National Technology Transfer & Advancement Act gives NIST responsibility for coordinating standards policy across the Federal government, including the coordination of Federal agency development (and use) of technical standards and alignment the standardisation activities of the private sector. NIST collaborates with ANSI on the development of the United States Standards Strategy. NIST's Standards Services Division (SSD) publishes information related to standards (and conformity assessment) as a service to producers and users within the private sector government.

Given NISTs strong scientific and technical base (especially in areas related to measurement, testing, materials and manufacturing), the Institute is particularly aware of the importance of standardisation issues facing emerging technologies. These technical insights are becoming increasingly important for the development of standards which underpin the increasingly systems-complex multi-sector technologies and their ability to connect and work together. Recently NIST highlighted the importance of interoperability standards for emerging technologies [NIST, 2011]. NIST has identified a number of emerging technologies which will involve systems of complex interconnected components which will need to be fully interoperable, for example: the smart electrical grid, IT for Healthcare System, and cloud computing. NIST hopes to make a particular difference in supporting the development of such standards for these emerging technologies, pointing to non-interoperability as a potential inhibitor of technology adoption of these emerging technologies.

Other Standards-related Federal Mission Agencies and Regulatory Bodies

- **Department of Energy (DOE):** The DOE not only participates in standards development through the technical activities of its national labs, but also has a dedicated 'Technical Standards Program' (TSP). The TSP promotes the use of consensus standards within the DOE as well as supporting the DOE's standards development effort, and disseminating information on emerging technical standards activities to DOE staff and collaborators engaged in developing or using technical standards. Individual DOE laboratories also make significant contributions to standards development in their particular areas of expertise, for example the National Renewable Energy Lab carries out a range of research and development activities related to 'Smart Grid' technologies, systems and standards (see Section 7).
- **Department of Defense (DOD):** The DOD has a major influence on standards development in the United States both directly, through its Defense Standardisation Program Office (DSP) and indirectly through its investment in emerging technology R&D and procurement. Standardisation is an important issue for the US military – standardized military equipment parts can help lower costs, reduce inventories, improve logistics chains, and enhance both integration between military and civilian value chains as well as improved interoperability between the equipment of joint and coalition forces. The mission of the DOD's DSP is to identify, influence, develop, manage, and provide access to standardisation processes, products, and services for warfighters, as well the US defense sector's acquisition and logistics communities. In particular the DSP aims promote interoperability, reduce costs, and help support sustain the military readiness of the United States.
- **Federal Communications Commission (FCC):** Some Federal regulatory agencies have statutory responsibilities which require them to develop technical regulations that mandate compliance with particular standards. For example the FCC, through its Wireless Telecommunications Bureau, regulates the use of radio spectrum to support the communications needs of firms (including aircraft and ship operators), the US military and individual citizens. The FCC is also an active participant in standards development activities for emerging technologies which have important ICT infrastructure-related dimensions, for example the development of smart grid interoperability standards discussed in Section 7.
- **Food and Drug Administration (FDA):** The FDA plays a significant role in supporting the development of medical and health technology-related standards, especially where there are consequences for compatibility with FDA regulations. The FDA's Center for Devices & Radiological Health (CDRH) is a significant player in the development of medical device standards. The Centre has a dedicated Standards Management Staff (SMS) responsible for

facilitating awareness of medical device consensus standards. SMS also manages the FDA's 'Standards Program', a regulatory support activity that works closely with SDOs to communicate FDA recommendations on particular standards activities. The Staff also maintains a standards database providing access to standards for FDA staff and firms.

3. 6 Some Important US Standardisation Initiatives: Strategies, Studies & Committees

- **US Standards Strategy:** An important document that helps nurture support, awareness, alignment and mission clarity of US public and private sector standards development stakeholders is the 'US Standards Strategy'. The first National Standards Strategy was developed under the auspices of ANSI in 2000. The Strategy reaffirmed the basic structure of the needs-driven voluntary consensus standards-led nature of the US standardisation system, as well as making recommendations for its improvement. A second edition was published in 2005.

- **'Federal Engagement in Standards Activities to Address National Priorities' Study**: In December 2010, NSTC's Subcommittee on Standards (SoS) commissioned NIST to carry out a study on public perspectives on the effectiveness of governmental agency participation in standards development and related programs in select technology areas of critical national importance. This study solicited input from a broad range of stakeholders and provides an overview how the US government engages in standards development activities; summarizes stakeholder observations; and offers specific recommendations to enhance agency standards development practices

- **Interagency Committee on Standards Policy (ICSP)** is an advisory body on standardisation policy and related issues that reports through the NIST Director to the Secretary of Commerce (and other agencies of the Executive Branch of the US Government). The ICSP aims to foster cooperation between government, and other private sector stakeholders involved in standards development, as well as endeavouring to support effective and consistent standards policies across the Federal government.

- **NSTC Subcommittee on Standards** is a forum for senior officials of federal agencies to address standards-related issues of critical national interest and effective standards-related policies and practices. The subcommittee has a particular focus on responsive and timely coordination among federal agencies for governmental engagement in standards development; increasing awareness of effective practices and lessons learned; improving awareness of the role of standardisation both enabling technology development as well as meeting governmental procurement needs and regulatory policy objectives.

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4- Standardisation Landscape in Germany

In comparison to its US counterpart, a defining feature of the standardisation landscape in Germany is its more centralised nature, with the German Institute for Standardisation (DIN) being responsible for most of the standardisation activities. In the specific context of standards in support of emerging technologies, an engagement of the Federal Government through its Ministry of Economics and Technology (BMWi) has led to the setting up of two programs of particular relevance. Funded by BMWi and managed by DIN, they aim to integrate standardisation aspects across the technology development process, including at the very early stage.

In this chapter, we highlight some important aspects of the German standardisation landscape, with special emphasis on the pivotal role played by DIN and on some key standardisation initiatives and programmes. These aspects include:

- The **coordinating and funding role** played by the Federal governmental in order to create a supportive environment for standardisation activities
- The **tailored approach** adopted by the German Institute for Standardisation (DIN) in support of emerging technologies
- The **systematic** integration of standardisation activities at all stages of the **technology development process**, including at the R&D phase
- The important role of **professional societies** in both assisting in standardisation work and assessing the potential for standardisation in emerging sectors
- The **engagement with the research community**, with academics helping define DIN's standards agenda and assess research projects of particular standards relevance

4.1 Main actors in the German Standardisation System

4.1.1 The German Institute for Standardisation (DIN)

In Germany, standardisation is mainly handled by the German Institute for Standardisation (DIN, standing for Deutsches Institüt fur Normung). This is according to a Federal Agreement signed in 1975. However, DIN is not a Federal body but a private organisation. At the national level, DIN is tasked with organising the entire standards development process, mostly through internal and thematically organised standards committees.

At the international level, DIN alone represents German interests in the European and international standards development organisations and is responsible for German participation in standards work carried out in those organisations. Also, it supports the transfer of international work results into German DIN standards

In its strategy document "The German Standardisation Strategy" released in 2010, DIN presents a number of guiding principles for standards development in Germany, informed by consultations of leading representatives from industry, politics, academia and standard-related bodies. The document lists some practical recommendations and defines a course of action in order to adapt the standards development process to a changing and evolving environment. In the specific case of standards in support of emerging technologies, the DIN document advocates several measures in terms of:

- promoting closer ties between standardisation and R&D; with standards development becoming an integral part of research programmes, potential for standardisation being assessed in R&D results at an early stage, especially in high-tech sectors and intensive monitoring of current trends in R&D
- making greater use of standards in public procurement; with the inclusion of standards in public procurement procedures to promote innovation
- incorporating specifications into full-consensus standardisation; with the development of procedures to better integrate specifications drawn up in for a and consortia into the standardisation activities of the standards bodies to enable shorter innovation cycles and rapid technological changes
- promoting technical convergence; with the setting up of structures and processes to support the special needs of converging and innovative technologies (semantic aspects, dialogue platforms for identifying innovative topics in R&D, interdisciplinary workshops, .)

The German landscape for standardisation also comprises a number of fora and consortia which have been set up by groups of companies in particular in fast-evolving technology sectors. Some of the standards developed through the less formal standardisation process of these instances may become "de facto" standards. DIN has started cooperating with some consortia and helped transfer a number of "de facto" standards into formal standards, at the national, European or international level.

4.1.2 The Federal Government

The main role of the Federal Government in standardisation is to create a supportive environment for the development of standards. Standards are recognised as strategic instruments to secure Germany as a leading economic power and the importance of conducting a "vigorous standardisation strategy" has been acknowledged by the Federal Government in a number of policy papers (e.g. the new "High-Tech Strategy for Germany" issued in 2006). Special attention is being paid to the early stages of the research process, when standards can enhance the translation of research findings into marketable products and services, therefore granting a competitive advantage for Germany.

From a practical perspective, the Federal Government mostly acts as a coordinator and a funder. For instance through the different Ministries which can fund standardisation work in their remit. In the Standardisation Policy Concept issued in January 2009, the Federal Government advocates a more concerted approach to standardisation and stresses upon the need to facilitate the cooperation of all the Ministries, organisations and bodies involved in the standards development process.

Five key goals are highlighted in the policy paper, goals No 1 and 2 being particularly relevant in the context of standards and emerging technologies:

1- To support standardisation to enhance Germany's competitiveness as an economic power and exporting country
2- To use standardisation to support the implementation and dissemination of innovation and research results
3- To foster a successful society and economy, particularly through greater use of public procurement and better integration of standards in higher education
4- To make increased use of standardisation to reduce the volume of legislation and accelerate the legislation process
5- To promote the information and involvement of stakeholders, in particular SMEs, in the standardisation process

Among its points of focus, the Standardisation Policy Concept lists the necessity to increase the awareness of, and engagement with, standards in order to disseminate more efficiently innovative technologies and services in the industry and the research institutes. It also advocates the provision of incentives to use and disseminate standards, with standards development as part of the evaluation of research and technology programmes.

Some Federal Ministries are particularly involved in standardisation, with the Federal Ministry of Economics and Technology (BMWi) playing a key role. BMWi is responsible for coordinating the strategic goals and their funding while the individual departments decide on and fund sector-specific standardisation initiatives. Interestingly, a set of funding criteria, aligned with the goals defined in the Standardisation Policy Concept, has been adopted to provide departments with a catalogue which is used as a guidance to select projects and grant funds.

In the specific context of standards and emerging technologies, BMWi, while not directly involved in the development of standards, has funded a number of projects that link to standardisation, especially at an early stage when industry is not willing to engage in standards development because the market is too uncertain. For instance, BMWi has initiated and funded the Innovation with Norms and Standards (INS) project (see section below for a detailed presentation of the project). The Federal Ministry of Education and Research (BMBF) has asked, in the High-Tech strategy document it issued in 2010, for a better integration of standardisation possibilities into research funding.

4.1.3 Federal Institutes

Bodies engaged in the development of standards at the Federal level also includes the National Metrology Institute (PTB, standing for Physikalisch-Technische Bundesanstalt) which is tasked with developing, maintaining and improving measurement techniques and measurement standards and the Federal Institute for Materials Research and Testing (BAM), which is involved in the development of standards associated with issues around the safety and environmental compatibility of new technologies.

These two Federal institutes are entirely funded by BMWi. 500 experts work in each of them and participate in standardisation processes at national (in mirror committees for instance), EU and international levels

4.1.4 Professional Societies

Association for Electrical, Electronic and Information Technologies (VDE)
The VDE is the Association for Electrical, Electronic and Information Technologies (and their related sciences, technologies and applications). This association of 35 000 members conducts a rather broad range of activities, with a main point of focus on safety standards development for electrical and electronic products. To this aim, VDE drafts technical standards and tests and certifies electrical products, equipment and systems.

With Din, VDE has created a joint organisation named DKE. DKE is responsible for the development and maintenance of standards and safety specifications in the domains of electrical engineering, electronics and information technology and can therefore be considered as another standardisation body. Interestingly, DKE is also tasked with monitoring technology developments and identifying new trends emerging from research and development in innovative technological fields in order to assess their potential for standardisation.

A number of services are provided by DKE. The main ones are:

- Development of standards with a view to quick-starting the development of consensus-based standards, when a large number of stakeholders can be involved in the process.
- Assistance in standardisation work, for instance by providing guidance about the relevant publication category and format
- Participation in research projects receiving public funding, for instance by providing assistance in drafting the research proposal

Association of German Engineers (VDI)
The Association of German Engineers (Verein Deutscher Ingenieure or VDI) is the largest Engineering society in Western Europe with a membership of almost 140,000 profession engineers, engineering academics and natural scientists. The society represents the interests of both engineers and of German engineering firms, as well as promoting advances in technology and engineering systems.

One important activity of the Association is the publication of 'VDI Guidelines' by the VDI's technical divisions. The VDI has issued guidelines based on the latest engineering research findings and technology developments since 1884 and now issues almost 200 guidelines per year and has a library of over 1800 currently valid technical regulations covering emerging technology-related topics within domains from civil engineering to telecommunications systems to bioengineering. VDI Guidelines play a very important role within the German industrial-innovation system, and provide a platform for many international standardisation efforts.

4.1.5 The Research Community
Research institutes can also be involved in standardisation process. They include:

- The Fraunhofer-Gesellschaft , an application-oriented research organization, composed of 80 research units (with 60 institutes located in Germany) which undertake research in seven different sectors, namely: information and communication technology, life sciences, microelectronics, light and surfaces, production, materials and components, defense and security.
- The Gottfried Wilhelm Leibniz Scientific Community (WGL), known as the Leibniz Association, which is composed of 87 research institutes. These institutes "provide infrastructure for science and research and perform research-based services – liaison, consultation, transfer – for the public, policy-makers, academia and business" (http://www.research-in-germany.de/leibniz)
- The Max Planck Society (MPG), an independent, non-profit research organisation focussing on basic research in the natural sciences and humanities.
- The Helmholtz Association, largest scientific organisation in Germany, which is composed of 18 scientific-technical and biological-medical research centres involved in six core fields: energy, earth and environment, health, key technologies, structure of matter, aeronautics, space and transport.

The involvement of research institutes in standardization activities is encouraged and facilitated through different initiatives. For instance, researchers from these institutes can participate on a regular basis to DIN committees (that is the case for up to 100 experts from Fraunhofer) or get involved in a specific project. To this regard, the Fraunhofer Institute participated in the "NO REST" EU initiative (NO REST standing for "Networked Organisations - REsearch into STandards and Standardisation Project"). This initiative was funded under the 6th EU Framework Programme to look at the dynamics of standards in the e-business, e-government and ICT sectors. Another example at the EU level concerns the STAIR initiative whose chairman is Dr Knut Blind, a German researcher from the Fraunhofer.

4.2 Key Standardisation Initiatives and Programs

4.2.1 Integration of Standardisation Aspects across the Technology Development Process

Three main initiatives are being managed by DIN to foster the development of standards in support of emerging technologies, with special attention being paid to the early stages of the research process, when industry may be reluctant to take up standardisation activities (see figure 1). They are:

- the EBN Initiative (R&D Phase Standardisation)
- the TNS Program (Transfer of R&D results through Standardisation)
- the INS Program (Innovation with Norms and Standards)

The EBN Initiative and the TNS- INS programs have been developed to address the shortcomings of formal standardisation processes. Indeed, formal standards occur when the R&D phase is completed and they take time to be developed. They cannot keep pace with technology evolution while, at the same time, technology involves "complex systems which cannot function without the structures provided by standardisation" (DIN).

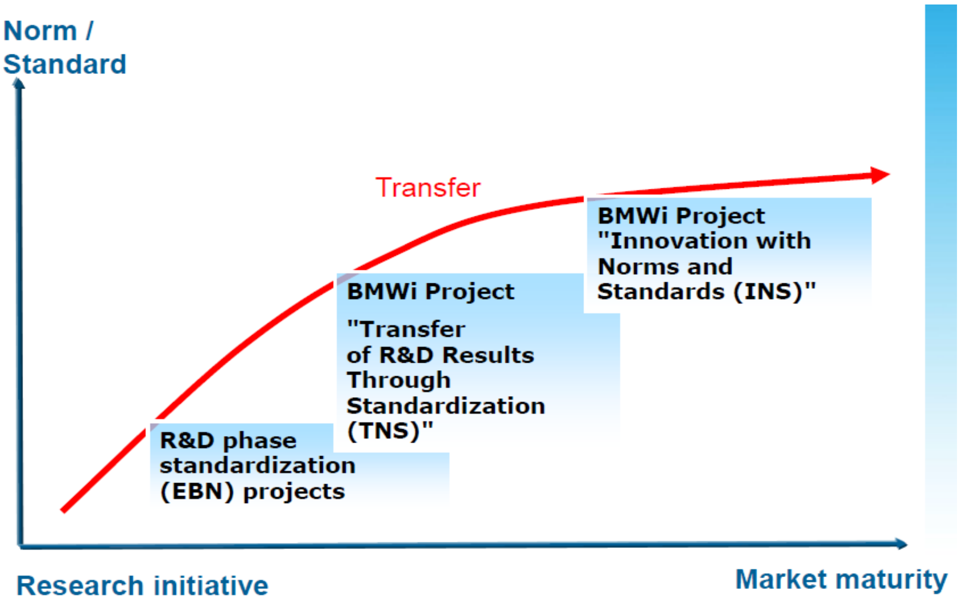

Fig 1: Promotion of innovation through standardisation
(source: DIN – H. Behrens, 2011)

Under these three different programs, DIN aims to adopt a tailored approach to support each phase of the innovation process:

- Basic research: terminology, measurement and testing standards or specifications:
  - consistent and independent methods to assess the quality of the innovative product
  - exchange of knowledge facilitated between the different partners
  - lower information and transaction costs.
- Applied research: interface standards or specifications:
  - interoperability between the different components
  - reduction of adjustment costs.
- Experimental development: Compatibility standards or specifications:
  - integration of the different product components into existing systems
  - creation of an infrastructure for future technology generations.
- Technology transfer and entry into market: quality, product and service standards or specifications:
  - assessment of environmental, safety and ergonomic aspects
  - improved uptake of innovative products and services
  - reduction of risks
  - promotion of market penetration

4.2.2 The R&D Phase Standardisation (EBN) Initiative

The R&D Phase Standardisation can provide projects with a range of services. It was initiated in 1989 and has been managed by a special committee established within the DIN Presidential Board, consisting of experts from the business and scientific communities. The R&D Phase Standardisation aims to support technology development processes through different instruments, with the special committee:

- assessing the potential of standardisation of particular sectors at the R&D stage;

- recommending and initiating the appropriate activities to make this standardisation possible early in the technology development process.

The instruments used by DIN aim to disseminate results faster as they allow recommendations and preliminary results to be taken into account during the R&D phase. They include Publicly Available Specifications (DIN PAS), DIN Technical reports, DIN pre-standards and CEN-Workshop Agreement (CWA) (see figure 2). Such instruments are especially relevant at this stage as they are quicker to develop, can be rapidly published and can still be used as a basis for formal standards.

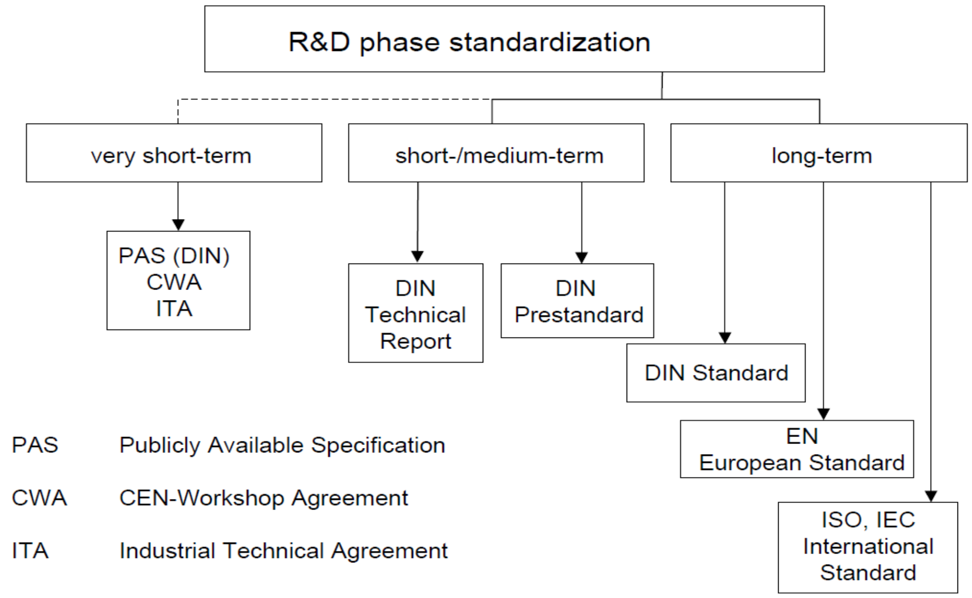

Fig 2: R&D Phase Standardisation – Instruments and Timeframe
(source: DIN - P. Weiler, 2001)

From a practical perspective, the services offered under the DIN R&D Phase Standardisation include:

- informing about the R&D Phase Standardisation initiative in conferences/events
- assessing standardisation potential in current innovative projects (e.g. by holding workshops)
- translating standardisation results in the right format and in the appropriate document (Technical Reports, PAS, pre-standards, etc.)
- identifying project activities that may be relevant to R&D Phase Standardisation
- reviewing and informing on existing standards
- providing contacts with relevant standardisation bodies (e.g. DIN Technical Committee)
- providing assistance during standardisation procedures (i.e. by making proposals to the relevant Technical Committees and preparing the relevant documents)
- assisting in the draft of standards in compliance with the national, European or ISO requirements.

The R&D Phase Standardisation is especially relevant to address the specific issues faced by developers of innovative products as it is a fast and flexible process which enables technology convergence. It also takes into account the ways in which research projects are conducted, as they often involve several partners from different fields, including partners supported by public funds. DIN, through the R&D Phase Standardisation, can create a common basis for knowledge among all the different partners.

Early involvement with the R&D Phase Standardisation enhances the possibilities of technology transfers. The research projects, and more broadly the innovation process, are supported by DIN at different levels: through R&D Phase Standardisation, different and complementary research partners can be brought together, the potential for standardisation is identified in a quicker way and the market penetration is accelerated.

4.2.4 The "Transfer of research and development results through standardisation" (TNS) program

The "Transfer of research and development results through standardisation" (TNS) is a program which is funded by BMWi. It was initiated in 2009 and has been managed since by DIN. Through early consideration of standardisation aspects in the research process, the TNS program aims to facilitate the knowledge transfer from R&D through to standardisation in order to benefit companies.

