

A Four-Step Framework to Manage the Collaboration with Subject Matter Experts on Regulatory Standardization Projects

By Moutaz Zakkar

INTRODUCTION AND BACKGROUND

Some technical projects and assignments require collaboration with individuals who possess field or industry-specific knowledge, competence, competencies, and skills. Such individuals are needed to perform different tasks or assume certain roles and responsibilities such as planning, monitoring and evaluation, strategy setting, policy making, auditing, research, review, management, advising, training, interviewing candidates, and membership of committees and working groups, to name a few. They are usually referred to as subject matter experts (SMEs), and the knowledge they pass on to the project is intuitive or tacit (Centers for Disease Control and Prevention-National Center for Injury Prevention and Control, n.d.). SMEs play a pivotal role in standardization. The International Society for Quality in Health Care (ISQua) considered the “input from technical experts” among the core requirements for the development of Health and Social Care Standards (ISQua, 2018, p. 23). The outcome of collaboration with an SME is value and credibility added to the standardization project.

The purpose of this article is to propose a framework to manage the relationship with SMEs in regulatory standard development,

referred to in this article as a regulatory standardization project.

WHO IS THE SUBJECT MATTER EXPERT?

An SME is an individual who possesses “bona fide expert knowledge” (U.S. Office of Personnel Management, 2019, p. Glossary-14), skills, education, training, expertise, experience, and a track record of working in a particular field or business area. Potential SMEs should “have been in their roles for a long enough period of time for their knowledge and skills to be ‘second nature’” (The University of Waterloo-IST Project Management Office n.d.).

Criteria for selecting a subject matter expert should include *inter alia* their years of experience; records of achievement; licensure or ex-licensure from a professional body or governmental authority; recommendation letters; and basically, any proof that they hold values that can be added to the standardization project.

POTENTIAL ROLES OF SMES IN STANDARD DEVELOPMENT PROJECTS

SMEs are essential members of the standard development project team. They can help with the following tasks:

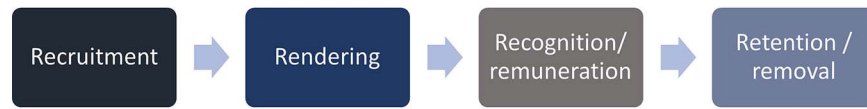


Figure 1. *A four-step framework to manage the relationship between the project team and SMEs.*

- Scoping of the standard (i.e., identifying the most critical areas to focus on when such areas have not been identified in a need assessment).
- Sharing real-life examples of issues that support the standardization approach based on their hands-on experience.
- Proofreading and editing.
- Sharing perspectives, insight, and critique.
- Acting as devil's advocate to sharpen and well-round the standard.
- Sharing lessons learned from other jurisdictions.
- Engaged as researchers and literature reviewers.
- Providing advice to address change requests from stakeholders during the project.

A FRAMEWORK FOR MANAGING THE PROFESSIONAL RELATIONSHIP WITH SMES: 4R'S

The professional relationship with an SME progresses through a life cycle of phases that consists of:

Recruitment; Rendering; Recognition/remuneration; Retention/removal, which is described as the "4R's" framework (Figure 1).

Recruitment

In this phase, the standardization project team identifies, screens, verifies, short-lists, and contacts potential SMEs. Several bio-data hubs can be utilized for this exercise including member directories of professional societies and organizations; certificant directories of professional certification organizations; business-oriented, career-oriented, or professional social-networking platforms; job banks; scientific and professional journals.

Upon SME's preliminary approval of the scope of work, engagement with SMEs must be

made formal through a contract or agreement. The details and type of the contract depend on several factors including the domestic legal requirements (e.g., labor laws/employment regulations); regulatory body by-laws; complexity, and timeframe of assignment. Formality will impose obligations and ascribe certain rights to both parties (regulatory body and SME). See for example a model contract of the European Commission (2022) and a template agreement by the City of Portland (n.d.). The contract should include Terms of Reference (ToR) or equivalent provisions that provide background about the project and clarify the purpose and scope of the regulatory instrument, the roles of SMEs, expected deliverables, type and frequency of engagements (meeting, email, focus groups, etc.), reimbursement, and code of conduct.

SMEs should observe a code of conduct that describes certain behaviors expected of them while carrying out their assigned tasks, including the obligation to:

- Abide by the scope, schedule, and quality attributes of the assignment.
- Avoid conflict of interest that may jeopardize the quality, credibility, and reliability of their contribution to the task.
- Act in the public interest.
- Participate in their personal capacity rather than as representatives of any entity or persons including their institutions.
- Share state-of-the-art information that enriches the standard.
- Respect and protect the privacy, confidentiality, intellectual property, and ownership of data, information, and references.
- Reflect impartiality, objectivity, and independence.

A code of conduct document should be shared with and accepted by SMEs before starting any assignment. A record of the signed

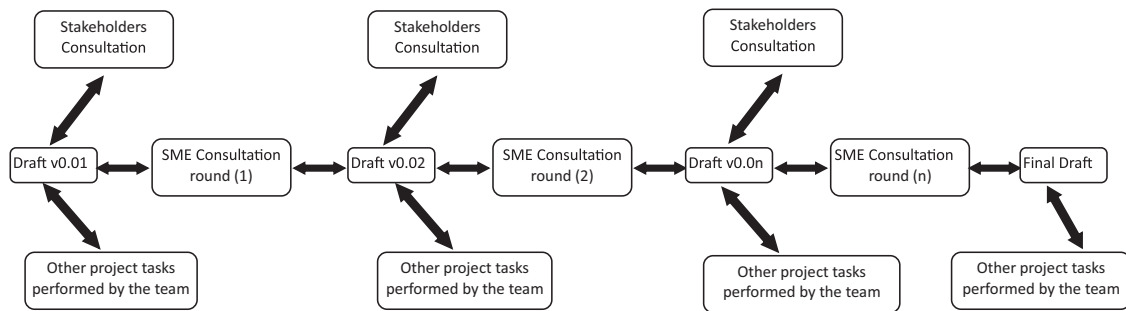


Figure 2. A schematic representation of interaction with SMEs and stakeholders during the standardization project.

code of conduct must be maintained. It could also be part of the contract. (See examples of code of conduct in European Commission, 2023; International Labour Organization, 2021; The World Health Organization, n.d.).

Other important elements that must be agreed upon with SMEs include expected timeframe, quality of deliverables, performance indicators, and methods of communication. The availability of SMEs is of paramount importance and should be factored in when finalizing the project schedule. Performance indicators must cover timeliness and quality of participation among other parameters.

The number and specialties of SMEs depend on the wider scope of the standardization project, the collective competencies and skill mix of the project team, and technical areas of the scope that are beyond the capabilities and expertise of the team. For example, developing a scope of clinical practice document for dermatologists requires the involvement of dermatologists, whereas developing a standard for the diagnosis of brain death requires the input of a multi-specialty group of experts including neurologists, neurosurgeons; intensivists; critical care nurses; social workers; pediatricians; neonatologists; psychologists; medico-legal experts; pharmacists; radiologists; electroencephalographic (EEG) technicians or technologists; bioethicists.

Compensation for SME services is yet another factor to be considered. Some SMEs are willing to work voluntarily, pro bono, or for nominal fees, whereas others may demand a

specific per-hour rate or per-assignment flat rate. With free of charge type of engagements, the project team should seek to obtain a strong commitment from SMEs to complete the tasks on time, otherwise, busy SMEs might not keep the momentum throughout the lifecycle of the project.