To this aim, grants are allocated to projects concerned with the translation of R&D findings and results into standards. Funding criteria include:

- the development and implementation of strategies to foster the translation of R&D results into standards
- participation in SDOs at the national, European or international level
- technology convergence relevance
- setting up of events to raise awareness about the potential of standards to integrate R&D results

Projects developed by companies with operations in Germany, SMEs as well as universities and research institutions are eligible to TNS grants. Grants cannot exceed 150 000€ and eligible research projects should be 6 to 24 month long. The funding process consists of two stages: a submission to DIN via a user-friendly application form named “Easy” and a selection by DIN and its General Committee on Research, Innovation and Development (SO-FIE) based on a number of criteria. They regard the degree of innovation of the product, the benefits for the German economy (e.g. market potential), the potential for standardisation and standardisation activities at national, European and international levels and, interestingly, their relevance for SMEs.

4.2.5 The “Innovation with Norms and Standards” (INS) program

The Innovation with Norms and Standards (INS) program is funded by BMWI and managed by DIN. It started in 2006 and aims to create “an innovation structure for German standardisation, while achieving a sustainable integration of standardisation in the research process itself”.

INS consists of two strands. One focuses on projects in specific sectors, with projects concerning a large range of technologies (aerospace, energy, health research, materials, optics, etc.). From 2006 to 2010, 59 one-to two year projects were launched and 33 were completed. The second strand is referred to as “Basic Investigations”, with investigations being conducted to identify new areas of standardisation on the basis of an open survey developed in collaboration with two research institutions (the Berlin Institute of Technology and the Fraunhofer Institute of System and Innovation Research). The survey results, refined through some innovation indicators, represent a good indicator of the fields in which standards are increasingly needed and are often taken into account in the work of the relevant DIN committees.

Key findings regarding the “Basic Investigations” program include the proactive stance adopted by DIN to anticipate the needs for standardisation in new technologies. They also include a positive “side effect” on the research community and on product developers as the program helps increase awareness of the benefits of standardisation. Further, German researchers are given an opportunity to define in advance new topics for fundamental research but also to help set standards. For instance, in the e-mobility sector, quality, safety and compatibility standards with regard to the disposal and recycling of spent energy accumulators were identified as lacking.

4.2.6 Engagement with the Research Community

A significant role is played by research organisations like the Fraunhofer-Gesellscaht, The Leibniz Association and the Max Planck Society in the German standardisation system. To this regard, the development of MP3 technology by the Fraunhofer Institut Integrierte Schaltungen research center, (Fraunhofer IIS) which triggered the creation in 1988 of a subcommittee of the International Standards Organisation/International Electrotechnical Commission (ISO/IEC) is considered by German researchers as a very inspiring success story.

The involvement of research organisations in standardisation processes is encouraged and facilitated. For instance, a permanent committee dedicated to “Research, Innovation and Development” (SO-FIE) was established in 2008 within the DIN Presidential Board. SO-FIE is composed of representatives from research institutes, with a chairman (Pr. Dr. Hartwig Steusloff) belonging to the Fraunhofer Institut fur Informations und Datenverarbeitung in Karlsruhe (Fraunhofer IITB).

SO-FIE’s main tasks are to advise DIN on new emerging fields for which standards are needed and to assist in assessing the research projects submitted to DIN. In a more detailed way, SO-FIE:

- assists in the steering of different DIN initiatives, like the R&D Phase Standardisation and the Innovation with Norms and Standards,
- helps identify innovative areas in standards work and determine the need for standardisation on the basis of research projects and results
- helps raise awareness about standardisation and its benefits among research organisations and make standardisation a topic in research and education curriculum, including non-academic education
- coordinates measures for using standards and specifications to transfer research results to industry,

At a more anecdotic level, a series of lectures about strategic standardisation is held every semester at the Department of Innovation Economics of the Technical University Berlin and is attended by more than 50 students. The lectures are practically oriented, with representatives from industry and SDOs being invited as guest speakers and the possibility to take part in some DIN technical committees. In 2010, other initiatives in education include the supervision by DIN of students exploring the economic benefits of standards and a conference hosted by DIN about the different ways to make the development of standards part of the academic training. DIN also awarded a special Science prize of 3.000€ to a doctoral student whose dissertation was about the management and economics of standards and standardisation.

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5. Additive Manufacturing Technologies

Additive manufacturing is a collective term for those technologies which enable the production of 3D objects by 'adding' successive layers of materials in configurations based on digital model data. Not only does this technology enable the direct manufacture of highly complex shapes, without the need (and cost) of additional processing, but there is extremely little waste, and – critically – creates enormous opportunities and freedom for designers.

Additive manufacturing distinguishes itself from other emerging technologies considered in this study in terms of: (a) its impact on a multiplicity of sectors – from aerospace and automotive, to machine tools, to medical devices; and (b) the multiplicity of technical approaches with the potential to ultimately implement the process – from 3D printing, stereo-lithography, selective laser sintering, to fused-deposition modeling. Additive manufacturing technologies are still in the early stages of emergence, however, with many machines still highly sensitive and in need of careful calibration.

5.1 Overview

Despite the extraordinary potential and demonstrated value of existing additive manufacturing technologies, there remain many uncertainties – associated with the diversity of sector applications and multiplicity of technological approaches, system complexity and technological maturity – which mean AM technologies have not yet been widely adopted, with many AM users still using their machines for prototyping rather than actual production.

There is, however, significant belief among the AM development community that the standardisation of additive manufacturing approaches (including testing methods, etc) will lead to 'validated' processes that will enable the full emergence of hugely important and highly disruptive new production technologies. Key observations regarding the development of standards for additive manufacturing to date include:

- **The important role played by professional societies** – the Society of Mechanical Engineers - in both laying the groundwork and initiating a formal standards development process (under the auspices of ASTM International)
- **The value of roadmapping exercises** (e.g. a critical 2009 NSF-supported Roadmap for Additive Manufacturing workshop) which helped a diverse AM development community coalesce around need and approach to standards development
- **The impact of key individual R&D leaders** in driving the standards development process. In particular, the potential role of 'honest broker' academic leaders with deep insight into the relevant industrial sectors and real passion to see AM technologies reach their full potential
- **The potential of technical conferences** (involving industry and academia) to provide a forum to engage the broader stakeholder community in the standards development agenda
- **The importance of an internationally and technologically inclusive process** for standards development body. Attempts driven by interests of particular firms or narrow technological approaches are less likely to succeed

These observations are explored in more detail in the following sections. Other themes (e.g. the role of academic R&D in informing the standards agenda and to ensure ongoing research is consistent with standards development) are also discussed, as are some of the main national standards development stakeholders and initiatives.

5.2 Introduction to Additive Manufacturing and Standardisation

Additive manufacturing (AM)[1] is a collective term for those technologies which involve the production of objects by joining successive layers of material in configurations based on three-dimensional digital model data.

5.2.1 Overview of Additive Manufacturing Technologies

Additive manufacturing processes are often defined by contrast with traditional approaches to the production of parts: Conventional processes are typically either '*subtractive*' in nature (e.g. machining, drilling, grinding, etc) or '*formative*' (e.g. casting, pressing, etc). Additive manufacturing approaches generally incur less cost in terms of energy consumption and generation of material waste. Additive manufacturing applications fall into the following broad categories:

- **Rapid Prototyping (RP)**
- **Rapid Tooling (RT)**
- **Rapid Manufacturing (RM)**

And the term additive manufacturing includes the following technological approaches:

- **Selective Laser Sintering (SLS)** produces parts using high-powered lasers to fuse layers of small particles (of powdered plastic, metal, ceramic, or glass)
- **Electron Beam Melting (EBM)**, makes 3D objects by melting successive layers of metal powders with electron beams in high vacuum conditions
- **Fused deposition modelling (FDM)**, produces parts by extruding small beads of thermoplastic material from a nozzle to form fast-hardening layers
- **Stereolithography** - often referred to as 'stereo lithographic apparatus' **(SLA)** manufacturing – involves constructing 3D objects from liquid photopolymers that are selectively cured using UV lasers
- **Laminated object manufacturing (LOM)** produces 3D parts by successively gluing together layers of adhesive-coated (paper, plastic, or metal) laminates, which are cut to shape
- **Inkjet** builds up 3D objects by propelling small droplets of inks onto substrates which are made solid upon deposition by heating, chemical reaction or UV curing

5.2.2 Motivation and history of recent AM standards development

As discussed above, despite the immense promise of additive manufacturing technologies, standardisation and adoption were inhibited by a number of uncertainties, partly associated with the multiplicity of potential sector applications and technological approaches, as well as technological maturity (and related machine sensitivity).

[1] A range of different terms continue to be used to label additive technology approaches to manufacturing, e.g. 'additive layer manufacturing', 'additive fabrication', 'freeform fabrication'. There is, however, increasing acceptance of the term 'additive manufacturing', not least since the adoption of this label by the American Society for Testing and Materials (ASTM) technical committee F42.

By 2008, despite both industry growth (an estimated total value of all markets of ~US$1.2B) and increasing agreement that standardisation of AM approaches would help validate processes and improve conditions for further investment and industry adoption, there were still no dedicated technical standards committees within industry bodies or SDOs. Furthermore, there was growing concern that some existing standards (evolving within particular technologies, processes or sectors) were either not universally applicable or were potentially restrictive.

5.2.3 Additive Manufacturing Standards Development Stakeholders

ASTM Committee F42

The principle international AM standardisation initiative is led by Committee F42 of ASTM International. The remit of ASTM F42 is:

> "*The promotion of knowledge, stimulation of research and implementation of technology through the development of standards for additive manufacturing technologies.*

The formation of ASTM F42 was strongly supported by the Society of Manufacturing Engineers' Rapid Technologies Additive Manufacturing community (see Section 4.8.1). In this context, a number of key individuals from the additive manufacturing R&D community, notably Professor Brent Stucker, were central to driving this process and bringing the broader AM community together (see Section 4.4).

ASTM F42 has a diverse range of members including not only representatives of ASTM and SME, but also other professional and industrial associations (e.g. NCMS), multinational corporations (e.g. BMW, Siemens, Stryker, GE, Honeywell, etc), small and medium-sized enterprises, academics from leading universities (e.g. Cornell, North Carolina State, University of Kentucky, GATech, etc), and several Federal agencies and research institutes, especially from the aerospace and defence sectors (e.g. NASA, Naval Air Warfare Center, Air Force Research Laboratory, etc)

Both companies and academics have joined ASTM because of the organisations activities in AM standards development. Indeed, one expert interviewed in the course of this study estimated that a significant majority of participants in F42 are new ASTM International members.

Other additive manufacturing standardisation stakeholder organisations in the US

While ASTM F42 leads the principle additive manufacturing standardisation initiative active today, a range of other governmental, professional and private sectors also make valuable and evolving contributions to standards development for this important emerging technology. Other important stakeholder communities include: professional societies, federal mission agencies, academic (and other public sector) researchers, public-private sector research networks. The roles and contributions of some of the stakeholders are discussed in more detail in the final sections of this chapter.

DIN's activities related to additive manufacturing

Additive manufacturing technologies are an important emerging technology theme within DIN and its Materials Technology Standards Committee, NWT. In September 2010, DIN held the founding meeting of the Committee (NA 145-04 FB) for Additive Manufacturing Processes under the auspices of NWT.

DIN standardisation activities relevant to additive manufacturing include "Additive Fertigungsverfahren" (Additive Manufacturing Processes), the subordinate committees associated with ISO / TC 261. This subcommittee looks additive manufacturing (AM) standards related to processes, terms and definitions, process chains (hardware and software), testing, quality, supply chain agreements, etc.

5.3 AM Standards Stakeholder Community Coordination, Awareness & Alignment

5.3.1 Emerging Technology Strategy Frameworks and Roadmapping

Throughout this study several experts have pointed to the value of roadmapping-type exercises in supporting emerging technology development communities coalesce around the need for and approaches to standards development. Roadmapping is often perceived as complementary process to standards development activities (often happening in parallel). Both are considered reflections of the increasing confidence of the development stakeholders that its worth coming together as a community, indicating that uncertainties associated with the emergence of the technology have been reduced to the point where both mapping future R&D priorities and coordinating around common standards has become worthwhile.

***Roadmap for Additive Manufacturing* (RAM) Workshop**

Organized by three AM research leaders and supported by the NSF and the Office of Naval Research, the 2009 *Roadmap for Additive Manufacturing* (RAM) Workshop was attended by a broad range of AM technology development stakeholder – including representatives of US academic engineering researchers, industry and the US government science, health, defense and aerospace R&D agencies – with a view to developing a 10-12 year roadmap for the emergence of additive manufacturing technologies.

Although the principal focus of the RAM effort was the systematic identification of high potential priority R&D areas to accelerate the deployment of freeform manufacturing technologies and processes into the marketplace, the roadmapping activities also supported the networking of leading experts and stakeholders from industry, academia and government.

A repeated theme that arose across all workshop themes was importance of the development and adoption of robust standards to the emergence of additive manufacturing technologies and their deployment across a range of high value manufacturing sectors. The workshop produced greater awareness, clarity and consensus around the critical role of internationally recognized product, process and material standards that conform to internationally recognized standards in driving the adoption of AM technologies.

5.3.2 Technical Conferences

Several AM standards development stakeholders interviewed in the course of this study pointed to the value of hosting standards development workshops that ‘piggy-back’ on broader technological conferences or meetings. This approach is considered to have a number of potential advantages. In particular, both the technical and standards meetings benefit in terms of increased attendance with technical experts more likely to prioritize attending a standards meeting if they can also participate in a conference of their peers, similarly standards development activities can take advantage of the gathering of a broader spectrum of stakeholder input.

Furthermore, technical conferences are likely to have greater international involvement. Standards development sessions can take advantage of this attendance to increase the international inclusivity of their endeavours – helping ensure community is paying more than lip-service to international consensus and awareness.

Additive Manufacturing Conference (Loughborough, UK)
The ASTM International F42 committee held one of their annual workshops alongside the Additive Manufacturing Conference in Loughborough, UK, for the reasons outlined above. It is worth noting that this model of relatively short conferences (2-3 days of technical conference with satellite sessions on standards development) is considered particularly attractive. This timeline ensures the meetings don't take up more than one working week, which is often critical in order to engage leading international emerging technology developers. Furthermore, focused conferences of this type – i.e. conference addressing a specific technology domain such as AM (rather than, for example, much larger and wider ranging manufacturing engineering-related events) are considered especially appropriate for incorporating standards development sessions or satellite events, as all participants more motivated to help the particular focus technologies emerge – and hence more interested in standards development and more likely to engage.

5.3.3 Stakeholder Networks: Rapid Manufacturing Platform Deutchland
The Rapid Manufacturing Platform Deutschland network provides a platform for additive manufacturing stakeholders to identify R&D priorities and strategies, as well as address other challenges and opportunities to the emergence and adoption of AM, and promote its advantages. The network of stakeholders includes equipment manufacturers, industry users and engineering experts organized into three main working groups including: technology, education *and standards*.

5.4 AM Standards Stakeholder Community: The Importance of individual leaders

A number of AM stakeholders consulted in the course of this study pointed to the important role played by a small number of key individuals driving the standards development process. In particular, experts pointed to the role of 'honest broker' academic leaders – notably Professor Brent Stucker of the University of Kentucky – who offered not only deep technical expertise and awareness of challenges across a range of industrial sectors, but also a real passion to see AM technologies reach their full potential. In particular, Professor Stucker was considered to have played a critical role in bringing together the larger AM community together within the ASTM F42 committee.

Professor Stucker is the current Chair of ASTM F42 and an SME Community Advisor for the Rapid Technologies Additive Manufacturing community. In 2010 Professor Stucker received the 2010 Robert J. Painter Award from ASTM International and the Standards Engineering Society for his contributions towards the ASTM F42 committee

Professor Stucker himself points to the value of being able to take academic sabbatical and devote time to supporting the AM standards development effort. Furthermore, the fact that he was on sabbatical in Europe at the time, served to enhance his ability to ensure the international inclusivity of the standardisation effort. Professor Stucker also credits ASTM's practical and logistical support for his personal efforts.

5.5 The National Research Base

Several additive manufacturing stakeholders consulted during the course of this study pointed to the value and ongoing contribution of academic (and other public sector R&D institution) researchers to AM standards development, at this stage in the technologies' maturity. This is considered especially important when, as in the case of additive manufacturing, multiple potential technological approaches are still be refined within the public sector research base.

Not only does ongoing engagement with academic research help inform the evolving standards development agenda, but is also important for academic engineers working on AM-related research to ensure their R&D plans are consistent with standards development, for example materials testing standards could have particular impact on university-based research project design.

It was also suggested that for a set of emerging technologies such as AM – which have implications for a number of diverse industry sectors and applications – there is value in academic researchers taking a leading role in driving standards development, not least as a trusted coordinator. Academic researchers' strong international networks of research collaborators also have the potential to enhance the international inclusivity (and trust) associated with standards development efforts.

Given the potential value of engaging academic (and other public sector) researchers in the standards development process, some of those interviewed during the course of this study pointed to the importance of research funding agency mechanisms to facilitate involvement of researchers – in particular associated with making it as easy as possible to bring the community together at the earlier stages of initiating a standards development initiative. Such potential research agency funding mechanisms included:

- Supplement grants for travel
- Standards Development Organisation membership (as an eligible cost item on research grants)
- Workshop grants (with additional funds to incorporate standards development-related sessions)
- University-industry research centre programmes (e.g. the NSF I/UCRCs or EPSRC IMRCs) which offer a potential platform for industry-engaged, critical mass, emerging technology challenge-driven centres to participate in standards development
- International collaborative cost-share mechanisms between R&D funding agencies, e.g. EU-NIST support for international effort at early stages

5.6 Federal Government Agencies

5.6.1 The National Institute for Standards & Technology

Earlier convening activities paved the way for the SME-ASTM initiative. For example, in 1997 the National Institute of Standards and Technology (NIST) hosted a 'rapid manufacturing' workshop that made recommendations for the development of formalized standards for the emerging rapid prototyping sector to help continued advancement of early additive manufacturing-related technologies. The event focused on methods for identifying and then measuring the benefits and limitations of emerging technological approaches in order to facilitate the transition of promising technological processes from laboratory conditions to commercial deployment. NIST went on to promote awareness and discussion, for example through the dissemination of a discussion paper [Jurrens, 1998] to gather additional information and stakeholder perspectives regarding standardisation needs for (and, if appropriate, potential content).

5.6.2 The Department of Defense (and the role of government technology procurement)

There seems to be some evidence that activities of the Department of Defense were a significant stimulus to AM standards development in the United States, including through ASTM F42.

The DOD makes significant investments in emerging technologies with the potential to advance the effectiveness of products and services supporting US warfighters (and the associated military logisitics system). Given the potential impact of additive manufacturing to the rapid production of parts in aerospace and other military applications, the DOD make significant investments in additive manufacturing-related technology development.

Because of the imperative to improve performance and reliability in the battlefield, the DOD want technologies that are interoperable, useable and repeatable. Standardisation can play an important role in addressing these concerns. Researchers pursuing DOD technology procurement R&D projects, frequently cite their intention to address and/or create standards, in order to enhance the case for the reliability and repeatability of their outputs.

Furthermore, in the case of additive manufacturing, defense sector firms (e.g. Boeing, GE, etc) regularly engage in technology development projects for the DOD, which they ultimately hope to deploy into their civilian manufacturing supply chains. Both the DOD's requirements for repeatability and usability, along with these firms interests in deployment within mature value chains, increase firms' motivation to engage in standards development processes.

5.7 Professional & Learned Societies

5.7.1 Society of Manufacturing Engineers (SME)

In 2008, the Rapid Technologies Additive Manufacturing (RTAM) community of the Society of Manufacturing Engineers took a leadership role to initiate a formal additive manufacturing standards development process that was inclusive both technologically and geographically. After discussions with a number of international bodies, the SME RTAM team selected ASTM International as the body with the most appropriate fit for these materials-related processing technologies at their particular stage of technological maturity. Towards the end of 2008, a small group of representative technology and industry experts met and identified four priority domains for AM-related standards development: Terminology, testing, materials, and process-specific specifications.

Within only a few months of the SME-ASTM engagement and prioritisation of standardisation needs, a group of over eighty expert representatives of both academic research and industry R&D met to form the ASTM International committee *F42 – Additive Manufacturing.*

5.7.2 Association of German Engineers (VDI)

Verein Deutscher Ingenieure (or VDI) is the largest Engineering society in Western Europe with a membership of almost 140,000 profession engineers, engineering academics and natural scientists. VDI Guidelines play a very important role within the German industrial-innovation system, and provide a platform for many international standardisation efforts. The VDI has a dedicated Technical Committee (FA105) for 'Rapid Prototyping / Rapid Manufacturing' chaired by Professor Dr.-Ing. hab. Gerd Witt. The committee aims to share lessons learned and knowledge related to technical progress on topics related to additive manufacturing technologies and rapid manufacturing processes through conferences and workshops as well as VDI Guidelines.

Existing VDI guidelines related to Additive Manufacturing include: VDI 3404 "Generative production methods - Rapid technologies (rapid prototyping) - basics, terms, quality parameters, delivery arrangements".

In addition to being of significant value to the German additive manufacturing community, efforts are ongoing to enhance and transform these guidelines into an international standard, as well as develop further technical standards in support of DIN and international efforts.

5.8 References

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6- Regenerative Medicine-based Tissue Engineering

Regenerative Medicine is a technology that "replaces or regenerates human cells, tissues or organs to restore or establish normal functions" and can address unmet clinical needs, especially in a context of ageing population. It covers a number of therapeutic applications: cell-based therapies, gene therapy, biomedical engineering and tissue engineering. This report focuses on this last category, with tissue engineered products (TEPs) being defined as products involving the growth and the seeding of cells on a supporting structure to form a piece of tissue or organ to be implanted into a patient body.

Tissue engineering presents some particular characteristics. The technology is developed in a highly regulated environment, it combines cellular and material components and possesses multiple application areas, and it faces important scale-up issues. The field has significant promises, including the creation of ex-vivo organ substitutes, but only a few TEPs, mostly bio-engineered skin products to treat burns or chronic wounds, have reached the market and are currently available for clinical use. Complex in both structures and functions, TEPs raise particular challenges in order to achieve their transition process "from bench to bedside" and deliver safe and effective therapeutic products which can meet regulators' approval. They have to demonstrate that they can be reliably and reproducibly made.

In this context, standardisation appears pivotal in enabling technology advances, from testing methods to characterization of the final product in vitro and in vivo, to make TEPs available and affordable to large patient populations.

6.1 Overview

This chapter contains an introduction to tissue-engineering reviews and describes key features of the policy environment and of governmental modes of engagement with standardisation activities, stressing upon initiatives and good practices of possible relevance for the UK innovation system.

It highlights some important aspects and emphasis regarding standardisation activities in support of tissue-engineering. They include:

- **Policy and governmental interest in standardisation activities** In a context of intensified competition for industrial activity, emerging technologies have been earmarked by governments to drive national economies as they offer important prospects for growth. With standards being recognised as possible enablers to emergence, standardisation activities have gathered a significant interest at the policy and governmental level. Measures and programmes have been adopted to foster standards development in support of emerging technologies.