Rendering

In this phase, SMEs carry out their assigned tasks and responsibilities. The actual engagement with SMEs runs through several iterations of review and revision or cycles of consultations as illustrated in Figure 2. During each cycle, the project team creates or updates the draft and performs other tasks related to the project (e.g., doing further research; context analysis to ensure the proposed standard is aligned with the current best practices and regulatory framework; arranging for the translation of the standard into another domestic language; studying SMEs' input and analyzing stakeholders' feedback, record keeping; etc.). A robust version control procedure must be implemented to ensure that SMEs and the project team are working on the same document version in any consultation round.

Communication and exchange of information and insight can be done through email, meetings, surveys, and the Delphi technique. Meetings with SMEs can be held virtual or in person and can be one-to-one or as a focus group, to arrive at a rational, and evidence-driven consensus. The regulatory body should establish ground rules for expert focus group

meetings that ensure SMEs get equal opportunity to present their viewpoints, arguments, and supporting evidence without monopolizing or diverting the discussion toward individual agendas.

In focus group meetings, a project team member should act as facilitator or moderator, another member should record the minutes of the meeting and support the moderator. Although recommendations vary, the number of experts attending a focus group session should not exceed 6 SMEs. The project team may need to hold several meetings with different groups of SMEs to discuss certain topics, challenges, and stakeholder feedback.

The standardization officer or project team must keep track of all notes and suggestions received in each round of consultation as these will be shared with the same or the next batch of SMEs. It is advisable to always engage a “first-time reviewer” (i.e., first-timer) in the final consultation round to ensure fresh insight from people who were not involved in the previous discussions.

The standard development function must also have a document control procedure to maintain a paper trail that facilitates quality assurance and internal audit of the standardization tasks. Individual SME feedback must be categorized into evidence-based or personal-experience-based.

As stated earlier, SMEs provide extra knowledge that is not available at the level of standardization function permanent staff; however, the latter still have the responsibility to compare and contrast SMEs’ input. SMEs’ opinion is “based on experiential evidence” (Walden University, n.d.), and if it is unsubstantiated, it usually ranks low in the hierarchy of evidence. And they might have different priorities about the content of the standard, which influence their recommendations. Accordingly, it is prudent that the strength of evidence presented by SMEs is carefully graded utilizing a fit-for-purpose evidence classification. (For further discussion about the hierarchy of

evidence see Evans, 2003; NSW Government-Department of Communities and Justice, 2020; Walden University, n.d.; Winona State University, 2023).

It is not unusual to have diverging views and opinions from SMEs who work in different fields, with diverse educational backgrounds and scope of practice. The project team should aim at achieving consensus between SMEs and keep alignment with the latest knowledge. Reconciling divergent recommendations is fraught with challenges. Utilizing consensus-building techniques including the Delphi technique and focus group meetings, virtual or in-person is essential.

Just like any human being, SMEs have their blind spots. According to Nesta (2016, p. 12): “Research has shown that experts can sometimes get it horribly wrong, and they are not immune from a whole range of social and cognitive biases.” Yet SMEs have pivotal roles to play in standardization projects, but their contributions must be examined and aligned with other sources of information and knowledge. For further discussion on experts’ biases see Abels et al., 2023; and Wilson et al., 2020.

Recognition/remuneration

At this stage, the regulatory standard is developed, and no further involvement of SMEs is needed. SMEs’ efforts must be acknowledged in the form of a letter of appreciation or acknowledgment, and financial compensation if this was specified in the contract.

Retention/removal

In this last phase, SME performance is evaluated against a set of performance indicators. A decision should be made on whether to keep or remove that SME from the list of experts for future standardization work.

CONCLUSION

This article proposed a framework to manage the relationship between the standardization project team and SMEs, to ensure that the relationship remains fair, mutually beneficial, and adds value to the project and its stakeholders and beneficiaries. The “4R’s” framework can be considered as standalone steps or integrated into an overarching project management or standard development approach.

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Moutaz Zakkar (PMP; CPHQ; ASQ CQA; IIA CGAP; ASHRM CPHRM; ASQ CSQP) is a Senior Specialist of Workforce Policies and Standards, at the Department of Health- Abu Dhabi-United Arab Emirates. He is a pharmacist by training and has over 25 years of experience and a wide range of expertise in the fields of regulatory standardization, organizational standardization, quality auditing of different pharmacy practice settings, performance monitoring and medical supply chain management. **Email:** moutaz.zakkar@gmail.com; **LinkedIn:** <http://www.linkedin.com/in/moutazzakkar>

Leadership Skills Make the Most of Technical Know-how

By Suzanne Golisz

I first became active in standards setting when I assumed the voting responsibilities for ASTM International Subcommittee D02.H0 Liquefied Petroleum Gas (LPG) on behalf of Chevron, my employer at the time. My first semester included two ballots for new test methods to determine the water content in LPG. For both methods, I identified technical issues that convinced me to cast negative votes.

I felt quite nervous when it came time to hit the submit button. And since I wasn't yet attending in person, I was left in suspense on the outcome.

I learned after the meeting that both technical contacts found my negative votes persuasive and stopped the ballots from moving forward. I felt validated—for the time being.

I soon moved from Chevron to Exxon-Mobil, where again I assumed the voting responsibilities for D02.H0. I also became the technical contact for one of the methods that I had stopped with my negative vote. (Oh, the irony.) Now I was responsible for getting a new method approved that I knew had technical issues, but with no idea how to solve them.

Because I had participated in the Emerging Professionals Program sponsored by ASTM International, which exposed me to the operations of a consensus-based standards organization, I had become familiar with the collaboration and problem-solving skills necessary to achieve progress. I had

also cultivated relationships with the officers and other subcommittee members of D02.H0. With this knowledge, I set out to ensure we could pass the ballot.

Because this ballot had stalled for some time, I reconvened the working group to review the current status and describe the reasons behind my negative vote. After multiple discussions with all stakeholders, we reached consensus that if we narrowed the scope of the method such that we eliminated LPG containing the class of molecules that interferes with the detection method, the test method would be technically sound. With this agreement in place, I reviewed the proposal with the subcommittee chair and received his endorsement.

I then updated the ballot for the subcommittee to review at the next ballot opportunity. Completing the ballot submission process was clear because of my training in the Emerging Professionals Program. After receiving the required affirmative votes (and no negatives!), the ballot passed at both the subcommittee and main committee levels. This ballot is now ASTM D8094-21 Standard Test Method for Determination of Water Content of Liquefied Petroleum Gases (LPG) Using an Online Electronic Moisture Analyzer.

I've continued to participate in ASTM International and now hold the D02.E0 and D02.07 votes for my current employer, Innospec Fuel Specialties. I learned that developing new

methods takes a combination of technical expertise and collaboration. As scientists who contribute to standards setting, it's important that we rely on technically correct information to draft new test methods. While knowing we're technically correct may be enough to draft a new method, getting it approved through the ballot process takes listening, understanding, and problem solving.

Sure, we could have started an extensive test program for ASTM D8094 to quantify the interaction of alcohols with the detector. But understanding the concerns of the stakeholders and the test method's most common user, as well as building consensus around adjusting the scope, allowed us to get the test method approved sooner.

Having this test method as an alternative to the valve freeze test method allows users to

reduce the amount of LPG released into the environment during the test. It was perhaps better to have a method that works for 90% of users available immediately versus waiting years to have a method that 100% of users could employ. Users of ASTM D8094 are realizing the environmental benefit today!

The leadership skills that I gained serving as the technical contact for a new standard test method have translated well to my current role at Innospec. I regularly build consensus both internally with peers and senior leaders and externally with customers. I listen to our customers' needs and develop fit-for-purpose solutions. I am grateful for the opportunity to participate in a consensus-based standards organization like ASTM International that helps me develop the skills I need to be successful in my career.



Suzanne Golisz is an organometallic chemist who has been working in liquid fuels for the majority of her career. Prior to joining Innospec as the technical director of cold flow improvers, Suzanne worked at both ExxonMobil and Chevron in fuel product quality. In her role at Innospec, Suzanne is responsible for the cold flow improver product line in the Americas, where she is focused on ensuring that their additive packages have the best-performing technology to properly support their customers' existing and future needs.

LEADING THROUGH CHANGE

Reflexivity in Leadership

By Alexis Shoemaker

INTRODUCTION

Research insights and business intelligence are the cornerstones of informed business decisions. When these functions within a company are led effectively and work well, their value speaks for itself.

To address the challenges of leadership, especially change leadership through programmatic growth, this column has provided a conceptual and theoretical framework and guide for effective leadership. Thus far, I have elucidated concepts ranging from leadership fundamentals, leadership theories, change theories, guiding principles, and visioning to communication, team development, strategic planning, and building capacity.

In this final installation of the column, I will discuss how to conduct a reflexive, metacritical analysis of one's own leadership practices. Taking time to engage in reflexive analysis allows for more effective incorporation of the theory-based actions I have discussed, augments existing practices, and inspires productive and rewarding growth.

Effective leadership requires reflexive self-awareness. This process includes identifying strengths, weaknesses, and one's position in the fabric of the team and the organization. Leaders serve as the fulcrum for the creation of guiding principles and a vision for the team and are relied upon to set forth a roadmap for the team to follow.

REFLEXIVITY

Underpinning the leadership function is the need for perpetual revisitation and fine-tuning of one's vision and strategy. This metacritical analysis operates on three levels:

- It brings to the forefront guiding principles that might otherwise be lost in the day-to-day shuffle.
- It encourages a habit of perpetual reflexivity and makes adjusting to new circumstances and information easier.
- It models positive metacritical behavior and demonstrates a willingness to learn and develop.

To conduct this analysis, leaders can borrow from metrics used in other aspects of business. For example, you can employ one or more quantitative, qualitative, outcomes-based, activity-based, short-term, and long-term measures.¹

Ultimately, reflexivity is a necessary facet of transformational leadership.

"Transformational leadership, as the name implies, is leadership that changes people," says James MacGregor Burns.² "Transformational leadership inspires and enables people to grow, both morally and in terms of their levels of motivation. It empowers individuals to go beyond self-interest and pursue goals that are in the common interest. Transformational leaders accomplish this by developing a relationship with followers and tapping into their personal values in a way that matches them to the values of the organization."³

This form of leadership requires the practitioner to examine, re-examine, and revise their leadership techniques to best fit the changing dynamics of team research.

Leadership literature reveals four frames that provide context for transformational leadership and drive home the importance of intentional consideration of oneself and one's team. The four frames are as follows:

- Structural, which focuses on structures and formal relationships;
- Human resources, which emphasizes interpersonal relationships and worker morale;
- Symbolic, through which a leader may see events, rituals, and stories as central to his or her work; and
- Political, which recognizes the inevitable interplay among the organization's important constituencies.⁴

By employing reflexivity as a core practice of leadership in agile and fast-paced research and business intelligence environments, leaders ensure their practices effectively cater to and support the group and their goals.

Against this backdrop, I will leave readers of this column with two recommendations:

First, engage with literature on leadership. This will ensure you stay up to date on leadership theories, styles, style theories, approaches,

and change theories. This commitment to constant improvement leads to better performance, not just for you but for your team.

Second, take time for reflexivity and actively engage in your own growth and development. Get off the metaphorical treadmill and take time to engage in metacritical analysis of your leadership practice. During this time, you should revisit and fine-tune your guiding principles and vision. The act of investing in yourself ensures your leadership practices are effectively supporting the success of your team and the ultimate realization of the vision. Do this regularly (perhaps once per quarter), with a more dedicated effort put forth at the beginning and end of the year.

Ultimately, I hope this column inspires productive and rewarding engagement with the practice of leadership.

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Alexis Shoemaker is manager of research and consumer insights at SKIM Group, a global decision behavior and insights agency. She holds a bachelor's degree in anthropology and a master's in research administration. She is the author of *Leadership in Research Insights and Business Intelligence: A Conceptual Framework and Guide*, published in 2022.

Disclosing and Licensing Standard-Essential Patents: A Proposed EU Regulation

By Arnold Brown

The European Commission (EC) has issued a Proposal for a Regulation of the European Parliament and of the Council on Standard Essential Patents amending Regulation (EU) 2017/1001, COM (2023) 232 final 27 Apr 2023. After issuing the proposal, the EC solicited feedback from stakeholders (including patent holders and implementers), with a response deadline of August 10.

This article explores what the proposed regulation would mean for standards development organizations (SDOs) and for companies that participate in standards development. In addition, this article explores some of the noteworthy comments made during the public comment period and offers an analysis of the future of the proposed regulation based on a recent conversation with the Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs (small and medium-sized enterprises), the unit within the EC responsible for the proposed regulation.

Note: A standard-essential patent (SEP), as used in this article, is a patent that is technically essential to a technical standard. In other words, it is a patent necessarily infringed by an implementer of that standard. The proposed regulation addresses many key aspects of how SEPs are determined and licensed. (Standards organizations with royalty-free licensing obligations

appear to be outside the scope of the proposed regulation.¹)

NOTHING SHORT OF TRANSFORMATIVE

If enacted, the proposed regulation would be nothing short of transformative in the patent world, with impacts ranging far beyond the EU. In describing the background and reasons for the proposed regulation, the EC makes salient arguments about the need to improve the transparency and accessibility of standardized technology and to remove or reduce barriers or friction that can be created by the current patent licensing framework.

Under the proposed regulation, the following would be established:

- an SEP register with essentiality checks;
- a “Competence Centre” under the aegis of the EU Intellectual Property Office (EUIPO) to manage the registry, conduct the essentiality checks, and provide objective information regarding aggregate royalty rates to implementers;
- conciliation procedures that are required before launching patent infringement litigation for SEPs; and
- a process for determining an aggregate royalty for using a standard before, or shortly after, its publication.

The EC states that with these changes, the licensing landscape for SEP will benefit because the proposed regulation does the following:

- reduces the information asymmetry between a SEP holder and an implementer by providing the implementer with more information about SEP holders through the mandatory registry;
- creates a mechanism to derive the aggregate royalty for using a standardized technology; and
- reduces potential litigation friction through a pre-trial obligatory conciliation and through the additional information and services the Competence Centre will provide.

There are several concerns often raised by implementers regarding the existing SEP licensing framework. Four of the most frequently cited concerns are the following:

- a lack of transparency regarding who owns SEPs and what the royalty rate will be for implementers;
- the difficulties that arise when a single technology specification has many different licensors or multiple patent pools with differing royalty rates (e.g., HEVC)²;
- the expense of negotiating with licensors; and
- the prospect that some of the licensors may be non-practicing entities (often referred to as patent trolls in the media) whose sole interest is royalty revenues.

The EC appears ready to upend the existing patent licensing framework to promote the use of technology standards by emerging EU technology companies (many of which are SMEs) and to encourage those companies to participate in the standards development process, all in furtherance of improving the EU's ability to compete globally in the technology arena. The EC also anticipates a significant benefit to consumers in the form of reduced prices of

products and services as cost savings from lower royalties due to SEP owners are passed down.

But by proposing to upend the existing framework, the EC has stirred up a hornet's nest, judging by the public comments. The EC's efforts to significantly alter this system may need to be phased in over a number of years to be palatable to certain stakeholders, while other stakeholders believe the change cannot come fast enough.