- **Emphasis on national competitiveness** Combating rising healthcare costs and improving the quality of life in an ageing society are not the only points on governments' agenda. The development of a competitive tissue-engineering industry is also one of their declared goals, with funding programs aiming at bringing the emerging tissue-engineering technology over technical barriers toward commercialisation.

- **The relationship between regulation and standards** Regulation is one of the different factors which can affect the trajectory of new technologies. This has some implications from a standards perspective, with regulators having an interest in getting involved in standardisation activities and in using standards to achieve regulatory objectives.

- **Value of a strategy framework** Given the multi-actor nature of the technology emergence process, there is value in setting up a platform for relevant stakeholders to stay informed of each other's' activities and to better coordinate their efforts.

6.2 Introduction to Tissue Engineering & Standardisation

6.2.1 Introduction to Tissue Engineering

Tissue engineering is an emerging multidisciplinary field involving biology, medicine, and engineering that seeks to create, repair and/or replace tissues and organs by using combinations of cells, biomaterials, and/or biologically active molecules. It focuses on cures rather than treatment, and may dramatically improve the current methods of treatment of a number of medical conditions. Possible applications include repair of long bones, cartilage, connective tissue; replacement of worn and poorly functioning organs like liver, heart, pancreas, and kidney; and therapies for Alzheimer's and Parkinson's disease.

Providing more efficient and less expensive alternatives to tissue restoration, tissue engineering-based products (TEPs) are anticipated to participate to the reduction of direct hospital and medical costs as well as those costs associated with the long-term care of the ill or disabled. There is therefore a value for governments in accelerating the development of TEPs with a view to reducing health care costs but also to extending and improving life quality, especially for countries with an ageing population.

In addition to having a therapeutic application, tissue engineering can have diagnostic applications with tissue created in vitro being used for testing drugs. The foundation of tissue engineering, either for therapeutic or diagnostic applications, is the ability to exploit living cells for multiple application areas.

Tissue engineering includes the following therapeutic applications:

- Bioartificial liver device
- Artificial pancreas and bladders
- Cartilage
- Tissue-engineered airway and vessels
- Bioengineered skin
- Artificial bone marrow
- Artificial bone
- Artificial penis

As pointed out by one of the tissue-engineering stakeholders interviewed for this study, tissue-engineering has been emerging for “a long time”, with main hurdles to the field being the lack of appropriate measurement tools and standards to understand and predict complex biology.

6.2.2 Standardisation Process for Tissue Engineering: Rationale & History

In the US, standardisation activities are primarily driven by the private sector. In the case of TEPs, standardisation process for TEPs has been underway since 1997 within the Committee F04 Division 04 of the American Society for Testing and Materials (ASTM).

There had been early recognition that standards were needed to codify the tissue-engineering field and the standardisation process for TEPs has been underway within ASTM since 1997. It was triggered when a workshop sponsored by one of ASTM committees, the Committee F04 on Medical and Surgical Devices & Materials, took place. To this regard, ASTM played a decisive role in the emergence of the tissue-engineering community stakeholders.

Acting as a convening event for experts in the field, this workshop, which was focusing on the possible role of ASTM in tissue-engineering, provided an opportunity to discuss standardisation needs and challenges. It led some months later to the setting up of a new ASTM Committee dedicated to TEPs: the Committee F04 Division 04 which brought together 85 participants from academia, industry and Federal agencies and was further structured into task group activities.

In order to develop standards in a timely manner, ASTM Committee F04 conducts on a regular basis workshops and scientific conferences in areas identified as rapidly evolving and in need of standards. These events are meant to inform future standards development and, as pointed out by some experts, represent an interesting proactive initiative and “a unique opportunity for consensus standards to accelerate the product development phase and regulatory processes”. They also act as conveners of the community, involving ASTM, regulators and professional societies.

ASTM started by developing terminology documents to establish common and agreed definitions of terms while expert committees have been set up to develop standard guides and procedural standards in key areas. ASTM guides are aimed at a non-specialist audience in acknowledgement of the fact that tissue-engineering is a multi-disciplinary activity and are descriptive documents. They intend to expand the knowledge base of researchers and of the regulators regarding the different options which are available for assessing a number of characteristics of TEPs. For instance, they can list the advantages and limitations of a range of techniques. Some ASTM guides have started being translated into procedural documents known as reference materials.

To date, the ASTM Committee F04 Division 04 has played a leading role in the standardisation field for tissue engineering. In comparison, the German Institute for Standardisation (DIN) has been involved in fewer activities related to tissue engineering In Germany. Its involvement includes:

- mirroring the work undertaken by the ISO sub-committee on Tissue-Engineered Medical Products (ISO TC 150/SC7);

• holding secretariat of a number of CEN and ISO committees on topics of direct relevance to advance the tissue-engineering field (e.g. medical products utilising cells);

• funding a number of TEP-related projects through the Innovation with Norms and Standards (INS) program. For instance, one of the projects has been dealing with some preparatory work for the development of a standard covering the handling, risk assessment, marking and documentation of tissue-engineered implants. Some of the work conducted under the INS program led to the set up of an ISO working group under German chairmanship.

6.3 Coordination & Alignment of Federal Actors involved in Tissue-Engineering

In the US, the multiplicity of Federal departments, agencies and institutes involved in the development of tissue-engineering raised issues in terms of mission clarity and alignment of activities, including standards development. In this context, a Multi-Agency Tissue Engineering Science (MATES) Working Group was created in 2000 with a view to promoting awareness and coordination of Federal actors. The working group includes numerous participants and agencies, including: the Department of Commerce (NIST), the Department of Energy (DOE), the Department of Defence (DARPA), the Department of Health and Human Services (FDA, NIH), the National Aeronautics and Space Administration (NASA), the National Science Foundation (NSF), Department of Agriculture (USDA), Department of Veterans Affairs (VA), the Office of Science and Technology (OSTP).

MATES has been tasked with promoting communication across departments and agencies, monitoring technological advances in the field, enhancing co-operation through co-sponsorship of scientific meetings and workshops and facilitating the development of standards. To this regard, MATES has offered a “vehicle” for agency participation in standards development. For instance, the cooperation between NIST and the FDA which has been facilitated through MATES has resulted in several fruitful standards-related activities, like joint scientific meetings and workshops (e.g. FDA/NIST workshop on cell/scaffold products) and participation both in the ASTM’s efforts and in the USP’s Cell and Gene Therapy initiative to develop tissue engineering- related standards. Interestingly, numerous agency-related links on tissue engineering are posted on the MATES website, with among them the Tissue Engineering Medical Products (TEMPS) webpage which informs and provides updates on the ASTM standards development process.

6.4 Policy Environment & Government Engagement

6.4.1 US landscape

Regenerative Medicine-based Tissue Engineering has been earmarked by the US Government given its important prospects in terms of health benefits and in terms of industry growth and job creation. A report published in January 2005 by the Department of Health and Human Services (HHS) developed a vision for the field, aiming at engaging the Government and Federal agencies in a forward-looking approach to make regenerative medicine-based products a reality by 2020. Interestingly, the establishment of standards in support of regenerative medicine-based products approval by the Food and Drug Administration (FDA) is among the milestones which should have been reached by 2010.

The Regenerative Medicine Promotion Act of 2011 has launched a national strategy to support regenerative medicine-based products in the US. Measures include funding for research and commercial development as well as development of a regulatory environment that shortens time to market by enabling faster approval of safe and effective products. The Act asks for a review of the current standards portfolio for these products and for the identification of key domains for which standards are needed. NIST is specifically called for to develop standards. Further, under the last Commerce, Justice, Science Appropriations Bill, funding NIST has been recommended to expand laboratory initiatives that support core measurements and standards programs which are critical for innovation, competitiveness, and economic growth. Special emphasis was put on NIST's work regarding standards and measurement techniques in support of regenerative medicine technologies.

Many Federal departments and agencies are involved in the development of tissue-engineering through one or several of their units: the Department of Defense (DOD), especially but not only through its Defense Advanced Research Projects Agency (DARPA); the Department of Veteran Affairs which has developed a Rehabilitation Research and Development program and a Center for Restorative and Regenerative Medicine; the Food and Drug Administration (FDA), the National Aeronautics and Space Administration (NASA) and a number of National Institutes: National Institute of Standards and Technology (NIST), National Institutes of Health (NIH) and National Science Foundation (NSF). The multiplicity of Federal actors made necessary a coordination effort which led to the setting-up in 2000 of a Multi-Agency Tissue Engineering Science (MATES) Working Group (see section above for a more detailed presentation of MATES).

6.4.2 German landscape

In Germany, tissue-engineering technology has been earmarked in two successive policy papers as an innovation sector to support (namely, the High-Tech Strategy 2006-2009 and the High-Tech Strategy 2010-2013). The field has also been recognized as a funding priority by the Federal Ministry of Education and Research (BMBF), with an emphasis on developing an internationally competitive industry. 49 projects have been approved so far under the BMBF "Tissue Engineering" funding program for an amount of 21 million € out of a total of 35 million €. Some standards-related issues for tissue-engineered products are being addressed under the Innovation with Norms and Standards project funded by the Federal Ministry of Economics and Technology (BMWi) and managed by the German Institute for Standardisation (DIN). Federal funds are also used through the BMBF "Tissue Engineering" initiative to foster the collaboration between SMEs and scientists.

6.5 Engagement of regulators in the Standards Development Process

6.5.1 Development and adoption of standards

As a Federal Agency responsible for assessing the safety, effectiveness, and security of healthcare products, including biological products, the Food and Drug Administration (FDA) has an interest in supporting standards development for TEPs and has been active participant in the relevant ASTM Committee. A number of reports point to the fact the agency has been "instrumental in allowing products to move to market". For instance the FDA fostered the development of standards to measure devices. The involvement of FDA regulators in standards organisations like ASTM has been recognized of crucial importance by one of the tissue-engineering stakeholders interviewed in this study as it represents a way to “bridge possible gaps between documentary standards and FDA guidance documents like industry guidelines”, therefore facilitating the process of commercialisation.

It seems important to highlight that the development and use of standards are an integral part of the missions conducted by the FDA. Under the Code of Federal Regulation (Title 21), “FDA employees are encouraged to participate in outside standard-setting activities”. Further, FDA’s engagement with ASTM is consistent with the 1997 Food and Drug Administration Modernization Act (FDAMA) that contains provisions for standards development for device products. Under this Act, the regulatory agency has been further encouraged, where feasible, to select and to adapt consensus standards to achieve its regulatory objectives with a view to streamlining product approval.

FDA’s standardisation activities include matters such as the development of performance characteristics, testing methodology, manufacturing practices, product standards, scientific protocols, compliance criteria, ingredient specifications, labeling, or other technical or policy criteria. The three internal Centres of the FDA, namely the Center for Biologics Evaluation and Research (CBER), the Center for Drug Evaluation and Research (CDER) and the Center for Devices and Radiological Health (CDRH), participate in the development, and uses, of standards developed by outside organisations.

6.5.2 Multi-Center Fellowship in Regenerative Medicine

The FDA has also undertaken some efforts to extend and enhance its knowledge base and its ability to regulate TEPs through a Multi-Center Fellowship in Regenerative Medicine. Under this program which started in 2008 and focuses on regulatory issues, fellows are trained and participate in biologic and device regulation in the FDA internal centers responsible for over viewing tissue-engineered products.

One of the main objectives of the fellowship is to gain an understanding of and to participate in standards development activities, including with the Multi-Agency Tissue-Engineering Science Interagency (MATES) Working Group. Examples of projects under this program include the identification of standards gap in the pre-clinical and clinical review of TEPs and the identification of areas in the review process for TEPs that could benefit from additional standards. 50 fellows, with background in science, engineering, physics, are currently trained under this program.

6.6 Role of National Institutes

6.6.1 National Institute of Standards (NIST)

The National Institute of Standards (NIST) is a non-regulatory agency of the United States Department of Commerce. As a measurement standards laboratory, NIST develops, and supplies industry, academia and government with, products known as Standard Reference Materials (SRMs). SRMs are used to verify measurements’ accuracy and to support the development of new measurement techniques and methods in sectors like manufacturing, clinical chemistry, environmental monitoring, etc.

In May 2009, NIST issued its first SRM for tissue engineering, enabling research conducted in scaffold material. Interestingly, this SRM was the result of a multi-year collaborative work between NIST, the FDA, the National Institute of Health (NIH) and one of the ASTM Committee F04 working groups. Efforts from NIST researchers to develop assays and instrumentation are of particular relevance in fields like tissue engineering where issues around measurement are keys.

In conjunction with MATES, NIST sponsors on a regular basis topical workshops to identify areas where advances in measurement could enable tissue engineering research and manufacturing. For instance, in 2007, NIST co-sponsored with the FDA a workshop on cell/scaffold products to explore available test methods and to look into standardisation issues around the safety, purity, potency and consistency of cell/scaffold products.

6.6.2 National Institutes of Health (NIH)

The National Institutes of Health (NIH) is part of the U.S. Department of Health and Human Services. It is involved in standardisation activities in support of tissue engineering:

- Interesting approach: work as a follow-up of private initiatives from the Society for Biomaterials Devices and Materials, through its Biomaterials Standards Subcommittee and Tissue Engineering Special Interest Group (TE SIG)
- through MATES with NIH representatives from different divisions participating in this working group
- hESC (standards contained in the NIH & Academy of Sciences Amendment to the Guidelines for Human Embryonic Research).

Through one of its institutes, the National Institute of Biomedical Imaging & Bioengineering (NIBIB), it has also engaged in standardisation activities for tissue-engineered products. For instance, a call for proposals to address research challenges in tissue engineering was put forward in 2002 with a view to initiating a collaboration between biologists, engineers and clinicians and to tackling issues such as cell sourcing, cell identification and characterization for which the development of standards is key. Interestingly, NIBIB has also launched a Tissue-Engineering Program, known as the NIBIB TE Program, under which the Institute explores future opportunities in the field in collaboration with the research community. Initiatives under the NIBIB TE Program include the meeting between some NIBIB staff with key researchers in the field, taking advantage of a conference they were all attending to contact them. This proactive approach adopted by NIBIB reflects the efforts undertaken by the Institute to get input from the scientific community to shape their research agenda, including standardisation needs.

Another interesting initiative from NIBIB, even if implemented at a small scale, was launched in 2009 by one of the NIH institutes: the National Institute of Biomedical Imaging & Bioengineering (NIBIB). This initiative was aiming to foster the involvement of NIBIB-funded researchers in standards activities related to their current work. Under this participation program, supplemental funding could be allocated to support attendance and travel to meetings and to pay for time and efforts spent on drafting and reviewing standards documents, for instance. However, as pointed out by one of the tissue-engineering stakeholders contacted during this study, only a very small number of applications (less than 10) have been received by NIBIB.

6.6 Professional and learned Societies

- **Society for Biomaterials Devices and Materials**: this US professional society is interested in advancing all phases of material research and development and is engaged in standardisation activities to serve this purpose. Through its Biomaterials Standards subcommittee and its Tissue Engineered Products Special Interest Group, the Society has been contributing to the development of ASTM standards. It has also launched interesting initiatives, like the formulation of an approach to the standardisation of components of TEPs.

- **Pittsburgh Tissue Engineering Initiative (PTEI)**: PTEI is a not-for-profit organisation created in 1996 to foster the growth of a regional tissue-engineering industry by facilitating the commercialisation of technologies developed in university labs. Its work has helped establish Pittsburgh as an important hub of U.S. research and technology development in tissue engineering. Since its creation, PTEI has provided research funding, sponsored innovative professional training and education programs for scientists, students, and the general public. In terms of standardisation activities, PTEI has acted as a pioneer in the field, with some of its academic experts leading the way as early as 1997.

- **TÜV SÜD**: TÜV SÜD is a German Notified Body whose remit includes, among many other sectors, medical device conformity assessment. It provides testing, inspection, certification, knowledge services and training services. It is also involved in a number of standardisation activities, with TÜV SÜD experts presiding on international standardisation committees, like the ISO standardisation committees on Biological Safety and Cell-Based Medical Products.

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7. Smart Grid Technologies

'Smart grid technologies' is a collective term for those ICT-enabled automation and control technologies expected to underpin the next generation electrical power networks – creating utility electricity generation, storage and delivery-systems that are more 'intelligent' and consequently more efficient, reliable and secure. In particular, it is anticipated that these technologies will underpin a 'smart grid' of interoperable electricity networks that deliver electricity from a diverse range of power plants (including renewable energy sources) to consumers, reducing both carbon emissions and reliance on foreign energy sources. Smart Grid technologies play also a key role in supporting Smart City initiatives, with smart grid infrastructure development allowing for the improved and sustainable energy management called for in these initiatives.

Standardisation is considered critical to the success of the Smart Grid. Because of the highly complex system of devices, systems and infrastructure associated with the Smart Grid, as well as the large numbers of actors involved in its development and operation, standards will play a major role in supporting the interoperability and efficient integration between the different system elements, sub-systems and systems.

7.1 Overview

There are major 'Smart Grid' initiatives in both the US and Germany designed to modernize national electric power networks. These activities are being driven by a perceived urgency to enhance energy security and economic competitiveness, and to reduce in carbon emissions (through support of a transition to more renewable sources of energy).

The standards development environment for Smart Grids has a number of characteristics which distinguish it from those of many other emerging technologies, for example:

- the enormous technological system-complexity of the Smart Grid (and need for subsystem and device interoperability)
- the huge number of actors involved in the development and operation of the smart grid
- the potential added value of interoperability with civil infrastructure across regional and national boundaries
- the highly regulated nature of technology systems related to civil infrastructure, energy usage, carbon emission reduction and other environmental impacts
- the implications for energy security through diversification of national sources of power
- the consequences of greater ICT-enabled critical national infrastructure in terms of increased vulnerability to cyber attack

These factors have led to major coordinated efforts to efficiently develop Smart Grid standards that support interoperability, integration and security. Key observations to date regarding international approaches to standardisation of smart grid technologies include:

- **The role of governmental support and engagement:** Because of the multiplicity of regulatory issues, scale of public R&D investments, challenges associated with transnational integration, as well as energy and cyber security implications, governmental agencies have taken more proactive positions in mandating, coordinating and funding the development of smart grid-related standards
- **The importance of engagement with regulators:** Future smart grids must be compatible with a broad range of regulations, including those related to utility electricity generation and environmental impact (including CO_2 emissions). Early engagement with regulators in the standardisation process, including governmental encouragement for regulators to adopt developed standards, is critical
- **The value of technology stakeholder awareness and coordination:** Standards are only one aspect of a complex emerging smart grid development agenda. Standards development needs to take place within the context of the larger smart grid innovation system. There appears to be significant value in forums and stakeholder exercises which create awareness of challenges and opportunities, new smart grid developments, as well as coalescing around approaches to standardisation (e.g. through roadmapping, wiki-based community input, workshops at larger technology-based conferences)
- **The impact of a national lead coordinator:** Although private sector-led standards initiatives are critical to the success of the smart grid, the multiplicity of governmental stakeholders mean there is potential value in a lead government representative who can not only fulfill an 'honest broker' role, but can bring clarity about the roles, responsibilities and interests of participating government bodies
- **The high level of engagement by academic research community:** By contrast with the other case studies considered in this report, there are reportedly high levels of proactive engagement by academic researchers (e.g. IT, systems engineering and power engineering communities), enlarging the pool of standards development participants

This chapter contains an introduction to smart grid technologies, an overview of standards development activities for emerging Smart Grid technologies (and systems) in US and Germany, including brief summaries of some key national actors and initiatives, as well as particular insights and observations related to effective practices and lessons learned.

7.2 Introduction to Smart Grid Technologies and Standardisation

7.2.1 Introduction to Smart Grid

The national electrical energy systems of most major economies are facing increasing challenges and opportunities, including issues associated with: climate change, renewable energy, electric vehicles, energy security and cyber terrorism threats, increasing energy market liberalization and integration of international energy markets.

Much national infrastructure supporting utility energy networks have not yet fully integrated modern information and communications system technologies. Many energy generation and distribution systems are still relatively isolated and inefficient. Advances in ICT and sensor technologies offer the potential to more fully optimize the efficiency of complex grid systems, building in 'intelligence' to better monitor and control network activities through more effective two-way flow of electricity and information between power plants and consumers, with benefits including:

- enhanced storage capacity and distribution efficiency (through more efficient generation during variable usage periods)
- improved power reliability and resilience to disruption (through 'predictive and automated maintenance' and 'self-healing')
- increased deployment of renewable energies from novel, often distributed, power sources (and consequent reductions in carbon emissions and oil consumption)

Although there are variations in the definition and emphasis of what constitutes smart grid technologies, most stakeholders identify a common range characteristics [NIST, 2011], including: the increased use of ICT and control systems technologies; the dynamic optimization of grid operations and resources; the integration of distributed energy sources; the use of 'smart' technologies (for metering, automated distribution, etc); 'smart' devices (in businesses and homes); the deployment and integration of advanced storage systems. And, critically, the ***development of standards*** for interoperability of devices and equipment connected to the electric grid, as well as the infrastructure underpinning the grid itself.

7.2.2 Importance of Standards Development for Smart Grid Technologies

Central to addressing the demand for linking novel distributed system technologies, devices and equipment within a national energy infrastructure is the ***interoperability*** of the system elements developed by a range of stakeholder and manufactured by a large number of firms. This challenge can only be addressed by the systematic and collective development of standards.

Smart grid standards experts consulted for this study, highlighted this issue by pointing to lessons learned from the recent histories of other highly networked emerging technologies, notably wireless telecoms. In particular, it was emphasized that that interoperability standards are essential to ensure that public and private sector technology development investments do not occur in isolation, with the risk of wastefully creating system technologies that are incompatible.

In this context, experts highlighted the value of efforts to increase awareness and alignment between all stakeholders to ensure that the standards development process is appropriately systematic (i.e. not 'ad hoc') and that resulting standards are capable of underpinning the interoperability of a range of systems, subsystems and devices. It was also stressed that while interoperability standards for technologies, devices and systems are necessary, they are not sufficient and other types of standardisation and quality assurance (e.g. conformance testing and certification) are also important.

7.2.3 Stakeholders in the Smart Grid Standards Development Process

The development of standards for the 'Smart Grid' involves a large and diverse range of stakeholders from national and international organisations, from multinational companies and small- and medium-sized enterprises ranging from major utility firms to appliance to consumer electronics providers, and a range of other organisations including professional engineering societies and federal and regional regulators. The US National Institute for Standards & Technology has illustrated this scale and diversity of stakeholders in a schematic illustrated the many complex relationships and interactions and flows of information and energy.