IMPACT ON SEP OWNERS

If one were to consider the current state of patent licensing as a dire situation, then the EC's approach could be summed up as "drastic times call for drastic measures." One of the most drastic measures in the proposed regulation is that a patent holder may not assert its SEP in litigation in an EU member state (and presumably before its Unified Patent Court) without first registering the SEP with the Competence Centre and engaging in the conciliation process established by the regulation.

The disclosure requirement alone may be considerable. Under the rules of large standards-setting organizations such as the European Telecommunications Standards Institute, members are already obligated to disclose their SEPs. Even though it may be best practice to encourage or foster SEP disclosure, very few SDOs have a mandatory SEP disclosure policy.³ If the proposed regulation is adopted, a member of an SDO with no SEP disclosure requirement will need to review its patent portfolio to determine whether it holds SEPs related to those standards.

Even for the SDOs with mandatory SEP disclosure policies, the policies only apply to their members. However, it would appear that the requirement under the proposed regulation would extend beyond SDO members to all SEP holders, meaning all companies seeking to assert their SEPs regardless

of whether they have been involved in the development of a standard.

The proposed regulation is strongly opposed by patent licensors, who argue that their fundamental ownership rights in their patents are being curtailed. They assert that filing a patent infringement lawsuit is both a fundamental right and critical to getting licensees to agree to pay royalties. Their argument is that the value of their property will be decreased because they will be compelled to accept the royalty rate established by the Competence Centre.

This state of affairs would be, in their view, equivalent to technological rent control. A property owner suddenly finds that its apartment building's rents are controlled by a local municipal board and tenants can remain in their apartments in perpetuity, with rent increases set by the board and not by arm's-length negotiations between landlord and tenant. (On the other side of the argument, rent control is an enormous benefit to renters.)

This is perhaps an oversimplification of the situation. Detractors of the proposed regulation have provided detailed and sophisticated arguments as to how patent owners would be deprived of their fundamental rights. Some commenters have argued that requiring patent holders to register their SEPs and limiting the ability to assert patents would violate the TRIPS Agreement (Trade-Related Aspects of Intellectual Property Rights Agreement), the provisions of EU treaties on property rights, and the national laws of several EU countries.⁴

IMPACT ON SDOS

The proposed regulation calls for SDOs to notify the Competence Centre when they publish a new technology standard. There are thousands of technology standards published each year. In addition, organizations often publish errata or addenda, which may

contain normative requirements; presumably a notice would also be required when such documents are published.

It is unclear how the actual published technical specification would be made available to the Competence Centre. While it may not appear to be a large burden, this could present issues with SDOs that only publish their specifications to their members. It is unclear whether the EC will require that the technology specifications be made public. If the obligation to disclose SEPs is imposed on all purported SEP holders (not just members of the SDO that developed the technical standard), it is likely that the final regulations would need to require that technical standards be made public when submitted by an SDO.

Lastly, it is unclear how the determination of an aggregate royalty would affect standards development timetables given (1) the lengthy, difficult, and contentious process of setting royalty rates and (2) the extent to which this eventually will be an opt-in regime for determining aggregate royalties. The EC has indicated that its intent is not to slow down the standards development process—indeed, one of the goals of the proposed regulation is to foster the speedy commercial introduction of new standards-based products and services.

NOTABLE COMMENTS ON THE PROPOSED REGULATION

Many comments were filed during the public comment period. Apple, Inc. filed comments arguing that many criticisms of the proposed regulation were not grounded in reality and that non-judicial essentiality determinations could provide useful information (i.e., the essentiality checks managed by the Competence Centre in the proposed regulation). Apple concluded by encouraging the EC to continue its efforts to increase fairness in SEP licensing.

The American Intellectual Property Law Association (AIPLA) filed comments critical of the proposed regulation. AIPLA's comments can be said to fall into four areas:

- the proposed regulation would violate international and European laws (e.g., the TRIPS Agreement);
- the proposed regulation is overly broad;
- the proposed regulation will require more resources than planned; and
- the transparency enabled by the proposed regulation will not achieve the results envisioned.

AIPLA also argues that the proposed regulation has far-reaching impacts and will affect SEP holders throughout the world. While much of its criticism is valid, AIPLA may have gone a bit too far in its rebuke of the purpose and potential impact of the proposed regulation. Its comment states, "[w]hile the EC has identified a few high-level concerns with SEP transparency and FRAND licensing efficiency, i.e., which patents are SEPs and what terms are FRAND, such concerns are largely expressed as unsupported conclusions and speculation."⁵ The existing framework for licensing SEPs is inefficient, and to diminish the concerns raised by the EC is probably overstating the point when AIPLA's real argument is that the proposed regulation goes too far.

I would argue that the EC's concerns are well-founded and its solutions would be transformative. However, reasonable people will differ regarding whether the proposed regulation is necessary or even lawful. To its credit, the proposed regulation points out that other countries have adopted or are exploring corrective solutions⁶ to the system of patent licensing that currently exists.⁷

WHAT LIES AHEAD?

My understanding is that the SEP regulation is still on schedule for adoption in 2024 even though EU parliamentary elections are

scheduled for mid-2024. For those concerned about the impact on SDOs, my understanding is that the goal of the proposed regulation is not to delay the adoption of standards (quite the opposite, in fact) and that the Competence Centre may be able to provide information or assistance if there are problems or difficulties complying with the SEP regulations.

Additionally, there is apparently a misunderstanding about the amount of staffing the EC expects to put in place if the proposed regulation is adopted. The 12 employees mentioned in the proposed regulation represent the initial staff needed to organize the registry, which will grow to something like 30 employees when operational.

The EUIPO will handle this part of the administrative function, which DG GROW believes should be in its wheelhouse. However, the validation of the SEPs (the technical essentiality check) and the conciliation procedures will require outside experts, who will be hired by the Competence Centre. The centre may establish a roster of qualified personnel (for example, patent attorneys) who would be hired to conduct the essentiality checks on the purported SEPs.

Even with the roster of outside experts, the ability to perform technical essentiality checks in a uniform manner may prove challenging without the aid of sophisticated technology tools. Much of the credibility of the Competence Centre will turn on the accuracy of these essentiality checks.

THE ROLE OF AI IN TECHNICAL ESSENTIALITY CHECKS

One recurring concern expressed in the public comments regarded the EUIPO's ability to manage the essentiality checks and the availability of skilled attorneys due to anticipated conflicts. Artificial intelligence (AI) tools offer the promise of reducing the staffing burden under the proposed regulation and creating a standardized way for patent professionals to perform a technical

essentiality check. AI could help bridge the gap and improve the credibility of the essentiality checks.

However, AI by itself will not be able to address this task—it will also require professionals to provide their expertise to produce the best results. This combination has the promise of gaining industry credibility and withstanding judicial scrutiny.

Over the past five years, I have been involved in creating an AI tool specifically designed for identifying and validating technical essentiality. At its core, this tool uses multiple machine learning models that are trained on various different technology domains. (In order for the system to best understand what a particular technical specification means, it needs to be trained using information associated with that particular technology field because technical words in one field have a different meaning in another field.) An effective system also needs to be able to understand the meaning of each patent claim and each element of a patent claim.

Using this approach, our AI tool matches both the patent claim and its constituent elements to specific sections of a technical specification, creating a virtual claim chart for a patent professional to check and validate. The scoring algorithm, which determines the closeness of a match, was calibrated by examining hundreds of known SEP matches. This baseline unique algorithm can be improved by an individual evaluator via feedback, but its improvements are not applied system-wide, so the baseline remains intact across evaluators. This AI-based system emulates how patent professionals perform matches, taking into account the meaning of the words in the technical specification and the meaning of the words in the patent claim and elements (as well as a patent's specification language).

Over the five years of developing this system, we have had several breakthroughs, including discovering that we had to train different models for different types of technologies to get good results. The promise is

that AI tools will play a significant role in helping to improve the credibility, efficiency, and predictability with which SEPs are identified and disclosed.

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- Public comment of Apple, Inc. filed on August 10, 2023 to Proposal for a Regulation of the European Parliament and of the Council on Standard Essential Patents COM(2023) 232 final (27 Apr 2023): Submission in Response to the European Commission's Consultation Regarding Its Proposed Regulation on Standard Essential Patents.

NOTES

- ¹ Proposed Regulation, Explanatory Memorandum page 12. “It does not apply to SEPs that are subject to royalty-free intellectual property policy of the SDO that has published the standard.”
- ² See “HEVC Royalty Stacking and Uncertainty Threaten VVC Adoption,” published on ipwatchdog.com by Craig Thompson, August 13, 2021. Also, see C. Eltzroth and J. Cary, “Fostering of Patent Pools Covering Cable Technology: Lessons from VVC Pool Fostering,” a technical paper prepared for SCTE (2021), available at <https://ssrn.com/abstract=3949545>.
- ³ The EU already has indicated that it is best practice for purposes of EU Competition Law that a standards organization require the disclosure of SEPs. See Guidelines on the applicability of Article 101 of the Treaty on the Functioning of the European Union to horizontal co-operation agreements C(2023) 3445 final (1 Jun 2023), para 457.
- ⁴ The EC argues that the proposed regulation is lawful, claiming “Limitations on the exercise of IP rights are allowed under the EU Charter of Fundamental Rights, provided that the proportionality principle is respected. According to settled case-law, fundamental rights can be restricted provided that those restrictions correspond to objectives of general interest pursued by the EU and do not constitute, with regard to the aim pursued, a disproportionate and intolerable

interference which infringes the very essence of the rights guaranteed.” Proposed Regulation, page 10 (Explanatory Memorandum, Impact Assessment: Fundamental rights). The Commission cites several cases in this line of reasoning including: Judgment of the Court of Justice of 13 December 1979, *Hauer v. Land Rheinland-Pfalz*, C-44/79, EU:C:1979:290, para. 32.

⁵ AIPLA comments dated August 10, 2023 to the Proposed Regulation at page 2.

⁶ The proposed regulation cites initiatives in Japan, South Korea and Singapore, as well as a withdrawn proposal in the United States to improve the current framework of patent licensing (page 4). Japanese

Patent Office Guide to Licensing Negotiations Involving Standard Essential Patents; South Korean Guidelines on unfair exercise of Intellectual Property Rights; Singapore’s Competition & Consumers Commission Guidelines on the treatment of Intellectual Property Rights.

⁷ The current framework is a mix of patent pools, patent licensing packs (quasi-patent pools), non-practicing entities, and individual practicing company patent licensing programs (together with catch-and-kill patent companies and various other players that assess, research, buy and sell SEPs).



Arnold Brown is an attorney who has worked with technology standards organizations and technology companies that participate in technology standards. He was instrumental in developing Daystrom Solutions (daystromsolutions.io), an artificial intelligence solution for SEP patent discovery. He is a partner at Seyfarth Shaw, LLP. He would like to acknowledge the comments that Carter Eltzroth made to an earlier version of this article. This article is not legal advice, is provided for informational purposes only, and represents the views of the author and not the views of any other individual, organization or firm. The author is not licensed to practice law in the European Union.

THE STANDARDIZATION OF SMART SYSTEMS

Today's Situation and Some Future Problems

By Kai Jakobs

This article raises some issues in relation to the standardization of smart systems that the author believes need (urgent) answers and will thus hopefully trigger future research.

The past couple of years have witnessed a development that will have major ramifications for society: the injection of “smartness” into traditional technologies. This has resulted from the merger of information and communication technology (ICT) with well-known application areas like transportation systems, manufacturing, and power supply. Ongoing mergers include intelligent transport systems (ITS), smart manufacturing, the smart grid, e-health, and smart cities. These smart applications are here to stay.

A similar trend may be observed in the underlying communication infrastructure. Here, cyber-physical systems (CPSs) and the Internet of things (IoT) will enable “smart” things to interact with each other as well as with their environment (including humans).

To make such “smartness” a reality, globally accepted standards are a *sine qua non*. These standards will shape technological development and thus, to a certain extent, the future. More than 25 years ago, the European Commission observed the following:

Standards are not only technical questions. They determine the technology that will implement the Information Society, and consequently the way in which industry, users, consumers and administrations will benefit from it (CEC 1996, p. 1).

This holds all the more for smart systems given their likely future ubiquity. Billions of sensors will collect data that, in turn, will be processed using big data analytics and machine learning. Obviously, this will have major societal, economic, ecological, legal and ethical ramifications and will directly affect citizens, businesses and administrations alike.

Depending on your point of view, this omnipresence may equal inescapability (think Aldous Huxley). Smart systems may indeed foster the good of humankind, but they may just as well enable the emergence of a surveillance society. Accordingly, their development (and specifically their standardization) must not be based solely on technical and economic considerations, as is typical of ICT standardization; rather, societal, legal, environmental, and ethical aspects also need to be considered. To do so in a credible way will require active participation by the widest possible range of stakeholders during the early stages of the system development process, most notably in standardization.

Such broad participation will also help increase the eventual standards' legitimacy and thus contribute to a higher degree of acceptance (Werle and Iversen 2006). Adequate consideration of non-technical aspects early in the research and innovation (R&I) process (possibly along with technology assessment exercises) will help shape the process in a way that reduces the risk of non-desirable developments

from a broader societal perspective. As Williams and Edge (1996, p. 874) put it, "The shaping process [of a technology] begins with the earliest stages of research and development."

In most cases, standardization will not be the first stage of an R&I process, but it will certainly be one of the earliest. And it will be the earliest stage to which all stakeholders can contribute (at least in theory), as opposed to, for example, corporate R&I.¹

Against this background, the remainder of this article will discuss some issues that need to be addressed in the context of smart systems standardization. These discussions are intended more to provide food for thought than to offer solutions, although there will be one attempt at a solution. I will first address the different forms of multi-disciplinarity that I consider inevitable for the standardization of smart systems (and other technologies with similarly severe societal ramifications) and the associated different types of knowledge that will need to be available in this process. I will then look at the somewhat bleak situation of societal stakeholders in standards setting today and propose a way to improve this situation. I will conclude with some brief remarks.

Multi-Disciplinarity and Knowledge in Smart Systems Standardization

Today's standards-setting process typically involves one discipline (or a very limited number of closely related ones) for any given standard. For smart systems, things will look very different. Most notably, various disciplines from the ICT sector will join the game and will need to interact closely with a variety of mostly engineering disciplines. Table 1 shows an incomplete list of technical disciplines contributing to sample smart application areas.

This "technical" multi-disciplinarity is one aspect of smart systems standardization but not the most important one. Figure 1 shows the four areas where multi-disciplinarity in smart systems standardization will be required. Each such system is depicted as a simple three-level

hierarchy in which a smart application deploys its underlying communication infrastructure and is subject to its governing policies and objectives.

Horizontal technical multi-disciplinarity relates to the standardization of a smart communication infrastructure. It used to be the domain of telecommunication engineers, but this is changing. For example, AI-based methods and tools will increasingly be deployed in communication systems; expertise from these realms will also be required for ICT standardization. Moreover, the likely eventual omnipresence of the IoT, especially in combination with AI-based tools, may interfere with privacy legislation and necessitate ethical and legal input (nip it in the bud!).

Horizontal technical cross-domain multi-disciplinarity refers to integrating today's smart systems silos, each of which has very limited or no links to the others. This is not a sustainable situation—interfaces between, e.g., the smart grid, intelligent transport systems, and smart buildings will be necessary, and most (if not all) smart applications will be building blocks of a smart city. To break up these silos, experts from different application domains will be needed to ensure semantic interoperability and other integrated functionality.