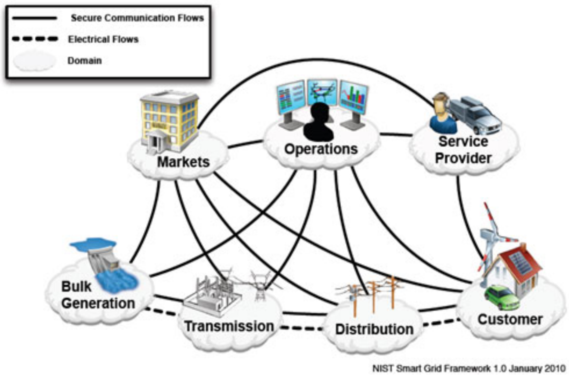

Figure 6.1: Smart Grid domain actors [NIST, 2010]

7.2.4 Comparison of National Smart Grid Standardisation Landscapes

7.2.4.1 The US Smart Grid Standardisation Landscape: Some Key Features

There are a number of factors which characterise and distinguish the US 'Smart Grid' technology development and standardisation landscape:

- **Scale and complexity of the US utility energy network:** The US 'national' grid is fragmented to extraordinary degree, with over 3000 utility firms alone.
- **Number and diversity of standards development stakeholders:** The variety of standardisation stakeholders in the US include groups such as:
    - Standards Development Bodies: ANSI, etc
    - Federal technical agencies: NIST, DOE, DOD, etc
    - Firms: Utility firms, equipment and device manufacturers, software firms, etc
    - Profession and industry associations: IEEE, ASHRAE, NEMA, etc
    - Regulators: Federal Energy Regulatory Commission (FERC); the Environmental Protection Agency (EPA); and the Federal Communications Commission (FCC)
    - State governments
- **High priority of government:** The US federal government has made the development of a US 'Smart Grid' a high priority as a piece of critical national infrastructure with the importance of the smart grid (*and* associated standards development) enshrined in a major piece of legislation, accompanies by significant investment – over $4.5B of direct federal funding to match private sector funding
- **The role of federal agencies:** Federal mission and regulatory agencies e.g. Department of Energy, the Federal Energy Regulatory Commission play a significant role in a variety of smart grid-related initiatives. The National Institute for Standards & Technology, in particular, playing a critical coordination role (mandated by Act of Congress)
- **Professional and industry associations:** The US is home to a number of important professional associations and industry bodies (and associated conferences) which play an active role in the development of smart grid-related standards, including areas where standards development organisations may not yet be active, thus creating a platform for more effective (and efficient) development of formal standards by SDOs

7.2.4.2 The German Smart Grid Standardisation Landscape: Some Key Features

There are a number of distinct factors which characterise the German 'Smart Grid' innovation and standardisation systems:

- **Role of Central Government:** Driven by Federal Ministry of Economics and Technology: Maintain and expand the leading role of German science and industry in the field of energy generators, network equipment, control systems and technologies – opportunities associated with new technological and industrial domains in the overlapping sectors of ICT and energy technology.
- **"Internet for energy" ICT Emphasis**: Much of the 'smart grid' discourse in Germany refers to an 'internet for energy' - an information structure similar to the internet flexible generation, distribution storage and use of renewable energies will be based on. As with the internet, this new information network has implications for cyber security and privacy and consequent need for regulation, legislation and public acceptance.
- **European Context.** Deepening of European integration of European energy markets. Mandate M/490 of the European Commission designed to develop or update a set of consistent standards within a common European framework
- **Competitiveness of German manufacturing focus:** There is more direct emphasis within the German policy discourse on smart grid technology development (and standardisation) on supporting the competitiveness of German firms operating in this domain. It is the German Federal Ministry of Economics & Technology (BMWi) funds the 'E-energy / Smart Grids' funding programme, which has the declared goal of maintaining and expanding the leading role of German science and industry in the field of energy generators, network equipment, control systems and technologies**.**
- **Connecting R&D investments to standardisation efforts:** There is significant emphasis in Germany on ensuring major e-Energy R&D programmes inform smart grid standards development and vice versa. The development of practical standards to ensure interoperability is a particularly important aspect of the E-Energy / Smart Grid projects. The *E-Energy Expertise Centre* of the DKE was specifically set up to act as an interface between Federal BMWi-funded smart grid-related R&D projects and related standardisation initiatives led by DKE.
- **Role of Professional Societies:** The German Commission for Electrical, Electronic & Information Technologies (DKE), an organisation run jointly by the Association for Electrical, Electronic and Information Technologies (VDE) and DIN run a *Center of Excellence standards E-Energy/Smart Grids* the central body for all matters of standardisation on E-Energy in Germany

7.3 Government Engagement & Policy Environment

7.3.1 The US Energy Independence & Security Act (EISA)

Title XIII of the Energy Independence and Security Act of 2007" sets forth the policy of the U.S: "to support the modernization of the nation's electricity transmission and distribution system to maintain a reliable and secure electricity infrastructure." The Act further stipulates initiatives for government programs to undertake in smart grid investments, including coordinated research, development, demonstration, and information outreach efforts. EISA also mandates particular roles for federal mission agencies, in particular: NIST, the Department of Energy, and the Federal Energy Regulatory Commission (FERC).

EISA specifically references NIST-identified standards both in the context of standards that FERC may consider for adoption and also as potential evaluation and investment criteria for DOE technology development grants.

7.3.2 Intra-Governmental Coordination: The US Federal Smart Grid Task Force

The Federal Smart Grid Task Force[2] is led by the US Department of Energy's 'Office of Electricity Delivery and Energy Reliability' (OE). The Taskforce include experts from a range of other Federal departments and agencies (including the Departments of Commerce, Defense, Homeland Security, State and Agriculture, National Institute for Standards and Technology) as well as regulatory bodies (including the Federal Energy Regulatory Commission, Environmental Protection Agency, Federal Communications Commission). Its mission is to ensure awareness, coordination, and integration of the diverse activities of the Federal Government related to Smart Grid technologies, systems, applications, services and practices.

7.3.3 The German E-energy / Smart Grids Programme

'E-energy / Smart Grids' is a funding programme of the German Federal Ministry of Economics and Technology (BMWi) Driven by Federal Ministry of Economics and Technology: Maintain and expand the leading role of German science and industry in the field of energy generators, network equipment, control systems and technologies. Because of the role of smart grid technologies in advancing the deployment of renewable energies and enhancing of energy efficiency, the programme is funded in collaboration with the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety (BMU).

Following an open competition the BMWi funded six 'model projects' exploring a whole system approach, covering all energy-relevant economic activities including technical and market challenges. By 2012, the selected model regions are expected to have developed proposals to the point of readiness for marketability testing and launch. Because of the highly complex system nature of 'E-Energy' technologies, the development of practical standards to ensure interoperability is a particularly important aspect of the E-Energy / Smart Grid projects.

In addition to the project funding directly available through the 'E-energy / Smart Grids' programme, the BMWi also encourages related research addressing strategic Smart Grid-related challenges, including the standardisation of Smart Grid system 'open interfaces'.

7.3.4 The German National Smart Grid Standardisation Strategy

The German strategy for national Smart Grid Standardisation is led by DKE - the German Commission for Electrical, Electronic & Information Technologies. DKE convened academic researchers, other technical experts and stakeholders including: regulators (e.g. BNetzA 'Federal Network Agency' – the German regulatory agency for electricity and other utilities), the Federal Ministry of Economics and Technology (BMWi), as well as energy utility firms, equipment vendors, and the German

[2] *Task force stablished under Title XIII of the 'Energy Independence and Security Act' (2007).*

Institute for Information Technology (OFFIS). In addition to analysis of existing national and international studies and roadmaps related to smart grid, as well well as engagement with international initiatives, the strategy development process include a number of couple tasks focused on German industry and society:

- Pre-Study used to solicit feedback and comments from the general public and a diverse range of national stakeholders
- The development of German e-Energy Standardisation Roadmap

7.4 Federal Government Agencies

7.4.1 US Department of Energy

- **National Renewable Energy Lab**
  The Department of Energy's National Renewable Energy Lab carries out a range of research and development activities related to 'Smart Grid' technologies, systems and standards. NREL also hosts a national database of Smart Grid and government-sponsored projects on the **SmartGrid.gov** website - a national information portal about the Smart Grid and government-sponsored Smart Grid projects. The information on SmartGrid.gov is intended to help consumers, large and small technology firms, equipment manufacturers, utility companies and other stakeholders understand the key issues related to the Smart Grid and related technologies, practices and socio-economic benefits.

- **Office of Electricity Delivery and Energy Reliability**
  The Office of Electricity Delivery and Energy Reliability (OE) of the US Department of Energy has national leadership role in the delivery of the smart grid in the United States. OE works with stakeholders from industry, federal agencies, academia, and state governments to modernize the US utility electricity delivery system. OE works with these stakeholders to identify R&D priorities that address barriers, opportunities and challenges to the emergence of smart grid technologies in the United States – not only technological challenges, but also issues associated with business models, regulation, policy, and socio-economic impact.

- **Federal Smart Grid Task Force**
  Key activities of the OE include its leadership of the Federal Smart Grid Task Force. This Task Force promotes awareness, coordination, and alignment of Federal activities relevant to the successful emergence of the smart grid technologies. The group includes expert representatives from both federal government departments (e.g. Commerce, Defense, Homeland Security, etc), as well regulators (e.g. the Federal Energy Regulatory Commission, Environmental Protection Agency, Federal Communications Commission, etc). The OE identifies a range of activities critical to the successful emergence of the US smart grid, including: Smart grid R&D, demonstration and deployment activities; R&D; Interconnection planning; Workforce development; Stakeholder engagement and outreach; Monitoring national progress, and – critically – '*Interoperability and Standards'*. The OE-led task force highlights the importance of a smart grid interoperability development process that ensures flexible, technology-neutral standards that support private sector innovation and consumer choice. In this context, interoperability and standards activities refer not only to technical

information standards but also encompass related business practices and processes, and account for the necessary engagement with the national and state-level regulatory environments.

7.4.2 US National Institute of Standards & Technology

The National Institute of Standards and Technology (NIST) plays a critical role in the emergence of the 'Smart Grid'—convening key stakeholders including equipment manufacturers, consumers, energy providers, and regulators to develop 'Interoperable standards'. NIST plays "honest broker" role, working collaboratively with private sector firms as well as a range of governmental agencies, academia and regulators. The 2007 Energy Independence and Security Act charged NIST with "primary responsibility to coordinate development of a framework that includes protocols and model standards for information management to achieve interoperability of smart grid devices and systems."

NIST Smart Grid Programme

The National Institute for Standards and Technology, based on its EISA mandate to help support the coordination of smart grid standards development, developed a plan for Smart Grid Program to engage the broader community of Smart Grid stakeholders, including activities such as:

- Hosting public workshops involving stakeholders and standards-setting organisations;
- Convening a 'Smart Grid Interoperability Panel' (SGIP) – a consensus-based body to coordinate the development of standards;
- Hosting a smart grid 'wiki' portal for the exchange of information among SGIP members and other technical experts; as well as an online solicitation of input from the public to inform the consumer interfaces aspects of Smart Grid
- Developing a roadmap for smart grid standards to help guide and align the development of interoperability standards
- Developing guidelines for Smart Grid cyber security;
- Identifying 'foundational' sets of standards for Smart Grid interoperability

7.5 The Role of Professional Societies in Smart Grid Standards Development

7.5.1 The IEEE

Although IEEE is a fully international professional engineering association with members in over 160 countries, it still has a strong US centre of gravity (reflecting its origins as the American Institute of Electrical Engineers). The IEEE is headquartered in New York City and over half its members are based in the United States. The engineering and technical expertise within the IEEE's professional, academic and corporate membership across the entire spectrum of technical domains relevant to smart grid – including IT, control systems, networking, cyber security, sensors, metering, power engineering, renewable energy technologies. This enables the Institute and its members to play a range of roles in standards development.

IEEE is participating in a number of US and international smart grid activities, in particular the IEEE is playing an active role in the initiatives of the NIST, but is also collaborating with global standards bodies to facilitate coordination and impact. IEEE has more than 100 standards and/or standards in development which are relevant to the smart grid [IEEE, 2011]. Several of these standards are explicitly cited within in the NIST 'Framework & Roadmap for Smart Grid Interoperability Standards' [NIST, 2011].

7.6 Smart Grid Stakeholder Community Coordination, Awareness & Alignment

7.6.1 Technical conferences

Similar to practices associated with other emerging technologies considered in this study, there appears to be significant added value in standards development workshops which are "woven" into larger technology meetings, at which a broader range of technical and regulatory stakeholders are participating. For example, representatives of Federally-convened initiatives related to standards development for smart grid actively participate in events such as:

- GridWeek - : http://gridweek.com/2011/
- ConnectivityWeek: http://www.connectivityweek.com/2011/
- Grid Interop: http://www.grid-interop.com/2011/

7.6.2 Smart Grid Wikis

- **NIST Smart Grid Collaboration Wiki:** As part of its Smart Grid initiative on interoperability standards, NIST hosts a 'Smart Grid Wiki' – a website for the extended smart grid community to enable stakeholders to work with NIST and contribute content towards the development of a standardisation framework. The NIST wiki also acts a webportal giving access to technical documents created by working groups and committees under the guidance of the Smart Grid Interoperability Panel.
- **Smart Grid Information Clearing House Wiki:** In 2009 the US Department of Energy invested in a 'Smart Grid Information Clearing House' – a website portal website designed to provide information to the public and firms regarding the entire range of smart grid initiatives occurring nationwide [SGIC, 2011]. The 'Clearing House' is managed by and run from the Virginia Tech Advanced Research Institute in collaboration with the IEEE Power & Energy Society and the EnerNex Corporation. The website contains a range of information including a searchable database of SG-related standards, but also information about demonstration projects and case studies (including lessons learned and best practices), as well as information about policies and regulations, and advanced topics covering emerging technology R&D breakthroughs

7.6.3 Roadmapping

- **The German E-Energy / Smart Grid Standardisation Roadmap**
  The roadmap is also intended as a basis for a German position within national and international standardisation development activities. It also provided an opportunity to feed the knowledge generated by the e-Energy R&D projects into the standardisation development process. The German E-Energy / Smart Grid Standardisation Roadmap was developed in consultation with the researchers and stakeholders involved in the E-Energy projects. The Roadmap is designed to identify which relevant standards already exist and makes prioritized recommendations regarding standardisation gaps which need to be addressed. The roadmap focuses on standardisation issues associated with priority domains

for relevant German manufacturing sectors and the national energy strategy. These domains include: power system management, electricity storage, distributed generation systems, safety and security, automation technology, smart meters and home automation systems.

- **NIST Roadmap for Smart Grid Interoperability Standards**
  In 2008 NIST commissioned the Electric Power Research Institute (EPRI) to engage with a broad spectrum of stakeholders within the US smart grid innovation system in the development of a draft standards roadmap for a US smart grid. This ultimately formed the basis of NIST interim roadmap for Smart Grid interoperability standards. EPRI technical staff gathered inputs from hundreds of stakeholders through a range of sources including to public workshops, NIST's smart grid expert working groups and the cybersecurity coordination task group. NIST released version 1.0 of its 'Framework & Roadmap for Smart Grid Interoperability Standards' in 2010. Among other things, this document included: a 'conceptual reference model' for the Smart Grid; identified 75 existing standards that were likely to be relevant and applicable; specified 15 high-priority gaps and 'harmonization issues' for new (or revised) standards; developed action plans for nominated standards-setting organisations (SSOs) to address these gaps. Version 2.0 of the 'Roadmap' was released late in 2011.

7.7 Standards Stakeholder Community Coordination: The role of National Standardisation Coordinator

Stakeholders participating in the development of smart grid standards in the US are careful to emphasize the lead role of the private sector and the importance of voluntary standards to the success of the smart grid. Nevertheless, there is also recognition that the multiplicity of governmental stakeholders (including those from regulatory bodies and federal mission agencies), there an important role for government. More specifically, there seemed to be significant agreement about the value a lead Federal government representative who can not only fulfill an 'honest broker' role, but can also bring clarity about the roles, responsibilities and interests of participating governmental bodies.

In particular, several US stakeholders pointed to the role of the NIST-based 'Smart Grid National Coordinator', Dr George Arnold. Some of those interviewed pointed to the Dr Arnold's career history and highlighted the importance of his very particular expertise and experience in terms of how he was able to command trust, respect of the different public and private sector smart grid community members. Not only did Dr Arnold have senior roles in important standards-related bodies (e.g. IEEE, ANSI, and ISO), but had significant technical credibility from his time at Bell Laboratories addressing analogous telecoms network systems interoperability challenge and associated standardisation issues.

7.8 Industry Associations & Smart Grid

- **The National Electrical Manufacturers Association**
  The National Electrical Manufacturers Association (NEMA) is the US-based trade association of choice for the electrical manufacturing sector. The association has 450 member firms involved in manufacturing equipment and systems used for electricity generation,

transmission, and distribution. NEMA was specifically named in the US Congress 'Energy Independence and Security Act' as a participant in efforts to develop a 'smart grid'. NEMA is also an active participant in a range of standards development initiatives. NEMA publishes over 500 standards, application guides, white papers, and technical reports [NEMA, 2011].

- **UCA International Users Group**

  UCA International Users Group is a not-for-profit organisation made up of utility firms which have a common goal to advance the interoperability and integration of electricity and other utility systems through the use of standards-based technologies. The UCA Users Group works on areas of firm interest where standards development bodies may not yet be active or where the interests of members goes beyond currently identified standards – for example: user guides, industry education, marketing support, identification of user needs and proof of concept demonstrator opportunities) [UCA, 2011].

- **The Federation of German Industries**

  The Federation of German Industries (BDI) is an association of industry associations representing 38 different sector bodies which in turn collectively represent over 100,000 large, medium-sized and small enterprises. In 2006, the BDI launched its 'Internet of Energy' initiative, which aimed to identify, in close cooperation between industry and academia, priority issues to support the development of the smart grid. At the top of the BDI Internet of Energy 'Catalog of demands' was a set of priorities related to standardisation, including:
  - Harmonization and integration of existing standards and protocols
  - Extending the standardisation efforts to gas, heat and water
  - Coordinated promotion of interoperability
  - Open communication standards for new technologies

7.9 National Standards Institutes

- **ANSI**

  ANSI members support the national smart grid initiative and the Smart Grid Interoperability Panelled by NIST. For example, the American Society for Heating, Refrigeration, and Air-Conditioning Engineers (ASHRAE) and the National Electrical Manufacturers Association (NEMA) are both members and accredited standards developers of ANSI. These organisations have collaborated together to develop standards under the national Smart Grid initiative – the *Facility Smart Grid Information Model*, designed to "define an object-oriented information model to enable appliances and control systems in homes, buildings and industrial facilities to manage electrical loads and generation sources in response to communication with a 'smart' electrical grid and to communicate information about those electrical loads to utility and other electrical service providers."

- **The German Institute for Standardisation (DIN)**

  In addition to its engagement in smart grid standards development activities through DKE, DIN has a range of activities related to the Smart Grid, for example:

- **DIN's Standards Committee for Information Technology and Applications (NIA)** set up a working group (JTC1/WG7) to support the development of an international standard for *'Sensor networks and their access to the Smart Grid'*.
- **The DIN INS programme** funds relevant projects, e.g. 'Distributed grid support'
- **Cooperation with DKE on the Center of Excellence standards E-Energy/Smart Grids** – an organisation that acts as the interface between smart grid-related R&D projects and national standardisation efforts.

7.10 The National Research Base: Engaging Researchers in Standards Development

By contrast with research communities associated with emerging technologies considered in this report, large sections of the Smart Grid related research community are relatively proactive in their engagement with standards development. For the ICT and computer science 'cyber' research community, the smart grid is an invaluable testbed for ICT-enabled control system theories and systems. Furthermore, resurgence of interest in power engineering driven in part by renewable energy research community motivated to ensure their technologies are adopted within the grid.

Research-Standardisation Interfaces: Center of Excellence standards E-Energy/Smart Grids

The German E-Energy Expertise Centre of the DKE *('Kompetenzzentrum Normung E-Energy/Smart Grid')* specifically acts the interface between smart grid-related R&D projects and standardisation. The E-Energy Expertise Centre is also the central contact for all matters of standardisation on E-Energy in Germany, including: optimization, networking, control systems, 'intelligent' generators, storage, network equipment, consumer systems and devices that are supported by ICT – i.e. 'e-energy / Smart Grid'.

The centre has a range of activities related to smart grid and the coordination of standardisation, not only coordination of standardisation related to smart grid, intelligent power supply system development, but also endeavours to anticipate and address standardisation issues at an early stage in the emergence of novel smart grid-related technologies as innovative results emerge from the national e-energy projects and other federal research. The competence center helps connect a national (and international) interdisciplinary network of experts in domains related to the Smart Grid and e-energy. It also endeavours to communicate information regarding international standardisation activities to Smart Grid stakeholders within DKE and other German organisations

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8. Synthetic Biology

Synthetic biology is a rapidly emerging area of biological research. It aims to develop engineering principles for biology in order to design and build biological components and systems which display new functions that do not exist in nature. It is also concerned with gaining a better understanding of the fundamental properties of living organisms. Potential applications of synthetic biology are vast and could have an impact on medicine/health, energy, environment, chemicals and materials.

Based on the creation and integration of a large variety of components into a larger system in order to create new and more complex structures and functions, standardisation of parts and interfaces is a key issue to advance the field.

8.1 Overview

Both the US and German Federal Governments are actively involved in funding research supporting the development of synthetic biology. Their increasing interest in the field in the last 6-8 years has been driven by a perceived necessity to explore the new opportunities offered by this field in order to establish leadership, with huge economic benefit especially in the energy sector and chemical industries, and to benefit society.

The standards development environment for synthetic biology has a number of distinctive characteristics, for example:

- the very early stage and amorphous (not completely defined) character of the field
- the application of engineering principles to non-engineering based research areas
- the multiplicity of expertise needed (from mathematical modeling and IT science to advanced molecular biology and chemical engineering…)
- the necessary pooling of research activities
- the multiple application areas (biofuels, drug synthesis, food, new materials, environmental technology…)
- biosafety and biosecurity concerns related to biological safety, potential misuse and bioterrorism

Several key themes regarding international approaches to standardisation of synthetic biology have emerged throughout the interviews and research conducted for this report. They include:

- **The high level of engagement by the research community:** Evidence gathered in this report points towards a proactive involvement of researchers in standardisation-related issues, with pioneering initiatives leading to registries of standardized biological components
- **The engineering dimension of the discipline:** Synthetic biology, by relying on the application of engineering principles to biology, necessarily involves issues in terms of standardisation; with emphasis being put on registering and characterizing biological parts, developing assembly, interface and performance standards and finding standardized ways to handle and transfer data.

- **The open source approach:** In contrast to the traditional use of intellectual property rights to protect biotechnology innovation, an “open source” approach has been so far mostly adopted by researchers in the field of synthetic biology. This approach is expected to allow for a “public commons” of parts and to foster the development of a community of biological engineers.
- **The value of discussion forums and convening stakeholder exercises:** Given the very diverse research communities involved in synthetic biology and the importance of standardisation issues in the field, there seems to be significant value in wiki platform for sharing standard biological parts and foresight initiatives to support debates about standardisation-related issues and put these issues in perspective.