Vertical technical multi-disciplinarity deals with applications' potentially hard requirements on the underlying communication infrastructure (like guaranteed levels of latency, resilience, reliability, and predictability). As a consequence, application design, communication technology, operating systems, and control loops will need to be extremely closely coupled, as loosely coupled systems will rarely, if ever, be able to meet these requirements. To achieve this, close multi-disciplinary cooperation will be necessary from the outset.

Vertical non-technical multi-disciplinarity is probably the most relevant variety for the case at hand. It represents the main link between the societal and the technical world. This link will be discussed in more detail below.

Table 1. Technical disciplines involved in sample smart application areas (excerpt)

Smart Buildings	Smart Manufacturing and Production	Intelligent Transport Systems
Architecture	Production Engineering	Transport Telematics
Civil Engineering	Telecommunication	Traffic Engineering
Computer Science	Computer Science	Power Engineering
Telecommunication	Robotics/AI	Automotive
.....	Data Science	Computer Science,
	Control Engineering	Telecommunication
		

First, however, a few research questions may be derived from the above, including the following:

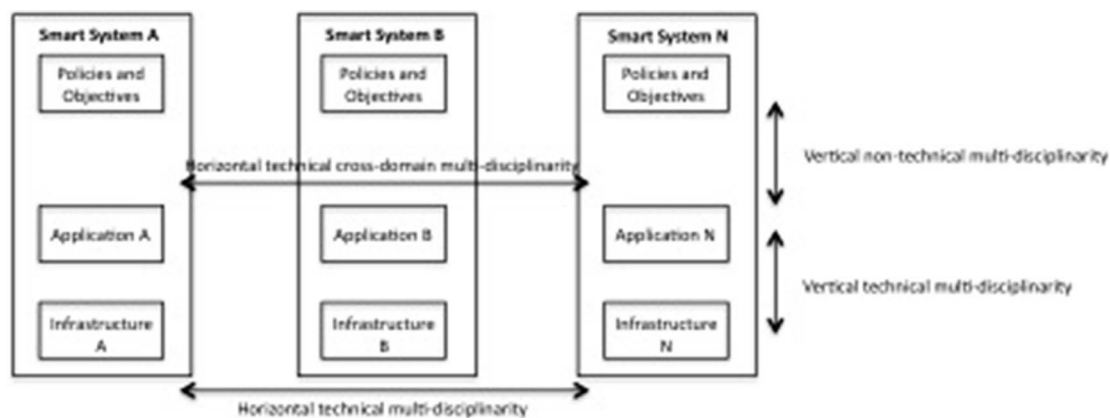
- How can the boundaries between the individual “standardization silos” be overcome?
- How can the (typically detached) work on (a) policies and applications and (b) applications and infrastructure be aligned?

Expert vs. Lay Knowledge

The discussion above suggests that very different areas of expertise will need to be involved in developing technically sound and societally desirable smart systems and their defining standards. Both relevant technical expertise and non-technical knowledge will have to go into the standardization process (and into its final outcome, the standards). Depending on the concrete problem at hand, this non-technical knowledge may need to cover environmental, legal, socio-economic or ethical aspects, to name a few.

This may appear a bit odd. After all, setting ICT standards would seem to be a purely technical activity, albeit with potentially strong economic consequences. Indeed, in many cases, this “technology/economy-centric” scenario will be adequate—the nuts and bolts of the USB protocol, for example, will hardly be of interest to those who just want to transfer data to a USB stick, nor will they have any societal impact.

Things look very different for smart systems, though. Eventually they will collect and process unprecedented volumes of information, including personal data. At the very least, adequate measures to render any misuse of this information impossible and to guarantee their privacy will need to be in place. Moreover, smart systems hold the promise of making energy supply, traffic, manufacturing, and cities more environmentally friendly. To reap such potential benefits, sustainability aspects should already be considered during the standardization process.

**Figure 1.** Multi-disciplinary in smart systems standardization.

Obviously, the above has a strong technical dimension. Beyond that, however, legal and regulatory issues will come into play, as will societal and cultural aspects. Privacy, for example, is crucially important in some countries and much less so in others; even within countries, its perceived importance differs between groups of citizens.

The preceding suggests that for smart systems, technical expertise (expert knowledge) will need to be complemented by (application) domain knowledge from relevant non-technical disciplines and by what has frequently been termed “lay knowledge.” The expert knowledge/lay knowledge dichotomy is, however, completely misleading. In the context of smart systems standardization, as well as in other cases where the resulting technology is likely to have major societal ramifications, any such distinction becomes void.

What may be seen as lay knowledge for purely technical deliberations may become expert knowledge when it comes to the consideration of, say, societal impacts. That is, only expert knowledge, albeit from different domains, will need to be made available. Then, technical knowledge will refer to the core technology to be standardized, societal knowledge will be knowledge to be contributed by members of the public, and domain knowledge will refer to knowledge from application domains whose requirements may affect the underlying (communication) technology. In any case, all types must be of equal value.

Incorporating such non-technical aspects into R&I activities is at the core of responsible innovation (RI). Grunwald (2011) argues that the ethical dimension needs to be considered and observes that “. . . Responsible Innovation unavoidably requires a more intense inter- and trans-disciplinary cooperation between engineering, social sciences, and applied ethics” (p. 17).

That is, RI provides guidelines on addressing potential societal ramifications that may be an (unintended) outcome of a research project

or an innovation. Von Schomberg (2011 p. 19) defines RI as “a transparent, interactive process by which societal actors and innovators become mutually responsive to each other with a view to the (ethical) acceptability, sustainability and societal desirability of the innovation process and its marketable products (in order to allow a proper embedding of scientific and technological advances in our society).”

Of course, the participation of a broader range of stakeholders comes with problems. For one, Graz and Hauert (2019) observe that it is very difficult to actually mobilize stakeholders that may contribute societal knowledge to the day-to-day activities of standards-setting organizations’ (SSOs) working groups. This holds primarily for public engagement (as opposed to, for example, technical/scientific domain experts). Moreover, the more stakeholders contribute, the longer the process may last (see, e.g., de Vries et al. 2009 and Riillo and Jakobs 2022). Also, inter-domain communication and differences in perceptions will likely be issues that need to be addressed (see, e.g., Koizumi and Yamashita 2021).

This discussion suggests a number of open questions and issues that future research will need to address. These include the following:

- How can stakeholders from the non-technical domains (those who can contribute societal knowledge) be motivated to contribute to the standardization of smart systems?
- How can the standardization of smart systems establish a level playing field where all forms of relevant knowledge are considered of equal value?
- How can the various aspects that contribute to the communication gap between representatives of different disciplines be addressed?
- Can insights from other disciplines (such as innovation management) be deployed, given the differences between standardization and innovation processes?

Societal Stakeholders' Representation in Standards Setting

The previous section has shown that any meaningful standardization of smart systems will necessitate the participation of experts from different disciplines and, most notably, of different societal stakeholders. In the following, the current situation of the latter will be discussed, followed by a discussion of the importance of the individual in standards setting.

RI stipulates that R&I should focus on technical and possibly economic aspects but that societal and environmental aspects (to take two examples) should also be taken into account. Grunwald (2011, p. 17) adds the ethical dimension and observes that "... Responsible innovation unavoidably requires a more intense inter- and trans-disciplinary cooperation between engineering, social sciences, and applied ethics."

To this end, RI provides guidelines on how to address potential societal ramifications that may be (unintended) outcomes of a research project or an innovation. Von Schomberg (2011, p. 19) defines RI as "a transparent, interactive process by which societal actors and innovators become mutually responsive to each other with a view to the (ethical) acceptability, sustainability and societal desirability of the innovation process and its marketable products (in order to allow a proper embedding of scientific and technological advances in our society)."

It is safe to say that (large) manufacturers with strong technical and resulting economic interests in the technology to be standardized are the dominant group of stakeholders in ICT standardization today. Accordingly, technical aspects (often rooted in economic interests) inform the process.

Other stakeholders, including consumers and small and medium-sized enterprises (SMEs), have long been under-represented (see, e.g., Gupta 2017 and Riillo and Jakobs 2022). This holds even more so for societal stakeholders, despite the recognized need to include these as well:

European standardization organisations shall encourage and facilitate an appropriate represen-

tation and effective participation of all relevant stakeholders, including SMEs, consumer organisations and environmental and social stakeholders in their standardization activities (European Union 2012, Article 5).

The European Commission considers umbrella organisations² the most appropriate means of representation for these groups of stakeholders. The work of these organizations is definitely valuable, but there are some issues to be considered. For one, they are not overly active in ICT, let alone in the area of smart systems.³ Moreover, Jakobs (2015), for example, argues that umbrella organizations should not automatically be the representatives of choice for their constituency because the diversity within a group of stakeholders suggests that common ground will not exist. This holds particularly true for SMEs.

In addition, the general call for broad stakeholder participation (such as that issued by the European Commission) may be contested. Egyedi (2003), for example, argues that democratic standardization is not necessarily a value per se—it depends on the type of standard at hand. However, adequate stakeholder representation needs to be guaranteed for standards with potential societal ramifications (as in the case of smart systems).

Adequate is a tricky term, however. Numerically adequate representation is one thing; adequate influence may be something entirely different. There is ample evidence that representatives' diplomatic, negotiation, rhetorical, and other non-technical skills may enable even a very small organization to punch well above its weight. As Umapathy et al. (2007, p. 296) put it, "The human dimension of standards setting is an important component of the consensus-based process ...".

This "human dimension" primarily relates to the capabilities (both technical and otherwise) of the individuals who participate in the standards setting process and the relations between them. I will discuss this topic next.

The Human Dimension in ICT Standardization

Technical standardization work takes place in working groups (WGs). Each WG is a microcosmos of its own. Firms' interests are channeled into these WGs through their respective representatives.

Kang et al. (2007, p. 219) note that "Performance in standardization is naturally affected by that of individual standardization experts." This simple fact is associated with a number of issues. For one, the education, training and skills of an entity's representatives play a decisive role. Moreover, even if alliances at the firm level have been established up front, they do not necessarily translate into the same alliances at the personal level ("just because my company trusts your company, I do not necessarily trust you")⁴ or to the intended voting behavior (see also below).

According to Bourdieu and Wacquant (1992), social capital is "the sum of the resources, actual or virtual, that accrue to an individual or a group by virtue of possessing a durable network of more or less institutionalized relationships of mutual acquaintance and recognition." A WG member's most valuable (soft) skill is the ability to accumulate such social capital. To be able to do so, an adequate level of trust is a crucial pre-requisite. A functioning personal network can hardly be established without it.

Trust is particularly important in informal negotiations and deal striking, which do not necessarily happen during the discussions within the WG (Dokko and Rosenkopf 2003). This is further corroborated by Grundström and Wilkinson (2004), who quote several high-level standards setters⁵ who emphatically stress the importance of trust. Trust can only be earned over time, so longstanding, continuing involvement in a standardization activity is important (as opposed to showing up only occasionally).

But social capital may be a double-edged sword. The bonds established between long-time co-workers in a WG may eventually

become stronger than the loyalty toward their respective employer or client, as noted by Isaak (2006) and Henrich-Franke (2008). As a result, informal personal alliances may be formed that may or may not be in any firm's best interest. Moreover, depending on things such as character, abilities, and attitudes as well as on external influences (like employers' interests or societal and cultural aspects), individuals may assume a variety of roles.⁶

The goals underlying a firm's participation in standards setting will differ according to the activity at hand (see, e.g., Jakobs 2014 for a range of such goals). Moreover, the characteristics of these activities will also differ—the standardization of a physical layer communication protocol is a much more technically oriented exercise than developing high-level standards for smart cities. Accordingly, the necessary skill sets of the respective representatives will need to differ as well. In the former case, technical expertise will be most important; in the latter case, presentation and rhetoric skills will be more important. Especially when strong economic interests are present, negotiation and deal-breaking skills will become crucial.

The growing complexity of smart systems' standardization is most likely to increase the diversity of stakeholders and the associated expertise and interests represented in the WGs. This variety will heighten the importance of delegates' soft skills and specifically communication and negotiation skills as well as the ability (and willingness) to see beyond one's own nose. Accordingly, companies will likely invest in additional training efforts to this end and/or try to hire well-known standards setters who already have these abilities.⁷

Some questions worth discussing in this context include the following:

- Which skills and capabilities will be required from future standards setters in the field of smart systems (especially those who will represent societal stakeholders)?

- How can these representatives be best prepared for their task?
- How might processes be adapted to reduce the influence of obstructionists, naysayers and loudmouths (Spring et al. 1995)?

A Potential Way Forward

The preceding discussion suggests that simply bringing additional stakeholders into the standardization process may not be the most promising approach. So, let us consider a different idea.

Standards may bridge the gap between research and innovation (see, e.g., Botterman et al. 2020). And in ICT, specifically in telecommunications, standardization often functions as an early stage of innovation. I would thus argue that principles of RI⁸ should also be applied to standardization, yielding “responsible standardization” (RS). In fact, RI’s main principles (Stilgoe et al. 2013) nicely reflect the requirements of smart systems standardization:

- *Anticipation*: Consider possible future societal and ethical impacts during the standardization process.
- *Inclusion*: Bring in additional stakeholders to identify socially more desirable outcomes of a standardization activity.
- *Responsiveness*: React to new knowledge and newly emerging views, norms⁹ and circumstances.
- *Reflexivity*: Place research into its wider societal and ethical context by reflecting on values and beliefs¹⁰ during research and development.

Applying RI principles not just in innovation but also in standards setting has already been suggested by van de Kaa (2013), who proposes introducing value-sensitive design into standards setting. This is further elucidated in a case study on smart metering by Ligtoet et al. (2015). Yet neither of these studies discusses how this could be operationalized.

Along similar lines, Wickson and Forsberg (2015) argue that the notion of “responsibility”

needs to be incorporated into the standardization process (at least in cases of technologies with considerable uncertainties attached to them; they use nano-technology as an example). They highlight a number of the process’s deficiencies in this respect and observe that SSOs fail to apply their own relevant standards internally. Yet, they also do not offer any proposals on how this situation might be improved in terms of the design of the process. It is hardly surprising, then, that a recent survey of standardization experts found that the vast majority feel that (de jure) standardization is not “responsible enough to establish socially desirable standards” (Wiarda et al. 2022, p. 14).

The argument that all relevant types of knowledge need to be considered of equal importance has consequences for how the principle of inclusion can be realized. The International Association for Public Participation (IAPP) identifies five different options: inform, consult, involve, collaborate, and empower (IAP2 2018). According to the IAPP, collaborate means to “look to you (providers of societal and domain knowledge) for advice and innovation in formulating solutions and incorporate your advice and recommendations into the decisions to the maximum extent possible.” Meanwhile, empower means “We will implement what you (providers of societal and domain knowledge) decide.” Something in between would appear to be an adequate model for the participation of non-technical stakeholders.¹¹

To achieve this in practice, I propose modifying the current standards-setting process, at least for technologies with major societal ramifications. The box titled “Technical Standardization” in Figure 2 represents the traditional process of technical (ICT) standardization. This is now preceded by a “Desirability Analysis” during which societal, environmental, legal, ethical, and other non-technical aspects of a technical proposal are considered. This step addresses the principles of inclusion, anticipation, and reflexivity.