This chapter contains an introduction to synthetic biology, an overview of standards development activities for synthetic biology in the US and Germany as well as particular insights and observations related to effective practices and lessons learned.

8.2 Introduction to Synthetic Biology and Standardisation

8.2.1 Introduction to Synthetic Biology

Synthetic biology has the potential to address some of the major challenges raised by climate change, healthcare delivery, energy security, food availability and environmental sustainability. The field is still at an early stage of development but applications are expected to come to market within a few years.

Synthetic biology is expected to lead to an important diversity of applications and to provide benefits in numerous areas, which include:

- Health, with the development of biotechnological production of medicines, customised vaccines and targeted medicines
- The environment, with the development of environmental cleansers like air and wastewater purification
- Energy, with the development of new biofuels, derived from microorganisms, plant or animal material (biomass), as clean energy substitutes for fossil fuels
- Agriculture, with the development of feed- and food additives, fertilisers and pesticides

At this early stage of development, synthetic biology is not considered as posing threats fundamentally different from those caused by traditional biotechnology. The Bioethics Commission of the President of the United States, which developed in 2010 a number of recommendations for a responsible development of synthetic biology, regards as sufficient current regulations and guidance, including standards, which apply to research, workplace, environmental risks, and in some cases pre-market review of safety and efficacy for new products. However, in the longer term, the field raises issues in terms of biosafety and bioterrorism and new safety standards may need to be developed. The National Institute for Health, with its recent promulgation of a widely agreed on industry standards on Biosafety in Microbiological and Biomedical Laboratories (known as BMBL) establishing specific procedures for laboratory safety, has already started amending some of its guidelines to encompass synthetic biology.

8.2.2 Importance of Standards Development for Synthetic Biology

Although the boundaries of the field are still evolving, a core definition of synthetic biology refers to the introduction of engineering principles and concepts into biology. They include: "ready access to off-the-shelf parts and devices with standard connections; a substrate onto which one can assemble the parts and devices and a power supply for the devices; standards for the basic components to enable their ready integration into a larger functional system; and open-source availability of parts, devices, and chassis"[3].

Central to enabling these different features is the development of assembly and measurement standards. But also, as highlighted by the synthetic biology experts interviewed for this study, there is a need to go beyond these standards. Standards for handling, storing, displaying and transferring data on biological parts are also considered as key to advance the field.

8.2.3 Stakeholders in the Synthetic Biology Standards Development Process

People interviewed in this report and literature point towards the key role played by researchers from academia and industry in developing standards for synthetic biology. They highlight the need for intensive interactions and dialogue between the scientific communities, people from industry and standards development organisations. In this context, governmental institutions' involvement could be to act as facilitator or moderator.

8.3 Government engagement and Policy Environment

8.3.1 Role of Federal Agencies in the USA

The interest of the US Government in synthetic biology has been increasing, with public funding for synthetic biology projects amounting to more than $430 million since 2005. Standardisation aspects are explored in some of the projects.

- **National Institutes of Health (NIH)**

Synthetic biology has been earmarked as a "NIH Challenge and Grand Opportunity". The NIH has awarded approximately $108 million in grants for work in this area, with some of this work looking into standards-related issues like the development of standards for handling data about biological systems. Additionally, the NIH has reviewed the biosafety standards of its guidelines for research involving synthetic biology.

- **National Science Foundation (NSF)**

Since 2006, NSF has funded a total of approximately $72 million in research associated with synthetic biology. NSF is also funding the Synthetic Biology Engineering Research Center (SynBERC) through its Engineering Research Center Program. SynBERC is a multi-institution research institute based in California which involves public and private partners and which explores, among other topics, the standardisation of biological components and systems. For instance, SynBERC devices working group has been exploring standards for measurement and characterization of standard biological parts.

- **Department of Defense (DOD)**

[3] See SynBERC homepage on http://www.synberc.org/about

In May 2011, the Defense Advanced Research Projects Agency (DARPA) launched the Living Foundries program. This program is about the development of new tools and technologies to transform biology into an engineering practice and deals with some standardisation issues as it aims to address "design and automation tools, modular genetic parts and devices, standardized test platforms and chassis, …"

- **Department of Energy (DOE)**

Standardisation issues are being considered by the DOE Joint BioEnergy Institute (JBEI). Created in September 2007, this Institute has been tasked with exploring the biological mechanisms underlying biofuel production so that those mechanisms can be redesigned, improved, and used to develop novel, efficient bioenergy strategies.

8.3.2 Federal led programmes in Germany

The synthetic biology community is relatively small in Germany, even though it has been growing during the last 4/5 years. In 2006, only one German team participated in the International Genetically Engineered Machine Competition (iGEM); in 2011, there were nine German teams.

- **Federal Ministry for Education and Research (BMBF)**

BMBF is very active in the field, with the strengthening of the national research base as a key goal. Through the promotion of international cooperation between systems biology centers (mainly located in Germany, in the UK and in the Netherlands) and of standardisation activities, BMBF has fostered the development at the EU level of some worldwide leading integrated systems biology programs.

Under the BMBF biotechnology programme, emphasis is being put on combining innovation with social responsibility. To this regard, BMBF has funded the "Engineering Life" project, which looks into the ethical, philosophical and theological implications of synthetic biology, and the SynBio TA (Innovation and Technology Analysis of Synthetic Biology) project, which adopts a technology foresight approach to identify the risks and opportunities related to synthetic biology.

In order to support the development of biotechnological processes over the coming 10 to 15 years, BMBF has embarked upon a strategic planning entitled Biotechnology 2020+. In July 2010, around 200 experts met in a conference to discuss and identify the main milestones in support of the next generation of biological processes and develop a roadmap. 200 experts from government, industry and the research base, many of them representing major German research organisations (the Helhmoltz Association, Max-planck Society, Fraunhofer Society and the Leibniz Association) and universities, agreed that the integration of biotechnology and engineering would likely be the key driver of the field in the future. Piggybacking the conference, a lecture symposium on synthetic biology took place to further inform on technological aspects and opportunities of the field. In July 2011, at the second annual Biotechnology 2020+ conference, experts got together to reflect on the progress accomplished. Interestingly, emphasis was put on the importance of research communities and SMEs as key drivers of the innovation process.

Focus has also been by BMBF put on enabling technologies for synthetic biology, like systems biology which deals with the integration of complex data about interactions in biological systems.
Computational model used in synthetic biology can be encoded using the standard formats

developed for systems biology. BMBF recognized the potential of the field at an early stage and developed a funding program entitled «Systems of Life – Systems Biology » to support it. For instance, the HepatoSys Competence Network, which focuses on the development of standards and methods to produce a virtual liver cell is part of this funding program. Other funding measures are aimed at establishing research centres with a view to pooling the interdisciplinary expertise needed in systems biology. Four research centres have been launched since 2007 with the participation of Länder. From a standards perspective, the Heidelberg Institute for Theoretical Studies organised in September 2011 a meeting of the Computational Modelling in Biology Network (COMBINE). This recent international initiative, set up in October 2010, is dedicated to the development and the improvement of interoperability standards. It addresses concerns in the field that standards for systems biology largely depend upon the activity of individual scientists and that they may be at risk if one of those leading individuals were to cease their activities. It also aims to foster harmonised standardisation activities.

- **German Research Foundation (DFG)**

On the basis of a joint 2009 position paper on the opportunities and risks of synthetic biology, the Deutsche Forschungsgemeinschaft (DFG, or German Research Foundation) considers synthetic biology a funding priority and is planning to invest approximately $3.5 million in the field. It has funded the cluster of excellence "Centre for Biological Signalling Studies" at the University of Freiburg whose research areas are partly related to synthetic biology. It has also funded one Emmy Noether Scholar in the field of synthetic biology.

8.4 Engagement of the national research base

Standardisation activities in support of synthetic biology have been mostly launched by the research communities, with the US currently leading. Among the initiatives these communities have embarked upon, it is worth mentioning:

- **The BioBricks Foundation (BBF)**

The BioBricks Foundation is a US nonprofit organisation which has been created by the Massachusetts Institute of Technology (MIT). BBF has developed a repository of standardised biological building blocks (BioBrick parts) and aims to promote the open development of biological technology. It has established itself as the world leader in developing and promoting technical standards for synthetic biology parts.

Even though its coverage is limited at the moment, it is very active. BBF plays a key convening role between the experts involved in synthetic biology through sponsorship of events such as international conferences which draw hundreds of participants.

The BBF is currently refining a technical standards framework and process for synthetic biology based on BioBrick™ parts. Four standardisation areas have been earmarked by BBF:

- physical assembly standard,
- reference standards for making measurements,
- functional composition standards,
- data exchange standards.

- **The Synthetic Biology Institute at UC Berkeley (SBI)**

It was established in 2010 to investigate ways for a widespread production of new biological systems to benefit society. Through the combined effort of its researchers, partners and industry members, SBI is developing standards and advancing research to engineer cells and biological systems. The new institute – aiming to create "an industrial revolution in biological engineering" – is launching a collaborative effort with Agilent Technologies, a leader in measurement technologies and products to advance science and engineering research. Agilent helped initiate SBI research with a multi-year, multi-million dollar commitment, including early access to new technologies through the active participation of the company's research scientists and engineers.

- **The Knowledgebase of Standard Biological Parts (SBPkb)**

The Knowledgebase of Standard Biological Parts (SBPkb) is a publically accessible Semantic Web resource for synthetic biology which allows researchers to query and retrieve standard biological parts for research and use in synthetic biology. It includes all the information about parts stored in the Registry of Standard Biological Parts (see above) and transforms this information so that it is computable, using a standardised semantic framework for synthetic biology parts. It aims to improve the distribution and exchange of descriptions of biological parts.

8.5 Standards Development Organisations

As pointed out in the previous section, standardisation activities related to synthetic biology have been mostly led by the research community. However, there has been some involvement from standards development organisations like ASTM. Within its Committee E48 on Biotechnology, which includes manufacturing products using living organisms in the process, issues in terms of identification of biological materials, GMP process validation, biosafety risks and process equipment design, are being addressed. Committee E48 has membership from industry, research institutions, government and academia and has engaged in some cooperative work with other countries like Japan, Netherlands, and Germany.

About 40 standards have been published by Committee E48, with many more currently under study. Standards have been in development for:

- Manufacturing Process Control - Facilities
- Bio-Safety - Biomass
- Environmental - Terminology
- Validation - Biological Systems Characterisation
- Equipment - Materials
- Standards for Materials, Products, Systems and Services and the Promotion of Related Knowledge

8.6 Coordination and Foresight exercises

- **EU-US Task Force**

An EU-US Task Force on Biotechnology Research was jointly established in June 1990 by the EU Commission and the US Office of Science and Technology Policy with a view to promoting information exchange and coordination between biotechnology research programmes funded by the EU Commission and different US funding agencies. As an initiative of this task force, a workshop was held in June 2010 and specifically tackled standards development issues for biological functions. The participants, 24 senior scientists from the US and the EU, decided on the establishment of a Synthetic Biology Working Group focusing as a priority on standardisation needs in the coming years.

- **The TESSY project**

"Towards a European Strategy in Synthetic Biology" (TESSY) is a 2 year research project which started in January 2007 and was funded within the New and Emerging Technologies (NEST) pathfinder initiative launched by the EU Commission. Its aim was to develop European synthetic biology by identifying areas for future applications and defining measures in support of research and development. The project included a roadmapping exercise in which standardisation-related issues emerged as one of the key issues to be tackled, with participants advocating the development of standards in a number of consecutive steps.

8.7 Industry Associations and Professional Societies

Synthetic biology is still at an early stage of development and not many industry associations or professional societies seem to be active in the field. Among synthetic biology related organisations which have developed an interest in standardisation activities, it is worth mentioning:

- **The International Association Synthetic Biology (IASB):** IASB is based in Heidelberg (Germany) and was founded by a consortium of biotech companies. It represents providers, users and consumers of synthetic biology and is engaged in the development of best practices and standards.

- **The Institute of Biological Engineering (IBE):** IBE is a US professional organization which supports the development of biological engineering through scholarship in education, research and service; meetings between academia, industry and government; development of professional standards for engineering practices, etc.

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9. Practices accounting for standards development

Standards are only one aspect of an emerging technology development agenda. Because of the complex, dynamic and multi-actor nature of the technology emergence process, there can be significant value in exercises and practices which raise awareness among all the different innovation system's actors about standardisation needs, opportunities and challenges.

Such exercises not only help the various communities -industrial, technical, academic, regulatory, and governmental- share a vision but also coalesce around approaches to standards development and therefore result in an acceleration of standardisation processes.

It can also assist in highlighting potential co-evolution and alignment issues which arise between the different innovation system's dimensions during technology emergence. It can therefore inform government's strategies which need to identify those instances where it needs to take a leadership, coordinating or convening role in standardisation activities.

9.1 Overview

Throughout this study, several experts have pointed to the value of holding forward looking stakeholder workshops as a complementary process to standards development activities. Such roadmapping-style exercises can take a variety of forms with different levels of emphasis on standards, with standards-related issues as explicit dimensions of the roadmap or as aspects emerging during the discussion.

Key observations include:

- **The different roles played by roadmapping-style exercises:** Roadmapping-type activities can be "informative" and of educational value by creating awareness and leveraging the knowledge base among stakeholders regarding different standards-related issues. They can also be effective in supporting alignment among innovation system actors, common vision around standards needs and strategic approach to standards development.
- **The value of community building:** Because of the multi-actor nature of the process of technological emergence, standards involve various innovation systems' actors and there can be significant value in endeavours that make stakeholders coming together as a community and solicit input from them (e.g. through preparatory work and submission of working papers to shape workshops'agenda). Further, the collective and cooperative nature of roadmapping-style activities enhances networking opportunities.
- **The importance of an integrating framework:** The journey from emerging technology to commercialization is a multi-dimension and evolving process in which standardisation represents only one factor. There is therefore an interest in acknowledging the standards dimension within a broader emerging technology-related "roadmap" or "innovation framework" to integrate standardisation issues into a larger perspective including science evolution, technology applications, manufacturing issues, systems engineering, manufacturing aspects, etc.

This chapter contains an introduction to foresight and roadmapping exercises as well as a presentation of several roadmapping-type activities reported on in the case study chapters. It explores effective practices, potential limitations and highlights a number of learned lessons.

9.2 Introduction to roadmapping

Technology roadmapping is widely used within industry and has proved to be a useful foresight exercise for helping managers develop a vision and support strategic planning for their company. It offers a structured, and often visual, means for exploring in a dynamic way the challenges and the commercial opportunities associated with the development of a technology over time. Being based on a collaborative and participative process, roadmapping also allows for community building and can create common awareness among stakeholders regarding various issues.

Process inspired from technology roadmapping has also proved useful in the context of policy-making, with governments, funding agencies, research institutions and standards organisations having to deal with science and technology developments in a strategic way in order to capture value and foster national competitive advantage. In this context, roadmapping activities have been increasingly applied in support of regulation and standards development:

- to identify needs and challenges,
- to gain a forward view of the desirable regulatory/standards pathway,
- to plan regulatory/standards developments informed by technology evolution.

From an innovation process perspective, standards can assist in tracing emergence and evolution of scientific and technological fields. As potential indicators of the extent to which an evolving industrial community feels the need to coordinate, they may also offer a milestone of the maturity of a new industry.

9.3 Towards a European Strategy in Synthetic Biology (TESSY) project

9.3.1 Context and motivations

The TESSY project was funded within the New and Emerging Technologies (NEST) pathfinder initiative launched by the EU Commission. It was aiming to give an outlook on future perspectives in synthetic biology and to provide information to the EU commission and to member states, assisting national policymakers in shaping their innovation policy regarding synthetic biology and was involving a roadmapping exercise. The project lasted from January 2007 to December 2008. It encompassed 4 work packages, among which a roadmapping exercise.

9.3.2 Lead convener

TESSY was initiated and coordinated by one of the Department heads of the Fraunhofer-Institute Systems and Innovation Research (FH-ISI), Dr Thomas Reiss and two of his colleagues. It was carried out by a consortium involving the Fraunhofer, the European Science Foundation, the Albrecht-Ludwig University Freiburg, and the ATG biosynthetics GmbH.

9.3.4 Format of the roadmapping process

The roadmapping process was triggered by an initial one-day workshop “piggy-backing” an international symposium on synthetic biology, the SB3.0 conference carried out under the auspices of the BioBricks Foundation. A limited number of participants (i.e. 10), representing different actors of the innovation system (academia, industry and funding organisations), were personally invited to form an advisory board to discuss the activities, trends and perspectives of the field. At this stage, standards were already mentioned as one of the issues to tackle even though this point, which was reached in a consensus, was made among many others. Based on the output of this workshop, the TESSY project team drafted an initial roadmap.

9.3.5 Stakeholders

An online survey was developed to get experts' views on the relevance of the different milestones presented in the initial roadmap and on possible additional trends and/or milestones. 588 experts were identified from the broader synthetic biology community and invited to participate in the survey, with the possibility to co-nominate several colleagues and have them participated as well. Additionally, the online survey was promoted at two international conferences. Interestingly, a feature in the online survey allowed the participants to get their own "personal roadmap" populated with the information they were providing.

Being knowledgeable about standards was not one of the criteria adopted to select the experts. However, as researchers involved in the iGEM competition were targeted among the people to invite and as iGEM competition put an emphasis on the importance of standardised parts and interfaces, those experts coming from this background brought interesting knowledge about standardisation issues. People with a pure biological background were much less familiar with standardisation issues and, to this regards, the TESSY roadmapping exercise fulfilled an educational purpose. This can be seen as especially important as synthetic biology involves the application of engineering principles to biotechnology, often in an open innovation context, and calls therefore for the adoption of a standardized approach.

9.3.6 Outputs

A revised roadmap was developed, based on the survey results (see figure 3). Standardisation-related issues were consolidated within the regulation dimension of the roadmap, with four consecutive phases being identified:

- Phase 1: standards for reporting
- Phase 2: standards for methods and components
- Phase 3: general standards for all –omics approaches[4]
- Phase 4: standards for the underlying mathematics

[4] General term referring to a broad field of study in biology, ending in the suffix -omics such as genomics, proteomics or Interactomics, with omes being the objects of the study (for instance, genome or proteome)

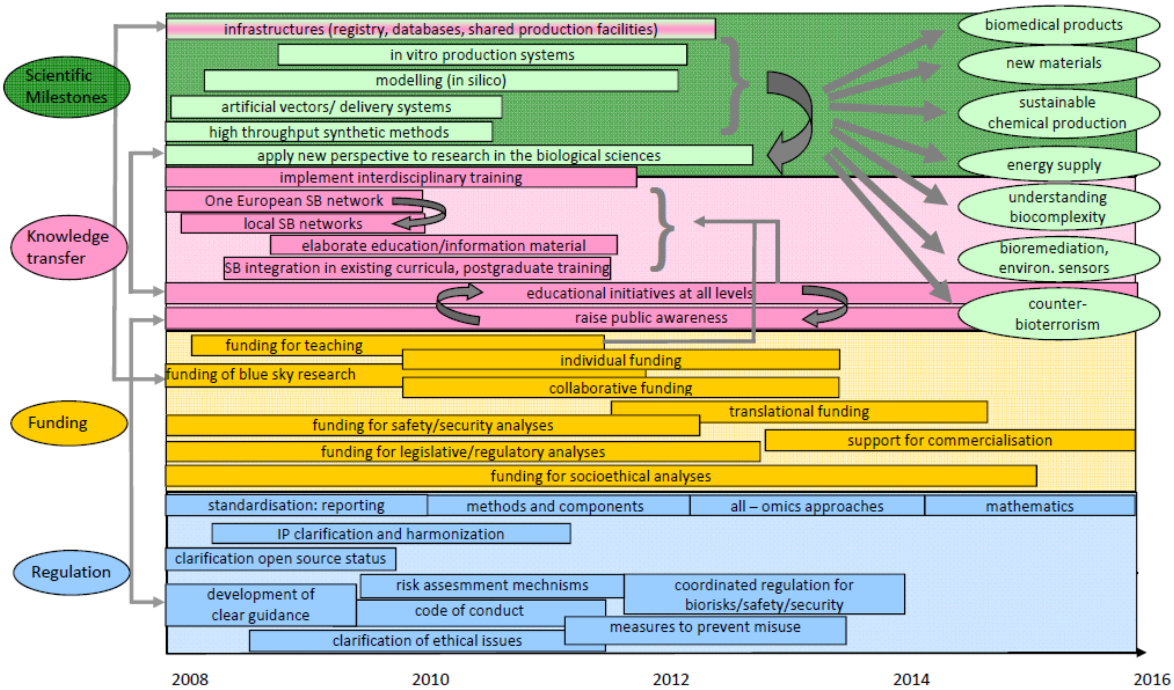

Fig. 3: Roadmap towards successful synthetic biology
(source: TESSY project, 2007)

9.3.7 Good practices and learned lessons

Among the learnt lessons, when asked about potential aspects of the roadmapping exercise which could have been done differently or improved, interviewees highlighted two points:

- The lack of time to develop a more detailed roadmap, for instance: the regulation dimension could have been more populated with further indications about the different types of regulation and standards and the ways in which they interplay
- The adoption of an EU centric approach, excluding from the roadmap activities and initiatives coming from the US, Brazil, Japan, …

9.4 NIST Framework and Roadmap for Smart Grid Interoperability Standards

9.4.1 Context and motivations

Under the Energy Independence and Security Act (EISA) of 2007, the National Institute of Standards and Technology (NIST), the Federal Energy Regulatory Commission (FERC) and the Department of Energy (DoE) are being mandated particular missions to modernize the nation's electricity infrastructure. EISA specifically tasks NIST with supporting the coordination of smart grid standards development but without granting any funding to the Institute.

In collaboration with DoE, NIST created several working groups using resources across the Institute and outreaching to members from the smart grid community. This phase can be considered as a very initial preparatory phase of the NIST roadmap exercise. With smart grid being earmarked as a priority by the Obama administration and a $4,5 billion stimulus dedicated to implementing part of the smart grid initiative, focus was put on the insufficient development of appropriate standards. A decision was reached by Congress, the Secretariat of Energy and the Director of NIST to accelerate standards development in support of smart grid. A team, led by George Arnold, was established within NIST.

9.4.2 Lead convener and format of the roadmapping process

To develop its Framework & Roadmap for Smart Grid Interoperability Standards, NIST convened a series of workshops in 2008 and 2009 to get input toward this framework. Its aim was to accelerate the identification, and coordinate the development, of the standards necessary to achieve the interoperability and integration of devices and systems in support of a smart electric grid. Three types of workshops were set up: some were carrying a standards inventory; some were looking into "use cases" (case studies) and some were organized around each of the PAPs with NIST ensuring that experts from standards development organisations were represented in each group. It was at that time that George Arnold developed the 3-phase plan which has been used as guidance for NIST's work in the smart grid area.