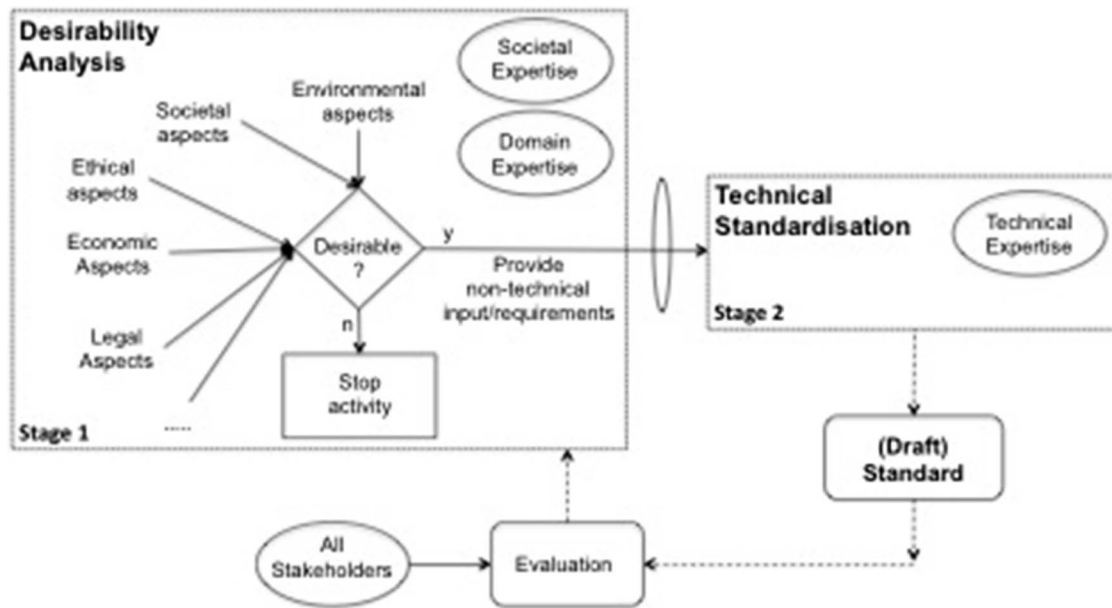


Figure 2. A modified standardization process (adapted from Jakobs 2020).

Based on the outcome of this analysis, a go/don't go decision is made. In case of a go, a list of requirements to be met and boundary conditions not to be violated is provided as a basis for the technical work. To also address the responsiveness principle, this analysis should continuously complement the technical work—for example, through regular input in case of new relevant developments.

One benefit of such a process would be that the technical part will remain largely unchanged. Another benefit would be that the communication between the technical and societal worlds would largely take place at one well-defined interface (the contribution, explanation, and discussion of societal requirements). Benefit number three would be that such a split significantly reduces the necessary level and duration of societal stakeholders' involvement (and thus the associated costs), which should encourage more of them to become active in the process (and thus at least reduce the mobilization problem). A subsequent joint evaluation of the draft standard by all stakeholders, potentially initiating a new round of technical work, will also be performed.

Smart systems standardization is still at a comparably early stage, so it should not be

too late to implement a process that adequately caters to the standardization of a technology that has the potential to dramatically change society—for better or worse.

This model comes with open (essential) questions, including, among others:

- Could the model be a realistic option in real-world standards setting?
- What would be needed to actually implement it?
- Specifically, how could the interface between the two stages be implemented?
- Even if it were implemented, how could individuals with societal or domain expertise be motivated to participate?

Some Brief Concluding Remarks

Smart systems that autonomously collect and process huge amounts of data are likely to become ubiquitous in the not-too-distant future. This suggests that their design and development should not be based solely on technical and economic considerations. While these systems must be technically sound and economically viable, they must also be ethically, societally, and environmentally desirable and legally above board (especially with

respect to data security and privacy). To achieve this, the international standards-setting process may be deployed.

In its current form, however, this process is very much tailored to support purely technical and mostly mono-disciplinary work. These characteristics render it largely unsuitable for smart systems standardization. To overcome this problem, some things will need to happen.

For one, a much more diverse universe of stakeholders will need to contribute to the process (including societal stakeholders). Moreover, the distinction between (technical) expert knowledge and (societal) lay knowledge has to be overcome. All stakeholders will need to realize that knowledge is “expert” only in one domain and is “lay” in another (the reverse holds as well). The standardization process for societally relevant technologies (like smart systems) will need to reflect that. It will have to provide a level playing field where all kinds of relevant knowledge are considered equal.

The process proposed in this paper may be considered a first step. It takes into account practical constraints and boundary conditions like inter-domain communication problems and lack of funding on the side of the societal stakeholders. But much further research (and ideally practical experience) will be needed to develop it further and refine it.

To reiterate, the standardization of smart systems needs to overcome the distinction between so-called lay knowledge and the coveted expert knowledge. Both are equally important for the design of sustainable smart systems that will be beneficial to all.

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NOTES

1. See, e.g., van Mierlo et al. (2020) for a discussion of the issues to be associated with wider stakeholder participation in corporate R&I.
2. The respective representing organisations include Small Business Standards (SBS), representing SMEs, the European consumer voice in standardization (ANEC), the European Environmental Citizens' Organisation for Standardization (ECOS) and the European Trade Union Institute (ETUI).
3. See <https://www.cencenelec.eu/societal/Pages/default.aspx> for a list of committees and working groups where the four organizations are represented; there is a remarkable activity of ETUI in the field of ITS, though.

4. Zaheer et al. (1998) distinguish between inter-personal trust and inter-organizational trust.
5. Including Ericsson's then-director of Product and Business Strategies and Director Access Standardization, Corporate Technology.
6. See, e.g., Spring et al. (1995) and Umapathy et al. (2007) for detailed discussions about potential such roles.
7. It could be observed that some of the big names in standardization, especially those active in the standardization of the Internet, gravitated to the big players. For instance, Harald Alvestrand was hired by Cisco in 2001, three months after he had become chair of the Internet Engineering Steering Group. Vint Cerf, the so-called "Father of the Internet" and co-designer of the TCP protocol, went to Google in 2005 when he was chairman of the Internet Corporation for Assigned Names and Numbers (ICANN).
8. According to Wickson and Carew (2014), the numerous definitions of RI agree on "(1) A focus on addressing significant socio-ecological needs and challenges; (2) a commitment to actively engaging a range of stakeholders for the purpose of substantively better decision-making and mutual learning; (3) a dedicated attempt to anticipate potential problems, assess available alternatives and reflect on underlying values, assumptions and beliefs; and (4) a willingness among all participants to act and adapt according to these ideas."
9. Specifically including societal and cultural ones; this does not necessarily refer to technical norms and standards.
10. Including own ones.
11. Consultation is a "classical" approach to stakeholder engagement. The associated promise would be, "We will keep you informed, listen to and acknowledge concerns and aspirations, and provide feedback on how public input influenced the decision" (IAP2 2018). Given the massive impact smart technologies are likely to have, I do not consider this form of engagement adequate.



Kai Jakobs has been with RWTH Aachen University's Computer Science Department since 1985. His activities and research interests focus on ICT standards and the underlying standardization process. He has (co)-authored/edited 30+ books and published 250+ papers. He is on the board of the European Academy for Standardization (EURAS) and is founding editor in chief of the *International Journal on Standardization Research*. He is also a Certified Standards Professional.