9.4.3 Stakeholders

The workshops brought together experts and stakeholders from a number of different communities including government, industry, research, insurers… The setting of a 'Smart Grid Interoperability Panel' (SGIP), a consensus-based body to coordinate the future development of standards, was already in NIST's plan as a follow-up of the workshops. The Institute was therefore willing to involve key categories of stakeholders in this series of workshops, particularly targeting people who had already participated in standardisation activities. An ambitious invitation list was put together. It included experts identified in the Energy Independence and Security Act (EISA), standards development organisations relevant in the field and personal contacts of George Arnold. It was further extended to industry people after a high-level meeting with George Arnold at the White House with the Secretary of Energy, the Secretary of Commerce and more than 60 CEOs, the latter agreeing to devote time's staff to NIST initiative.

9.4.4 Outputs

NIST released version 1.0 of its 'Framework & Roadmap for Smart Grid Interoperability Standards' in 2010 reported on the progress made up to that time. This document identified 75 existing standards that were likely to be relevant and applicable. Version 2.0 of the 'Roadmap' was released in February 2012. This new document detailed progress made in the second and third part of the NIST's three-phase plan, with the second part dealing with the work accomplished by the Smart Grid Interoperability Panel (SGIP) and the third part concerned with creating a conformity testing and certification infrastructure (see Figure 4).

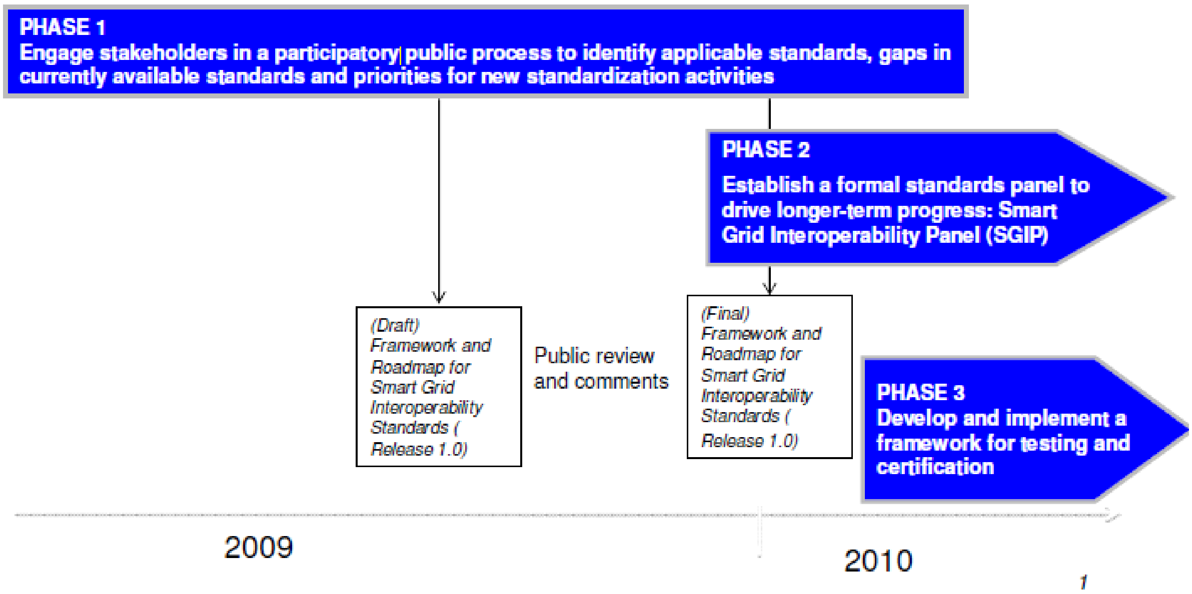

Fig.4: NIST role in smart grid development and three-phase plan
(source: George W. Arnold, 2011)

Further outputs of the NIST includes the development of several Priority Action Plans (PAPs) which define 15 high-priority gaps and 'harmonization issues' for new (or revised) standards and coordination plans with standards-setting organisations (SSOs) to address these gaps, the setting up of the Smart Grid Interoperability Panel, a conceptual reference model (describing the interactions between the different smart grid stakeholders), a table detailing the domains and actors of the conceptual reference model and a Testing and Certification Framework.

NIST roadmap has also resulted in a collaborative process which engages not only smart grid stakeholders in identifying potential interoperability standards but also FERC in reviewing these standards for adoption. Even though the first families of standards identified by NIST as being ready for consideration by regulators have not been adopted by FERC, there is an explicit endorsement of the NIST process by the regulatory commission. Indeed, FERC encourages "utilities, smart grid product manufacturers, regulators and other smart grid stakeholders to actively participate in the NIST interoperability framework process".

9.4.5 Good practices and learned lessons

NIST initiative has forced several industry sectors to work together. This allowed for an acceleration of the discussion and a sharing of lessons learned in different industries. It has also exposed regulators to technical standards, whose level of details was new to them. Used to dealing with high-level standards, this exposure had an educational value in their case.

NIST initiative also illustrates a possible mode of governmental engagement, with NIST taking temporary leadership to convene an emerging and very diverse community with a view to accelerating standards development and advancing the modernization of the national electricity infrastructure. Very illustrative of this "temporary" stance is the public-private nature of SGIP which is meant to turn into a more private entity with government as one among several stakeholders.

9.5 Multi-Agency Tissue Engineering Science (MATES) Interagency Working Group

9.5.1 Context and motivations

MATES is a platform set up in 2000 across which federal agencies involved in tissue science and engineering stay informed of each other's activities and coordinate their efforts. This coordination effort was rendered necessary due to the multiplicity of Federal departments and agencies involved in the development of tissue-engineering (see table 1)

Strategic Priorities (c=contributor of basic tissue science and engineering knowledge; u=user of tissue science and engineering knowledge)								
Agency *Mission relevance*	1. Understanding the Cellular Machinery	2. Identifying and Validating Biomarkers and Assays	3. Advancing Imaging Technologies	4. Defining Cell/Environment Interactions	5. Establishing Computational Modeling Systems	6. Assembling and Maintaining Complex Tissue	7. Improving Tissue Preservation and Storage	8. Facilitating Effective Applications Development and Commercialization
DOD *Engineering, battlefield applications*	u/c	u/c	u/c	u/c	u	u/c	u/c	u
DOE *Imaging technologies, in vivo gene assays*	u/c	u/c	u/c	u/c	u/c			
EPA *Molecular, cellular & computational approaches for prioritizing and screening chemicals for toxicity*	u/c	u/c	u/c	u/c	u/c			
FDA *Regulation of diagnostic and therapeutic products*	u/c	u/c	u	u/c	u	u/c	u	u/c
NASA *Engineering, in-space technologies*						c		
NIH *Biomedical applications*	u/c	u/c	u/c	u/c	u/c	u/c	u/c	u/c
NIST *Measurement science, standards, and technology*	c	c	c	c	c			
NSF *Fundamental science and engineering*	c	c	c	c	c	c	c	c
CMS *Health care payer*		u	u	u		u	u	u

Table 1: Roles of Agencies in Strategic Priorities
(source: MATES, 2007)

MATES' approach shares a number of common characteristics with roadmapping: convening aspects, vision, strategic plan, tackling of co-ordination and alignment issues.

MATES' main mission has been to promote awareness and coordination of Federal activities relevant to the successful emergence of tissue-engineering technologies, with "promoting the formulation of standards for the development of products based on tissue science and engineering "as one of its explicit goals.

9.5.2 Format of the forward looking process

From a practical viewpoint, MATES has developed a portal for all stakeholders wanting to gain an understanding of the field. The idea was to establish a "one-stop-shopping" website with information about a large range of issues and topics: from federal funding to technical workshops and regulatory guidance/ standards development.

9.5.3 Outputs

A major output from MATES was the publication in 2002 of the World Technology Evaluation Center (WTEC) study on tissue engineering. It was a comparative review of tissue engineering research and development activities in the United States and a number of other countries. It was summarizing the state-of-the art regarding tissue-engineering technologies and paid a special attention to the legal and regulatory issues associated with tissue engineering research and applications. This study acted as a convening task for all the agencies and institutes participating in MATES and its results, integrated in MATES's strategy, led to a joint interagency program.

Another major output from MATES had been the strategic plan it defined and published in 2007. In this plan were not only identified the "overarching strategic goals for tissue science and engineering" but also defined the role federal agencies could take in advancing this field, with an emphasis being put on potential for concerted approaches.

9.5.4 Good practices and learnt lessons

Under certain circumstances, there can be a need for an instance to play an "honest broker" role to facilitate the involvement of different agencies and departments and to help develop a common strategic vision. To this regard, OSTP seems to have played a significant role in driving the MATES process. For instance, it supported the change of the MATES initial action plan, mostly descriptive, into a much more strategic document, with identification of key goals to advance the field. OSTP played also a role in encouraging collaborative work between measurement scientists and other groups to work toward developing standards in various relevant fields.

8.6 "Roadmap for Additive Manufacturing (RAM) Workshop: Identifying the Future of Freeform Processing"

9.6.1 Context and motivations

The meeting of researchers in additive manufacturing at an international conference, the 2008 Solid Freeform Fabrication Symposium, to discuss the future of the field under the auspices of Office of Naval Research (ONR) officials triggered the setting up of the Roadmap for Additive Manufacturing (RAM) Workshop. At this conference, leading experts, namely Professors Bourell, Leu and Rosen, discussed about and agreed on an idea to hold a dedicated workshop to advance their field. Even though they were not collaborating in research, they were familiar about each other's work.

The objective of the workshop was to develop and articulate a roadmap for research in the area of additive manufacturing (AM) for the next 10-12 years, with identifying high potential priority R&D areas to accelerate the deployment of freeform manufacturing technologies and processes into the marketplace as a focal point.

9.6.2 Lead convener(s)

Pr. Bourell, Leu and Rosen's initiatives were decisive in making the RAM Workshop happen. They approached NSF and ONR with a proposal to receive some funding and obtained $60k. They also dealt themselves with some very practical workload, from arranging for venues and meals to contacting participants individually and getting the keynote presentations, etc.

9.6.3 Format of the roadmapping process

The workshop combined keynote briefing presentations, breakout groups and long slots for discussion (see figure 5). Keynote presentations gave a state-of-the art of additive manufacturing, developed a vision for the 10-12 coming years and highlighted obstacles to overcome in order to achieve this vision. Discussions in breakout groups focused on seven different topics:

- Industry targets
- Goals and barriers
- Design and analysis
- Processes and machines
- Materials and processing
- Nano/biotechnologies
- Energy and sustainability

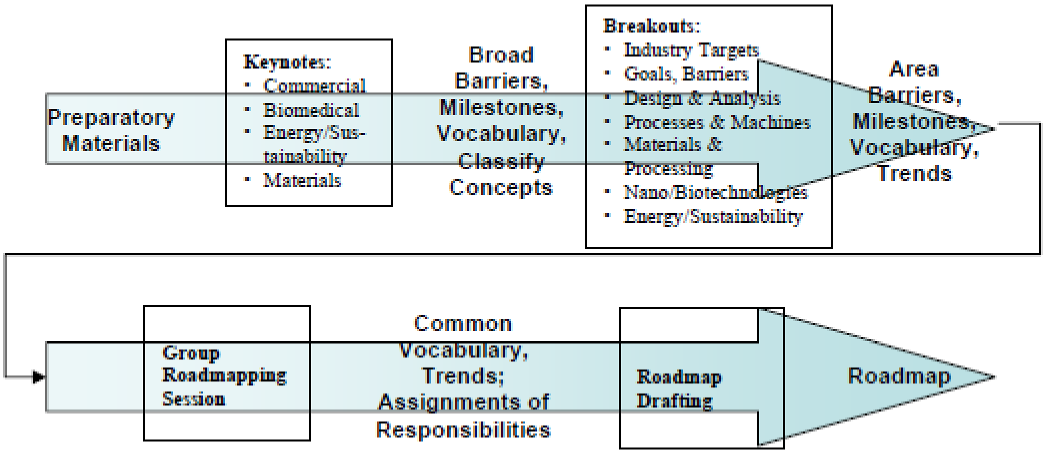

Fig. 5: Activities and Information Flows at the RAM Workshop
(source: RAM Workshop Report, 2009)

Interestingly, some preparatory work was asked from the participants who were invited to submit two-page white papers prior to the workshop on what the future of AM might be and how research might impact the path to that future.

9.6.4 Stakeholders

As pointed out by Pr. Bourell, selecting participants was a very difficult task. It was undertaken collaboratively by the three professors. The idea was to have represented leaders in all aspects pertaining to research (academics/educators, academics with strong company formation skills, industry, government labs, AM machine builder executives, parts builders, parts customers, software developers, artists, etc.) while observing some geographical representation and technical areas identified as important. Several foreign experts were invited to provide a "sanity check "on the effort. Some areas were difficult to populate, like sustainability-related issues, because at the time there were very few AM researchers in this domain. The decision was made to contact experts in sustainability who were not AM experts but whose knowledge could be applied to AM manufacturing processes. Representatives from US government science, health, defense and aerospace R&D agencies were also among the participants. In total, the workshop brought together 65 persons, among whom historic innovators in terms of research and technology transfer.

9.6.5 Outputs

Discussion in each breakout group was encapsulated and fed into a summary report of the workshop. This report has been mentioned as a motivation for research in journal articles (19 citations on Google Scholar) and proposals for future research. There was also some hope from the organizers that it would serve as a blueprint for federal agency topical funding calls.

The posting of the report at the Wohlers Associates' website, a consulting firm that provides technical and strategic advice on the new developments and trends in rapid product development and additive manufacturing, has provided it with further visibility among a broader community.

9.6.6 Good practices and learned lessons

Although the RAM workshop was not standard-focuses, it produced greater awareness and clarity among a broad spectrum of stakeholders around the critical role of internationally recognized product, process and material standards. The event helped the AM community realize the need for standardization to facilitate growth by simultaneously increasing consumer confidence while controlling manufacturer cost.

From a practical perspective, bidding for some public funding forced the organizers to develop a very structured and detailed proposal which proved very useful in the following organization and execution phases.

The significant discussion time between keynote talks, as long as or longer than the presentation itself, provided a very good opportunity for synergistic discussions.

Making breakout session and workshop leaders stay one full day after the meeting to write a chapter embodying the discussions, ensured that was the subject matter was reported on in an accurate and timely manner.

9.7 References

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10. Concluding Observations

In this final 'Concluding Observations' chapter, we highlight some important emerging technology standardisation themes that arose from interviews with international experts, SDO and Federal agency officials in the US and Germany; as well as from reviews of published strategies, reports and analyses carried out by standardisation stakeholder organisations.

There is increasing recognition among many innovation system stakeholders in the US and Germany of the potentially critical role standardisation can play in supporting the emergence of new technologies. There is growing governmental interest in ensuring an effective national standardisation system to support economic competitiveness and growth in emerging technology-based industries. There is also a related policy interest in better understanding the appropriate roles of government (and Federal agencies) in standardisation – not least to ensure value is captured from public sector investments in technology R&D. There is also increasing awareness that there is no 'one size fits all' approach to standardisation of emerging technologies. Different technologies will have different standardisation needs involving different combinations of stakeholders at different phases of technology and industry lifecycles. It is, therefore, critical to have processes which convene the right mix of stakeholders to support awareness, alignment and consensus building at the right phases of emergence. In this context, there are increasing efforts to find appropriate ways to engage the public sector research base in standardisation at earlier phases in an emerging technology's lifecycle, with a view to obtaining early competitive advantage for national firms in emerging high value industries. These themes are discussed in more detail below.

1. **Importance of standardisation to support emerging technologies:**
   There is increasing recognition among many US and German industrial bodies, innovation agencies and regulators about the potential influence of standards on innovation, productivity and growth within key emerging technology domains.

- **Evidence from existing studies and practice:** There is growing body of insight into the role of standardisation in technological emergence from a range of policy studies, academic literature, governmental R&D strategies, stakeholder consultation exercises , etc (see Section 1.3). In particular, there is growing recognition that standards can significantly influence practices associated with research, development, design, manufacturing and market development; and consequently influence innovation, productivity and growth within key emerging technology domains [for example: Tassey, 2000; Blind, 2010].
- **Analysis and insights from this study:** Innovation activity related to those emerging technologies selected for this study also point to increased interest, awareness and efforts to address the evolving standardisation needs of emerging technologies in a timely and systematic way. In all cases, there was strong stakeholder support for the need for standards initiatives in the selected emerging technologies. The importance of standardisation emerged from a range of stakeholder technology development strategy exercises (e.g. 'roadmapping') and is reflected in stakeholder participation in standards development

2. **Governmental engagement & supportive policy environment**
   Building on increased policy interest in emerging technologies as a source of future industries, economic competitiveness, growth and employment, the role standardisation plays in supporting this agenda is also receiving increased governmental attention.
   - **Policy interest in ensuring standardisation systems works for emerging technologies**: Evidence of increased policy interest in national standardisation systems comes not only from government commissioned reports and analyses (discussed in Section 1.3 and elsewhere), but also from novel governmental practices, programmes and initiatives. For example, in 2010 the US Federal Government for a Subcommittee on Standards within the National Science & Technology Council **–** a forum for senior officials of Federal agencies to address standards-related issues, with particular focus on responsive and timely coordination of governmental standards-related activities; increasing awareness of effective practices and the role of standardisation in both enabling technology development and governmental procurement needs. In Germany, the importance of standardisation (as well as a range of standards-related issues, challenges and opportunities) features prominently throughout the *High Tech Strategy for Germany* [BMBF, 2010]. The Federal government's intent to ensure a more systematic approach to integration of standardisation processes within the German innovation system is also illustrated by new Federally-backed initiatives, for example the TNS ('Transfer of R&D Results Through Standardisation') and INS ('Innovation with Norms and Standards') programmes operated by the German Institute for Standards (DIN).
   - **Policy interest in role(s) of governmental agencies in standards development:** The growing policy interest in standardisation (of emerging technologies) is accompanied by increased attention paid to the different roles of governmental agencies. A recent US study [NIST, 2011] explored stakeholder perspectives on the effectiveness and potential functions of governmental agency participation in standards development in emerging technology areas of critical national importance. This study solicited input from a broad range of stakeholders and provides offers specific recommendations to enhance Federal agency standards development engagement practices. In Germany, the '*Standardisation Policy Concept'* [Bundesregierung, 2009] of the Federal Government advocates a concerted and systematic approach to standardisation, with attention paid to the particular standardisation aims and measures implemented in each governmental department, as well as coordination across Ministries and agencies.
   - **Standardisation and effective allocation of public technology R&D investment:** One particular policy interest in standardisation is its potential to minimise the allocation of the technology R&D investments to contradictory research agendas by supporting consensus and alignment between participating emerging technology stakeholder communities [Blind, 2010]. This appears to have been an important motivating factor in, for example, the US government's proactive role in supporting standardisation development activities for smart grid technologies (see Section 4.2.2).

3. **Difference standards for different phases of technological emergence:**
   There appears to be significant consensus that a lack of standards at key phases in an emerging technology's lifecycle can potentially result in large economic inefficiency [Tassey, 2000]. Although the innovation trajectories of emerging technologies are typically highly non-linear,

there seems general acknowledgement that there are evolving levels of emphases on different types of standards at different phases in the emergence of a new technology, with typically more attention to terminology and semantics standards in the earlier stages, followed by efforts to address materials testing and measurement standards, then interface and interoperability standards, and eventually standards associated with quality, compatibility and variety-reducing endeavours [Blind, 2009]. This sequence of emphases is broadly reflected in histories and current standardisation efforts associated with the emerging technology domains explored in this study: Early additive manufacturing efforts addressing terminology and testing, tissue engineering efforts now more focused on measurement and characterization standards, while smart grid standardisation efforts (partly reflecting smart grid's system-complexity) have a particular emphasis on interoperability. Awareness of the need for a more tailored approach to standards development for emerging technologies at different phases of maturity is reflected in national programmes, for example the German Standard Institute's suite of mechanisms for supporting standards development needs throughout a technology's lifecycle from early research phases to market maturity (see Section 3.2.1).

4. **Different standardisation approaches for different technologies:** Range of factors that influence the different trajectories of new technology emergence and associated evolving standards development needs. Factors include: Multiplicity of stakeholders; societal infrastructure; degree of regulation, system complexity of application; multiplicity of competing technological approaches; multiplicity of application domains; interest and investment of Federal mission agencies (e.g. Departments of Defence, Energy, etc). These factors can have a significant influence on which organisations are most appropriate to lead, fund and convene standards development activities at different phases in the life-cycle of an emerging technology.

5. **Convening the emerging technology stakeholder community – creating awareness.** Standards are, of course, only one aspect of complex emerging technology development agendas. Consequently, there can be significant value in endeavours that create awareness among all innovation system actors – industrial, technical, regulatory, and governmental – regarding standardisation issues, opportunities and challenges. This process can be enhanced by fully exploiting a range of initiatives and activities, including: satellite events associated with major technical conferences (especially those attended by a broad range of stakeholders, see for example Sections 6.6.1 and 4.3.2), wiki-style information-sharing and input-solicitation 'portals' (e.g. Section 6.6.2), and roadmapping-style exercises (see below).

6. **Strategic policy frameworks – stakeholder alignment and coordination:** Throughout this study experts have pointed to the value of strategy development frameworks (and associated exercises, e.g. technology roadmapping) in supporting emerging technology development communities coalesce around needs, priorities and approaches for standards development (for example, see Sections 6.6.3 and 4.3.1). It is both important to fully acknowledge the standards dimension within any broader emerging technology-related strategy architectures (e.g. 'technology roadmaps', 'foresight' or 'policy framework'). There is, depending on the system-complexity and application diversity of the emerging technology, also value in standards-focused roadmapping initiatives. Such roadmapping-style exercises can not only have value in terms of integrating standardisation issues into private and public sector

technology R&D agendas, but can also create awareness among stakeholders regarding technology development and standardisation sequencing issues, as well as competing technological approaches and trajectories, regulatory issues, etc.

7. **Public research & technology development:**
   - **Emerging technology development investments** and procurement practices of some international governmental agencies appear to offer potential stimulus (and indirect sources of funding) for standards development. Because of 'prudency of investment [of public monies]' imperatives to procure emerging technology-based applications that are reliable, interoperable, repeatable, etc standardisation can play an important role in addressing these issues. The evaluation and investment criteria of (R&D-based) emerging technology programmes offer an opportunity to encourage researchers and technology developers to engage in standards development to enhance the case for the reliability and repeatability of their outputs.
   - **Connecting the national research base to the standardisation system:** Public sector researchers can make significant contributions to standards development for emerging technologies, both at the earliest stages in a technology's maturity and later in the industrial lifecycle. Under certain circumstances, academic researchers can play a useful 'honest broker' role in leading standards development efforts, especially for technologies relevant for a multiplicity of application domains and industrial sectors. Some international R&D agencies make particular efforts to facilitate the involvement of researchers, through a variety of funding mechanisms. These practices can have significant implications for the 'business models' of particular standards development endeavours. There are also instances of initiatives specifically designed to ensure that major Federally-funded R&D initiatives in emerging technologies are sufficiently informed by and contributing to parallel standardisation efforts (e.g. the e-Energy R&D initiative in Germany, see Section 6.10). DIN's *Research, Innovation and Development Presidential Committee (SO-FIE)* was set up in 2008 to further promote standardisation (both formal and informal) as an instrument for innovation. As part of SO-FIE's mission, it is charged with steering and supporting R&D phase standardisation within DIN; networking standards work among German research organisations; integrating the idea of standardisation within the public research base; and coordinating measures for determining the need for standardisation on the basis of research projects and results,

8. **Areas for further exploration:**
   Throughout the course of this study, individual international experts and studies pointed to a range of potentially important standards-related issues which may have implications for emerging technology development, but where there has been relatively little analysis to date or where evidence is fragmented or poorly quantified. While it is beyond the scope of this short study to provide such an evidence base, we highlight the following themes and issues as areas which may merit further attention or analysis.
   - **Engaging Small & Medium-sized Enterprises:** A number of sector-specific analyses of standard setting for emerging technologies [e.g. Gerst, 2007; Jakobs, 2010] point to the dominant role played by large multinational companies and the potential danger that standards are based on the interests of a small but influential set of stakeholders. Some

stakeholders interviewed during the course of this study suggested that most standards development initiatives do not take into account SMEs' unique requirements, which may have consequences for the success of particular standards development endeavours. It is worth noting, however, that some international schemes, for example the German Standards Institute's TNS programme ('Transfer of R&D Results Through Standardisation') prioritizes support for SMEs

- **The Role of Intermediate R&D Institutes:** Throughout this report, there are particular instances of important roles played by intermediate public R&D institutes (for example NIST's Manufacturing Engineering Lab, the DOE's National Renewable Energy Lab, etc) in particular standards development initiatives. The relatively high level of participation of representatives of certain public applied R&D institutions (e.g. Fraunhofer Institutes) within key standards-related advisory committees and strategy development exercises is also noteworthy. Some experts consulted as part of this study also pointed to the potential value of insights from intermediate institutes (or critical-mass university-industry research collaboration initiatives) which work at key transitional phases in the emergence of new technologies and which engage with a broad range of industry partners (including SMEs)
- **Benchmarking national investments in standards development support:** It was beyond the scope of this short study to quantify the levels of Federal government investment (including those of its mission agencies) in support of standards development of emerging technologies. Not only do levels of Federal engagement and investment in standardisation vary strongly from technology to technology, but there is also a multiplicity of governmental agencies involved in emerging technology development, whose activities and investments have both direct and indirect impacts on standards development. A number of experts consulted during the course of this study suggested that appropriate benchmarking of Federal investments in support standards development (between the US, Germany and UK) would be highly informative.
- **Characteristics and experience of effective standardisation leaders:** A repeated theme raised by many interviewees during the course of this study was the often critical role of key individual leaders in bringing emerging technology stakeholder communities together to address standardisation needs. There appears to be significant added value in identifying and supporting standardisation leaders (e.g. committee chairs, coordination initiative leads, etc) who have both the passion and energy to drive the process forward as well as the background, experience and skills that ensure the trust of all stakeholders while consensus on standards is being built. There also seems to be evidence that individuals with different types backgrounds and expertise may prove more appropriate and impactful for different types of initiative and at different stages of an emerging technologies lifecycle (see for example Sections 4.4 and 6.7). There may be value in better understanding evolving roles and functions of leaders at different stages in the emergence of a new technology, in particular what background, experience, expertise may be important.

Acknowledgments

The authors would particularly like to thank for their insightful contribution to this report: Mr David Alderman (NIST), Pr J. Christopher Anderson (University of California, Berkeley), Dr George Arnold (NIST), Hermann Behrens (DIN), Pr David Bourell (UT Austin, Texas), Dr Louisa Chapman (CDC, HHS), Leonard Chamberlin (FERC), Mr Jason Christopher (FERC), Mr Peter Churchill (JRC-EU Commission), Ms Mary Donaldson (NIST), Pr Michael Doser (ITV – Denkendorf), Dr Sybille Gaisser (Anbach HS, Germany), Mr Gordon Gillerman (NIST), Dr Patrick Ginty (Loughborough University), Pr. Richard Hague (Loughborough University), Dr Bastian Kern (German Federal Ministry of Economics and Technology), Dr Nicolas Le Rovère (EBI Cambridge), Joerg Lenz (EOS GmbH), Mr Ray Palmer (FERC), Dr Anne Plant (NIST), Pr Thomas Reiss (Faunhofer ISI), Dr Fabiana Scapolo (JRC- EU Comission), Stephanie Sabourin (NIBIB / NIH), Johannes Stein (DKE), Pr. Brent Stucker (University of Louisville, KY), Pr David Williams (Loughborough University), Dr David Wollman (NIST).

The authors acknowledge financial support for this report from the Department of Business, Innovation & Skills (BIS) and the British Standards Institution (BSI).

Glossary

AIA	Aerospace Industries Association (USA)
ACUS	Administrative Conference of the United States
ANSI	American National Standards Institute
ASME	American Society of Mechanical Engineers
ASTM	American Society for Testing and Materials
BAM	Federal Institute for Materials Research and Testing (Germany)
BBF	BioBricks Foundation
BDI	Federation of German Industries
BMBF	Federal Ministry of Education and Research
BMWi	Federal Ministry of Economics and Technology
BSI	British Standards Institution
CWA	CEN-Workshop Agreement
DARPA	Defense Advanced Research Projects Agency (USA)
DFG	Deutsche Forschungsgemeinschaft (German Research Foundation)
DIN	Deutsches Institüt fur Normung (German Institute for Standardisation)
DKE	German Commission for Electrical, Electronic and Information Technologies
DOD	Department of Energy (USA)
DOE	Department of Defense (USA)
EBN	R&D Phase Standardisation Initiative (Germany)
EIA	Electronics Industries Association (USA)
EISA	US Energy Independence & Security Act
EPA	Environmental Protection Agency (USA)
FCC	Federal Communications Commission (USA)
FDA	Food and Drug Administration (USA)
FERC	Federal Energy Regulatory Commission (USA)
FH-ISI	Fraunhofer-Institute Systems and Innovation Research
ICSP	Interagency Committee on Standards Policy
IEEE	Institute of Electrical and Electronics Engineers
IETC	Internet Engineering Task Force
iGEM	International Genetically Engineered Machine Competition
INS	Innovation with Norms and Standards programme (Germany)
ISO	International Standards Organisation
MATES	Multi-Agency Tissue Engineering Science working group (USA)
NASA	National Aeronautics and Space Administration (USA)

NEMA	National Electrical Manufacturers Association
NIBIB	National Institute of Biomedical Imaging & Bioengineering
NIH	National Institute of Health (USA)
NIST	National Institute for Standards & Technology (USA)
NNI	National Nanotechnology Initiative (USA)
NO-REST	"Networked Organisations - REsearch into STandards and Standardisation Project" (EU research project)
NSF	National Science Foundation (USA)
NTTAA	National Technology Transfer and Advancement Act (USA)
OFFIS	German Institute for Information Technology
OSTP	Office of Science and Technology Policy (USA)
PAS	Publicly Available Specifications
PTEI	Pittsburgh Tissue Engineering Initiative
PTB	Physikalisch-Technische Bundesanstalt (German National Metrology Institute
TIA	Telecommunications Industry Association (USA)
TNS	Transfer of research and development results through standardization Program (Germany)
RAM	Roadmap for Additive Manufacturing
SAE	Society of Automotive Engineers
SBPkb	Knowledgebase of Standard Biological Parts
SDOs	Standards Development Organisations
SGIP	Smart Grid Interoperability Panel
SME	Society of Mechanical Engineers (USA)
SO-FIE	Research, Innovation and Development Committee (Germany)
TEPs	Tissue-engineered products
TESSY	"Towards a European Strategy in Synthetic Biology" (EU research project)
VDE	Association for Electrical, Electronic and Information Technologies (Germany)
VDI	Association of German Engineers

11. Appendix 1: Context and Dimensions of Research

Gaining a better understanding of the role of standards in emerging technologies requires taking into account several different dimensions. These dimensions include:

- The technology journey from an investment perspective
- The technology life cycle's stages
- The types and functions of standards
- The infrastructure aspects and their implications
- The different actors engaged in the standards development process and their role
- The innovation process

Below is a collection of key diagrams and frameworks which describe and analyse these different dimensions.

- "Valley of Death" diagram

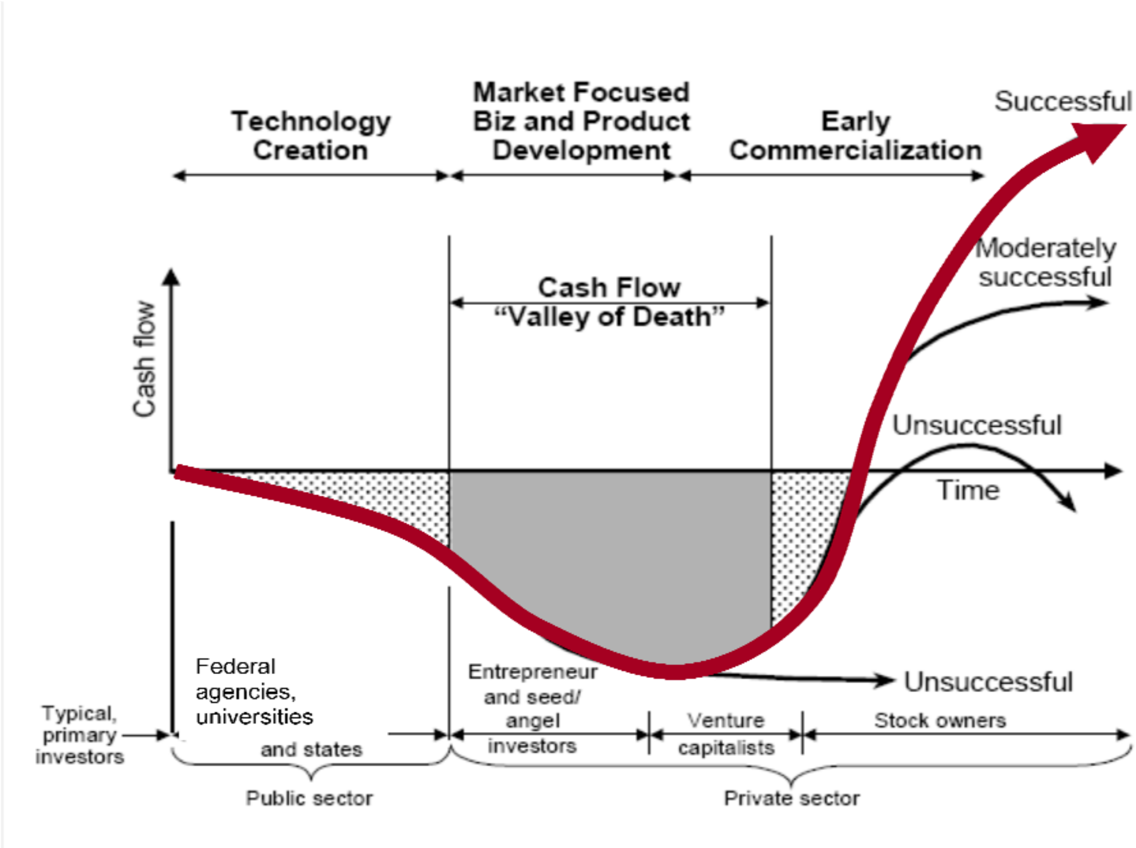

Fig 1: Emerging technologies and the "Valley of Death"
(source: inspired from Murphy & Edwards, 2003)

From an investment perspective, the emergence of a new technology goes through different phases, from the public research base into established application markets. A lack of funding, the familiar "Valley of Death" effect, can occur between basic research and commercial operation. The different dimensions relevant to understand the role of standards in emerging technologies are happening in a "Valley of Death" journey.

- **Types and functions of standards**

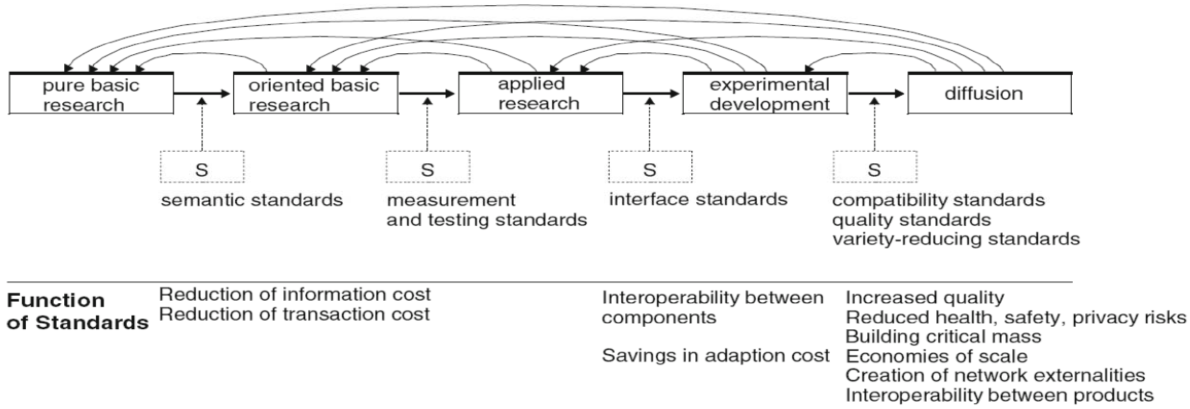

Fig 2: Types and functions of standards (source: Blind & Gauch, 2009)

Different types of standards exist. They matter at different stages of the emergence journey of a technology where they fulfill different functions. The classification developed by Blind and Gauch against a time axis provides a useful theoretical guidance to identify possible variations in the standards journeys of different technologies.

- **Types and role of actors engaged in the standards development process**

Federal Government Engagement Role	Example
Convener/Coordinator Identifies needs and directions, useable standards, and architectures in cross-sectoral collaborations to meet national priorities	• Smart Grid • Nuclear Energy Standards Coordination Collaborative
Technical Leader Agency staff are leaders in SDO/SSO governance and program execution	• The U.S. government participates in a leadership role in standardisation work by private sector standards bodies
Participant Agency staff as members of a standards writing committee	• Over 748 federal agency staff are members of ASTM standards committees
Facilitator Includes contracting for services to enable standards writing	• In Health IT: CDC and other agency contracts result in development of standards and implementation guidance
Implementer/Adopter Selects and implements a private sector-developed standard or requires its implementation through regulation.	• ASME standards on thermometers satisfy procurement needs of DoD and eliminate need for unique Federal standard
Technical Advisor Provides R&D to support standards development or develops test methods to support a technical standard	• Homeland Security: U.S. Government provided baseline test environment for DICOS
Coordinator of Federal Agency Needs Formally collaborates to address common problem, transferring knowledge to an SSO/SDO	• Federal Geographic Data Committee
Interested observer On an ongoing basis, monitors developments and assesses opportunities for engagement	

Fig 3: Engagement of actors in standards-setting (source: NIST, 2011)

Several actors can be involved in the development of standards in emerging technologies, with two main implications. The identification and clarification of the types of engagement associated with each actor may be needed in order to improve their participation in the standards development process. From a government perspective, convening can considered as one of its most appropriate role in this process.

- **Provision of an infrastructure**

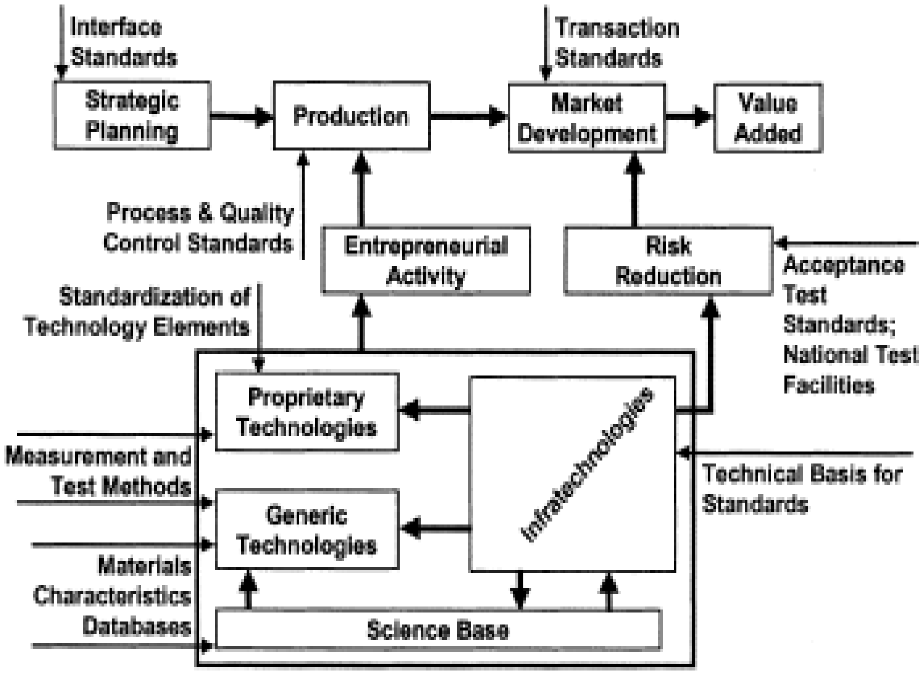

Fig 4: Role of standards in a technology-based industry (source: Tassey, 2000)

Standards play an infrastructure role by performing several functions which support the R&D, production and commercialisation phases in a technology life cycle. Emerging technologies consisting of a number of components, which require different types, combinations and interaction of standards for their development and utilisation, make it challenging to manage the timing and content of standards. This highlights the need for some kind of convening structure and/or process to ensure that all the actors engaged in the standards development process can adopt a more collaborative approach within this process.

- **Timing of standards in relation with the technology life cycle**

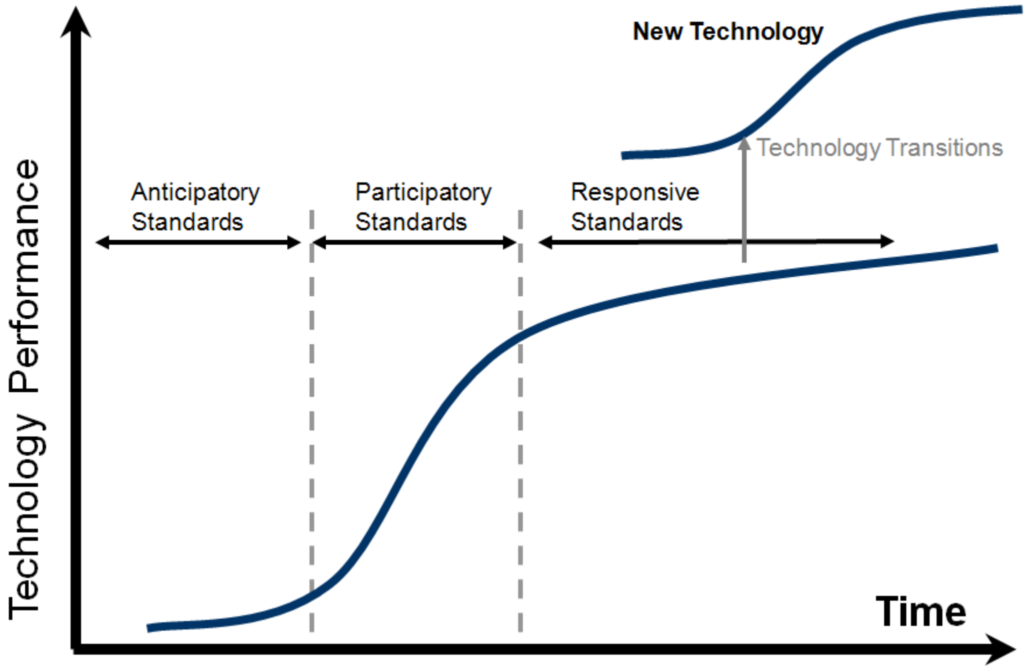

Fig 5: Timing of standards in relation with the technology S-curve (source: Sherif, 2001)

There is a timing relationship between standards and a technology life cycle and successful standards are the ones which meet the needs of the technology users at the different stages of this life cycle. One could therefore talk about a level of standards readiness with, as pointed out by Tassey "different degrees of standardisation (which) are optimal at different points in the technology's evolution".

- **Multiplicity of actors**

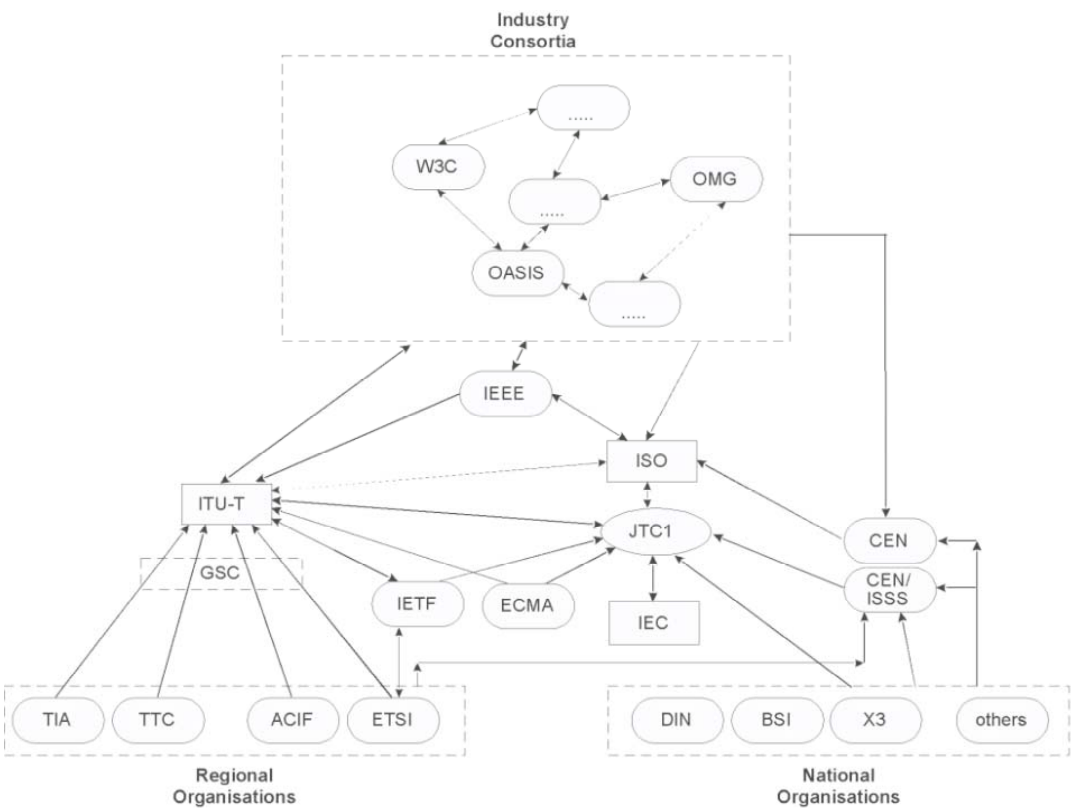

Fig 6: The ICT

Standardisation universe today (source: Jakobs & Blind, 2009)

The need for shorter and more market responsive standardisation processes has led to the emergence of a number of industry driven consortia in addition to the existing, more formal Standards Developing Organisations. This trend away from SDO-sourced standards has led to a very complex standards setting landscape and has raised a number of issues around the participants to standards setting processes. The need for some kind of structure and/or process to convene all the actors involved in the standards development process of an emerging technology is further highlighted.

12. Appendix 2: Towards a practitioner's perspective on standards

As part of the Emerging Industries Programme, an EPSRC-IMRC research project run by the Institute for Manufacturing (IfM) at Cambridge University, a policy study was conducted for the Department of Business, Innovation and Skills in 2011.

It aimed to provide a first structured exploration of the practitioner perspectives on the ways in which standards can foster or hinder emergence. It helped identify some of the key issues, lessons and recommendations emphasised by these practitioner communities, with a view to delivering information of direct relevance and utility for regulators and policymakers. It involved a selective overview of literature combining journal articles, white papers, workshop and conference proceedings as well as documents issued by industry associations and standardisation bodies.

Five main issues put forward by practitioners were highlighted in the final report:

- **Dynamic issues**: Standards are subject to changes for maintenance, succession or adaptation purposes. Such changes can be necessary to keep pace with technology evolution but can also provoke some disruptive effects and result in incompatibility and lack of market stability.
- **Timing issues and level of standardisation readiness**: The dynamic character of standardisation over a technology lifecycle raises issues in terms of timing: different types and combinations of standards being needed to support the development and utilisation of the elements which compose a technology.
- **Strategic management issues**: Companies, and especially SMEs, find it challenging to keep track of standards in a constantly evolving environment. Public initiatives are needed to simplify the standards environment.
- **Interplay issues between standards and the regulatory environment**: Standards can act as a supplement or replacement for regulation where appropriate but the ways in which regulation and standards can be best combined to support innovation are still in an exploratory phase.
- **Limitations of current standardisation processes**: A number of industry driven consortia have emerged in addition to the existing, more formal Standards Developing Organisations. Their engagement in a complementary rather than substitutive relationship raises the question of the reference to consortia standards in established regulatory frameworks.

• DYNAMICS OF STANDARDS

Gaining a better understanding of the nature of standards dynamics has been a concern of a number of practitioners. A major initiative was funded under the 6th EU Framework Programme in order to find out some patterns which could inform and accelerate the development of standards in the future. Entitled NO REST, this initiative focussed on the ICT sector and offers an interesting perspective given the infrastructure and interoperability related issues which are associated with this sector.

Based on the analysis of NO REST, standards are depicted as inherent to technology and market developments and therefore to be dynamic by nature. Standards maintenance, standards succession and standards adaptation are identified as the three main types of dynamics. Standards maintenance relates to the revision of standards through technical amendments, mergers, split-ups or withdrawals. At this stage, the nature of changes is incremental. In the case of standards succession, standards are abandoned to be replaced by new standards in response to radical technological evolutions. Changes are not caused by incremental learning but by novelty and are of a radical nature. With standards adaptation, changes occur during the implementation phase. For instance, standards' specifications have to be revised to allow for an extension of its implementation or a partial implementation.

The particular nature of standards dynamics is technology-specific and depends on the pace at which technologies, and their applications, change. It is also affected by four main factors which are the technology development, the market environment, regulatory changes and the characteristics of the standards setting body. The technology development can affect standards dynamics in a direct way, for instance when the technology embedded in the standards has improved, or in an indirect way, when standards are applied to new areas. The market environment is more or less supportive, depending on the level of interest showed by market players in a given standard. Regulatory changes can also be a significant factor. For instance, the change in radio frequency bandwidth had a significant impact on standards development. The characteristics of the standards setting body also have some consequences for standards dynamics. Standards which are originally of poor quality and difficult to implement are highly likely to undergo early changes.

In the context of emerging technologies and emerging industries, as highlighted by Sherif in the sectors of telecommunications and information technology, standards will inevitably be subject to change (see Figure 1). Stable and incrementally changing standards reduce market uncertainty, but may not support radical innovation in an optimal way. Progress and innovation are associated with responsive standards. Consequently there is a dilemma between "stable" standards and "responsive" standards.

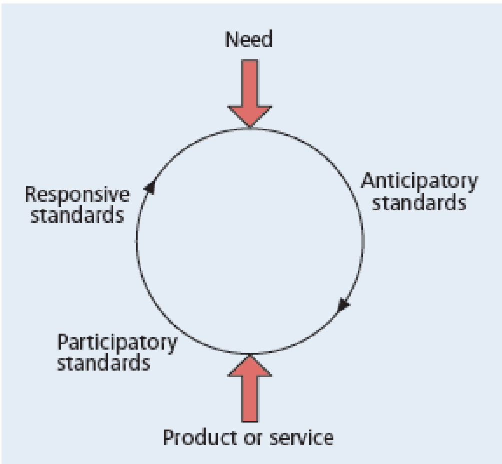

Fig.1: Standardisation within the product or service life cycle
(Source: Sherif, A Framework for Standardisation in Telecommunications & IT, IEEE Com. Mag. 2001)

From a practical perspective, the ways in which the negative impact of standards dynamics could be alleviated are being explored and a distinction is made between unnecessary and necessary dynamics. On one hand, in order to avoid any unnecessary dynamics, the quality of standards, and therefore the quality of the standards process, needs to be improved as an improved process is expected to allow for the development of more stable and less disruptive standards. On the other hand, keeping pace with technology evolution represents a "desirable" change which has to be facilitated.

Two complementary strategies are put forward by the literature: the design of original standards permitting certain flexibility and the prioritisation of downward compatibility (or grafting). The impact of standards dynamics depends to a large extent on whether or not individual standards are compatible (NO-REST, 2005a). The grafting approach is deemed all the more sensible given the incremental, rather than radical, nature of most of the changes standards undergo.

• TIMING ISSUES AND LEVEL OF STANDARDS READINESS

In order to foster economies of scale and realise network externalities, components of a product, or elements of a service, have to be standardised. However, "the marketplace dynamics that result in one firm's version of the technology becoming the standard do not guarantee that this version is the optimal one". The economic efficiency which can result from standardisation occurring at an inappropriate time is a frequent concern for practitioners who are aware that standardisation too early may prematurely lock an industry into a technology whereas standardisation too late may be ignored by industry as some technological options have already become entrenched.

Standards & Technology Lifecycle

Some practitioners have linked standards timing issues with the technology lifecycle, arguing that the time at which standards are issued is related to the level of technology maturity. Some of them also show that timing impacts on the types of standards developed.

By relating the technology S-curve (which depicts the trajectory of a technology, from its emergence to its transition to a new technology) to standards, they observe three categories: anticipatory, participatory and responsive standards (see Figure 2). Anticipatory standards specify the production system of the new technology. For instance, they define any new concepts and components needed to proceed with trial implementations and are crucial for widespread acceptance of a product or a service. Participatory standards are generated when the knowledge of the technology is diffused and products start being commercialised. They are said to "refine the production system" as well as "define the product systems that embody the technology" and allow for a testing of specifications prior to adopting them. Responsive standards codify knowledge already established in practice through precursor products or services. They accelerate the diffusion of scientific information and "provide avenues for sharing technical know-how". Both technology and product life cycles are considered by some practitioners are relevant tools to support standards management strategy.

The dynamic character of standardisation over a technology lifecycle also leads to some interesting analysis in terms of standards readiness. Standards have to be available at various stages in a technology's life cycle but, as highlighted by a practitioner from the US National Institute of Standards and Technology (NIST), "different degrees of standardisation are optimal at different points in the technology's evolution". Managing the timing of standards therefore poses strategic issues. The different elements that a technology consists of require different types and combinations of standards to support their development and their utilisation.

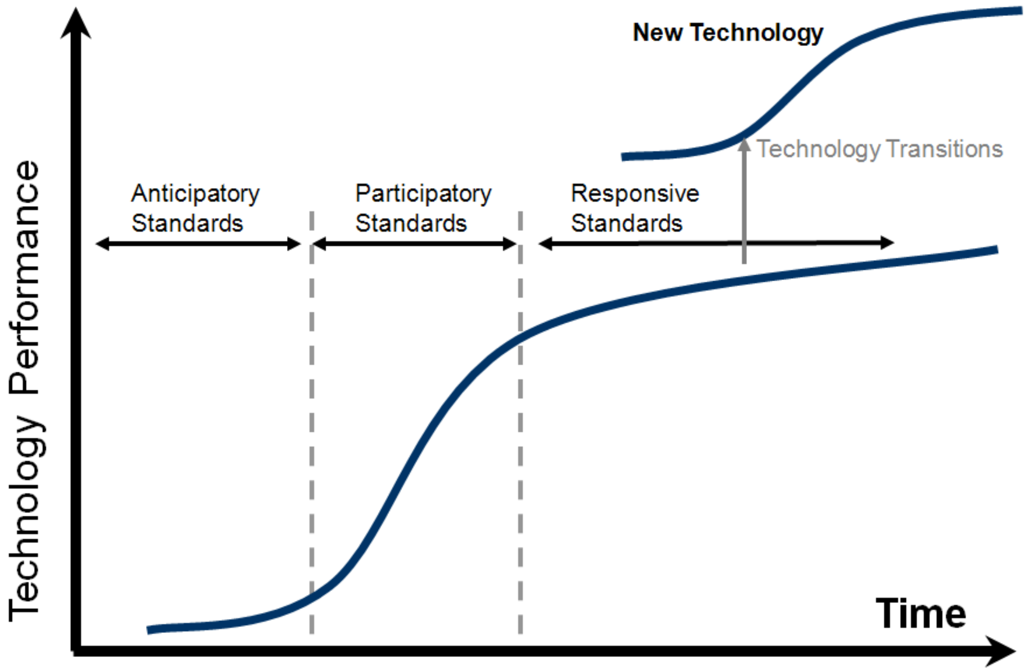

Fig.2: Timing of standards in relation with the technology S-curve
(source: Sherif, A Framework for Standardisation in Telecommunications and Information Technology, IEEE Com. Mag. 2001)

Standards & Product Lifecycles

In a related way, the product life cycle also offers an interesting perspective to explore the ways in which standards can facilitate product innovation. In the early stages, standardisation may be used to apply and trial new technologies as well as encourage adoption. In later stages, standardisation can help leverage mature technologies into new opportunities and lower costs through improved efficiency. However, as the timescale for standardisation is longer than for the innovation process, there is a concern that the introduction and diffusion of innovations may be delayed or stifled.

Timing issues are also being explored in the literature on innovation journeys and roadmaps. Such an approach highlights the non-linear nature of technological evolution and can address the full range of non-technical barriers and enablers, like standards, to industrial growth. Standards have the potential to indicate the extent to which the evolving industrial community feels the need to coordinate and may consequently offer a milestone of the maturity of an emerging industry. They can play a rather unique role at creating awareness among public stakeholders (government's departments, regulatory and funding agencies, arm's length bodies) about a given sector's level of emergence.

• STRATEGIC STANDARDS MANAGEMENT

Strategic standards management is about "leveraging all aspects of the standardisation process to optimise competitiveness" and concerns all areas of the value chain (see Figure 4). From a business perspective, the management of standards and regulatory information to support strategic decision making is deemed challenging and the experience shows that firms in general, and SMEs in particular, need guidance in standardisation. Two key issues are highlighted by practitioners. There is the lack of transparency in a dynamic standards environment which makes it difficult for companies, especially for SMEs, to decide to opt for a standard. The need for constant monitoring and updating is also challenging.

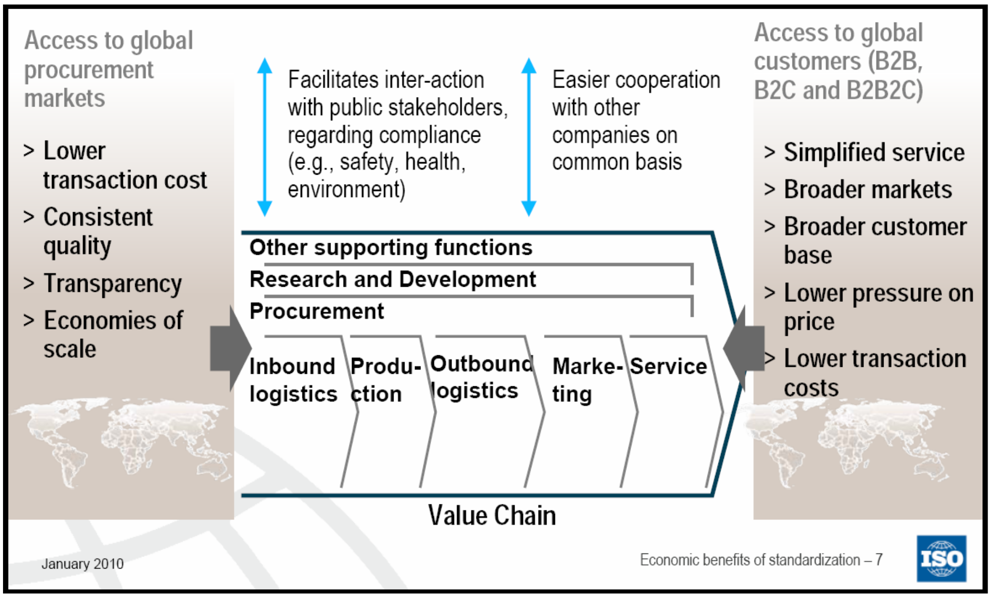

Fig.4: standardisation and value chain
(Source: ISO – Economic benefits of consensus-based standards: The ISO Methodology – 2010)

In this context, some public initiatives are reported in a positive way in the practitioners' literature as they have led to a greater clarity in the standards environment. For instance, the initiative launched by the Department of Trade and Industry, and developed through the British Standards Institution in 2007 in the specific sector of regenerative medicine, is positively perceived by practitioners. Named PAS 83, the document is a code of guidance which maps the standards and regulatory requirements for the development of cell-based therapeutics and informs product developers about possible regulatory bottlenecks and the ways in which they can be tackled.

Processes and tools allowing a simplified use of standards and standardisation are also welcomed by practitioners, as illustrated by the Harmonised European Standards (known as EN standards) trend. It is recognised that EN standards to make the standards environment simpler by allowing businesses to simultaneously achieve domestic and European compliance and by offering a "presumption of conformity" to the requirements laid down in any New Approach Directives.

• STANDARDS & THE REGULATORY ENVIRONMENT

A supportive regulatory environment is deemed as one of the factors which are the most likely to positively impact on the creation of new industries. A number of public reports have further demonstrated that the pace of the transition from emerging technologies to a new industry highly depends on the degree of appropriateness, clarity and predictability provided by the regulatory framework in place. Standards are acknowledged to be part of the regulatory framework. For instance, the US Federal Drug Administration (FDA) in a report on the improvement of medical product development highlighted the interrelation and mutually informative areas of technical standards and regulatory policies in order to foster innovation and to ensure that regulatory modernisation keep pace with scientific changes (see Figure 3).

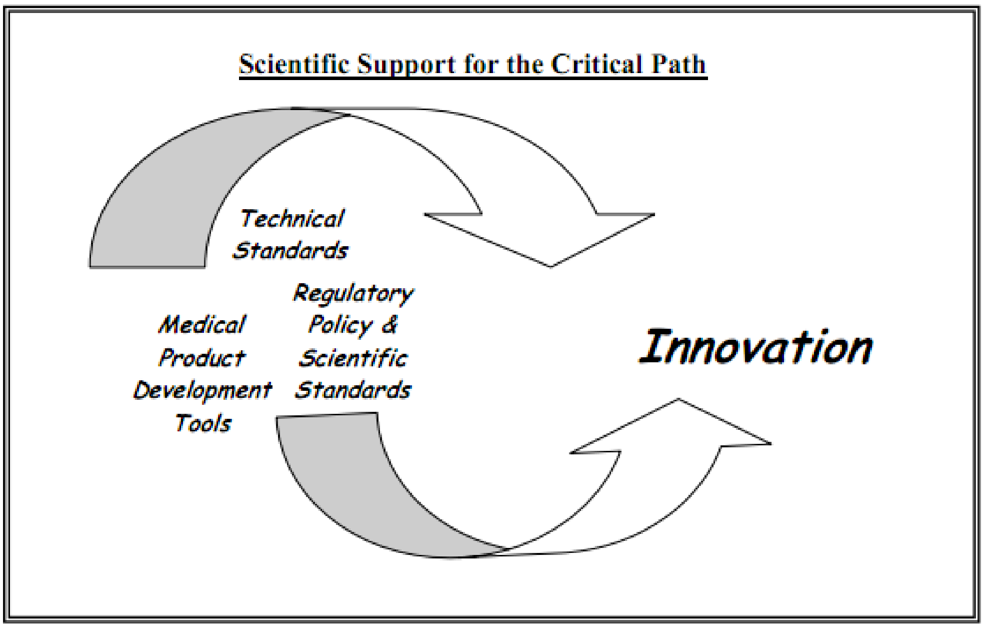

Fig.3: Regulatory environment in support of medical product development
(Source: FDA, Critical path Opportunities report, 2006)

In the UK, the change in approach to regulation following the Hampton Report's recommendations and the work conducted by the Better Regulation Task Force has pointed towards a better use of standards as complements to, but also as substitutes for regulation. The division of labour between regulatory and standardisation bodies is reported on by practitioners. Evidence of such a division can be found in the "New Approach" launched by the EU Commission. The separation of tasks established between EU regulators, who set essential requirements through Directives, and the European standards bodies, tasked with drawing up the technical specifications to implement these requirements, is described as a positive and innovative regulatory strategy. The applications of standards as alternatives to, or in place of, regulations have been reported on in a number of documents. The Lead Market Initiative also offers an interesting case study as it is underpinned by a combination of legislation, public procurement and standardisation to support the emergence of new technologies and new industries.

However, the ways in which regulation and standards can interplay in an optimal manner to support innovation are still in an exploratory phase. Moreover, if some self-regulatory practices via standardisation are well documented and provide some interesting insights regarding the interrelationship between regulation and standardisation, the introduction of consortia standardisation into regulatory frameworks still remains a very open question.

• LIMITATIONS OF CURRENT STANDARDISATION PROCESSES

The capability of traditional Standards Developing Organisations (SDOs) to keep pace with technology evolution or/and to deliver good quality standards is being questioned by a number of practitioners, especially in the IT sector. Competing standards consortia like the World Wide Web Consortium (known under the W3C acronym) or the Object Management Group (OMG) in the ICT sector, have put forward their ability to deliver better designed and more market responsive standards.

For instance, W3C allows non-members to participate in its process as invited experts and several working groups have been opened to the public. W3C “standards” (officially called recommendations) are thoroughly tested for implementation. If not enough implementation experience can be gathered, the recommendation concerned is left aside and simply recorded as a Note. Implementation is also a major point of focus for an organisation like Wi-Fi Alliance. Composed of a whole range of companies and consumers involved in Wi-Fi networking, it mostly aims to test and certify the interoperability of Wi-Fi standards as implemented across product lines from multiple vendors. Wi-Fi Alliance, whose certification concerns standards sourced not from a SDO but from IEEE, represents a very interesting case study in terms of market-responsiveness. Indeed, it happened that Wi-Fi Alliance certified standards which were not yet ratified at the IEEE level, jump-starting a huge market while the standards were being refined. Still in order to be more responsive to the fast moving Wi-Fi market, it has also started developing some specifications in an independent way (Wi-Fi Alliance).

The trend away from SDO-sourced standards has led to a very complex standards setting landscape (see Figure 5) and the ways in which such a landscape could be fully exploited is being investigated by practitioners. For instance, possible synergies between European standardisation bodies and standardisation consortia are touched upon in a White Paper recently issued by the EU Commission. Issues around the participants to standards setting processes are also discussed by practitioners with some interesting initiatives launched by SDOs like the European Telecom Standards Institute (ETSI). Aware that the R&D base (universities and public research bodies) and SMEs were not involved enough in standardisation processes, ETSI has decided to host workshops and events with the R&D community. As it is a “pay to play” organisation, it has also reduced its fees for SMEs.

The ways in which the standardisation process could be accelerated have been explored by SDOs. New standard categories – e.g. “pre-standards” and “interim standards” – have been created in some of these organisations.

Pre-standards

In order to address the industry’s needs to quickly achieve technical agreements, the European standardisation body for electrical standards (CENELEC) has initiated the creation of “pre-standards” through Workshop Agreements. Developed in a workshop widely advertised in advance and largely open, they represent a fast and flexible way to set standards even though they encompass important limitations. For instance, they cannot support legislative requirements nor address significant health and safety issues. They also cannot conflict with existing or forthcoming European standards. They nonetheless offer a useful solution to bridge standards gaps in technical domains and can be confirmed as European standards by going through the traditional CENELEC process.

Interim Standards

The initiative launched in the photovoltaic sector by the Global Approval Programme for PV (PV GAP), a not-for-profit organisation based in Geneva, to develop “interim standards” is also worth mentioning. The need for this sub-category of standards was identified in the mid 1990s by the PV industry itself which had a growing concern about the lack of standards for PV quality. The programme, officially set up in 1997, was initiated by the PV industry and was intended to encourage the acceptance of the standards set by the International Electrotechnical Commission (IEC). However, due to the delays involved, PV GAP decided to create some interim standards while IEC standards were in development and until they were issued (Kay & Bergmann, 2003). This initiative therefore helped fill standards gaps in areas like quality managemenFt processes and PV systems design and installations. It provided developers and manufacturers with certification standards with which to comply, as well as a PV quality mark and seal to label their products to certify their approval under the PV GAP Programme.

Looking ahead, some practitioners foresee a growing number of ad-hoc industry-based organisations and a decline of proprietary standards. They also predict an increased competition between SDOs and consortia. Conversely, some others do not consider the opposition between SDOs and consortia as relevant, arguing that the standardisation processes they have respectively adopted present many convergent points and that successful innovation will rely both on consortia and traditional standards bodies. A study carried out on ICT standards in the EU by Blind and Gauch hints at a complementary, rather than substitutive, relationship between formal and consortia standardisation with synergies likely to exist between the two types of standardisation activities. Intensive contacts are maintained between SDOs and consortia and a number of formal standards were initially developed through consortia processes. Companies have an interest to get involved both in consortia, which tend to develop standards closer to their own R&D activities, and in SDOs which reflect more implementation issues and are based on a larger consensus. A better acknowledgement of this complementary trend at the EU level would allow for the development of a regulatory framework in which consortia standards could be referred to, for instance in public procurement processes of ICT equipment and infrastructure.